FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 34 AND MENTAL HEALTH AND SUBSTANCE USE DISORDER PARITY IMPLEMENTATION

October 27, 2016

Set out below are additional Frequently Asked Questions (FAQs) regarding implementation of the market reform provisions of the Affordable Care Act and the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), as amended by the Affordable Care Act. These FAQs have been prepared jointly by the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at www.dol.gov/ebsa/healthreform/index.html and www.cms.gov/cciio/resources/fact-sheets-and-faqs/index.html), these FAQs answer questions from stakeholders to help people understand the laws and benefit from them, as intended. These FAQs also contain two separate requests for comments, as described below.

Coverage of Preventive Services under the Affordable Care Act

Public Health Service Act (PHS Act) section 2713 and its implementing regulations relating to coverage of preventive services[1] require non-grandfathered group health plans and health insurance coverage offered in the individual or group market to cover without the imposition of any cost-sharing requirements, the following items or services:

- Evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved, except for the recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention issued in or around November 2009, which are not considered in effect for this purpose;[2]
- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) with respect to the individual involved;
- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA); and

[1] See 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, 45 CFR 147.130.

[2] The USPSTF published updated breast cancer screening recommendations in January 2016. However, section 229 of the Consolidated Omnibus Appropriations Act, 2016 requires that for purposes of PHS Act section 2713, USPSTF recommendations relating to breast cancer screening, mammography, and prevention issued before 2009 remain in effect until January 1, 2018. Pub. L. 114-113.

- With respect to women, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by HRSA, to the extent not included in certain recommendations of the USPSTF.[3]

Coverage of Tobacco Cessation Interventions, Including Request for Comments

In 2009, the USPSTF recommended with an "A" rating "tobacco cessation interventions" for non-pregnant adults who use tobacco. On May 2, 2014, the Departments provided a safe harbor in FAQs stating that the Departments will consider plans and issuers to be in compliance with the requirement to cover tobacco use counseling and interventions based on the 2009 USPSTF recommendation, if for example, the plan or issuer covers without cost sharing: (1) screening for tobacco use; and (2) for those who use tobacco products, at least two tobacco cessation attempts per year. For this purpose, covering a cessation attempt includes coverage for: (i) four tobacco cessation counseling sessions of at least 10 minutes each (including telephone counseling, group counseling and individual counseling) without prior authorization; and (ii) all Food and Drug Administration (FDA)-approved tobacco cessation medications (including both prescription and over-the-counter medications) for a 90-day treatment regimen when prescribed by a health care provider, without prior authorization.[4]

Q1: The USPSTF updated its recommendation for tobacco cessation interventions on September 22, 2015. Did the USPSTF recommendation for tobacco cessation for non-pregnant adults change?

Yes. On September 22, 2015, the USPSTF extended its recommendation for non-pregnant adults and recommended with an "A" rating that "clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide both behavioral interventions and FDA-approved pharmacotherapy for cessation to adults who use tobacco." The Final Recommendation Statement states that "[b]oth intervention types (pharmacotherapy and behavioral interventions) are effective and recommended; combinations of interventions are most effective, and all should be offered."

[3] "Women's Preventive Services: Required Health Plan Coverage Guidelines" (HRSA Guidelines) were adopted and released on August 1, 2011, based on recommendations developed by the National Academy of Medicine (formerly Institute of Medicine). Women's preventive services recommended therein are required to be covered without cost sharing for plan years (or, in the individual market, policy years) beginning on or after August 1, 2012. Under the HRSA Women's Preventive Services Guidelines, group health plans established or maintained by religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the requirement to cover contraceptive services under section 2713 of the PHS Act, as incorporated into the Employee Retirement Income Security Act (ERISA) and the Internal Revenue Code (the Code). 45 CFR 147.131(a). Additionally, accommodations for religious objections to contraception are available to group health plans established or maintained by certain eligible organizations (and group health insurance coverage provided in connection with such plans), as well as student health insurance coverage arranged by eligible organizations, with respect to the contraceptive coverage requirement.

[4] See Frequently Asked Questions about Affordable Care Act Implementation, Part XII, Q&A-5, available at https://www.dol.gov/ebsa/faqs/faq-aca19.html and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19.html.

