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October

November

December

2024 State Bulletins

Idaho

Washington

Departments Issue Final MHPAEA Regulations

Issued date: 10/04/24

On September 9, 2024, the Departments of Health and Human Services , Labor, and the Treasury (collectively, the "Departments") released final rules pertaining to the Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA") with the aim of ensuring that individuals who seek treatment for mental health ("MH") or substance use disorder ("SUD") reasons do not face greater burdens than they would face when seeking coverage for medical/ surgical reasons. The final rules amend certain provisions of the existing MHPAEA regulations and add new regulations to set forth content requirements and timeframes.

Background

Briefly, MHPAEA:

- Provides that financial requirements (such as coinsurance and copays) and treatment limitations (such as visit limits) imposed on MH/SUD benefits cannot be more restrictive than the predominant financial requirements and treatment limitations that apply to substantially all medical/surgical benefits in a classification.

- Prohibits separate treatment limitations that apply only to MH/SUD benefits.

- Provides that non-quantitative treatment limitations ("NQTLs") may not be imposed on MH/SUD benefits in any classification unless they are comparable and applied no more stringently for MH/SUD benefits than for medical/ surgical benefits under the terms of the plan (or health insurance coverage) as written and in operation. Examples of NQTLs include prior authorization and medical management requirements. The focus here is not on whether the final result is the same for MH/SUD benefits as for medical/surgical benefits, but rather on whether the underlying processes, strategies, evidentiary standards, and other factors are in parity.

- Imposes certain disclosure requirements, including a requirement that group health plans conduct a comparative analysis of all NQTLs imposed on MH/SUD benefits and make that analysis available to the Departments and participants and beneficiaries (including their authorized representatives) upon request.

MHPAEA applies to:

- Employers with at least 51 employees offering a group health plan that provides coverage for any MH/SUD benefits; and

- Small employers with fully insured group health plans that are required to provide all essential health benefits, including MH/SUD benefits.

The Final Rules

The following summarizes some of the highlights applicable to employers sponsoring group health plans subject to MHPAEA.

Terms

The final rules amend the definitions of the terms "medical/surgical benefits," "mental health benefits," and "substance use disorder benefits" by removing a reference to state guidelines. The definition of whether a condition or disorder is a MH condition or SUD must follow the most current version of the International Classification of Diseases or Diagnostic and Statistical Manual of Mental Disorders. If generally recognized independent standards of current medical practice do not address how to treat a condition, disorder, or procedure, plans and carriers may define it in accordance with applicable federal and state law.

The regulations reinforce that the following conditions are MH conditions:

- eating disorders, such as anorexia nervosa, bulimia nervosa, and binge-eating disorder;

- autism spectrum disorder; and

- gender dysphoria.

Additionally, the final rules add new definitions for the following terms: evidentiary standards, factors, processes and strategies.

Requirements for NQTLs

Under the final regulations, a plan or carrier may not impose any NQTL with respect to MH/SUD benefits in any classification that is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification. For this purpose, a plan or carrier must satisfy two sets of requirements:

1. The design and application requirements; and

2. The relevant data evaluation requirements.

Design and Application Requirements

The general rule of the design and application requirements requires an examination of the processes, strategies, evidentiary standards, and other factors used in designing and applying an NQTL to MH/SUD benefits in the classification to ensure they are comparable to, and are applied no more stringently than, those used in designing and applying the limitation with respect to medical/surgical benefits in the same classification.

The final regulations also prohibit the use of discriminatory factors and evidentiary standards to design an NQTL to be imposed on MH/SUD benefits.

Whether information, evidence, sources, or standards are considered to be biased is based on all the relevant facts and circumstances and whether they systematically disfavor or are specifically designed to disfavor access to MH/SUD benefits as compared to medical/surgical benefits. Historical plan data/information from a time when the plan or coverage was not subject to or was not in compliance with MHPAEA is generally biased if it systematically disfavors access or is specifically designed to disfavor access to MH or SUD benefits as compared to medical/surgical benefits, and the plan has not taken the steps necessary to correct, cure, or supplement the data or information. Generally recognized independent professional medical or clinical standards and carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate MH/SUD benefits are not biased.

Relevant Data Evaluation Requirements

To ensure an NQTL applicable to MH/SUD benefits in a classification is no more restrictive than the predominant NQTL applied to substantially all medical/surgical benefits in the same classification, plans and carriers must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access to MH/SUD benefits and medical/surgical benefits and must carefully consider the impact. For NQTLs related to network composition standards, a plan or carrier must collect and evaluate relevant data in a manner reasonably designed to assess the NQTLs' aggregate impact on relevant outcomes related to access to MH/SUD benefits and medical/ surgical benefits.

As the relevant data for any given NQTL will depend on the facts and circumstances, the final rules provide flexibility for plans and carriers to determine what should be collected and evaluated, as appropriate.

The Departments may also request other data in addition to what a plan or carrier determines to be relevant data for any particular NQTL included in their comparative analyses.

If the evaluated relevant data suggest that the NQTL contributes to material differences in access to MH/SUD benefits as compared to medical/surgical benefits, it will be considered a strong indicator of a MHPAEA violation. Differences in access are material if, based on all relevant facts and circumstances, the difference in the data suggests that the NQTL is likely to have a negative impact on access to MH/SUD benefits as compared to medical/surgical benefits.

Differences in access to MH/SUD benefits are not treated as material if they are attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect, prevent, or prove fraud and abuse. If material differences in access exist, the plan or carrier must take reasonable action, as necessary, to address them to ensure compliance with MHPAEA in operation.

Examples of possible actions that a plan or carrier could take to comply with the requirement to take reasonable action, as necessary, to address any material differences in access with respect to NQTLs related to network composition include, but are not limited to:

1. Strengthening efforts to recruit and encourage a broad range of available MH and SUD providers and facilities to join the plan's or carrier's network of providers, including taking actions to increase compensation or other inducements, streamline credentialing processes, or contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network;

2. Expanding the availability of telehealth arrangements to mitigate any overall MH and SUD provider shortages in a geographic area;

3. Providing additional outreach and assistance to participants and beneficiaries enrolled in the plan or coverage to assist them in finding available in-network MH and SUD providers and facilities; and

4. Ensuring that provider directories are accurate and reliable.

Meaningful Benefits Standard

If a plan provides any benefits for a MH condition or SUD in any benefits classification, it must provide meaningful benefits for that condition or disorder in every classification in which meaningful medical/ surgical benefits are provided. Whether the benefits provided are meaningful is determined in comparison to the benefits provided for medical/surgical conditions in the same classification. Meaningful benefits require coverage of a core treatment (standard treatment or course of treatment by generally recognized independent standards of current medical practice) for that condition or disorder in each classification in which the plan or coverage provides benefits for a core treatment for one or more medical conditions or surgical procedures.

Comparative Analysis

Content

The final regulations require a comparative analysis of the design and application of each applicable NQTL. The analysis, at a minimum, must contain the following six content elements:

1. A description of the NQTL, including identification of benefits subject to the NQTL;

2. Identification and definition of the factors and evidentiary standards used to design or apply the NQTL;

3. A description of how factors are used in the design or application of the NQTL;

4. A demonstration of comparability and stringency, as written;

5. A demonstration of comparability and stringency, in operation, including the required data, evaluation of that data, explanation of any material differences in access, and description of reasonable actions taken to address such differences; and

6. Findings and conclusions.

Each plan (or carrier) must prepare and make available to the Secretary, upon request, a written list of all NQTLs imposed under the plan. For ERISA covered plans, this list must be provided to the named fiduciaries of the plan.

For plans subject to ERISA, the comparative analysis must include a certification by one or more named fiduciaries confirming the fiduciary's engagement in a prudent process to select one or more qualified service providers to perform and document a comparative analysis in connection with the imposition of any NQTLs that apply to MH/SUD benefits, as well as satisfaction of the duty to monitor those service providers.

Request and Review Process

The final regulations set forth the steps the Departments will follow to request and review a plan's or carrier's comparative analysis of an NQTL.

1. After an initial request for a comparative analysis, the plan or carrier must submit it to the relevant Secretary within 10 business days (or an additional period of time specified by the relevant Secretary).

2. If the Secretary determines the comparative analysis is insufficient, the Secretary will specify the additional information necessary, which must be provided by the plan or carrier within 10 business days (or an additional period of time specified by the relevant Secretary).

3. If the Secretary makes an initial determination of noncompliance, the plan or carrier has 45 calendar days to specify the actions it will take to comply and provide additional comparative analyses.

4. If the Secretary makes a final determination of noncompliance, the plan or carrier must notify all participants, beneficiaries, and enrollees enrolled in the plan or coverage not later than 7 business days after the Secretary's determination. The final rules set forth specific content for this notice and require that a copy of the notice be provided to the Secretary and relevant service providers and fiduciaries.

