



Welcome

Employee benefit laws change rapidly — UBA Partner Firms help their clients stay one step ahead with ongoing expert compliance resources.









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Consolidated Appropriations Act, 2021, Compliance Requirements





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Agenda

- 1. "No Gag Clause"
- 2. RxDC Reporting
- 3. Mental Health Parity Comparative Analysis
- 4. Plan Documents
- 5. Broker/Consultant Fee and Service Disclosures
- 6. Questions

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"No Gag Clause"

"No Gag Clause" Rule

- What is the "no gag clause" rule?
 - Health plans (or issuers of health insurance coverage offered in connection with such plans) cannot enter into agreements that directly or indirectly restrict the plans from:
 - disclosing provider-specific cost or qualityof-care information to providers, the plan sponsor, and participants;
 - electronically accessing de-identified claims and encounter information or data for each participant; and
 - sharing this type of information with a business associate.



"No Gag Clause" Rule

- Which contracts are subject to the "no gag clause" rule?
 - It applies to contracts between a group health plan and 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.
- Examples of gag clauses:
 - A contract between a group health plan and a TPA that states that the plan will pay providers at designated "Point of Service Rates," but the TPA contractually prohibits the plan from disclosing the rates to participants.
 - A contract between a group health plan and TPA that states the plan sponsor's access to provider-specific cost and quality-of-care information is available only at the TPA's discretion.

Reporting (Attestation) for "No Gag Clauses"

- A group health plan (or health insurance coverage offered in connection with such a plan) must submit an attestation each year that the plan or issuer complies with the "no gag clause" rule.
 - First attestation was due December 31, 2023
 - Attestations are due December 31 each year thereafter
 - Attestation is submitted online:
 <u>https://www.cms.gov/marketplace/about/oversight/other-insurance-protections/gag-clause-prohibition-compliance-attestation</u>
- Some plans, such as health reimbursement arrangements ("HRAs") and limited-scope standalone dental and vision plans are <u>not</u> required to attest.

Who Performs the Reporting?

Fully Insured Plan

- Insurance company submits the attestation, and
- Group health plan submits the attestation
 - If the plan's coverage consists of group health insurance coverage and the insurer submits the attestation on behalf of the plan, regulators consider the plan <u>and</u> insurer to have satisfied the attestation requirement.

Self-Insured Plan

- Group health plan submits the attestation
 - It can enter into a written agreement with its service provider (e.g., TPA) under which the service provider attests on the plan's behalf.
 - If service provider fails to submit the attestation, the plan is in violation of the attestation requirement.

Compliance Tips

- Review contracts (e.g., administrative services agreements, business associate agreements, pharmacy benefit management agreements, and statements of work) for prohibited "gag clauses."
 - Amend contracts if indicated
 - Include provisions for "no gag clause" rule in future contracts/amendments
- Determine who is responsible for preparing and submitting the attestation
 - Obtain written confirmation from insurers
 - For self-insured plans, obtain written agreements with service providers
- Submit by deadline if a third party will not do so for the plan.

Prescription Drug/Health Plan Reporting (RxDC)

RxDC Reporting

- Purpose of the reporting:
 - Regulators will use information to prepare publicly available reports on prescription drug reimbursements, prescription drug pricing trends, and how prescription drug costs contribute to premium increases (or decreases) under group health plans.
 - Information is confidential; no drug or plan-specific information will be made public.
- Reports are due June 1 of each year (e.g., 2023 is reported on June 1, 2024)

Which Plans Must Report?



- Various group health plans must report, such as:
 - Fully insured group health plans.
 - Self-insured group health plans.
 - Group health plans sponsored by state and local governments.
 - Church group health plans that are subject to the Internal Revenue Code.
 - Grandfathered and non-grandfathered group health plans.
- A group health plan can contract with an insurer, third-party administrator, pharmacy benefits manager, or other party to submit the information for the plan.

What Information Is Reported?