The Final Recommendation Statement provides additional detail on individual, group, and telephone behavioral interventions. It also describes the seven FDA-approved over-the-counter (OTC) and prescription medications for treating tobacco dependence that are now available. These include three types of OTC nicotine replacement products (transdermal nicotine patches, nicotine lozenges, and nicotine gum), two prescription-only nicotine replacement products (nicotine inhaler or nasal spray (Nicotrol®)); and prescription-only bupropion hydrochloride sustained release (Zyban® or generic)[5] and varenicline tartrate (Chantix®), which do not contain nicotine.[6]

Since the issuance of the updated recommendation, stakeholders have asked the Departments to clarify what items and services must be provided without cost sharing to comply with the updated recommendation, applicable for plan years (in the individual market, policy years) beginning on or after one year from the date of issuance of the updated recommendation (in this case, plan years or policy years beginning on or after September 22, 2016). The Departments are seeking comments in advance of providing future guidance. Specifically, the Departments seek comment on:

a) Whether all seven categories of FDA-approved pharmacotherapy interventions must be covered without cost sharing when prescribed by a health care provider or whether plans and issuers may use reasonable medical management techniques to determine which specific categories of FDA-approved pharmacotherapy interventions will be covered without cost sharing.

b) Whether plans and issuers may use reasonable medical management techniques to:
   i. Limit the number of quit attempts per year or the duration of the interventions prescribed;[7]
   ii. Manage the categories of FDA-approved pharmacotherapy interventions that may be covered without cost sharing when used in combination; or

[5] Although Wellbutrin SR® is not indicated for smoking cessation treatment, it contains the same active ingredient as Zyban®.

[6] See "Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions" available at http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions1.

[7] The use of reasonable medical management for benefit determinations regarding tobacco cessation pharmacotherapy and behavioral interventions is distinct from rules applicable to wellness programs, which require, among other things, that individuals eligible for the program must be given the opportunity to qualify for the reward under the program at least once per year. With respect to tobacco cessation wellness programs with an initial outcome-based standard that an individual not use tobacco, a reasonable alternative standard for obtaining the reward (or a waiver of the otherwise applicable standard) must be made available for any individual who does not meet the initial standard based on the measurement, test, or screening. An individual who meets the reasonable alternative standard is then entitled to the reward for that year, regardless of whether the individual stops using tobacco. For each subsequent year, the program must again provide the individual with an opportunity to qualify for the reward by either meeting the initial outcome-based standard (that is, not using tobacco), or meeting a reasonable alternative standard, which may be the same or different than the reasonable alternative standard offered in previous years, regardless of whether the individual stops using tobacco. Plans and issuers cannot fail to offer a reasonable alternative standard in subsequent years because the individual did not cease using tobacco in past attempts to quit. 26 CFR 54.9802-1(f)(4); 29 CFR 2590.702(f)(4); 45 CFR 146.121(f)(4) and 147.110.

iii. Limit the types of behavioral interventions that are covered without cost sharing.

This request for comment seeks input to inform any future guidance on tobacco cessation coverage. It does not supplement or clarify the USPSTF recommendation, and plans and issuers must offer coverage consistent with the specific recommendation made by the USPSTF.

Please send comments to marketreform@cms.hhs.gov by January 3, 2017. All comments will be shared among the Departments.

Mental Health Parity and Addiction Equity Act of 2008

Generally, the Mental Health Parity and Addiction Equity Act of 2008 requires that the financial requirements and treatment limitations imposed on mental health and substance use disorder (MH/SUD) benefits cannot be more restrictive than the predominant financial requirements and treatment limitations that apply to substantially all medical and surgical benefits.

Disclosures with Respect to MH/SUD Benefits, Including Request for Comments

The Departments have issued multiple rounds of guidance to address disclosure obligations under MHPAEA and other laws. The statutory MHPAEA provisions and implementing regulations expressly provide that a plan or issuer must disclose the criteria for medical necessity determinations with respect to MH/SUD benefits to any current or potential participant, beneficiary, or contracting provider upon request and the reason for any denial of reimbursement or payment for services with respect to MH/SUD benefits to the participant or beneficiary. However, the Departments recognize that additional information regarding medical/surgical benefits is necessary to perform the required MHPAEA analyses.[8] Accordingly, the Departments have clarified in previous regulations and guidance the breadth of disclosure required, as well as which documents participants, beneficiaries, and their authorized representatives have a right to receive (and generally may find helpful) under MHPAEA, ERISA,[9] and the Affordable Care Act.[10] For example, under ERISA, plans are required to provide participants, upon request, with

[8] See Code section 9812(a)(4), ERISA section 712(a)(4); PHS Act section 2726(a)(4). See also 26 CFR 54.9812-1(d); 29 CFR 2590.712(d); 45 CFR 146.136(d) and 147.160.

