FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION (PART XXIX) AND MENTAL HEALTH PARITY IMPLEMENTATION

October 23, 2015

Set out below are additional Frequently Asked Questions (FAQs) regarding implementation of the market reform provisions of the Affordable Care Act, as well as FAQs regarding implementation of 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 http://www.dol.gov/ebsa/healthreform/index.html and http://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.

Coverage of Preventive Services

Section 2713 of the Public Health Service Act (PHS Act) and its implementing regulations relating to coverage of preventive services¹ 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:

- Evidenced-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;
- 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
- With respect to women, evidence-informed preventive care and screening provided for in comprehensive guidelines supported by HRSA, to the extent not included in certain recommendations of the USPSTF.²

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

² "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 Institute of Medicine (IOM). 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 Guidelines, group health plans established or maintained by religious employers (and group health insurance coverage provided in connection

If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service, then the plan or issuer may use reasonable medical management techniques to determine any such coverage limitations.³

Q1: Are plans and issuers required to provide a list of the lactation counseling providers within the network?

Yes. The HRSA guidelines provide for coverage of comprehensive prenatal and postnatal lactation support, counseling, and equipment rental as part of their preventive service recommendations, including lactation counseling.⁴ While the preventive services requirements under PHS Act section 2713 do not include specific disclosure requirements, provisions of other applicable law require disclosure of lactation counseling providers available under the plan or coverage. Under PHS Act section 2715 and implementing regulations, group health plans and health insurance issuers offering group or individual health insurance coverage must provide a Summary of Benefits and Coverage (SBC) that includes an Internet address (or other contact information) for obtaining a list of the network providers.⁵

With respect to group health plans subject to the Employee Retirement Income Security Act (ERISA), ERISA section 102 and the Department of Labor's implementing regulations provide that a group health plan must provide a Summary Plan Description (SPD) that describes provisions governing the use of network providers, the composition of the provider network, and whether, and under what circumstances, coverage is provided for out-of-network services.⁶ For those plans with provider networks, the listing of providers can be furnished in a separate document accompanying the SPD, as long as the SPD describes the provider network and states that provider lists are furnished automatically, without charge, as a separate document.⁷

Finally, issuers of qualified health plans (QHPs) in the individual market Exchanges and the SHOPs currently must make their provider directories available online. For plan years beginning on or after January 1, 2016, a QHP issuer must publish an up-to-date provider directory, including information on which providers are accepting new patients, as well as the provider's contact information, specialty, medical group, and any institutional affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS, and OPM.⁸

³ <u>See</u> 26 CFR 54.9815-2713(a)(4), 29 CFR 2590.715-2713(a)(4), 45 CFR 147.130(a)(4).

⁴ <u>See</u> FAQs About Affordable Care Act Implementation (Part XII), Q18-20, available at <u>http://www.dol.gov/ebsa/faqs/faq-aca12.html</u> and <u>http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html</u>.

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 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.

⁵ See 26 CFR 54.9815-2715(a)(2)(i)(K), 29 CFR 2590.715-2715(a)(2)(i)(K), 45 CFR 147.200(a)(2)(i)(K)

⁶ <u>See</u> 29 CFR 2520.102-3(j)(3).

⁷ <u>Id.</u>

⁸ See 45 CFR 156.230(b)(2).

Q2: My group health plan has a network of providers and covers recommended preventive services without cost sharing when such services are obtained in-network. However, the network does not include lactation counseling providers. Is it permissible for the plan to impose cost sharing with respect to lactation counseling services obtained outside the network?

No. As stated in a previous FAQ⁹, while nothing in the preventive services requirements under section 2713 of the PHS Act or its implementing regulations requires a plan or issuer that has a network of providers to provide benefits for preventive services provided out-of-network, these requirements are premised on enrollees being able to access the required preventive services from in-network providers. The FAQ also stated that if a plan or issuer does not have in its network a provider who can provide a particular service, then the plan or issuer must cover the item or service when performed by an out-of-network provider and not impose cost sharing with respect to the item or service. Therefore, if a plan or issuer does not have in its network a provider who can provide lactation counseling services, the plan or issuer must cover the item or service when performed by an out-of-network provider service in the plan or issuer must cover the item or service when performed by an out-of-network provider and not impose cost sharing with respect to the item or service. Therefore, if a plan or issuer does not have in its network a provider who can provide lactation counseling services, the plan or issuer must cover the item or service when performed by an out-of-network provider without cost sharing.