Plans and carriers must make a copy of the comparative analysis available when requested by any applicable state authority, a participant or dependent who has received an adverse benefit determination related to MH/SUD benefits. ERISA-covered plans must provide the analysis to participants and dependents within 30 days of a written request.

If a plan receives a final determination that an NQTL is not in compliance with the comparative analysis requirements, including because the plan has not submitted a sufficient comparative analysis to demonstrate compliance, the relevant Department may direct the plan to stop applying the NQTL until the plan is compliant, which could result in increased claim costs and additional fees from the plan's service providers. Not impose the NQTL with respect to MH/SUD benefits unless and until the plan or carrier demonstrates compliance or takes appropriate action to remedy the violation.

Sunset of MHPAEA Opt-Out

The final rules implement the sunset provision for self-funded non-federal governmental plans to opt out of compliance with MHPAEA effective June 27, 2023.

Effective Dates

The final rules generally apply to group health plans and group health insurance coverage on the first day of the first plan year beginning on or after January 1, 2025. This includes the new fiduciary certification requirement.

However, the meaningful benefits standard, the prohibition on discriminatory factors and evidentiary standards, the relevant data evaluation requirements, and the related requirements in the provisions for comparative analyses apply on the first day of the first plan year beginning on or after January 1, 2026.

Until the applicability date, plans and carriers are required to continue to comply with the existing requirements, including the CAA amendments to MHPAEA.

Employer Action

Plan sponsors should:

- Note that compliance with MHPAEA rules as they currently exist remains ongoing and is an enforcement priority of the Departments.

- Continue to carefully evaluate their health plans for compliance with MHPAEA, especially in light of new requirements, and be prepared to respond to requests by the Departments for this information. Notably, this will include an analysis of network adequacy. Coordination with carriers, TPAs and other service providers will be essential.

- Review their plan's current limits on MH/SUD and the plan's written comparative analysis to determine whether changes are required in light of recent enforcement efforts.

- Evaluate whether to make plan design changes beginning in 2025. (The meaningful benefits standard, the prohibition on discriminatory factors and evidentiary standards, the relevant data evaluation requirements, and the related requirements in the provisions for comparative analyses apply on the first day of the first plan year beginning on or after January 1, 2026.)

It is important to note that, while all plan sponsors have the above responsibilities, in a fully insured arrangement, plan sponsors will not generally have flexibility as to plan design changes and carrier compliance will be crucial. For self-funded plans (including level-funded) it will be important that TPAs are able to support MHPAEA compliance.

Pennsylvania Regulates PBMs

Issued date: 10/04/24

On July 17, 2024, Governor Josh Shapiro signed House Bill 1993 ("the Bill") into law. The Bill seeks to further regulate pharmacy benefit managers ("PBMs") by, among other things, requiring pass-throughs for drug manufacturer rebates, requiring provider freedom of choice, and enacting provider network requirements.

The Bill is effective on November 14, 2024, and could have significant impacts on the prescription drug coverage offered under fully insured group health plans covering residents of the Commonwealth of Pennsylvania.

Applicability

The Bill amended the existing Pharmacy Audit Integrity and Transparency Act, with the amended statute now called the Pharmacy Benefit Reform Act ("the Act"). The Act applies to fully insured health plans offering prescription drug coverage in the Commonwealth. Importantly, self-insured ERISA plans, non-federal governmental plans, church plans, and Indian tribal government plans are not covered by the Act.

Impact of the Bill on Fully Insured Group Health Plans

The Bill is intended to regulate contracts between a pharmacy or PBM and a health insurer or health benefit plan. As a whole, the Act regulates a wide variety of PBM operations; however, specific to group health plans, the Bill imposes the following requirements on PBMs operating in the Commonwealth:

- **Pass-through of Drug Manufacturer Rebates.** If the health plan designates negotiation of a drug manufacturer rebate to a PBM, the PBM is required to pass through to the health plan at least 95% of any rebate received by the PBM on behalf of the health plan.

- **Freedom of Choice.** Provided that the provider agrees to the terms and conditions of the PBM's contract, an individual covered under the health plan must be permitted to select an in-network pharmacy or pharmacist of their choice and a PBM cannot:

- require the use of a mail order pharmacy or PBM retail pharmacy affiliate,
- transfer a covered individual's prescription from an in-network pharmacy to another pharmacy unless the individual requests it, or
- auto-enroll an individual in mail-order pharmacy services.

In addition, a PBM is prohibited from "steering" a covered individual to a PBM-affiliated retail pharmacy by using financial incentives.

- **Prohibition on Clawbacks.** Health plans, health insurers, and PBMs are prohibited from collecting the difference in the cost-sharing that a covered individual pays to a pharmacy and the applicable cost-sharing as defined by the health plan.
- **Network Adequacy.** A PBM is required to establish a provider network that allows for convenient access to providers within a reasonable distance from a covered individual's residence. In doing so, the PBM must adhere to the following requirements:
  - The network cannot be limited to only pharmacies affiliated with the PBM, and
  - The network must meet the requirements for pharmacy networks related to Medicare Part D drug coverage.

Beginning April 1, 2026, PBMs must file an annual network adequacy report with the Pennsylvania Insurance Department ("the Department").

- **Effects of Spread Pricing.** "Spread pricing" is where a PBM charges a health plan or health insurer a contracted price for prescription drugs, but that contracted price differs from the amount the PBM directly or indirectly pays the pharmacy for prescription drugs. The Department is permitted to request data from a PBM to analyze the impact of, among other things, spread pricing and steering on the cost of prescription drugs in the Commonwealth.

Employer Action

Employers sponsoring fully insured group health plans which cover residents of Pennsylvania should review their contracts with their carrier and/or PBM to ensure that they are compliant and amend them as necessary.

Final 2024 ACA Reporting Instructions And Forms Issued

Issued date: 10/04/24

The IRS released final instructions and forms for calendar year 2024 ACA reporting, including Forms 1094-C, 1095-C, 1094-B, and 1095-B. As a reminder, it is important to ensure the forms are accurate, timely furnished to participants and filed with the IRS as good faith relief from penalties is no longer available.

There are no significant changes to the 2024 forms.

Forms 1094-C/1095-C

Applicable large employers ("ALEs") must furnish Form 1095-C to full-time employees and file Form 1094-C and all 1095-Cs with the IRS. ALEs offering a self-insured group health plan (including level-funded arrangements and individual coverage health reimbursement arrangements ("ICHRAs") must also furnish Forms 1095-C to covered employees or other primary insured individuals in the self-funded health plan (e.g., covered part-time employees, COBRA qualified beneficiaries).

The calendar year 2024 Form 1095-C must be furnished to full-time employees and other individuals by March 3, 2025. The Form 1094-C and all Forms 1095-C must be filed with the IRS electronically by March 31, 2025.

ALEs, in coordination with their payroll or other reporting vendors, should have records to determine each employee's status as an ACA FTE or not an ACA FTE for each month during 2024 in preparation to complete, furnish and file these forms for 2024.

Forms 1094-B/1095-B

Employers that are not ALEs and offer self-funded group health plan coverage, including level-funded plans and ICHRAs, must furnish and file forms regarding minimum essential coverage. Specifically, as the provider of the self-funded plan, the employer reports to the IRS and all covered individuals (e.g., employees, COBRA qualified beneficiaries, spouses, dependents) the coverage they had during the calendar year. To meet this requirement, employers use Forms 1094-B and 1095-B.

The calendar year 2024 Form 1095-B must be furnished to covered individuals by March 3, 2025. The Form 1094-B and all Forms 1095-B must be filed with the IRS electronically by, March 31, 2025.

Employers should coordinate with payroll or other reporting vendors to assist in this process.

What's New?

There are no significant changes to the 2024 forms; however, the penalties for failures have increased.

2024 Penalties

The instructions reiterate that all ALEs and other employers that sponsor self-funded group health plans that fail to comply with the information reporting requirements may be subject to the general reporting penalty provisions for failure to file correct information returns and failure to furnish correct payee statements. *Good faith relief is no longer available*. However, penalties may be waived if the failure is due to reasonable cause and not willful neglect.

For 2024, the following penalties may apply:

- Failure to file a correct return is $330/statement (total calendar year penalty not to exceed $3,987,000).
- Failure to furnish a correct statement is $330/statement (total calendar year penalty not to exceed $3,987,000).

An employer that fails to both file and furnish a correct statement is subject to a combined penalty of $660/statement with a maximum penalty of $7,974,000.

Electronic Filing Required (10+ Forms)

Employers required to file 10 or more information returns (e.g., Forms W-2, 1094-C, 1095-C, 1094-B, 1095-B) during the year must file these forms electronically with the IRS on or after January 1, 2024. Previously, the IRS allowed employers filing fewer than 250 returns to file hard-copy (paper) forms.