[9] ERISA's general disclosure obligation in section 104(b) and the accompanying disclosure regulation at 29 CFR 2520.104b-1 provide that, for plans subject to ERISA, instruments under which the plan is established or operated must generally be furnished to plan participants within 30 days of request.

[10] See Code sections 9812(a)(4) and 9815; ERISA sections 104(b), 502(c), 503, 712(a)(4) and 715; PHS Act sections 2726(a)(4) and 2719; See also 26 CFR 54.9812-1(d)(3) and 54.9815-2719; 29 CFR 2520.104b-1, 2560.503-1, 2590.712(d)(3) and 2590.715-2719; 45 CFR 146.136(d)(3), 147.136 and 147.160; See also 78 FR 68240, 68247 (Nov. 13, 2013); See also Affordable Care Implementation FAQs, Part V, Q&A-10, available at https://www.dol.gov/ebsa/faqs/faq-aca5.html and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html; See also Affordable Care Act Implementation FAQs, Part XVII, Q&A-8, available at https://www.dol.gov/ebsa/faqs/faq-aca17.html and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs17.html; See also Affordable Care Act Implementation FAQs, Part XXIX, Q&A-12 and 13, available at https://www.dol.gov/ebsa/faqs/faq-aca29.html and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-XXIX.pdf; See also Affordable Care Implementation FAQs, Part 31, Q&A-9, available at https://www.dol.gov/ebsa/faqs/faq-aca31.html and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf.

information about the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation (NQTL)[11] with respect to medical/surgical benefits and MH/SUD benefits under the plan.

The Departments continue to receive questions and suggestions regarding disclosures with respect to NQTLs. The comments include requests from various stakeholders for model forms that group health plan participants, beneficiaries, covered individuals in the individual market, or persons acting on their behalf could use to request relevant disclosures. Commenters have also requested guidance on other ways in which disclosures, or the process for requesting disclosures, could be more uniform, streamlined, or otherwise simplified.

In addition, the Departments have received requests to explore ways to encourage uniformity among State reviews of issuers' compliance with the NQTL standards. Various stakeholders have stated that model forms to report NQTL information will help facilitate uniform implementation and enforcement of MHPAEA, and relieve some complexity that MHPAEA compliance poses for health insurance issuers operating in multiple States. Furthermore, other stakeholders have highlighted that the use of such model forms may also benefit consumers, as the consumers will be entitled to request the analysis performed to complete the model forms.

Accordingly, the Departments request specific comments on:

a) Whether issuance of model forms that could be used by participants and their representatives to request information with respect to various NQTLs would be helpful and, if so, what content the model forms should include. For example, is there a specific list of documents, relating to specific NQTLs, that a participant or his or her representative should request?

b) Do different types of NQTLs require different model forms? For example, should there be separate model forms for specific information about medical necessity criteria, fail-first policies, formulary design, or the plan's method for determining usual, customary, or reasonable charges? Should there be a separate model form for plan participants and other individuals to request the plan's analysis of its MHPAEA compliance?

c) Whether issuance of model forms that could be used by States as part of their review would be helpful and, if so, what content should the model form include? For example, what specific content should the form include to assist the States in determining compliance with the NQTL standards? Should the form focus on specific classifications or categories of services? Should the form request information on particular NQTLs?

[11] For more information on NQTLs, see the discussion below under the heading, "Nonquantitative Treatment Limitations."

d) What other steps can the Departments take to improve the scope and quality of disclosures or simplify or otherwise improve processes for requesting disclosures under existing law in connection with MH/SUD benefits?

e) Are there specific steps that could be taken to improve State market conduct examinations and/or Federal oversight of compliance by plans and issuers?

Please send comments to e-ohpsca-mhpaea-disclosure@dol.gov by January 3, 2017. All comments will be shared among the Departments.

Q2: After having a MH/SUD benefit denied by my plan, I've asked my plan for documents to show whether the plan is treating MH/SUD benefits differently than medical/surgical benefits, and I haven't received them (or I don't know how to interpret them). Is there a government agency that can help?