Q3: The State where I live does not license lactation counseling providers and my plan or issuer will only cover services received from providers licensed by the State. Does that mean that I cannot receive coverage of lactation counseling without cost sharing?

No. Subject to reasonable medical management techniques, lactation counseling must be covered without cost sharing by the plan or issuer when it is performed by any provider acting within the scope of his or her license or certification under applicable State law. Lactation counseling could be provided by another provider type acting within the scope of his or her license or certification (for example, a registered nurse), and the plan or issuer would be required to provide coverage for the services without cost sharing.

Q4: A plan or issuer provides coverage for lactation counseling without cost sharing only on an inpatient basis. Is it permissible for the plan or issuer to impose cost sharing with respect to lactation counseling received on an outpatient basis?

No. If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service, then the plan or issuer may use reasonable medical management techniques to determine any such coverage limitations. However, it is not a reasonable medical management technique to limit coverage for lactation counseling to services provided on an in-patient basis. Some births are never associated with a hospital admission (e.g., home births assisted by a nurse midwife), and it is not permissible to deny coverage without cost sharing for lactation support services in this case. Moreover, coverage for lactation support services without cost sharing must extend for the duration of the

⁹ <u>See</u> FAQs about Affordable Care Act Implementation (Part XII), Q3, available at <u>http://www.dol.gov/ebsa/faqs/faq-aca12.html</u> and <u>http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html</u>.

breastfeeding¹⁰ which, in many cases, extends beyond the in-patient setting for births that are associated with a hospital admission.

Q5: Are plans and issuers permitted to require individuals to obtain breastfeeding equipment within a specified time period (for example, within 6 months of delivery) in order for the breastfeeding equipment to be covered without cost sharing?

No. The requirement to cover the rental or purchase of breastfeeding equipment without cost sharing extends for the duration of breastfeeding, provided the individual remains continuously enrolled in the plan or coverage.

Q6: My non-grandfathered group health plan or coverage contains a general exclusion for weight management services for adult obesity. Is this permissible?

No. Consistent with PHS Act section 2713, its implementing regulations, and current USPSTF recommendations, non-grandfathered plans and issuers must cover, without cost sharing, screening for obesity in adults. In addition to such screening, the USPSTF currently recommends, for adult patients with a body mass index (BMI) of 30 kg/m2 or higher, intensive, multicomponent behavioral interventions for weight management. The recommendation specifies that intensive, multicomponent behavioral interventions include, for example, the following:

- Group and individual sessions of high intensity (12 to 26 sessions in a year),
- Behavioral management activities, such as weight-loss goals,
- Improving diet or nutrition and increasing physical activity,
- Addressing barriers to change,
- Self-monitoring, and
- Strategizing how to maintain lifestyle changes.

While plans and issuers may use reasonable medical management techniques to determine the frequency, method, treatment, or setting for a recommended preventive service, to the extent not specified in the recommendation or guideline regarding that preventive service, plans are not permitted to impose general exclusions that would encompass recommended preventive services.

Additionally, with respect to individual and small group market issuers subject to the essential health benefits (EHB) requirements under section 1302(b) of the Affordable Care Act and section 2707(a) of the PHS Act, to the extent the applicable EHB-benchmark plan does not include coverage of the required preventive services, including obesity screening and counseling, the issuer must nonetheless provide coverage for such preventive services consistent with PHS Act section 2713 and its implementing regulations, and with the regulation implementing the EHB requirements at 45 CFR 156.115(a)(4).

¹⁰ <u>See</u> FAQs About Affordable Care Act Implementation (Part XII), Q20, which states that "coverage of comprehensive lactation support and counseling and costs of renting or purchasing breastfeeding equipment extends for the duration of breastfeeding," available at <u>http://www.dol.gov/ebsa/faqs/faq-aca12.html</u> and <u>http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html</u>.

Q7: If a colonoscopy is scheduled and performed as a screening procedure pursuant to the USPSTF recommendation, is it permissible for a plan or issuer to impose cost sharing for the required specialist consultation prior to the screening procedure?