The IRS also encourages employers filing fewer than 10 returns to consider electronic filing.

Employer Action

It is important to identify vendors, like payroll or other reporting administrators, to assist in this process especially as most employers will be required to file forms electronically with the IRS. A health plan carrier typically does not prepare this reporting.

ALEs should begin preparing and ensure that Form 1095-C is furnished to full-time employees and other individuals by March 3, 2025. Form 1094-C and all Forms 1095-C should be electronically filed with the IRS by March 31, 2025.

Employers that are not ALEs but offer self-funded group health plan coverage should ensure a process is in place for furnishing and filings Forms 1094-B and 1095-B. Form 1095-B must be furnished to covered individuals by March 3, 2025, and all forms 1095-B along with Form 1094-B must be electronically filed with the IRS by March 31, 2025.

Employers should be certain the statements are complete and accurate since good faith relief is no longer available.

Employers may have additional reporting obligations for employees residing in states with an individual mandate (California, Massachusetts, New Jersey, Rhode Island, Vermont, Washington D.C.). Ensure vendors will assist with state reporting obligations.

San Francisco HCSO Expenditures and Reporting Update for 2025

Issued date: 10/04/24

The San Francisco Health Care Security Ordinance ("HCSO") minimum expenditure rates for 2025 have been released, and the HCSO Annual Reporting Form for calendar year 2024 is due on April 30, 2025.

2025 Minimum Expenditure Rates

Under the HCSO, covered employers must make minimum health care expenditures at the following rates for each hour worked by covered employees in San Francisco:

Employer Size	Number of Employees	2024 Health Care Expenditure Rate	2025 Health Care Expenditure Rate
Large	All employers with 100 or more employees	$3.51 per hour payable	$3.85 per hour payable
Medium	Businesses with 20-99 employees Nonprofits with 50-99 employees	$2.34 per hour payable	$2.56 per hour payable
Small	Businesses with 19 or fewer employees Nonprofits with 49 or fewer employees	Exempt	Exempt

The hours payable under the HCSO for each employee are capped at 172 hours per month. Therefore, for 2025 the maximum required health care expenditure for a covered employee of a large employer is $662.20 per month ($3.85/hour x 172 hours). For a medium-sized employer, the maximum required expenditure for a covered employee is $440.32 per month ($2.56/hour x 172 hours).

Managerial, supervisory, or confidential employees who earn more than a specified amount are exempt from the minimum health care expenditures requirement under the HCSO. For 2024, the earnings threshold for these employees to be exempt from the HCSO is $121,372 per year (or $58.35 per hour). As of January 1, 2025, the new threshold will be $125,405 per year (or $60.29 per hour).

Annual Reporting Form

Covered employers must submit an online report each year that summarizes how they complied with the HCSO. The web-based HCSO Annual Reporting Form for the prior calendar year is typically available on the San Francisco Office of Labor Standards Enforcement ("OLSE") HCSO website by April 1 and must be submitted by April 30. For example, the HCSO Annual Reporting Form for calendar year 2024 is expected to become available on the HCSO website by April 1, 2025, and is due by April 30, 2025.

Employer Action

Covered employers should ensure that they will be making the required minimum health care expenditures in 2025 at the new rates for employees in San Francisco and maintain records showing compliance with the HCSO requirements.

The 2025 version of the HCSO poster, which must be posted in all workplaces with covered employees, is expected to become available by December 2024. Covered employers should monitor the San Francisco HCSO website (linked below) to obtain and post the 2025 version of the poster by January 1, 2025.

https://www.sf.gov/information/health-care-security-ordinance

Covered employers should also be prepared to submit the HCSO Annual Reporting Form for calendar year 2024 no later than April 30, 2025.

Cybersecurity Guidance Applies To Health And Welfare Benefits

Issued date: 10/16/24

The Employee Benefits Security Administration ("EBSA") of the U.S. Department of Labor confirmed in Compliance Assistance Release No. 2024-01 that cybersecurity guidance issued in 2021 applies to all ERISA-covered health and welfare plans. This guidance goes beyond what is required under HIPAA for health plans, and includes "Tips for Hiring a Service Provider," "Cybersecurity Program Best Practices," and "Online Security Tips," which were updated to reflect this clarification.

Background

In April 2021, EBSA issued cybersecurity guidance for benefit plan fiduciaries and service providers, regarding best practices for maintaining cybersecurity. Recognizing that ERISA requires plan fiduciaries to take appropriate precautions to mitigate cybersecurity risks, EBSA's guidance came in three forms, directed at benefit plan sponsors, fiduciaries, record keepers, and participants.

The language in the original guidance led to confusion as to whether the guidance applied solely to retirement plans. With this new guidance, EBSA clarifies that its cybersecurity guidance does, in fact, also apply to ERISA-covered health and welfare plans.

Details of the Guidance

Cybercrime is a constant and growing risk across the globe, and employer-based benefit plans have not escaped falling victim to these crimes. Health and welfare benefit plans carry some risk of financial loss to plan sponsors and participants, but they generally carry significantly more risk of disclosure of personally identifiable information ("PII") and sensitive health information of plan members, as well as their covered family members, over multiple benefits and across multiple service providers.

The Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA") is designed to, among other things, impose extensive privacy and security requirements to employer-provided group health plans to secure protected health information ("PHI") and electronic PHI secure. Plan sponsors, fiduciaries, and business associates of group health plans, such as third-party administrators ("TPAs"), who take significant steps in ensuring compliance with HIPAA, will have already made strides in complying with EBSA's ERISA cybersecurity guidance. However, it is important to note that various ERISA-covered welfare benefits are not group health plans subject to HIPAA, including group-term life insurance, disability coverage, and accident-only coverage. Such benefits would generally be subject to ERISA and to which the EBSA cybersecurity guidance would apply.

Both the original 2021 guidance and the recent guidance provide links to three separate pieces. The first two are oriented towards plan fiduciaries and service providers, and the degree to which fiduciaries adopt the detailed suggestions may depend on the size and complexity of their plans, particularly the amount of plan assets and data that they may handle.

Tips for Hiring a Service Provider

EBSA provides six tips directed at a plan fiduciary as recommendations to support prudent selection and monitoring of service providers and recommends requesting the following information:

1. information on the service provider's cybersecurity standards and compare against recognized industry standards. Perhaps involve internal IT experts.

2. how provider validates practices.

3. provider's track record, including third party reports on the provider.

4. providers' prior experience with breaches.

5. information on insurance policies covering cybersecurity losses and identity theft breaches.

6. contract terms (to watch for and consider):

    a. attempts to limit service provider's responsibilities;

    b. service provider ideally obtaining annual third-party audit for compliance;

    c. high standards by provider to secure information;

    d. notify plan fiduciary of incidents/breaches promptly and to properly address;

    e. oblige provider to follow all laws (e.g., retention and destruction of information); and

    f. require insurance.

Health and welfare plan fiduciaries should keep these suggestions in mind for all plan service providers. Though this would mainly pertain to an insurer, TPA, or PBM, it extends to consultants, wellness vendors, data analysts, trustees, etc. as well.

Cybersecurity Program Best Practices – Service Provider

EBSA provides a highly detailed summary of best practices for ERISA plan services providers cybersecurity program. Health and welfare benefit plan fiduciaries may also use this piece to evaluate the extent to which such providers are applying best practices. There are twelve different recommendations, including:

1. having a formal, well documented cybersecurity program
2. conducting prudent annual risk assessments
3. having a reliable annual third-party audit of security controls
4. clearly defining and assigning information security roles and responsibilities
5. having strong access control procedures
6. ensuring that any assets or data stored in a cloud or managed by a third-party service provider are subject to appropriate security reviews and independent security assessments.
7. conducting periodic cybersecurity awareness training.
8. implementing and managing a secure system development life cycle ("SDLC") program.
9. having an effective business resiliency program addressing business continuity, disaster recovery, and incident response.
10. encrypting sensitive data, stored and in transit.
11. implementing strong technical controls in accordance with best security practices.
12. appropriately responding to any past cybersecurity incidents.

Online Security Tips

Lastly, the EBSA guidance provides 9 basic rules oriented to plan members when they are accessing online health, welfare, or retirement accounts, specifically:

1. register, set up and routinely monitor your online account.
2. use strong and unique passwords/passphrases.
3. use Multi-Factor Authentication.
4. keep personal contact information current.
5. close or delete unused accounts.
6. be wary of free Wi-Fi.

7. beware of phishing attacks.

8. use antivirus software and keep apps and software current.

9. know how to report identity theft and cybersecurity incidents.

