

CAA Benefits Alert: New Compliance Guidance and MHPAEA Action Items for Insurers and ERISA Covered Benefit Plans under the Consolidated Appropriations Act

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The Consolidated Appropriations Act, 2021 (the Act) provides additional funding for mental health and substance abuse services and also provides guidance and imposes additional reporting and compliance obligations on group health plans and health insurance issuers that provide mental health (MH) and/or substance use disorder (SUD) benefits. The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), as amended by the Affordable Care Act and state insurance laws, already requires parity between medical/surgical and MH/SUD benefits with respect to quantitative (e.g., visit limits) and non-quantitative treatment limitations (NQTL) (e.g., preauthorization and pre-service notification obligations); however, the Act goes further.

Group Health Plans Must Prepare a Comparative Analysis

Under the Act, there are new obligations applicable to group health plans and health insurers in the individual and group markets that provide medical, surgical, and MH and/or SUD benefits and that impose NQTLs on MH and/or SUD benefits. Under the new rules, which amend ERISA, the Code, and the Public Health Security Act, group health plans and issuers are required to formally analyze and document their compliance with the MHPAEA requirements related to NQTLs within 45 days after the date of enactment of the Act. Plans would have to document and make an analysis available, upon request, to the applicable regulator of the plan; i.e., the Secretary of Labor or the Secretary of Health and Human Services (collectively, the Regulators).

Such analysis must contain the following:

- i. The specific plan terms or other relevant terms regarding the NQTLs and a description of all MH or SUD and medical or surgical benefits to which each such term applies in each respective benefits classification;
- ii. The factors used to determine that the NQTLs will apply to MH or SUD or substance use disorder benefits and medical or surgical benefits;
- iii. The evidentiary standards used for the factors identified in clause (ii), when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTLs to mental health or substance use disorder benefits and medical or surgical benefits;

- iv. The comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification; and
- v. A disclosure of the specific findings and conclusions reached by the group health plan, including any results of the analyses described in the above, that indicate that the plan is or is not in compliance with this section.

Regulatory Audits

Under the Act, the applicable Regulator is required to request these analyses for plans/policies that involve potential violations or complaints regarding non-compliance and any other instances where the Regulator deems appropriate. The Regulators will be required to request no fewer than 20 of these comparative analyses per year. If the Regulator concludes that the group health plan has not submitted sufficient information for the Regulator to review the comparative analyses, the Regulator will then specify the information the plan must submit to be responsive. If the Regulator concludes the group health plan is not in compliance, within 45 days of that finding, it will require the group health plan to provide the Regulator an action plan that it will implement to bring the plan into compliance, as well as additional comparative analyses. Following the 45-day corrective action period, if the Regulator makes a final determination that the plan is still not in compliance, it will, not later than 7 days after such determination, notify all plan participants that the plan has been determined to not be in compliance with the NQTL requirements of the MHPAEA. Nevertheless, although the Regulators will notify participants regarding the plan's non-compliance, documents or communications produced in connection with the Regulators' recommendations to a group health plan are not subject to disclosure through a Freedom of Information Act request.

No later than 18 months after the date of enactment, the Act also directs the Secretary of Labor to finalize any draft or interim guidance and regulations relating to these mental health parity requirements under the Act, including guidance to clarify the process and timeline for current and potential participants and beneficiaries (and authorized representatives and health care providers of such participants and beneficiaries) with respect to plans to file complaints of such plans or issuers being in violation of these requirements, including guidance, by plan type, on the relevant State, regional, or national office with which such complaints should be filed.

Winston Takeaway: *The audit provisions of the Act will likely be onerous for group health plan administrators and insurers. Since no less than 20 such audits will take place annually, and with a 45-day disclosure period, it is advisable to have such analysis readily available soon after the date of enactment in order to be able to timely respond to a Regulator's request. Note that the DOL recently issued an updated [Self-Compliance Tool for the MHPAEA](#), which is a useful tool to assist plan sponsors in assessing compliance with MHPAEA requirements applicable to group health plans.*

Hall of Shame

The Act also requires the applicable Regulator to submit to Congress, and make publicly available, a report that contains those group health plans and issuers that are not in compliance with the MHPAEA. Also, the Regulator is required to share information on its findings of compliance and noncompliance with the states where the group health plan and/or issuer is located.

Winston Takeaway: *Group health plans will want to avoid being on this publicly available list, especially since it could open the plan up to potential liability in the form of private litigation and/or insurance premium risk.*

Compliance Program Guidance Document from the Regulators

The Act directs the Regulators and the Secretary of the Treasury to issue a compliance program guidance document to assist health plans and health insurers with respect to their MHPAEA compliance. The Regulators and the Treasury Department are required to update this document every 2 years. This compliance program guidance

document is similar to the directive under the 21st Century Cures Act, which in June 2020, directed the Regulators to make a compliance program guidance document and self-compliance tool publicly available to improve compliance with MHPAEA.

This document will include illustrative, de-identified (i.e., does not disclose any protected health information or individually identifiable information) examples of previous findings of MHPAEA compliance and noncompliance. Examples involving non-compliance with NQTLs are required to provide sufficient detail to fully explain the finding, including a full description of the criteria involved for approving medical and surgical benefits and the criteria involved for approving MH and SUD benefits. The goal is that the document will encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. The Regulators' and the Treasury Department's Inspector Generals are also directed to enter into interagency agreements, as well as with state regulatory agencies, to share findings of compliance and non-compliance.

The Regulators and the Treasury Department are also directed to provide clarifying information and illustrative examples of methods that group health plans may use for disclosing information regarding NQTLs. This does not seem to imply new disclosure obligations will be forthcoming, but rather this disclosure guidance will be in accordance with already required disclosure obligations, (e.g., summary plan descriptions and possible claim procedure disclosure materials and sample forms).

Clarifying Information and Illustrative Examples from the Regulators

The Regulators are instructed to provide “clarifying information and illustrative examples” of methods, processes, strategies, evidentiary standards, and other factors that group health plans may use regarding the development and application of NQTLs. This will provide appropriate types of NQTLs

pertaining to—

- Medical management standards based on medical necessity or appropriateness, or whether a treatment is experimental or investigative;
- Limitations with respect to prescription drug formulary design; and
- Use of fail-first or step therapy protocols;

and methods of determining—

- Network admission standards (such as credentialing); and
- Factors used in provider reimbursement methodologies (such as service type, geographic market, demand for services, and provider supply, practice size, training, experience, and licensure) as such factors apply to network adequacy.

Winston Takeaway: *The MHPAEA compliance guidance provisions of the Act do not raise any concerns and will likely be quite helpful. However, the Act contains other provisions that could be problematic for plan sponsors as the intent appears to regulate how an insurer and/or a group health plan will administer NQTLs with respect to mental health and substance use disorder benefits.*

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