No. The plan or issuer may not impose cost sharing with respect to a required consultation prior to the screening procedure if the attending provider determines that the pre-procedure consultation would be medically appropriate for the individual, because the pre-procedure consultation is an integral part of the colonoscopy. As with any invasive procedure, the consultation before the colonoscopy can be essential in order for the consumer to obtain the full benefit of the colonoscopy safely. The medical provider examines the patient to determine if the patient is healthy enough for the procedure and explains the process to the patient, including the required preparation for the procedure, all of which are necessary to protect the health of the patient.

Because the Departments' prior guidance may reasonably have been interpreted in good faith as not requiring coverage without cost sharing of consultation prior to a colonoscopy screening procedure, the Departments will apply this clarifying guidance for plan years (or, in the individual market, policy years) beginning on or after the date that is 60 days after publication of these FAQs.

Q8: After a colonoscopy is scheduled and performed as a screening procedure pursuant to the USPSTF recommendation, is the plan or issuer required to cover any pathology exam on a polyp biopsy without cost sharing?

Yes, such services performed in connection with a preventive colonoscopy must be covered without cost sharing. The Departments view such services as an integral part of a colonoscopy, similar to polyp removal during a colonoscopy¹¹. The pathology exam is essential for the provider and the patient to obtain the full benefit of the preventive screening since the pathology exam determines whether the polyp is malignant. Since the primary focus of the colonoscopy is to screen for malignancies, the pathology exam is critical for achieving the primary purpose of the colonoscopy screening.

Because the Departments' prior guidance may reasonably have been interpreted in good faith as not requiring coverage without cost sharing of a pathology exam on a polyp biopsy performed in connection with a colonoscopy screening procedure, the Departments will apply this clarifying guidance for plan years (or, in the individual market, policy years) beginning on or after the date that is 60 days after publication of these FAQs.

Q9: I am a qualifying non-profit or closely held for-profit employer who sponsors an ERISA-covered self-insured plan, and I have a sincerely held religious objection to providing coverage of contraceptive services. How do I effectuate the religious

¹¹ <u>See</u> FAQs About Affordable Care Act Implementation (Part XII), Q5, which states that "polyp removal is an integral part of a colonoscopy," available at <u>http://www.dol.gov/ebsa/faqs/faq-aca12.html</u> and <u>http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html</u>.

accommodation, relieving myself of any obligation to contract, arrange, pay, or refer for that coverage?

There are two methods:

- Complete the EBSA Form 700 (accessible at http://www.dol.gov/ebsa/pdf/preventiveserviceseligibleorganizationcertificationform.pdf) and provide it to the plan's third party administrator(s); or
- (2) Provide appropriate notice of the objection to the Department of HHS. A model notice is available at <u>https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Model-Notice-8-22-14.pdf</u>.

In the first instance, the EBSA Form 700 will be a plan instrument that relieves you from any obligation to contract, arrange, or pay for contraceptive services to which you object, and that has the legal effect of designating the third party administrator as the ERISA plan administrator responsible for separately providing payments for those services. In the second instance, HHS will forward the information to the Department of Labor, which will send a notification to the third party administrator responsible for separately providing coverage for any contraceptive services to which you object. In that instance, the notice of your objection sent to HHS will be a plan instrument that relieves you from any obligation to contract, arrange, or pay, or refer for contraceptive services to which you object, but will not have the legal effect of designating the third party administrator as the ERISA plan administrator for those services. Instead, the notification sent from the Department of Labor to the third party administrator will be a separate plan instrument, and that separate instrument will serve to designate the third party administrator as the ERISA plan administrator will be object.

Coverage of BRCA Testing

PHS Act section 2713 addresses coverage for evidence-based items or services with a rating of "A" or "B" in the current recommendations of the USPSTF, as well as, with respect to women, coverage for preventive care and screenings as provided for in comprehensive guidelines supported by HRSA. The USPSTF recommends with a "B" rating to "screen women who have family members with breast, ovarian, tubal or peritoneal cancer with 1 of several screening tools designed to identify a family history that may be associated with an increased risk for potentially harmful mutations in breast cancer susceptibility genes (BRCA 1 or BRCA 2). Women with positive screening results should receive genetic counseling and, if indicated after counseling, BRCA testing."

The Departments have answered two previous FAQs on this topic. In the first, the Departments clarified that HHS believes that the scope of this recommendation includes both genetic counseling and BRCA testing, if appropriate, for a woman as determined by her health care

provider.¹² In the second, the Departments addressed services for women who "previously had breast cancer, ovarian cancer, or other cancer."¹³ To address remaining questions, the Departments are issuing this additional FAQ.