Employer Action

EBSA has made clear that cybersecurity relating to plan assets and PII should be a point of emphasis for ERISA plan sponsors and fiduciaries, as well as plan service providers. This goes beyond the requirements of HIPAA (applies only to group health plans) and applies to all service providers, whether business associates or not. Employers who sponsor ERISA-covered health and welfare benefit plans, should review the EBSA guidance, confirm current safeguards, and implement additional safeguards, as appropriate, primarily to protect data and to include holding service providers to high standards.

Actions to consider, include:

- identifying all current service providers with whom PII and health data may be shared.
- requesting current service providers to provide written representations of steps it takes to secure PII and health data from cyber threats.
- on a periodic basis (perhaps yearly), requesting current service providers to provide written updates on changes and other developments in its cybersecurity efforts.
- posing questions in the request for proposal ("RFP") pertaining to cybersecurity, including confirmation of:
  - a formal cybersecurity program, perhaps with certification (e.g., SOC 1 or SOC 2);
  - access control procedures;
  - cyber insurance, with policy limits;
  - training of relevant employees on cybersecurity awareness;
  - use of secured networks for exchanging confidential information, including by email; and
  - security assurance when using cloud service providers.
- educating plan members with respect to using sound online security practices, perhaps through furnishing members with the EBSA "Online Security Tips."

New York Paid Family Leave 2025 Contributions And Benefits

Issued date: 10/21/24

The New York State Department of Financial Services has announced the contribution rate under the New York Paid Family Leave ("PFL") law effective January 1, 2025, will be set at **0.388%** of weekly wages.

Employee contributions for PFL are calculated as a percentage of an employee's gross wages per pay period up to the maximum contribution based on the *annualized* New York State Average Weekly Wage ("NYAWW"). For 2025:

- NYAWW in effect will be **$1757.19**, an increase of 2.3% from the 2024 NYAWW of $1,718.15. The *annualized* NYAWW is **$91,373.88**.
- The maximum annual employee contribution will be **$354.53** ($333.25 in 2024).

The PFL benefit is **67%** of an employee's Average Weekly Wage (up to the NYAWW) payable for **12 weeks**. For 2025:

- The maximum weekly PFL benefit will be **$1,177.32** ($1,151.16 in 2024).
- The maximum annual PFL benefit payable for 12 weeks will be **$14,127.84** ($13,813.92 in 2024).

The following should be noted:

- The maximum amount of PFL and disability leave under the New York Disability Law ("DBL") that may be taken in a *52-consecutive week period* is limited to 26 weeks.
- If an employee begins continuous leave in 2024 and the leave extends into the 2025, the benefit is based on the rate in effect on the first day of leave (i.e., in 2024) and is not recalculated at the 2025 rate.
- If an employee begins intermittent leave in 2024 and the leave extends into the following year and there is at least a three-month lapse in days taken under New York PFL, the leave is considered a new claim under the law in 2025 and the benefit is calculated at the 2025 rate.

Employer Action

Employers should prepare for the 2025 New York PFL contribution and benefit changes that begin in January. PFL coverage will typically be added as a rider on an employer's existing disability insurance policy, although benefits can be provided through a self-funded plan approved by the New York Workers' Compensation Board.

Annual Out-of-Pocket Maximum Adjustments Announced For 2026

Issued date: 10/21/24

The Department of Health and Human Services ("HHS") published the "payment parameters" portion of its Annual Notice of Benefit and Payment Parameters for 2026. For purposes of employer-sponsored health plans, the guidance includes the limits on annual out-of-pocket expenses (deductibles, co-payments, and other amounts, but not premiums) for non-grandfathered group medical plans for plan years that begin in 2026.

The Department also published the proposed Annual Notice of Benefit and Payment Parameters rule for 2026. While this annual guidance generally outlines rules and standards that apply to Marketplace coverage, sometimes it includes items that affect employer-sponsored coverage. In this publication, HHS indicates that, along with the Departments of Labor and the Treasury, future rulemaking to address the applicability of drug manufacturer support to the annual limitation on cost-sharing is expected, something that will impact employer-sponsored coverage. At this time, it's not clear when this guidance will be issued or what it will say.

Change to the Out-of-Pocket Maximums

Non-grandfathered group medical plans will see a significant increase in the out-of-pocket maximum for plan years beginning on or after January 1, 2026, as follows:

- $10,150 for self-only coverage (up from $9,200 for 2025)
- $20,300 for coverage other than self-only (up from $18,400 for 2025).

The out-of-pocket maximum limits for non-grandfathered group medical plans are different (and generally higher) than the out-of-pocket maximum limits required for high-deductible health plans ("HDHPs") that are compatible with health savings account ("HSA") eligibility.

Employer Action

For non-grandfathered group medical plans, employers should update out-of-pocket limits for plan years beginning on or after January 1, 2026.

Massachusetts Paid Family Leave 2025 Contributions And Benefits

Issued date: 10/22/24

The Massachusetts Department of Family and Medical Leave ("DFML") has recently announced the contribution rate, the State Average Weekly Wage, and the maximum weekly benefit amount for the Massachusetts Paid Family and Medical Leave ("PFML") program effective January 1, 2025. The DFML has also published the FY2024 Annual Report for the PFML program.

Contributions

The 2025 contribution rate on eligible wages will be **0.88%** (the contribution rate is unchanged from 2024). Individual contributions are capped by the Social Security income limit. The 2025 Social Security income limit is expected to be released later in October and will likely be significantly higher than the 2024 limit which is currently set at $168,600.

If an employer has at least 25 covered individuals (i.e., employees and 1099 contractors in MA), both the employer and the employee share in the cost of medical leave benefits. The employee is responsible for the entire cost of family leave benefits. The following illustrates the PFML contribution breakdown for 2025:

- Medical Leave Contribution: **0.70%** of eligible wages allocated as follows:
    - Employer: At least 60% of the medical leave cost is paid by the employer (0.42%)
    - Employee: No more than 40% of medical leave can be deducted from the employee's wages (0.28%).
- Family Leave Contributions: **0.18%** of eligible payroll deduction
    - May be paid entirely from employee wages (no employer contribution required).

If the employer has fewer than 25 covered individuals in Massachusetts, the employer is not required to contribute toward the medical or family leave portions of the benefit. The employee's 2025 contribution for medical and family leave benefits is 0.46% of eligible wages.

Amount of Benefit

The weekly benefit amount for employees and self-employed individuals on family or medical leave is determined as follows:

- The portion of an employee's or self-employed individual's average weekly wage ("AWW") that is equal to or less than 50 percent of the state average weekly wage ("MAAWW") is replaced at a rate of 80 percent; and
- The portion of an employee's or self-employed individual's AWW that is more than 50 percent of the MAAWW is replaced at a rate of 50 percent, up to the maximum allowed benefit amount.

For 2025:

- The MAAWW will be **$1,829.13**, an increase of 1.8% from the 2024 MAAWW of $1,796.72.
- The maximum weekly PFML benefit will be **$1,170.64,** an increase of 1.8% from the maximum weekly benefit of $1,149.90 in 2024.

FY2024 Annual Report

As required by the Family and Medical Leave Law, the DFML has issued its annual report containing information on benefits, applications, and certain characteristics of applicants during Fiscal Year 2024.

Employer Action

Employers should prepare for the 2025 PFML contribution and benefit requirements by working with payroll processors, approved private plan vendors and employment counsel to ensure their leave policies and procedures are compliant by January 2025. Updated workplace posters and notifications for the 2025 contribution rates and benefit amounts will be available to employers on the PFML website soon.

IRS Guidance Provides Helpful Clarification For HDHPs

Issued date: 10/29/24

On October 17, 2024, the IRS released two key pieces of guidance, Notice 2024-75 and Notice 2024-71, which provide important updates for plan sponsors offering certain tax advantage health plans.

Briefly, the guidance:

- Expands the items and services that may be treated as preventive care in a qualified high deductible health plan ("HDHP") with a health savings account ("HSA") to include:
    - all types of breast cancer screenings;
    - continuous glucose monitors ("CGMs") for individuals diagnosed with diabetes;
    - insulin delivery devices; and
    - over-the-counter ("OTC") oral or emergency contraceptives and male condoms.
- Creates a safe harbor to include condoms as a qualified medical expense under IRS Code Section 213(d).

Below you will find additional details from the guidance.

Definition of Preventive Care for HDHP/HSA Plans Expanded (Notice 2024-75)

Background

An HDHP, in part, is a health plan with a minimum deductible set by the IRS ($1,650 for self-only coverage and $3,300 for coverage other than self-only for 2025). Generally, an HDHP may not provide benefits for any year until the individual satisfies the minimum deductible. However, there is a safe harbor that permits coverage for preventive care prior to meeting the deductible.

Over the years, through statutory amendments as well as IRS guidance, the definition of preventive care has expanded and evolved.

What's New

Notice 2024-75 further expands the items and services that may be considered preventive care in an HDHP.

