Employer **focus**

Benefits Compliance Newsletter for Employers | Q3 2024

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Second Quarter Benefits News Highlights

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Instructions – 2024 Form 1094 and Form 1095

The IRS released the instructions for 2024 forms used by applicable large employers (50 or more FTEs) to report offer of coverage information for all full-time employees as well as the forms used by employers to report coverage under self-funded or level-funded plans. The instructions confirm that copies of Form 1095s must be delivered to full-time employees and covered individuals by March 3, 2025, and the Form 1094 and all Form 1095s must be submitted electronically to the IRS by March 31, 2025. The IRS instructions can be found here:

"B" Forms – **https://www.irs.gov/pub/irs-prior/i109495b–2024.pdf**

"C" Forms – **https://www.irs.gov/pub/irs-prior/i109495c–2024.pdf**

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2025 Affordability Percentage

In Revenue Procedure 2024-35, the IRS increased the affordability percentage from 8.39% in 2024 to 9.02% for 2025. This percentage determines which applicable large employers may face penalties under §4980H(b) for failure to offer affordable coverage as well as which individuals may qualify for subsidized Marketplace coverage. The 2025 affordability percentage is effective for plan years beginning on or after January 1, 2025. For calendar year plans, 9.02% applies beginning in January 2025, but for a non-calendar year plan that renews in September, 9.02% applies beginning in September 2025.

Revenue Procedure 2024-35 – https://www.irs.gov/pub/irs-drop/rp-24-35.pdf

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Updated HIPAA, MSP and SBC Penalties for Non-Compliance

The Department of Health & Human Services (HHS) announced updated penalty amounts for HIPAA, MSP and SBC violations. The updated penalties can be found here – https://www.govinfo.gov/content/pkg/FR-2024-08-08/pdf/2024-17466.pdf

- For HIPAA privacy and security non-compliance, the updated penalties range from $141 for lack of knowledge to $2,134,831 for willful neglect.

- For non-compliance with Medicare Secondary Payer (MSP) rules, including taking into account Medicare eligibility or incenting individuals to waive the employer's plan in favor of Medicare, the updated penalty is $11,162.
- For failure to timely distribute a current summary of benefits & coverage (SBC), the updated penalty is $1,406.

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Determining Creditable Status of Prescription Drug Coverage

Employers are not required to offer creditable prescription drug coverage, but any size employers that offer prescription drug coverage are required to determine and communicate creditable (or non-creditable) status to eligible individuals as well as report the status annually to CMS. Prescription drug coverage is creditable if the actuarial value of the coverage equals or exceeds the actuarial value of standard Medicare Part D prescription drug coverage. Often an insurance carrier or third-party administrator (TPA) will determine creditable status, but if not, the plan sponsor (e.g., the employer) must make the determination, or hire an actuary to help with the determination. If a plan sponsor is not applying for the retiree drug subsidy available to sponsors of a qualified retiree prescription drug plan, the sponsor can use a "simplified method" for determining whether the prescription drug coverage is creditable. CMS has confirmed that the simplified method will continue to be available in 2025. Employers who need help with the simplified method can use the MZQuick Creditable Coverage Calculator. See more information here – https://benefitcomply.com/partd/

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HIPAA Instructions & Model Attestation

HHS has issued the promised Model Attestation for a Requested Use or Disclosure of Protected Health Information Potentially Related to Reproductive Health Care. This form is a necessary component for HIPAA-regulated entities (like group health plans) to be able to comply with the new category of prohibited uses and disclosures of Protected Health Information (PHI) that is potentially related to reproductive health care, as introduced in the 2024 Privacy Rule that was released in late April and goes into effect in December 2024. The Model Attestation, along with other informational materials on the 2024 Privacy Rule (including a Social Media Toolkit and Fact Sheet) can be found here – https://www.hhs.gov/hipaa/for-professionals/special-topics/reproductive-health/index.html

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FTC Report on PBMs

As many employers are struggling to manage rising costs related to prescription drug coverage, the Federal Trade Commission (FTC) released a report highlighting the role that pharmacy benefit managers (PBMs) play in the accessibility and affordability of prescription drugs. The report is intended to make the FTC's findings available to the public, not requiring any particular action by any parties. You can find more detail here – https://www.ftc.gov/news-events/news/press-releases/2024/07/ftc-releases-interim-staff-report-prescription-drug-middlemen

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Hospital Price Transparency

In accordance with transparency legislation, beginning in January 2021, hospitals are required to make public their standard charges in two ways: (1) as a comprehensive machine-readable file (MRF); and (2) in a consumer-friendly format. CMS final rules updated the requirements and require hospitals to make changes in how this information is provided beginning July 1, 2024. Hopefully the changes will result in improved access and usability for the pricing information. More detail can be found in CMS' FAQ here – https://www.cms.gov/files/document/hospital-price-transparency-frequently-asked-questions.pdf

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Change Healthcare – HIPAA Breach Notifications

After a large-scale cybersecurity incident in February 2024, Change Healthcare has decided to go forward in contacting affected parties regarding the incident and offer to have those parties' notification duties delegated to Change Healthcare, according to communications received by clients on June 20, 2024.