Q10: Which women must receive coverage without cost sharing for genetic counseling, and if indicated, testing for harmful BRCA mutations?

Women found to be at increased risk using a screening tool designed to identify a family history that may be associated with an increased risk of having a potentially harmful gene mutation must receive coverage without cost sharing for genetic counseling, and, if indicated, testing for harmful BRCA mutations. This is true regardless of whether the woman has previously been diagnosed with cancer, as long as she is not currently symptomatic of or receiving active treatment for breast, ovarian, tubal, or peritoneal cancer.

For questions about this guidance, contact Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight at 1-888-393-2789, or the Department of Labor at www.askebsa.dol.gov or 1-866-444-3272.

Wellness Programs

Under PHS Act section 2705,¹⁴ ERISA section 702, Code section 9802, and the Departments' implementing regulations, group health plans and health insurance issuers in the group and individual market are generally prohibited from discriminating against participants, beneficiaries, and individuals when establishing eligibility, benefits, or premiums based on a health factor.¹⁵ An exception to this general prohibition allows premium discounts, rebates, or modification of otherwise applicable cost sharing (including copayments, deductibles, or coinsurance) in return for adherence to certain programs of health promotion and disease prevention, commonly referred to as wellness programs. The wellness program exception applies to group health coverage, but not individual market coverage.¹⁶

 ¹² See FAQs about Affordable Care Act Implementation (Part XII), available at <u>http://www.dol.gov/ebsa/faqs/faq-aca12.html</u> and <u>https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html</u>.
 ¹³ See FAQs about Affordable Care Act Implementation (Part XXVI), available at

http://www.dol.gov/ebsa/faqs/faq-aca26.html and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

¹⁴ Section 1201 of the Affordable Care Act amended and moved the nondiscrimination and wellness provisions of the PHS Act from section 2702 to section 2705, and extended the nondiscrimination provisions to the individual market. The Affordable Care Act also added section 715(a)(1) to ERISA and section 9815(a)(1) to the Code to incorporate the provisions of part A of title XXVII of the PHS Act, including PHS Act section 2705, into ERISA and the Code.

¹⁵ The Health Insurance Portability and Accountability Act of 1996 (HIPAA) nondiscrimination provisions and the implementing regulations published by the Departments on December 13, 2006 (the 2006 HIPAA regulations) set forth eight health status-related factors, which the 2006 HIPAA regulations refer to as "health factors" for simplicity. Under the statute and the regulations, the eight health factors are health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence), and disability. 71 FR 75014, 75030 (Dec. 13, 2006). In the Departments' view, "[t]hese terms are largely overlapping and, in combination, include any factor related to an individual's health." 66 FR 1378, 1379 (Jan. 8, 2001).
¹⁶ Note, however, that "it is HHS's belief that participatory wellness programs in the individual market do not violate the nondiscrimination provisions provided that such programs are consistent with State law and available to

On June 3, 2013, the Departments issued final regulations¹⁷ under PHS Act section 2705 and the related provisions of ERISA and the Code that address the requirements for wellness programs provided in connection with group health coverage. Among other things, these regulations set the maximum permissible reward under a health-contingent wellness program¹⁸ that is part of a group health plan (and any related health insurance coverage) at 30 percent of the total cost of coverage under the plan (or 50 percent for wellness programs designed to prevent or reduce tobacco use). The wellness program regulations also address the reasonable design of health-contingent wellness programs and the reasonable alternatives that must be offered in order to avoid prohibited discrimination.

Q11: My group health plan gives rewards in the form of non-financial (or in-kind) incentives (for example, gift cards, thermoses, and sports gear) to participants who adhere to a wellness program. Are these non-financial incentives subject to the wellness program regulations issued by the Departments?