1. *Breast Cancer Screenings.* The guidance clarifies that all types of breast cancer screening (e.g., mammograms, Magnetic Resonance Imaging ("MRIs"), ultrasounds, and similar breast cancer screening services) are considered preventive care. This change is effective as of the date of the original guidance, April 12, 2004.

2. *Continuous Glucose Monitors.* Earlier guidance permits an HDHP to treat a glucometer as preventive care for an individual who is diagnosed with diabetes for the purpose of preventing or exacerbating the condition or developing a secondary condition. This new guidance clarifies that a CGM is considered preventive care under the same circumstances as other glucometers if the CGM is measuring glucose levels using a similar detection method or mechanism to other glucometers (i.e., piercing the skin). If a CGM has additional functions, each function must be for preventive care for an HDHP to cover any benefits of the CGM before the deductible is satisfied. For example:

    - if the CGM both monitors glucose and provides insulin, it may be treated as preventive care because it is a device delivering insulin.

    - if the CGM provides additional medical or non-medical functions that are not preventive care (other than minor functions, such as clock and date functions), then the HDHP may not cover the CGM before an individual satisfies the minimum annual deductible for an HDHP.

This change is effective as of July 17, 2019.

3. *Insulin.* The Inflation Reduction Act ("IRA") created a statutory safe harbor that permits first-dollar coverage for "selected insulin products" in an HDHP effective for plan years beginning on or after January 1, 2023. IRS Notice 2024-75 confirms that "selected insulin products" is interpreted to include any device used to administer or deliver the selected insulin products. This guidance is effective for plan years on or after January 1, 2023.

4. *OTC oral contraceptives.* The guidance confirms OTC oral contraceptives for a covered individual potentially capable of becoming pregnant, including, but not limited to, OTC birth control pills and emergency contraception, regardless of whether they are purchased with a prescription may be treated as preventive care, effective for plan years that begin on or after January 1, 2023.

5. *Male condoms.* Male condoms (with or without a prescription) may be treated as preventive care regardless of the gender of the individual covered under the HDHP who purchases them, effective for plan years that begin on or after January 1, 2023.

This guidance addresses items that may be treated as preventive care in a HDHP. It does not address (or expand) the requirements under the Affordable Care Act for non-grandfathered group health plans to provide certain preventive care items and services without cost-sharing in-network.

213(d) Safe Harbor Includes Condoms as a Medical Expense (Notice 2024-71)

Background

Under Section 213(d), the IRS allows taxpayers to receive tax advantages for certain medical care. Certain services, such as hospital visits, prescription drugs, and recently certain OTC products like menstrual products are considered medical care under Section 213(d). Over the years, the IRS has expanded the definition of the items and services included in Section 213(d) for purposes of receiving reimbursement from a health plan with a tax advantage, such as health FSAs, HRAs, and HSAs.

What's New

IRS Notice 2024-71 provides a safe harbor and will treat amounts paid for condoms as a Section 213(d) medical expense. This means amounts paid for condoms are treated as an expense for medical care and eligible to be paid (or reimbursed) from an HSA, HRA, or health FSA.

Employer Action

Employers may wish to evaluate their plan offerings to enhance the overall value of their plans and explore opportunities to further support employee health and wellness through preventive services.

Specifically:

- While not required, employers with HDHP/HSAs may consider expanding what is considered preventive care under the HDHP to incorporate items and services in the updated guidance.

- Condoms may be reimbursed (or paid for) through a health FSA, HRA, or HSA on a tax favored basis.

These changes may require plan documents to be updated to accurately reflect changes to the plan. Any changes should be communicated to plan participants timely. Employers should confirm their carriers and TPAs are prepared to implement changes accordingly.

2025 Cost Of Living Adjustments

Issued date: 10/30/24

The IRS has released cost of living adjustments for 2025 under various provisions of the Internal Revenue Code (the Code). Some of these adjustments may affect your employee benefit plans.

Cafeteria Plans – Health Flexible Spending Arrangements

Annual contribution limitation

For plan years beginning in 2025, the dollar limitation under Code Section 125(i) for voluntary employee salary reductions for contributions to health flexible spending arrangements (health FSAs) increased from $3,200 to $3,300.

The Affordable Care Act (ACA) amended Code Section 125 to place a $2,500 limitation on voluntary employee salary reductions for contributions to health FSA, subject to inflation for plan years beginning after December 31, 2013.

Annual maximum carryover

For cafeteria plans that permit the carryover option, the maximum unused amount from a health FSA plan year that begins in 2025 that can be carried over to the following plan year is $660 (up from $640 in 2024).

In May 2020, the IRS issued Notice 2020-33 to increase the carryover limit for unused amounts remaining in a health FSA as of the end of a plan year from a static maximum of $500 to 20% of the currently indexed heath FSA contribution limit for plans that have adopted the carryover option.

Qualified Transportation Fringe Benefits

For calendar year 2025, the monthly exclusion limitation for transportation in a commuter highway vehicle (vanpool) and any transit pass (under Code Section 132(f)(2)(A)) and the monthly exclusion limitation for qualified parking expenses (under Code Section 132(f)(2)(B)) increased from $315 to $325.

The Consolidated Appropriations Act of 2016 permanently changed the pre-tax transit and vanpool benefits to be at parity with parking benefits.

Highly Compensated

The compensation threshold for a highly compensated employee or participant (as defined by Code Section 414(q)(1)(B) for purposes of Code Section 125 nondiscrimination testing) for calendar year 2025 is $155,000.

Under the cafeteria plan rules, the term highly compensated means any individual or participant who for the preceding plan year (or the current plan year in the case of the first year of employment) had compensation in excess of the compensation amount as specified in Code Section 414(q)(1)(B). Prop. Treas. Reg. 1.125-7(a)(9).

At the time of this Bulletin, the 2026 dollar limitation under Code Section 414(q)(1)(B) concerning the definition of highly compensated employee or participant looking back to 2025 is not available. This Bulletin will be updated with this information when released.

Key Employee

The dollar limitation under Code Section 416(i)(1)(A)(i) concerning the definition of a key employee for calendar year 2025 is $220,000.

For purposes of cafeteria plan nondiscrimination testing, a key employee is a participant who is a key employee within the meaning of Code Section 416(i)(1) at any time during the preceding plan year. Prop. Treas. Reg. 1.125-7(a)(10).

At the time of this Bulletin, the 2026 dollar limitation under Code Section 416(j)(1)(A)(i) concerning the definition of a key employee looking back to 2025 is not available. This Bulletin will be updated with this information when released.

Non-Grandfathered Plan Out-of-Pocket Cost-Sharing Limits

As previously reported, the 2025 maximum annual out-of-pocket limits for all non-grandfathered group health plans are $9,200 for self-only coverage and $18,400 for family coverage.

These limits generally apply with respect to any essential health benefits (EHBs) offered under the group health plan. For coverage other than self-only (e.g., family coverage), the self-only annual out-of-pocket limit applies to each covered individual.

Health Reimbursement Arrangements

Qualified Small Employer Health Reimbursement Arrangements

For tax years beginning in 2025, to qualify as a qualified small employer health reimbursement arrangement (QSEHRA) under Code Section 9831(d), the arrangement must provide that the total amount of payments and reimbursements for any year cannot exceed $6,350 ($12,800 for family coverage), which increased from $6,150/$12,450 in 2024.

Excepted Benefit Health Reimbursement Arrangements

For plan years beginning in 2025, to qualify as an excepted benefit health reimbursement arrangement (EB HRA) under Treas. Reg. Section 54.9831-1(c)(3)(viii), the maximum amount that may be made newly available for the plan year for an excepted benefit HRA is $2,150 (increased from $2,100 in 2024).

Health Savings Accounts

As previously reported, the inflation adjustments for health savings accounts (HSAs) for 2025 were provided by the IRS in Rev. Proc. 2024-25.

Annual contribution limitation

For calendar year 2025, the limitation on deductions for an individual with self-only coverage under a high deductible health plan is $4,300; the limitation on deductions for an individual with family coverage under a high deductible health plan is $8,550.

HSA-compatible high deductible health plan

For calendar year 2025, an "HSA-compatible high deductible health plan" is defined as a health plan with an annual deductible that is not less than $1,650 for self-only coverage or $3,300 for family coverage, and the annual out-of-pocket expenses (deductibles, co-payments, and other amounts, but not premiums) do not exceed $8,300 for self-only coverage or $16,600 for family coverage. It should be noted that for family HDHP coverage, an individual embedded deductible cannot be less than $3,300.