- Plan year.
- Number of participants and beneficiaries.
- State(s) where coverage offered.
- Top 50 brand prescription drugs most frequently dispensed and total number of paid claims for each drug.
- 50 most costly prescription drugs by total annual spending and the annual amount spent by the plan for each drug.
- 50 prescription drugs with the greatest increase in annual expenditures and, for each drug, change in amount the plan expended.

What Information Is Reported?

- Total spending on health care services, broken down by:
 - Types of costs (e.g., hospital, health care provider and clinical service costs, costs for prescription drugs, and other medical costs, including wellness services).
 - Spending on prescription drugs.
 - Average monthly premium (paid by employer and by participants).
 - Any impact on premiums by rebates, fees, and any other remuneration paid by drug manufacturers to the plan.
 - Any reduction in premiums and out-of-pocket costs associated with rebates, fees, or other remuneration paid by drug manufacturers to the plan.

How To Submit the Report

- The instructions and templates for preparing and submitting the report are online:
 - https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection
- Various Excel spreadsheets are used to report the different data elements:
 - Available online (link above).
- The report is submitted to the Centers for Medicare & Medicaid Services ("CMS"):
 - https://portal.cms.gov/portal/

Compliance Tips

- Consider contracting in writing with a third party to perform the reporting on behalf of the plan.
 - Insurer, third-party administrator, and pharmacy benefits manager.
 - Fully insured versus self-insured group health plans.
 - Review "form" agreement before signing!
- Review the instructions and reporting requirements.
- Obtain data and populate the various Excel files.
- Submit reports by deadline.
- Obtain confirmation that third party (if used) timely submitted reports.



Mental Health Parity Comparative Analysis

CAA Focused on Mental Health Parity

- The Consolidated Appropriations Act, 2021 ("CAA") requires group health plans to prepare a comparative analysis of the plan's nonquantitative treatment limitations ("NQTLs") that apply to mental health and substance use disorder ("MH/SUD") benefits and medical/surgical ("M/S") benefits.
- Helps demonstrate compliance with the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, as amended ("MHPAEA").

What Is an NQTL?

- An NQTL limits the scope or duration of treatment and is not expressed numerically.
- Examples of NQTLs:
 - Prior authorization requirements
 - Concurrent review requirements
 - Medical necessity requirements
 - Standards for provider admission to participate in a network, including reimbursement rates
 - Licensing/credentialing requirements for health care providers or facilities
 - Restrictions based on geographic location
 - Prescription drug formulary design

Regulators' Current NQTL Focus

- Prior authorization requirements for innetwork and out-of-network inpatient services
- Concurrent review for in-network and outof-network inpatient and outpatient services
- Standards for provider admission to a network, including reimbursement rates
- Out-of-network reimbursement rates, including plan methods for determining usual, customary, and reasonable charges



What Are Key Components of the Analysis?

- Identify all of a health plan's NQTLs
- Include a description of all the plan benefits to which the NQTLs apply
- Identify the factors used to determine that NQTLs will apply to a benefit
- Identify the evidentiary standards used for those factors
- Analyze whether the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to MH/SUD benefits, as written and in operation, are comparable to, and are applied no more stringently than, those used to apply the NQTLs to M/S benefits in the same classification
- DOL FAQs provide additional items the analysis must address

Example: Prior Authorization NQTL

- Factors used to determine NQTL:
 - Clinical appropriateness
 - Value
- Evidentiary standards used to determine the factors
 - Clinical criteria from third-party sources
 - Clinical assessment committees
 - Guidelines from professional health care associations
- Are the processes, strategies, evidentiary standards, and other factors used to apply prior authorization to MH/SUD benefits, as written and in operation, comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply prior authorization to M/S benefits?

Who Can Request the Comparative Analysis?