Yes. If a group health plan provides a "reward" based on an individual satisfying a standard that is related to a health factor, the wellness program is subject to the Department's wellness regulations. As provided in the regulations, a reward may be financial or non-financial (or in-kind). More specifically, the regulations provide that reference to an individual obtaining a reward includes both "obtaining a reward (such as a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as a deductible, copayment, or coinsurance), an additional benefit, or any financial or other incentive) and avoiding a penalty (such as the absence of a surcharge or other financial or nonfinancial disincentives)."¹⁹

Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) and Disclosure

MHPAEA amended the PHS Act, ERISA, and the Code to provide increased parity between mental health and substance use disorder (MH/SUD) benefits and medical/surgical benefits.²⁰ In

all similarly situated individuals enrolled in the individual health insurance coverage." 78 FR 33157, 33167 (Jun. 3, 2013). Provided that a wellness program does not offer incentives based on a health factor or achieving a health standard, it would not violate the non-discrimination provision in section 2705 of the PHS Act. While the wellness provisions under section 2705(j) of the PHS Act do not extend to the individual health insurance market, an issuer in the individual health insurance market can offer a wellness program that provides incentives based on participation since it does not violate the non-discrimination provision if it is made available to all similarly situated individuals enrolled in the individual health insurance coverage.

¹⁹ See 26 CFR 54.9802-1(f)(1)(i), 29 CFR 2590.702(f)(1)(i), and 45 CFR 146.121(f)(1)(i).

¹⁷ <u>See</u> 78 FR 33158 (Jun. 3, 2013). These regulations update the 2006 HIPAA regulations. The Affordable Care Act amended the statutory nondiscrimination and wellness provisions to in large part reflect the 2006 HIPAA regulations regarding wellness programs.

¹⁸ A health-contingent wellness program is a program that requires an individual to satisfy a standard related to a health factor to obtain a reward (or requires an individual to undertake more than a similarly situated individual based on a health factor in order to obtain the same reward). See 26 CFR 54.9802-1(f)(2); 29 CFR 2590.702(f)(2) and 45 CFR 146.121(f)(1)(iii).

²⁰ MHPAEA does not mandate that plans and issuers cover MH/SUD benefits. Rather, it applies only if a plan or issuer provides those benefits. However, other provisions of Federal and State law may require coverage of MH/SUD benefits, including the EHB requirements applicable to non-grandfathered individual and small group market coverage under the Affordable Care Act.

general, MHPAEA requires that the financial requirements (such as coinsurance and copays) and treatment limitations (such as visit limits), imposed on MH/SUD benefits cannot be more restrictive than the predominant financial requirements and treatment limitations that apply to substantially all medical/surgical benefits.

With regard to any nonquantitative treatment limitation (NQTL),²¹ the MHPAEA final regulations²² provide that a plan or issuer may not impose an NQTL with respect to MH/SUD benefits in any classification unless, under the 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 with respect to medical/surgical benefits in the same classification.

The MHPAEA final regulations provide express disclosure requirements. Specifically, the criteria for medical necessity determinations with respect to MH/SUD benefits must be made available by the plan administrator or the health insurance issuer to any current or potential participant, beneficiary, or contracting provider upon request.²³ In addition, under MHPAEA, the reason for any denial of reimbursement or payment for services with respect to MH/SUD benefits must be made available to participants and beneficiaries.²⁴ The Departments also explained in the preamble to the final regulations that, in addition to these specific disclosure obligations under MHPAEA, 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. Instruments under which the plan is established or operated include documents with information on medical necessity criteria for both medical/surgical benefits and MH/SUD benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply an NQTL with respect to medical/surgical benefits and MH/SUD benefits under the plan. In addition, 29 CFR 2560.503-1, 29 CFR 2590.715-2719 and 45 CFR 147.136 set forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) upon appeal of an adverse benefit determination (or a final internal adverse benefit determination) to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and MH/SUD benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply an NQTL with respect to medical/surgical benefits and MH/SUD benefits under the plan.

Contemporaneous with the issuance of the MHPAEA final regulations, the Departments published FAQs about Affordable Care Act Implementation Part XVII and Mental Health Parity

²¹ NQTLs generally are limits on the scope or duration of treatment that are not expressed numerically. MHPAEA regulations at 26 CFR 54.9812-1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii) and 45 CFR 146.136(c)(4)(ii) contain an illustrative list of NQTLs that includes, among other things, medical management standards limiting or excluding benefits based on medical necessity; formulary design for prescription drugs; network tier design; and plan methods for determining usual, customary, and reasonable charges. See also 45 CFR 147.160.

²² 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), 45 CFR 146.136(c)(4) and 147.160.

²³ 26 CFR 54.9812-1(d)(1), 29 CFR 2590.712(d)(1), 45 CFR 146.136(d)(1) and 147.160.