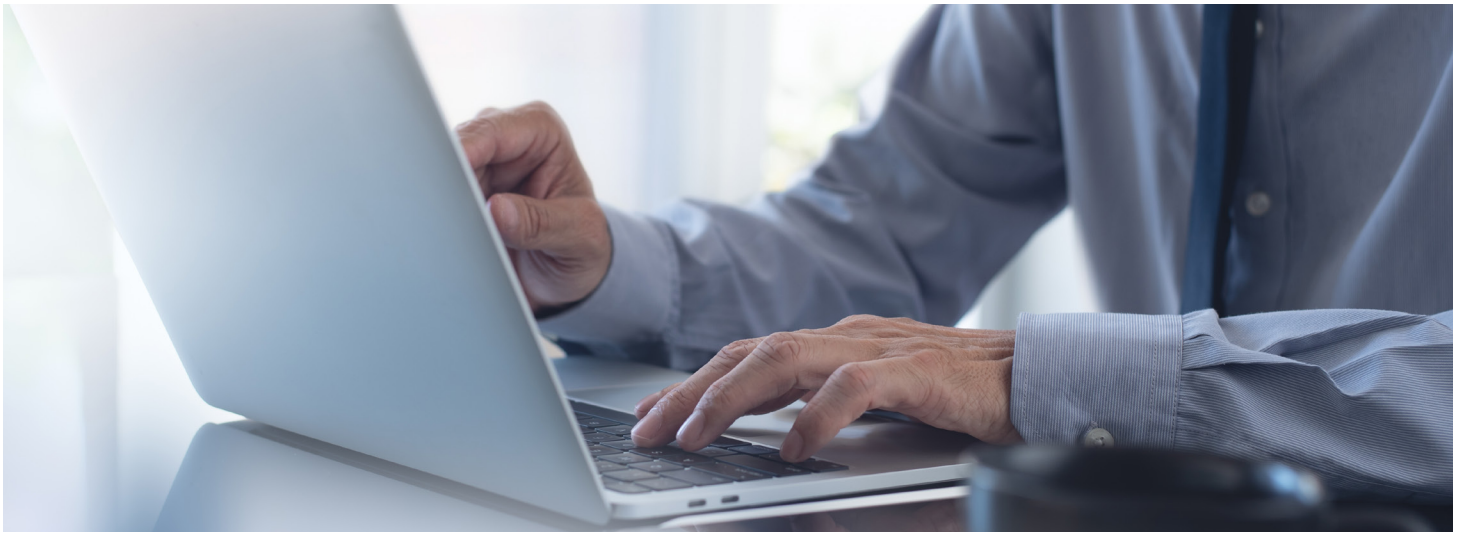
Non-calendar year plans: In cases where the qualifying high deductible health plan renewal date is after the beginning of the calendar year, any required changes to the annual deductible or out-of-pocket maximum may be implemented as of the next renewal date. See IRS Notice 2004-50, 2004-33 I.R.B. 196, Q/A-86 (Aug.16, 2004).

Catch-up contribution

Individuals who are aged 55 or older and covered by a qualifying high deductible health plan may make additional catch-up HSA contributions each year until they enroll in Medicare. The additional contribution, as outlined in Code Section 223(b)(3)(B), is $1,000 for 2009 and thereafter.

Employer Action

Employer with plan years beginning on or after January 1, 2025 should ensure the correct limits are applied to respective benefit plan options.



Reminder Massachusetts HIRD Reporting Due December 15 2024

Issued date: 11/06/24

As a reminder, Massachusetts employers must file the annual Health Insurance Responsibility Disclosure (HIRD) form through the MassTaxConnect (MTC) web portal. The HIRD reporting will be available to be filed starting November 15th and must be completed by December 15th.

The HIRD form collects employer-level information about employer-sponsored health insurance (ESI) offerings. The HIRD form assists MassHealth in identifying members with access to qualifying ESI who may be eligible for the MassHealth Premium Assistance Program.

State law requires every employer with six or more employees in Massachusetts to annually submit a HIRD form. If you are an employer who currently has (or had) six or more employees in any month during the past 12 months preceding the due date of this form (December 15 of the reporting year), you are required to complete the HIRD form.

- An individual is your employee if you, as the employer, included such individual in your quarterly wage report to the Department of Unemployment Assistance (DUA) during the past 12 months. You are required to complete the HIRD form if you reported six or more employees (includes all employment categories) in any DUA wage report during the past 12 months.

- If you are an out-of-state employer that is not required to file a quarterly wage report to the DUA, an individual is your employee if they are hired for a wage or salary in Massachusetts to perform work, regardless of full-time or part-time status.

For HIRD FAQs, visit: www.mass.gov/info-details/health-insurance-responsibility-disclosure-hird-faqs.

For more information about the Premium Assistance Program and additional employer resources, visit the MassHealth Premium Assistance web page: www.mass.gov/info-details/masshealth-premium-assistance-pa.

California Requires Insured Medical Plans To Provide Fertility Benefits

Issued date: 11/08/24

California has enacted legislation that will require large-group health insurance policies and HMO contracts to cover the diagnosis and treatment of infertility and fertility services, including in-vitro fertilization treatments. Small-group policies and HMO contracts must offer employers the option to cover these same services but are not required to provide the coverage automatically. The new law is generally effective for health insurance policies and HMO contracts that are issued, amended, or renewed on or after July 1, 2025. The new state law does not apply to self-funded plans.

Background

Since 1990, California has required every health insurance carrier and HMO to offer the employer (or other policyholder) the option to cover infertility treatments (except in-vitro fertilization) as part of hospital, medical, or surgery insurance, under the terms and conditions agreed to by the policyholder and the insurance carrier or HMO. Insurance carriers and HMOs are required to communicate the availability of this optional coverage to the employer (or other policyholder) but are not mandated to provide the coverage automatically.

New Requirements

The new state law requires large-group health insurance policies and HMO contracts to cover the diagnosis and treatment of infertility and fertility services, including a maximum of three completed in-vitro fertilization treatments. Small-group health insurance policies and HMO contracts are required to offer the employer (or other policyholder) the option to cover these same services but are not mandated to provide this coverage automatically.

California generally defines “small group” as a plan covering an employer that employs at least one, but not more than 100, full-time equivalent employees on at least 50% of its working days during the preceding calendar quarter or preceding calendar year, the majority of whom were employed in California.

The law prohibits health insurance policies and HMO contracts from excluding or denying coverage of fertility services provided by or to a third party, such as a gestational carrier, a surrogate who enables the intended recipient to become a parent, or the donor of an oocyte, sperm, or embryo. In addition, the new state law prohibits health insurance policies and HMO contracts from including any of the following provisions:

- Any exclusion, limitation, or other restriction on coverage of fertility medications that is different from those imposed on other prescription medications.

- Any deductible, copayment, coinsurance, benefit maximum, waiting period, or other limitation on coverage for the diagnosis and treatment of infertility that is different from those imposed upon benefits for services not related to infertility.

For purposes of the new coverage requirement, the term "infertility" is defined as a condition or status characterized by any of the following:

- A licensed physician's findings;

- A person's inability to reproduce as an individual or with a partner without medical intervention; or

- The failure to establish a pregnancy or to carry a pregnancy to live birth after regular unprotected sexual intercourse.

Effective Date

The new state law is generally effective for health insurance policies and HMO contracts that are issued, amended, or renewed on or after July 1, 2025. However, the new state law does not apply to health plans and policies with CalPERS (the benefit system for state employees) until July 1, 2027.

Exemptions

The law does not apply to accident-only, specified disease, hospital indemnity, Medicare supplement, or specialized disability insurance policies.

In addition, it does not apply to:

- A self-funded group health plan subject to ERISA;

- Any health insurance policy or HMO contract maintained by a "religious employer."

Extraterritoriality

The new state law applies to every health insurance policy that is issued, amended, or renewed to residents of California, regardless of the situs of the contract. This provision is identical to the provision under existing law.

Employer Action

Large employers with fully insured plans should be aware of the new fertility requirements that will take effect for plan years beginning on or after July 1, 2025.

Large employers with fully insured policies written outside of California, but providing coverage to California residents, should discuss compliance with the insurance carrier.

Small employers with fully insured plans should determine whether to opt in to the fertility coverage with the first renewal on or after July 1, 2025.

Gag Clause Attestation Due December 31 2024

Issued date: 11/08/24

As previously reported, insurance carriers and plan sponsors of group health plans must submit information annually to the Centers for Medicare and Medicaid Services ("CMS") attesting that their plan(s) do not include prohibited gag clauses by December 31st each year. The next attestation is due by December 31, 2024.

As a reminder, a gag clause is a contractual term that directly or indirectly restricts specific data and information that a plan or issuer can make available to another party. These clauses may be found in agreements between a plan or carrier and any of the following parties:

- a health care provider;
- a network or association of providers;
- a third-party administrator ("TPA"); or
- another service provider offering access to a network of providers.