Ideally, employers as plan sponsors will have their own HIPAA policies and procedures to guide them in their process of how to handle a breach of their participants' protected health information. A source of confusion in this case is that the incident has not yet been declared a breach by Change Healthcare (nor has Change Healthcare reported the incident as a breach to HHS), but this latest move seems to indicate that it is being treated like a breach and has employers questioning what their own notification obligations are.

Clearly, a vast amount of information was compromised in this incident, and affected individuals should be notified to mitigate any potential harm. However, the lack of available information in this case has made it difficult for employers to know who to notify and what to tell them – and a blanket notification of a potential threat to personal information would likely cause more confusion than clarity. For now, we have to recommend that employers take up Change Healthcare on their offer to take over notification duties to ensure that their participants get the latest information.

For more information, HHS has a FAQ page regarding this specific incident: https://www.hhs.gov/hipaa/for-professionals/special-topics/change-healthcare-cybersecurity-incident-frequently-asked-questions/index.html

In addition, if employers need help with their HIPAA policies and procedures for their group health plans, see how we can help here – https://benefitcomply.com/hipaa-compliance/

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Supreme Court Decision – Change in Administrative Power

A Supreme Court decision released last week overturned a 40-year precedent known as the Chevron Doctrine. Under the doctrine, when a federal statute was silent or ambiguous, courts were expected to defer to federal agency interpretations (e.g., for health and welfare benefits, regulations and guidance interpreting federal statutes are generally issued by the DOL, IRS and HHS). Going forward, courts have the power to interpret federal statutes that are silent and ambiguous and are not required to defer to federal agency interpretations. The court case was not benefits-related and does not have any immediate impact on any benefit-related regulations or guidance issued by federal agencies. Employers should continue to follow the current interpretations of agencies such as the DOL, IRS and HHS. However, such interpretations are perhaps more likely to be successfully challenged in the courts over upcoming months and years, potentially creating some confusion and instability for employers who currently rely heavily on federal agency interpretations of various requirements under ERISA, COBRA, HIPAA, ACA, tax law and more. For now, employers should stay the course. We'll see how this plays out over time as agency interpretations specific to health and welfare benefit compliance are challenged in the courts.

The Supreme Court's opinion in *Loper Bright Enterprises v. Raimondo* can be found here – https://www.supremecourt.gov/opinions/23pdf/22-451_7m58.pdf

Gag Clause Attestation Service

The MZQuick Attest Service will notify identified plan vendors of the plan's intention to consider any gag clauses found in their service agreements to be unenforceable as applicable under the Consolidated Appropriations Act, 2021 (CAA21) and complete the attestation requirements on behalf of group health plan sponsors.

The registration deadline to ensure timely filing and notice to vendors is December 9th each calendar year.

Up to 3 vendors: $500

Additional vendors: $100

SIGN UP AT: https://www.mzqconsulting.com/mzquick-attest-sign-up

MZQuick Attest™

FEATURE: Mental Health Parity Final Rules

The Department of the Treasury, Department of Labor and Department of Health & Human Services (collectively, "the Departments") released the much anticipated final rules further clarifying and implementing the requirements related to the Mental Health Parity and Addiction Equity Act (MHPAEA). As previously set forth in the 2023 proposed rules, with some modifications and clarifications, the final rules add further requirements for analyzing parity for non-quantitative treatment limitations (NQTLs), set specific requirements for achieving parity for network composition, and build on what is required to be analyzed and documented via the comparative analysis. The rules make it clear that enforcement of the mental health parity rules remains a priority for the administration as part of their commitment to improving access to behavioral health treatment and services.