- U.S. Department of Labor
 - Congress directed DOL to collect a minimum of 20 analyses per year
 - Requests can be random or in response to a participant complaint
 - Expects the analysis to be provided promptly upon request
 - Expects the analysis to be completed prior to the request
 - If parity violation found, must address within 45 days
- Plan participants must be provided a copy upon request
- State agencies (e.g., insurance commissioner)

Examples of Consequences for Non-Compliance

DOL

- Final determination of non-compliance results in all participants being notified of non-compliance within seven days
- Share findings with state officials

Participants

- ERISA remedies
- Potential civil penalties for failing to provide plan documents
- Lawsuits challenging denial of benefits

IRS

 Excise tax for a group health plan's failure to comply with mental health parity requirements (\$100/day/individual to whom failure relates)

Regulators Focused on Mental Health Parity



- 2023 annual report to Congress noted that of regulators' 182 requests for comparative analyses covering over 450 NQTLs:
 - 138 insufficiency letters were issued
 - 53 initial determination letters found MHPAEA violations
 - 3 final determinations found MHPAEA violations, thereby requiring the plans to send the statutorily required violation notice to their participants and beneficiaries

New Proposed Regulations

- On July 25, 2023, federal regulators proposed new mental health parity regulations. Among other things, these proposed rules would:
 - Establish new minimum standards for developing NQTL comparative analyses.
 - Set forth the required content elements of the NQTL comparative analyses.
 - Require ERISA plan fiduciaries to certify the comparative analysis.
 - Establish that a material difference in access to MH/SUD benefits (as compared to M/S benefits) would be considered a strong indicator that the plan violates certain MHPAEA requirements.
- These proposed rules, if finalized, would apply on the first day of the first plan year beginning on or after January 1, 2025.

Compliance Tips

- Review health plan document and summary plan description for mental health parity compliance
 - Modify non-compliant provisions
- Prepare the comparative analyses
 - Update annually
- Be prepared to <u>immediately</u> respond to regulator and participant requests for information



Plan Documents & SPDs

No Surprises Act

 Helps prevent certain surprise medical bills (sometimes called balance-billing).

Action Items:

- Ensure health plan summary plan descriptions ("SPDs") and plan documents are up to date and reflect requirements under the No Surprises Act.
- Include "Your Rights and Protections Against Surprise Medical Bills" notice
 - https://www.cms.gov/files/document/model-disclosure-notice-patient-protections-against-surprise-billing-providers-facilities-health.pdf

Broker/Consultant Disclosures

Fiduciaries Should Be Reviewing Disclosures

- In general, brokers and consultants to group health plans must provide a service and fee disclosure to the plan fiduciaries "reasonably in advance of" the contract or arrangement being entered into, extended, or renewed.
 - Detailed list of services, direct compensation, and indirect compensation that must be disclosed
- Group health plan fiduciaries must receive and review the disclosures prior to contracting for brokerage and consulting services!

Plan Fiduciary Action Items



- Identify all group health plans.
- Identify all service providers that are providing "brokerage services" and "consulting services."
- Determine when the contracts or arrangements with the service providers are (or will be) entered into, extended, or renewed.
- Obtain service and fee disclosures.
- Review disclosures; ask questions; obtain additional information if needed; ask broker/consultant to fix errors.
- Document process.

Q&A

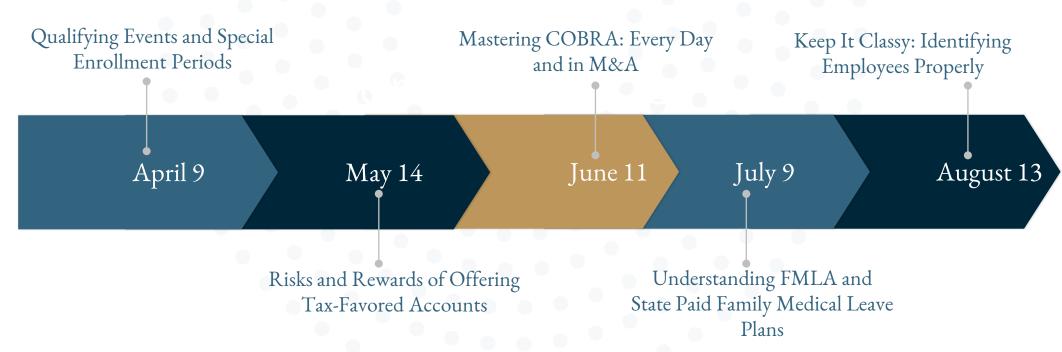






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