Carriers and TPAs are notifying clients how they intend to comply with the Gag Clause Prohibition Compliance Attestation ("GCPCA"). Again, it seems there is no uniformity as to how the various carriers/TPAs will address the attestation requirements.

Fully Insured Plans

If the group health plan is fully insured, the plan and the carrier both have the obligation to file an attestation; however, if the carrier submits the attestation on behalf of the fully insured arrangement, no further action should be required by the plan. Plan sponsors should not assume the carrier will submit the attestation on their behalf. The carrier may request information from the employer to enable submission on the employer's behalf or may decline to submit and place the obligation on the employer to file the attestation. It is important to confirm each particular carrier's approach.

Self-funded Plans

A self-funded plan (including level-funded) is responsible for the attestation; however, the plan sponsor may enter into a written agreement with the provider (TPA, PBM) to submit the attestation on behalf of the plan. TPAs may request information from the employer to enable submission on the plan's behalf. It is important to note that some TPAs have indicated they will not submit the attestation for the plan. If that is the case, plan sponsors will need to submit the attestation for their plans and should obtain written confirmation from the TPA and other service providers that the contractual arrangements do in fact satisfy the gag clause prohibition requirements.

Plan sponsors who will need to file an attestation will submit their attestation via the webform by selecting the link for "Gag Clause Prohibition Compliance Attestation" at hios.cms.gov/HIOS-GCPCA-UI.

Plan sponsors should carefully review any communication provided by the carrier or TPA to ascertain what approach they will undertake for the December 31, 2024 submission.

New PCOR Fee Announced

Issued date: 12/12/24

On December 3, 2024, the IRS released Notice 2024-83, announcing that the adjusted applicable dollar amount used to determine the PCOR fee for plan years ending on or after October 1, 2024, and before October 1, 2025, is $3.47.

The PCOR filing deadline is July 31, 2025, for all self-funded medical plans (including level-funded) and some HRAs (including ICHRAs) for plan years (including short plan years) ending in 2024. Carriers are responsible for paying the fee for insured policies.

PCOR fee due July 31, 2025:

Plan Years Ending on	Amount of PCOR Fee
January 31, 2024	$3.22/covered life/year
February 29, 2024	$3.22/covered life/year
March 31, 2024	$3.22/covered life/year
April 30, 2024	$3.22/covered life/year
May 31, 2024	$3.22/covered life/year
June 30, 2024	$3.22/covered life/year
July 31, 2024	$3.22/covered life/year
August 31, 2024	$3.22/covered life/year
September 30, 2024	$3.22/covered life/year
October 31, 2024	**$3.47/covered life/year**
November 30, 2024	**$3.47/covered life/year**
December 31, 2024	**$3.47/covered life/year**

Employer Action

For now, no action by employers with self-funded health plans (or an HRA) is required. We will send a reminder in mid-2025 of the fee and additional information for filing and paying the PCOR fee with the IRS.

It should be noted that we have seen increased enforcement activity from the IRS around missing PCOR fees. Specifically, the IRS is issuing CP161 notices to employers who appear to have missed a prior year PCOR fee filing, requesting payment (including interest and penalties).

New Jersey Releases 2025 Disability And Family Leave Amounts

Issued date: 12/16/24

New Jersey has announced the 2025 contribution rates and benefit level parameters for the Temporary Disability Insurance ("TDI") and Family Leave Insurance ("FLI") programs. Compared to 2024, the 2025 rates and benefit parameters are as follows:

	2025	2024
Maximum TDI and FLI Weekly Benefit	$1,081	$1,055
Alternative Earnings Test Amount for TDI and FLI	$15,200	$14,200
Base Week Amount for TDI and FLI	$303	$283
Taxable Wage Base (employers) for TDI	$43,300	$42,300
Taxable Wage Base (employees) for TDI and FLI	$165,400	$161,400
Employee Contribution Rate for TDI	0.23%	0.00%
Employee Contribution Rate for FLI	0.33%	0.09%

Temporary Disability Insurance 2025

TDI provides benefits to eligible New Jersey workers for non-job-related illness, injury, or other disability that prevents them from working or due to certain public health emergency reasons. To be eligible for TDI, employees must have worked 20 weeks earning at least $303 per week ("Base Week Amount") or have earned a combined total of $15,200 ("Alternative Earnings Test") in the four quarters ("base year") prior to taking leave. Following a 7-day waiting period (except for certain public health emergencies), the weekly TDI benefit is 85% of an employee's average weekly wage but no greater than $1,081. TDI may be payable for up to 26 weeks in a 52-week period.

Employees typically contribute to TDI; however, in 2023 and 2024, employee contributions were reduced to zero. For 2025, employee contributions have been set at 0.23% of wages. The maximum contribution for 2025 is 0.23% up to the Taxable Wage Base (Employee) of $165,400 equal to $380.42.

Family Leave Insurance 2025

Family Leave Insurance provides benefits to eligible New Jersey workers for (i) the first 12 months following the birth, adoption or foster care placement of a child, or (ii) to care for a seriously ill family member. Similar to TDI, to be eligible for FLI employees must have worked 20 weeks earning at least $303 per week ("Base Week Amount") or have earned a combined total of $15,200 ("Alternative Earnings Test") in the four quarters ("base year") prior to taking leave. The weekly FLI benefit is 85% of an employee's average weekly wage but no greater than $1,081. FLI may be payable for 12 consecutive weeks in a 12-month period, or up to 8 weeks (56 individual days) in a 12-month period, if taking leave intermittently.

Employees contribute 0.33% of wages up to the 2025 Taxable Wage Base (Employee) of $165,400 equal to $545.82 ($145.26 in 2024).

FAQ 68 Addresses Preventive Care And Mastectomy Coverage

Issued date: 12/19/24

On October 21, 2024, the Departments of Labor, Health and Human Services, and the Treasury ("the Departments") issued FAQ Part 68, providing guidance on:

- Pre-Exposure Prophylaxis ("PrEP") as a preventive care service for persons at high risk of HIV;
- Proper coding and claims management for preventive care services; and
- Coverage requirements under WHCRA for mastectomies.

Coverage of PrEP

Under the Affordable Care Act ("ACA"), non-grandfathered group health plans and health insurance carriers must provide certain preventive care services without any cost-sharing requirements. The list of preventive care services is based upon recommendations from various agencies and advisory organizations, including the United States Preventive Services Task Force ("USPSTF"). Plans and carriers are allowed to use reasonable medical management techniques should a preventive care service or item requirement fail to include information on frequency, method, treatment or setting to provide the preventive care service.

In 2019, the USPSTF recommended that clinicians offer PrEP with effective antiretroviral therapy as a preventive care service to persons with a high risk of becoming infected with HIV. This guidance was clarified to include U.S. Food and Drug Administration ("FDA")-approved PrEP antiretroviral medications and specified baseline and monitoring services necessary to the efficacy of PrEP. At that time, the only FDA-approved PrEP formulation was a once-daily oral treatment (TF/FTC, brand name Truvada).

In 2023, two additional FDA-approved PrEP formulations were added:

- Emtricitabine/tenofvir alafenamide (TAF/FTC; brand name Descovy), approved daily oral medication; and

- Cabotegravir (brand name Apretude), a long-acting injectable medication.

FAQ 68 requires that, for plan years beginning on or after August 31, 2024, most health plans must cover without cost-sharing the three FDA approved PrEP formulations. Where necessary, medical management techniques may be used except to direct individuals to use one formulation over another.

Coding and Claims Management

FAQ 68 also reminds plans and carriers about the importance of properly coding claims for preventive care or services. Items or services that are preventive care in nature should be properly coded and processed without cost-sharing unless there is individualized information to determine that the care or service was not preventive care. Participants, beneficiaries or enrollees (or their authorized representatives) have the right to appeal an adverse benefit determination consistent with ERISA's internal appeal and review requirements.

There are industry-standard coding practices to help differentiate preventive care or services from diagnostic, therapeutic or other non-preventive care purposes. For example, the American Medical Association ("AMA") maintains the Current Procedural Terminology ("CPT®") coding system and established "modifier 33" to provide a standard way to communicate that an item or service is recommended preventive care under the ACA. FAQ 68 includes additional examples.

Mastectomy Related Required Coverages

The Women's Health and Cancer Rights Act ("WHCRA") requires health plans to include coverage for mastectomies and certain services related to consultation with the patient and attending physician. These required coverages include all stages of care on the breast on which the mastectomy was performed, surgery and reconstruction of the other breast for symmetrical appearance, prostheses, and treatment of physical complications related to the mastectomy, such as lymphedema.

FAQ 68 clarifies that WHCRA includes coverage of chest wall reconstruction with aesthetic flat closure if chosen by the patient upon consultation with their attending physician in connection with the mastectomy. Further, plan sponsors and carriers may impose deductibles and coinsurance for WHCRA benefits if such costs are deemed appropriate and consistent with costs for other benefits covered by the health plan.