The final rules apply to group health plans beginning in 2025, except that the more significant changes related to the meaningful benefits standard, the prohibition on discriminatory factors and evidentiary standards, and relevant data evaluation requirements (along with associated content requirements in the comparative analysis) will go not go into effect until plan years beginning in 2026. In the meantime, however, the Departments emphasize that plans are already subject to MHPAEA requirements as set forth in the 2013 final regulations as well as the comparative analysis requirements added by the Consolidated Appropriations Act of 2021 and should comply accordingly while working toward bringing plans into compliance with these latest requirements by 2026. The final rules can be found here: https://public-inspection.federalregister.gov/2024-20612.pdf

Background

MHPAEA requires group health plans offering mental health (MH) or substance use disorder (SUD) benefits to provide such benefits "in parity" with (equal to or better than) the medical/surgical coverage available under the group health plan. MHPAEA does not require group health plans to provide MH or SUD benefits, but if the plan does offer such benefits beyond what is considered preventive under the Affordable Care Act (ACA), the parity requirements apply. MHPAEA applies to both fully-insured and self-funded group health plans, but not to excepted benefits or retiree-only plans.

If a group health plan provides medical/surgical benefits and MH or SUD benefits, the plan's MH or SUD benefits are subject to the following parity requirements (as compared to the plan's medical/surgical benefits):

- Same or more generous annual/lifetime limits;
- Equal financial requirements and quantitative treatment limitations; and
- Equal treatment for non-quantitative treatment limitations (e.g., prior authorization, medical necessity, provider network standards, fail first or step therapy policies, experimental treatment limitations, etc.).

The parity of any financial requirements or treatment limitations is determined on a classification-by-classification basis for six different classifications, as seen in the table below. Plans must provide MH or SUD benefits in parity for all classifications in which medical/surgical benefits are available.

MHPAEA Classifications	
Inpatient, in-network	Inpatient, out-of-network
Outpatient, in-network*	Outpatient, out-of-network*
Emergency Care	Prescription Drugs

**Outpatient services may be sub-classified into (a) office visits and (b) all other outpatient items and services but plans generally cannot further sub-classify generalists and specialists.*

Finally, specific to NQTLs, plans must evaluate and document the parity of any NQTLs applicable to MH or SUD benefits, as written and in operation, via a comparative analysis. The comparative analysis must be kept current and made available upon request by federal or state agencies as well as by ERISA plan participants.

Meaningful Benefits

The final rules clarify that if a plan provides any benefits for a specific MH condition or disorder or SUD, the plan must provide meaningful benefits for that condition or disorder in every classification in which medical/surgical benefits are provided. To satisfy this requirement, a plan must provide core treatment for that specific condition or disorder in each classification in which the plan provides benefits for a core treatment for medical conditions or surgical procedures. "Core treatment" is defined as "a standard treatment or course of treatment, therapy, service, or intervention indicated by generally recognized independent standards of current medical practice." Examples in the final regulations address how this new requirement may apply for autism spectrum disorder (ASD), eating disorders, and opioid use disorders.

New Requirements for NQTLs

NQTLs are permitted for MH or SUD benefits if they are no more stringent than those applied to medical/surgical benefits OR if they are consistent with generally recognized independent professional medical clinical standards or standards related to fraud, waste and abuse. To ensure these general requirements are met, the NQTLS are not subject to the same mathematical substantially all and predominant tests used to assess parity for financial requirements and quantitative treatment limitations (as suggested in the 2023 proposed rules), but NQTLs must meet certain design and application requirements and relevant data evaluation requirements. Also, the final rules clarify that a plan may not impose any NQTL on MH or SUD benefits if that specific NQTL does not also apply to medical/surgical benefits in the same classification.

Design and Application Requirement

A plan may not impose an NQTL for MH or SUD benefits in any classification unless any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH or SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits. A plan cannot rely upon discriminatory (biased or not objective) factors or evidentiary standards to design a NQTL to be imposed on MH or SUD benefits.

Relevant Data Evaluation Requirement

The plan must collect and evaluate relevant data (e.g., number and percentage of claims denials, network utilization, network adequacy metrics, provider reimbursement rates) to assess the application of an NQTL and how it impacts access to MH and SUD benefits. If there are material differences in access to MH or SUD benefits in comparison to medical/surgical benefits, the plan must take reasonable action as necessary to address any material differences in access. For example, within a classification, similar medical management techniques may apply to medical/surgical benefits and mental health benefits; however, if after analyzing the percentage of claims denied, the data shows mental health benefit claims being denied at a much larger percentage than medical/surgical benefits, the plan may need to make adjustments.

Specific to network composition, the plan must collect and evaluate relevant data to assess the aggregate impact of NQTLs on access to benefits. The rules suggest certain actions that could be taken if material differences in access are discovered related to network composition (e.g., recruit and encourage more network participation, expand telehealth, assist plan participants in finding in-network care, keep provider directories current).