Yes. Depending on the type of plan you have, there may be more than one government agency, including both Federal and State agencies, that can help you to obtain documents or understand the information you receive. There is a now a Parity Consumer Web Portal that can connect you to the appropriate agency to help you. You can use www.hhs.gov/mental-health-and-addiction-insurance-help to identify the agency that can help you. While different Federal and State agencies may be responsible for providing oversight for and assistance with respect to different plans, the agencies work together to ensure that any MHPAEA violations are corrected.[12]

In addition, if your plan is a non-grandfathered individual or group health plan and your claim for benefits has been denied for a reason that involves medical judgment (including if you have been denied a benefit and you are challenging the plan's or issuer's compliance with respect to parity in the application of its medical management techniques), you can seek external review after exhausting your internal appeals.[13] This gives you the right to review of your claim by an independent review organization, without deference to the decision of your plan or issuer. This review will determine whether the plan's or issuer's decision was correct. Your plan or issuer will be required to accept a favorable decision for you by the independent review organization.

General information regarding MHPAEA's requirements is also available on the web at https://www.dol.gov/ebsa/mentalhealthparity/index.html and https://www.cms.gov/cciio/programs-and-initiatives/other-insurance-protections/mhpaea_factsheet.html.

[12] In fiscal years 2011 through 2015, the DOL conducted 1,515 investigations of private-sector employment-based health plans, and answered 1,079 customer service inquiries, related to MHPAEA. States have primary enforcement responsibility with respect to health insurance issuers. If a State does not have authority to enforce or does not act in the areas of its responsibility, HHS may enforce directly. HHS also has direct enforcement authority over non-Federal governmental plans (those sponsored by State and local government employers).

[13] See 26 CFR 54.9815-2719(d)(1)(i)(A), 29 CFR 2590.715-2719(d)(1)(i)(A), and 45 CFR 147.136(d)(1)(i)(A), providing that a plan's or issuer's determination of whether it is complying with the MHPAEA's NQTL provisions involves medical judgment and, therefore, related adverse benefit determinations are eligible for external review.

Financial Requirements and Quantitative Treatment Limitations

A financial requirement (such as a copayment or coinsurance) or quantitative treatment limitation (such as a day or visit limit)[14] is considered to apply to substantially all medical/surgical benefits in a classification if it applies to at least 2/3 of all medical/surgical benefits in the classification. If it does not apply to at least 2/3 of medical/surgical benefits, it cannot be applied to MH/SUD benefits in that classification. If it does apply to at least 2/3 of medical/surgical benefits, the level (such as 80% or 70% coinsurance) of the quantitative limit that may be applied to MH/SUD benefits in a classification may not be more restrictive than the predominant level that applies to medical/surgical benefits (defined as the level that applies to more than one half of medical/surgical benefits subject to the limitation in the classification). In performing these calculations, the determination of the portion of medical/surgical benefits subject to the quantitative limit is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year. The MHPAEA regulations provide that "any reasonable method" may be used to determine the dollar amount of all plan payments for the substantially all and predominant analyses.[15]

Q3: If a group health plan or health insurance issuer does not have sufficient claims data to do either the MHPAEA substantially all or predominant analyses, what data can the plan or issuer use to conduct the analyses?

In general, if a group health plan or issuer has sufficient claims data for a reasonable projection of future claims costs for the substantially all or predominant analyses as described above, such claims data should be used for these analyses. An issuer's or third party administrator's broader book of business should not be used for the analysis, as the broader book of business includes many plans that may have benefit designs that bear little resemblance to the specific group health plan for which the MHPAEA analysis is being conducted. In certain circumstances, however, there may be insufficient reliable claims data for a group health plan, in which case the analyses will require utilizing reasonable data from outside the group health plan.

Under the Departments' MHPAEA regulations, group health plans and issuers must use a "reasonable method" for the substantially all and predominant analyses, which includes using reasonable data to produce reasonable projections. Group health plans and issuers should not use claims data from an issuer's or third party administrator's entire book of business in an unreasonable manner to calculate the amount of a particular group health plan's or issuer's payments under MHPAEA. A plan or issuer must always use appropriate and sufficient data to perform the analysis in compliance with applicable Actuarial Standards of Practice. For example, if there is not enough claims data, a group health plan significantly changed its benefit package, a group health plan experienced a significant workforce change that would impact claims costs, or a group health plan (or the plan design) is new, using only group health plan data also may be unreasonable.

[14] For ease of readability, such financial requirements or quantitative treatment limits are referred to in this document simply as "quantitative limits."