Employer Action

Employers should take the following steps concerning this guidance:

- Confirm that the listed PrEP formulations are identified as preventive care services under their group health plans beginning with plan years on or after August 31, 2024;
- Ensure carriers and TPAs have appropriate practices in place to properly identify whether a service or item should be covered as preventive care;
- Examine mastectomy-related services and care under the group health plan for any exceptions or limitations, including cost sharing provisions; and
- Continue to monitor ongoing litigation that could impact preventive care requirements for group health plans.

Idaho Enacts PBM Law

Effective January 1, 2025, Idaho HB 596 (the "Bill") will place new requirements on pharmacy benefit managers ("PBMs") and the plans they service. Idaho joins the growing list of states that have passed laws targeting PBM practices and prescription benefits. Whether and to what extent the law may be subject to ERISA preemption will not likely be known until the law becomes effective.

Key requirements of the Bill:

The Bill governs disclosure, reporting and contractual requirements for PBMs doing business in Idaho by:

- requiring PBMs to register with the state;
- requiring PBMs to pass through 100% of rebates to the plan;
- prohibiting spread pricing, the practice of charging a plan more than the pharmacy is paid for prescriptions services;
- requiring increased reporting to the Department of Insurance ("DOI");
- requiring increased reporting to plans related to costs for Rx services, fees charged, and rebates received related to the plans;
- requiring network adequacy standards that meet or exceed Medicare part D requirements; and
- continuity of care provisions related to mid-year formulary changes.

The Bill

Under the Bill, plans will be entitled to significant information related to how prescription services are provided by PBMs. This will include disclosure of:

- the cost, price, and reimbursement information of all prescription drugs;
- all fees, markups, and discounts charged or imposed on pharmacies with which the PBM has contracted; and
- the aggregate amount of all remuneration the PBM received from a drug manufacturer for a prescription drug including any rebate, discount, admin fee or any other payment or credit.

In addition to the increased disclosure requirements, PBM contracts will need to include the following:

- require pass through pricing where the PBM must charge the plan no more than the amount that they pay a pharmacy for prescription drugs;
- prohibit spread pricing where the PBM charges the plan more than a pharmacy is reimbursed for prescription drugs; and
- require 100% of manufacturer rebates to be provided to offset plan cost-sharing and reducing premiums with any remaining rebates to be used to reduce participant copayments in contracts that allow the PBM to negotiate rebates.

Network adequacy requirements are meant to expand pharmacy networks and increase options for covered members to obtain services at pharmacies of their choice. Additionally, network adequacy requirements often serve to counter a PBM from disfavoring unaffiliated or independent pharmacies that are often critical in providing services in rural areas. These requirements include:

- prohibiting a PBM from limiting a network to an affiliated pharmacy;
- prohibiting a PBM from limiting coverage to mail-order only;
- prohibiting the requirement that a covered member obtain services from an affiliated pharmacy; and
- prohibiting the participation in a network being conditioned on participation or non-participation in another network.

Additional requirements of the Bill include increased reporting to the DOI related to the difference in reimbursement rates, direct and indirect remuneration, fees or other price concessions, and clawbacks between an affiliated and unaffiliated pharmacy. Additionally, PBMs will be required to report an explanation of the reason why any drug was moved or reassigned to a formulary tier that has a higher cost, copayment, coinsurance, deductible for a covered individual or a lower reimbursement to a pharmacy.

Continuity of care provisions will require a PBM that implements mid-year formulary changes to allow a covered individual to continue to have access to the medication at the same cost for up to 60 days after the covered individual is notified of the change.

State PBM Laws and ERISA Preemption

ERISA preemption exempts self-funded ERISA-covered plans from the applicability of state law. As medical and prescription service costs continue to rise, there has been increased focus on PBMs at the state level. Various laws have been passed in different states that have placed requirements on PBM networks, contract provisions related to pricing and rebates, as well as setting rules and limits for how PBMs structure their pharmacy networks. Litigation has produced varied results related to ERISA preemption.

The U.S. Supreme Court held that an Arkansas statute that mostly regulated rate setting by PBMs was not preempted by ERISA. However, an Oklahoma law that included requirements directly affecting plan design and administration, as well as mail order pharmacy benefits, was found to be partially preempted by ERISA by the 10th Circuit Court of Appeals. The state has appealed the decision to the U.S. Supreme Court. It's uncertain whether the Court will accept the case and further weigh in on ERISA preemption.

Employer Action

Employers providing prescription drug benefits to Idaho residents should confirm their PBM's compliance with the new requirements.

- The provisions of the law related to contract requirements and network adequacy appear to be effective for any contract executed, amended, adjusted, or renewed on or after January 1, 2025.

- The disclosure requirements may be effective January 1, 2025, without any delay. Self-funded plan sponsors should confirm with their TPAs or PBMs whether and when those service providers intend to provide the required disclosures.

While ERISA preemption for some of the provisions of the law may be possible, self-funded plan sponsors should review PBM contracts to determine what changes may be needed to comply with the new requirements. The law allows for penalties against the PBM for any violation, enforceable by the DOI.

Washington State PBM Law

Washington state recently passed E2SSB 5213 which further regulates Pharmacy Benefit Managers ("PBMs") and Health Care Benefit Managers ("HCBMs" include PBMs) doing business in the state.

Unlike PBM laws passed in other states, the Washington law is clear that PBMs are not required to comply with E2SSB 5213 for self-funded ERISA group health plans unless that self-funded health plan opts into the protection of the law. This "opt-in" provision was likely added to the legislation to avoid ERISA preemption challenges that have occurred with respect to PBM laws in other states around the country.

Fully insured health plans and health plans offered to public employees are subject to these PBM requirements.

Under E2SSB 5213, a PBM may not:

- reimburse a network pharmacy an amount less than the contract price between the PBM and the third-party payor the PBM has contracted with to provide a pharmacy benefits plan or program;
- exclude a pharmacy from the network on the basis that the pharmacy is new, has only been open for a limited time, or has transferred locations, unless there is a pending investigation for fraud, waste, and abuse;
- reimburse a pharmacy or pharmacist an amount less than the amount the PBM would reimburse an affiliate for the same service
- require a covered person to pay more for a drug than the lesser of the applicable cost sharing for the drug or the amount the person would pay if buying the drug in cash; or
- require or coerce a covered person to use a pharmacy owned or affiliated with the PBM.

The law requires that PBMs must:

- apply the same fees, utilization review, and days allowance regardless of which participating pharmacy a covered person uses;
- permit the covered person to receive delivery or mail order of a medication through any network pharmacy that is not primarily engaged in dispensing prescription drugs to patients through the mail or common carrier; and
- for new prescriptions issued after January 1, 2026, receive affirmative authorization from a covered person before filling prescriptions through a mail order pharmacy.

In addition:

- Registration process for PBMs and HCBMs. All HCBMs, including PBMs, must register with the state's Office of Insurance Commissioner ("OIC") and meet other requirements.

- Mail order. If a covered person uses a mail-order pharmacy, the PBM must allow for dispensing at a local network pharmacy if the mail-order is delayed by more than one day after the expected delivery day provided by the mail-order pharmacy, or if the order arrives in an unusable condition. The PBM must also ensure that covered persons using a mail-order pharmacy have easy and timely access to prescription counseling by a pharmacist.

- Pharmacy appeals process. PBMs must establish a process by which a network pharmacy, or its representative, may appeal its reimbursement for a drug. A network pharmacy may appeal a reimbursement cost for a drug if the reimbursement for the drug is less than the net amount that the network pharmacy paid to the supplier of the drug.

- No fee for network participation. A PBM may not charge a pharmacy a fee related to credentialing, participation, certification, or enrollment in a network, and it may not condition or link restrictions on fees related to credentialing, participation, certification, or enrollment in a PBM's pharmacy network with a pharmacy's inclusion in the PBM's pharmacy network for other lines of business.

- Retaliation prohibited. A PBM may not retaliate against a pharmacy or pharmacist for disclosing information in court, an administrative hearing, legislative hearing, or to a law enforcement agency if the pharmacy or pharmacist has a good faith belief the information is evidence of a violation of a state or federal law, rule, or regulation.

These requirements apply to PBMs and HCBMs and become effective on January 1, 2026.

Employer Action

As much of the law appears to take effect January 1, 2026, PBMs will likely be making changes to their processes. The OIC is currently undergoing a ruling making process to further clarify these requirements.

Employers with an ERISA covered self-funded group health will need to determine whether to "opt-in" to the state protections. It will be important to discuss with the plan's third-party administrator and/or PBM to determine whether they will be able to comply with the requirements before making an opt-in election. The OIC is likely to establish a process for making an "opt-in" election in future guidance or rulemaking.

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