Updated Requirements for Comparative Analyses

Group health plan sponsors are required to prepare a comparative analysis documenting compliance for any NQTLs. The final rules clarify existing content requirements, providing much more detail about what is expected to be evaluated and included in the written analysis, and then also requires plans to include an evaluation of relevant data. Specifically, for each NQTL applicable to MH or SUD benefits, the written comparative analysis must contain the following content:

Comparative Analysis Content Requirements
1. Description of the NQTL, which benefits are subject to the NQTL, and which benefits are in which classification
2. List and definitions for any factors and evidentiary standards used to design or apply the NQTL
3. Description of how factors are used in the design and application of the NQTL
4. Demonstration of comparability and stringency of the NQTL, as written
5. Demonstration of comparability and stringency of the NQTL, in operation, including any material differences in access and reasonable action taken to address the material differences
6. Findings and conclusions, including the date the analysis was completed and the title and credentials of persons involved in preparing the comparative analysis

A thorough, compliant analysis cannot be quickly pulled together within the timeframe required to comply with a request from an agency or plan participant, so it is likely necessary for employers to complete it and have it ready and on file prior to any request.

Fiduciary Certification

To further enforce awareness of compliance requirements, for plans subject to ERISA, the final rules require that the comparative analysis include a certification by one or more named fiduciaries. The fiduciaries must certify that they "engaged in a prudent process to select one or more qualified service providers to perform and document a comparative analysis…and have satisfied their duty to monitor those service providers…" In other words, plan fiduciaries do not have to certify full compliance with MHPAEA, but instead must certify and take responsibility for due diligence in selecting a service provider that can provide what is needed to comply with MHPAEA.

Non-Compliance

For plans that fail to provide a complete and thorough comparative analysis and then fail to correct any insufficiencies within the timeframe required by the applicable agency, the agencies may direct the plan not to impose any NQTL that cannot be adequately shown to be in parity with medical/surgical benefits. In addition, the plan (or sponsoring employer) may be listed in the agencies' enforcement report to Congress and may have to notify plan participants with something similar to the following:

> "Attention! The [Department of Labor/Department of Health and Human Services/Department of the Treasury] has determined that [insert the name of group health plan or health insurance issuer] is not in compliance with the Mental Health Parity and Addiction Equity Act."

The notice would need to include a summary of the agency's finding of non-compliance and information about how participants can obtain a copy, information for where to direct any questions or complaints, and contact information for the applicable agency. The notice would also be required to include a summary of any changes the plan has made as part of its corrective action plan, including an explanation of any opportunity for a participant to have a claim for benefits reprocessed.

In addition to the potential consequences discussed above for failure to provide a complete comparative analysis when requested by a federal or state agency, for ERISA plans, there is risk of civil penalties for failure to provide the analysis within 30 days of request by a plan participant or beneficiary.

Employer Action

The MHPAEA requirements, including the plan design and administration requirements as well as the written comparative analysis, can be complex to navigate and implement. Most employers do not have the expertise needed to design a group health plan as required, are not directly involved in claims processing, and do not have access to the level of information needed to prepare a sufficient comparative analysis. Therefore, employers must rely heavily on carriers, TPAs and other service providers to offer a compliant plan design, to properly administer claims, and to evaluate and document compliance in a detailed comparative analysis. For fully-insured plans, the carrier is directly responsible for compliance and will generally only offer plans that comply with the MHPAEA (or will face direct consequences for failure to comply). However, for self-funded plans, while service providers may be co-fiduciaries under ERISA rules, the employer is primarily responsible for compliance and will need to take efforts to ensure that TPAs, PBMs and other service providers involved in designing and administering the plan on the employer's behalf are competent and willing to comply with the MHPAEA requirements and to prepare a comparative analysis on behalf of the plan, or at least provide the data needed for another vendor to prepare the comparative analysis.

For employers offering self-funded group health plan coverage, or who provide MH or SUD benefits in addition to their fully-insured coverage (e.g., via telehealth), the employer should review their plan design and ask their service providers what level of analysis has been done to ensure that any financial requirements (e.g., copays, coinsurance, deductibles) and quantitative treatment limitations (e.g., visit or treatment limits) are set up to be in parity with those that apply to medical/surgical benefits. Similarly, employers should ask service providers to confirm that NQTLs are designed and administered in accordance with MHPAEA requirements and confirm what role the service provider will play in completing a comparative analysis, including an assessment of all relevant data.