[15] See 26 CFR 54.9812-1(c)(3)(i)(E); 29 CFR 2590.712(c)(3)(i)(E); and 45 CFR 146.136(c)(3)(i)(E) and 147.160.

Accordingly, the Departments clarify that, for large group market and self-insured group health plans, a group health plan or issuer must consider group health plan-level claims data to perform the substantially all and predominant analyses and must rely on such data if it is credible to perform the required projections. Similarly, for small group and individual market plans, an issuer must consider "plan"-level (as opposed to the "product"-level) claims data to perform the substantially all and predominant analyses, as such terms are defined in 45 CFR 144.103, and must rely on such data if it is credible to perform the required projections.[16] However, if an actuary who is subject to and meets the qualification standards for the issuance of a statement of actuarial opinion in regard to health plans in the United States,[17] including having the necessary education and experience to provide the actuarial opinion, determines that a group health plan or issuer does not have sufficient data at the plan or product level for a reasonable projection of future claims costs for the substantially all or predominant analyses, the group health plan or issuer should utilize other reasonable claims data to make a reasonable projection to conduct actuarially-appropriate analyses. Data from other similarly-structured products or plans with similar demographics may be utilized for the analyses if actuarially appropriate. In addition, to the extent possible, the claims data should be customized to reflect the characteristics of the group health plan to which the substantially all and predominant analyses are being applied.

As part of using a "reasonable method" to make these projections, plans and issuers should document the assumptions used in choosing a data set and making projections. Furthermore, as stated in the preamble to the final regulations, a plan or issuer is not required to perform the parity analysis each plan year unless there is a change in plan benefit design, cost-sharing structure, or utilization that would affect a financial requirement or treatment limitation within a classification (or sub-classification).[18]

Nonquantitative Treatment Limitations

MHPAEA defines "treatment limitations" as limits on the scope or duration of treatment, such as limits based on the frequency of treatment, number of visits, or days of coverage. The regulations apply different tests to assess parity for two types of treatment limitations: quantitative treatment limitations, as discussed above, and NQTLs.

With regard to any NQTL, the MHPAEA regulations provide that a plan or issuer may not impose an NQTL with respect to MH/SUD benefits in any classification[19] unless, under the

[16] 45 CFR 144.103 generally defines "product" as a discrete package of health insurance coverage benefits offered using a particular product network type within a service area, and "plan" as the pairing of the health insurance coverage benefits under the product with a particular cost-sharing structure, provider network, and service area. In this context, the term "plan" is not synonymous with the term "group health plan."

[17] The U.S. Qualification Standards apply to members of the five U.S.-based organizations who issue Statements of Actuarial Opinion in the United States. The organizations are the American Academy of Actuaries, American Society of Pension Professional and Actuaries College of Pension Actuaries, Casualty Actuarial Society, Conference of Consulting Actuaries, and Society of Actuaries.

[18] See 78 FR 68243.

[19] The six classifications of benefits are inpatient, in-network; inpatient, out-of-network; outpatient, in-network, outpatient, out-of-network; emergency care; and prescriptions drugs. In addition, sub-classifications are permitted for office visits, separate from other outpatient services, as well as for a plan or coverage with multiple network tiers. 26 CFR 54.9812-1(c)(2)(ii) and (c)(3)(iii); 29 CFR 2590.712(c)(2)(ii) and (c)(3)(iii); and 45 CFR

terms of the plan as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the NQTL to MH/SUD benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation to medical/surgical benefits in the same classification.[20]

The regulations provide an illustrative, non-exhaustive list of NQTLs that plans and issuers commonly use. These NQTLs include, among other things:

- Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;
- Formulary design for prescription drugs;
- For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;
- Standards for provider admission to participate in a network, including reimbursement rates;
- Plan methods for determining usual, customary, and reasonable charges;
- Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);
- Exclusions based on failure to complete a course of treatment; and
- Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage.[21]

Other examples of NQTLs include limitations on inpatient services for situations where a participant is a threat to self or others, exclusions for court-ordered and involuntary holds when the included care would otherwise be considered medically necessary, service coding, exclusions for services provided by clinical social workers, network adequacy, and prior notification requirements.[22]

DOL, in conjunction with HHS, released a list of example NQTLs that are subject to the parity requirements in "Warning Signs – Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance."[23] These examples of NQTLs should be evaluated to determine whether or not they comply with parity in the context of a specific plan or coverage. Provided the plan or issuer can demonstrate that, both under the terms of the plan as written and in operation, the processes, strategies,

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146.136(c)(2)(ii) and (c)(3)(iii) and 147.160.