²⁴ 26 CFR 54.9812-1(d)(2), 29 CFR 2590.712(d)(2), 45 CFR 146.136(d)(2) and 147.160.

Implementation²⁵ addressing a group health plan's disclosure obligations under MHPAEA and ERISA generally, as well as the specific information a participant is entitled to receive when a claim for MH/SUD benefits has been denied. In addition to reiterating that "instruments under which the plan is established or operated" under ERISA section 104 includes documents with information on medical necessity criteria for both medical/surgical and MH/SUD benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply an NQTL, this guidance noted that other provisions of Federal law require such disclosures.

This guidance provided that "under the internal appeals and external review requirements added by the Affordable Care Act, non-grandfathered group health plans and health insurance issuers must provide to an individual (or a provider or other individual acting as a patient's authorized representative), upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the individual's claim for benefits consistent with the Department of Labor claims procedure regulation."²⁶ FAQ 8 of this guidance specifically noted that such information would include documents of a comparable nature with information on medical necessity criteria for both medical/surgical benefits and MH/SUD benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply an NQTL with respect to medical/surgical benefits and MH/SUD benefits under the plan.²⁷

Q12: I am a participant in a group health plan that provides treatment for anorexia as a mental health benefit. In accordance with the plan terms, my provider, on my behalf, requested prior authorization for a 30-day inpatient stay to treat my anorexia. The request was denied based on the plan's determination that a 30-day inpatient stay is not medically necessary under the plan terms.

I then requested from the plan administrator a copy of its medical necessity criteria for both medical/surgical and MH/SUD benefits (including anorexia), as well as any information regarding the processes, strategies, evidentiary standards, or other factors used in developing the medical necessity criteria and in applying them. May the plan administrator deny me this information based on an assertion that the information is "proprietary" and/or has "commercial value"?

No. The criteria for making medical necessity determinations, as well as any processes, strategies, evidentiary standards, or other factors used in developing the underlying NQTL and in applying it, must be disclosed with respect to both MH/SUD benefits and medical/surgical benefits, regardless of any assertions as to the proprietary nature or commercial value of the information.

²⁵ <u>See</u> FAQs about Affordable Care Act Implementation (Part XVII) and Mental Health Parity Implementation, available at <u>http://www.dol.gov/ebsa/faqs/faq-aca17.html</u> and <u>https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs17.html</u>.

²⁶ See 29 CFR 2560.503-1 and 2590.715-2719; 45 CFR 147.136. <u>http://www.dol.gov/ebsa/healthreform/</u> and <u>https://www.healthcare.gov/health-care-law-protections/</u> for consumer information on internal claims and appeals, external review of health plan decisions, and grandfathered health plans under the Affordable Care Act.

²⁷ <u>See</u> FAQs About Affordable Care Act Implementation (Part XVII) and Mental Health Parity Implementation, Q8 available at <u>http://www.dol.gov/ebsa/faqs/faq-aca17.html</u> and <u>https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs17.html</u>.

Whether a plan that is subject to ERISA can refuse to provide "instruments under which the plan is established or operated" on the basis that the information is "proprietary" was specifically addressed in the Department of Labor's Advisory Opinion 96-14A.²⁸ The Advisory Opinion rejected that basis for refusal. In that Advisory Opinion, the Department of Labor stated that any documents or instruments that specify formulas, methodologies, or schedules to be applied in determining or calculating a participant's or beneficiary's benefit entitlement under an employee benefit plan (in that case, a schedule of a plan's usual and customary fees) would constitute "instruments under which the plan is established or operated," and must be provided, notwithstanding that the plan asserted that such fee schedules are of a " proprietary" nature. Such information must be disclosed, even in cases where the source of the information is a third-party commercial vendor.

Q13: Can my plan, upon request, provide a summary description of the medical necessity criteria for both MH/SUD benefits and medical/surgical benefits that is written to be understandable for a layperson?

Yes. Although not required to do so, group health plans and issuers can provide a document that provides a description of the medical necessity criteria in layperson's terms. However, providing such a summary document is not a substitute for providing the actual underlying medical necessity criteria, if such documents are requested.

²⁸ See AO 96-14A, available at <u>http://www.dol.gov/ebsa/programs/ori/advisory96/96-14a.htm</u>.