[20] See 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) and 147.160.

[21] See 26 CFR 54.9812-1(c)(4)(ii); 29 CFR 2590.712 (c)(4)(ii); and 45 CFR 146.136(c)(4)(ii) and 147.160.

[22] See also 78 FR 68240, 68246 (Nov. 13, 2013).

[23] Available at https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/laws/mental-health-parity/warning-signs-plan-or-policy-nqtls-that-require-additional-analysis-to-determine-mhpaea-compliance.pdf and https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/MHAPEAChecklistWarningSigns.pdf.

evidentiary standards, or other factors used to apply an example NQTL to MH/SUD benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used to apply the limitation to medical/surgical benefits in the same classification, the NQTL would not violate MHPAEA.

As noted above, the Departments' regulations identify medical management standards as a type of NQTL. The regulations further provide that a plan or issuer may consider a wide array of factors in designing medical management techniques for both MH/SUD benefits and medical/surgical benefits, such as cost of treatment; high cost growth; variability in cost and quality; elasticity of demand; provider discretion in determining diagnosis, or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; and claim types with a high percentage of fraud.[24] Based on application of these or other factors in a comparable fashion, a medical management standard, such as a requirement to obtain prior authorization, may be required for some (but not all) MH/SUD benefits, as well as for some (but not all) medical/surgical benefits. The NQTL analysis does not focus on whether the final result is the same; instead, compliance depends on parity in application of the underlying processes and strategies. Among other things, there should not be arbitrary or discriminatory differences in how a plan or issuer applies those processes and strategies to medical/surgical benefits as compared to MH/SUD benefits.

Q4: Prior to authorizing admission to an inpatient, in-network facility for a mental health condition, my group health plan requires that a plan representative examine the individual in person to determine whether inpatient care is medically necessary. For all medical and surgical inpatient, in-network admissions, my plan also requires prior authorization but it is conducted over the phone without an in-person examination. Is this in-person prior authorization requirement for mental health inpatient admissions permissible?

No. The plan is imposing a prior authorization NQTL more stringently with respect to inpatient mental health benefits than to inpatient medical/surgical benefits. While some differences in prior authorization practices with respect to individual conditions or treatments might be permissible based on recognized clinically appropriate standards of care, the MHPAEA regulations do not permit a plan or issuer to apply stricter NQTLs to all benefits for mental health conditions in a classification than those applied to all medical/surgical benefits in the same classification. In this case, in order to receive prior authorization for any inpatient, in-network mental health benefits, a participant must undergo an in-person examination whereas prior authorization may be obtained more easily and quickly over the phone for any inpatient, in-network medical/surgical benefits. Accordingly, the plan's in-person prior authorization requirement for these mental health benefits does not comply with MHPAEA.

Q5: Before authorizing coverage for inpatient treatment for a substance use disorder, my plan requires that I first enroll in an intensive outpatient program. My plan applies similar requirements to medical/surgical benefits. However, unlike medical/surgical benefits for which the requirements can be satisfied by programs offered in my geographic area, no intensive outpatient programs are available to treat my substance use disorder in

[24] See 78 FR 68240, 68241, 68246 (Nov. 13, 2013).

my geographic area. I alerted my plan that no outpatient program is available in my geographic area, but the plan indicated that there are no exceptions. Is this permissible?

No. The requirement to try an intensive outpatient program before being admitted for inpatient treatment is a type of NQTL, often referred to as a fail-first or step-therapy requirement. The Departments' regulations require that a plan or insurance issuer may not impose an NQTL with respect to MH/SUD benefits in a benefit classification unless, under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, or other factors used in applying the NQTL are comparable and applied no more stringently with respect to MH/SUD benefits than with respect to medical/surgical benefits in the same classification.

If a fail-first requirement that applies to MH/SUD benefits includes a condition that an individual cannot reasonably satisfy (in this case, a condition to first attempt an intensive outpatient program, although there are no programs available), and the lack of access to programs necessary to satisfy the requirement exists only with respect to MH/SUD benefits, then the fail-first requirement is, in operation, applied more stringently with respect to MH/SUD benefits than medical/surgical benefits.

Because the Departments' prior guidance did not address the application of fail-first requirements in situations involving lack of access and may have reasonably been interpreted in an alternative manner, the Departments will apply this clarifying guidance for plan years (or, in the individual market, policy years) beginning on or after March 1, 2017.

Medication Assisted Treatment for Opioid Use Disorder

Medication Assisted Treatment (MAT) is the use of medication in combination with behavioral health services to treat substance use disorders, including opioid use disorder. There are currently three medications approved by the FDA for use in detoxification or maintenance treatment for opioid use disorder: (1) methadone, (2) buprenorphine, and (3) naltrexone.[25] On April 20, 2016, the Departments issued Affordable Care Act Implementation FAQs Part 31, addressing, among other things, whether or not MHPAEA applies to any benefits a plan may offer for MAT for opioid use disorder. The Departments reiterated that the regulations implementing MHPAEA define "substance use disorder benefits" as benefits with respect to items or services for substance use disorders, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law. Additionally, any condition defined by the plan or coverage as being or as not being a substance use disorder must be defined consistently with generally recognized independent standards of current medical practice. Opioid use disorder is a type of substance use disorder, under generally recognized independent standards of current medical practice, and therefore MAT is a "substance use disorder benefit" within the meaning of the term as defined by MHPAEA.

[25] See Center for Substance Abuse Treatment, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. Substance Abuse and Mental Health Services Administration (US); 2005. (Treatment Improvement Protocol (TIP) Series, No. 43.) Chapter 1. Introduction.

Q6: My plan requires prior authorization from the plan's utilization reviewer that buprenorphine is medically necessary for the treatment of my opioid use disorder. The plan says the prior authorization requirement is imposed due to safety risks associated with buprenorphine. Although there are prescription drugs to treat medical/surgical conditions that have similar safety risks, my plan does not impose similar prior authorization requirements on those drugs. Is this permissible?

No. A plan may impose an NQTL, including a prior authorization requirement for buprenorphine, if, under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors considered by the plan in implementing its prior authorization requirement with respect to buprenorphine to treat an opioid use disorder are comparable to, and applied no more stringently than, those used in applying its prior authorization requirement with respect to medical/surgical benefits in the prescription drug classification under MHPAEA.

In this scenario, the plan imposes the prior authorization requirement due to stated safety concerns. However, the prior authorization requirement is applied more stringently to buprenorphine when used to treat opioid use disorder than it is applied to prescription drugs with similar safety risks to treat medical/surgical conditions. Accordingly, the plan's prior authorization requirement on buprenorphine does not comply with MHPAEA.

Q7: My plan requires that I meet specific non-pharmacological fail-first requirements (for example, that I have tried counseling alone, failed at recovery, and resumed substance use) before it will authorize coverage for buprenorphine to treat my opioid use disorder. While comparable evidentiary standards and other factors indicate that similar fail-first requirements could be imposed on certain prescription drugs covered by my plan for medical/surgical conditions, the plan does not impose fail-first requirements in these instances. Is this permissible?

No. A fail-first requirement is an NQTL that must comply with the requirements of MHPAEA. A plan or issuer cannot impose a fail-first requirement on coverage for buprenorphine for opioid use disorder unless, under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors considered by the plan in designing and imposing this fail-first requirement are comparable to, and applied no more stringently than the processes, strategies, evidentiary standards, or other factors used in applying fail-first requirements to medical/surgical benefits in the prescription drug classification under MHPAEA.

In this case, the plan is imposing a non-pharmacological requirement that the individual fail first at recovery with counseling alone before the plan will authorize coverage of benefits for buprenorphine. While comparable evidentiary standards and other factors indicate that similar fail-first requirements could be appropriate before authorizing coverage for certain other prescription drugs covered by the plan for medical/surgical conditions, the plan does not in fact impose fail-first requirements in any of these instances. Accordingly, the fail-first requirement imposed on buprenorphine is an NQTL that the plan applies more stringently to a substance use disorder condition than medical/surgical conditions. This disparity violates MHPAEA.

Q8: My group health plan states that it follows nationally-recognized treatment guidelines for setting prior authorization requirements for prescription drugs, but requires prior authorization for my buprenorphine/naloxone combination at each refill (every 30 days) for my opioid use disorder, which is not consistent with nationally-recognized treatment guidelines. Is this permissible?

No. In setting the NQTL of prior authorization for the substance use disorder medication, buprenorphine/naloxone, a plan or issuer must apply comparable processes, strategies, evidentiary standards, and other factors no more stringently to buprenorphine/naloxone than those applied to medical/surgical medications. The plan states that it follows nationally-recognized guidelines. However, these guidelines,[26] such as the American Society of Addiction Medicine (ASAM) national practice guidelines,[27] do not support 30-day authorization practices for buprenorphine/naloxone. Furthermore, the plan does not deviate from nationally-recognized treatment guidelines when establishing prior authorization requirements for any prescription drugs to treat medical/surgical conditions. Accordingly, although the plan asserts that its process of setting the NQTL of prior authorization -- following nationally-recognized treatment guidelines -- is comparable as written, in operation, the plan's process departs from and provides less coverage than recommended under nationally-recognized treatment guidelines for buprenorphine/naloxone, in violation of MHPAEA.

However, as an alternative to simply mirroring nationally-recognized treatment guidelines, many plans' and issuers' use Pharmacy and Therapeutics (P&T) committees in deciding how to cover prescription drugs and evaluating whether to follow or deviate from nationally-recognized treatment guidelines for setting the prior authorization requirements. The Departments' note that while the use of P&T committees to inform prior authorization requirements for prescription drugs in this manner may not violate MHPAEA *per se*, these processes must also comply with MHPAEA's NQTL standard in operation. For example, if the plan deviates from nationally-recognized treatment guidelines for buprenorphine/naloxone based on P&T committee reports, then use of the P&T committee would be evaluated for compliance with MHPAEA's NQTL requirements (for example, by evaluating whether the P&T committee is comprised of comparable experts for MH/SUD conditions, as compared to the experts for medical/surgical conditions, and how such experts evaluated nationally-recognized treatment guidelines in setting prior authorization for medications for both MH/SUD and medical/surgical conditions).

Under nationally-recognized treatment guidelines, authorization for a prescription drug intended for extended use to treat a chronic MH/SUD or medical/surgical condition is often appropriate at six or 12 months; as a result, even in a plan that uses a P&T committee to set standards, an authorization of buprenorphine/naloxone that is limited to 30 days could be inconsistent with authorization practices for chronic medical/surgical conditions. Therefore, in such a plan, absent comparable restrictions on medications for medical/surgical conditions, this 30-day limit is a

[26] A current summary of these treatment guidelines is available at: https://aspe.hhs.gov/report/review-medication-assisted-treatment-guidelines-and-measures-opioid-and-alcohol-use.

[27] The current ASAM national practice guideline for the use of medication in the treatment of addiction involving opioid use is available at: www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf.

"red flag" or "warning sign" that the plan may be imposing an impermissible NQTL.[28] Unless the plan provides evidence from P&T committee reports regarding the 30-day limit to substantiate its compliance, the plan's prior authorization requirement on buprenorphine would not be in compliance with MHPAEA.

Court-Ordered Treatment

Plans and policies may sometimes exclude coverage of court-ordered treatment. MHPAEA prohibits separate treatment limitations in a plan or coverage that are applicable only with respect to MH/SUD benefits.[29] It has come to the Departments' attention that there are questions regarding whether exclusions for court-ordered treatment are subject to MHPAEA, and how the MHPAEA analysis would apply.

Q9: Is an exclusion of court-ordered treatment for substance use disorders permissible under MHPAEA for a plan or coverage that does not exclude court-ordered treatment for medical/surgical conditions?

No, if the exclusion applies only to court-ordered treatment for substance use disorders. MHPAEA prohibits separate treatment limitations in a plan or coverage that are applicable only with respect to MH/SUD benefits.

Alternatively, plans often apply medical necessity criteria to all treatment requests, and may do so in the case of court-ordered treatment for substance use disorders, if that is consistent with MHPAEA's parity requirements for NQTLs. If the plan determines that court-ordered treatment is not medically necessary and denies a claim for benefits, then an individual would be informed of his or her right to appeal and request external medical necessity review, consistent with the Departments' regulations for claims, appeals, and external review.[30]

[28] For other warning signs, see the publication "Warning Signs- Plan or Policy Non-Quantitative Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance," available at: https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/laws/mental-health-parity/warning-signs-plan-or-policy-nqtls-that-require-additional-analysis-to-determine-mhpaea-compliance.pdf and https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/MHAPAEAChecklistWarningSigns.pdf.

[29] See ERISA section 712(a)(3)(ii); PHS Act section 2726(a)(3)(ii); Code section 9812(a)(3)(ii).

[30] See 26 CFR 54.9815-2719; 29 CFR 2590.7152719; and 45 CFR 147.136 and 147.160.