

FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 31, MENTAL HEALTH PARITY IMPLEMENTATION, AND WOMEN'S HEALTH AND CANCER RIGHTS ACT IMPLEMENTATION

April 20, 2016

Set out below are additional Frequently Asked Questions (FAQs) regarding implementation of the market reform provisions of the Affordable Care Act, the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), and the Women's Health and Cancer Rights Act of 1998 (WHCRA). 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/ccio/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

Public Health Service Act (PHS Act) section 2713 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:

- 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 purpose²;
- 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 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 screening provided for in comprehensive guidelines supported by HRSA, to the extent not included in certain recommendations of the USPSTF.³

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.⁴

Coverage of Colonoscopies Pursuant to USPSTF Recommendations

Q1: If a colonoscopy is scheduled and performed as a screening procedure pursuant to the USPSTF recommendation, can a plan or issuer impose cost sharing for the bowel preparation medications prescribed for the procedure?

No. Consistent with a previous FAQ,⁵ the required preparation for a preventive screening colonoscopy is an integral part of the procedure. Bowel preparation medications, when medically appropriate and prescribed by a health care provider, are an integral part of the preventive screening colonoscopy, and therefore, are required to be covered in accordance with the requirements of PHS Act section 2713 and its implementing regulations (that is, without cost sharing, subject to reasonable medical management).

Coverage of Food and Drug Administration (FDA)-approved Contraceptives

The HRSA Guidelines include a recommendation for all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity, as prescribed by a health care provider. On February 20, 2013, the Departments issued an FAQ stating that the HRSA Guidelines ensure women's access to the full range of FDA-approved contraceptive methods including, but not limited to, barrier methods, hormonal methods, and implanted devices, as well as patient education and counseling, as prescribed by a health care provider. The FAQ further clarified that plans and issuers may use reasonable medical management techniques to control costs and promote efficient delivery of care, such as covering a generic drug without cost sharing and imposing cost sharing for equivalent branded drugs. However, in these instances, the FAQ stated that a plan or issuer must accommodate any

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 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 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.

⁴ See 26 CFR 54.9815-2713(a)(4), 29 CFR 2590.715-2713(a)(4), 45 CFR 147.130(a)(4).

⁵ See FAQs about Affordable Care Act Implementation and Mental Health Parity Implementation (Part XXIX), Q7, available at www.dol.gov/ebsa/faqs/faq-aca29.html and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-XXIX.pdf.

individual for whom a particular drug (generic or brand name) would be medically inappropriate, as determined by the individual's health care provider, by having a mechanism for waiving the otherwise applicable cost sharing for the brand or non-preferred brand version.⁶

On May 11, 2015, the Departments issued an FAQ clarifying that plans and issuers must cover without cost sharing at least one form of contraception in each of the methods (currently 18) identified for women by the FDA. The FAQ further clarified that to the extent plans and issuers use reasonable medical management techniques within a specified method of contraception, plans and issuers must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or provider (or other individual acting as a patient's authorized representative, including a provider) to ensure coverage without cost sharing of any service or FDA-approved item within the specified method of contraception.⁷ The FAQ also stated that if an individual's attending provider recommends a particular service or FDA-approved item based on a determination of medical necessity with respect to that individual, the plan or issuer must cover that service or item without cost sharing. The plan or issuer must defer to the determination of the attending provider. Medical necessity may include considerations such as severity of side effects, differences in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service, as determined by the attending provider. The FAQ also clarified that the exceptions process must provide for making a determination on the claim according to a timeframe and in a manner that takes into account the nature of the claim (*e.g.*, pre-service or post-service) and the medical exigencies involved for a claim involving urgent care.

Additionally, health insurance issuers in the individual and small group markets that are required to provide essential health benefits (EHB) must have an exceptions process that meets the standards in 45 CFR 156.122(c).

Q2: If a plan or issuer utilizes reasonable medical management techniques within a specified method of contraception, can the plan or issuer develop and utilize a standard exception form and instructions as part of its steps to ensure that it provides an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other individual acting as a patient's authorized representative)?

Yes. Plans and issuers may develop a standard exception form with instructions that an attending provider may use to prescribe a particular service or FDA-approved item based on a determination of medical necessity with respect to the individual involved. The Medicare Part D Coverage Determination Request Form may serve as a model for plans and issuers when developing a standard exception form.⁸

⁶ See FAQs about Affordable Care Act Implementation (Part XII), Q14, available at www.dol.gov/ebsa/faqs/faq-aca12.html and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html.

⁷ See FAQs about Affordable Care Act Implementation (Part XXVI), Q2 and Q3, available at www.dol.gov/ebsa/faqs/faq-aca26.html and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

⁸ A copy of Medicare Part D Coverage Determination Request Form is available at www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/downloads/physiciancoveredeterminationrequestform.pdf.

Rescissions

PHS Act section 2712 and its implementing regulations generally provide that group health plans and health insurance issuers offering group or individual health insurance coverage must not rescind coverage unless the individual (or a person seeking coverage on behalf of the individual) commits fraud or makes an intentional misrepresentation of material fact as prohibited by the terms of the plan or coverage. A rescission is a cancellation or discontinuance of coverage that has a retroactive effect, except to the extent attributable to a failure to pay timely premiums towards coverage (including COBRA premiums) or in certain other limited circumstances specified in the implementing regulations.⁹

Other requirements of Federal or State law may apply in connection with a rescission of coverage.

Q3: I am a school teacher who was employed by a school district through a 10-month teaching contract from August 1 to May 31. My health coverage through the school district health plan was for the plan year from August 1 to July 31, and the full premium was paid during that period. I provided my resignation on July 31 indicating that I did not intend to continue my employment with the school district for the following school year. The plan terminated my coverage retroactively to May 31. I did not request that my coverage be retroactively terminated, or commit fraud or make an intentional misrepresentation of a material fact. Is the retroactive termination of coverage permissible?

No. The plan's termination of health coverage retroactive to May 31 is a rescission that is prohibited under PHS Act section 2712 and the implementing regulations, because (i) it is a cancellation or discontinuance of coverage that has retroactive effect, (ii) it is not attributable to a failure to timely pay premiums toward coverage, (iii) there was no fraud or intentional misrepresentation of material fact, and (iv) the other limited circumstance exceptions specified in the implementing regulations do not apply. The plan may terminate coverage prospectively, subject to other applicable Federal and State laws or collective bargaining agreements.

Out-of-Network Emergency Services

Under PHS Act section 2719A and its implementing regulations, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage cannot impose cost sharing (expressed as a copayment amount or coinsurance rate) on out-of-network emergency services in a greater amount than what is imposed for in-network emergency services.¹⁰ However, balance billing is not included in the statutory definition of cost sharing. Balance billing refers to the practice of providers billing patients for the difference between (i) the provider's billed charges and (ii) the amount collected from the plan or issuer plus the amount collected from the patient in the form of a copayment or coinsurance amount. Accordingly, PHS Act section 2719A does not prohibit providers from balance billing.

⁹ 26 CFR 54.9815-2712; 29 CFR 2590.715-2712; 45 CFR 147.128.

¹⁰ 26 CFR 54.9815-2719A(b)(3); 29 CFR 2590.715-2719A(b)(3); 45 CFR 147.138(b)(3).

To avoid the circumvention of the protections of PHS Act section 2719A, in the implementing regulations, the Departments determined it is necessary that a reasonable amount be paid by a plan or issuer before a patient becomes responsible for a balance billing amount.¹¹ Therefore, under the Departments' regulations, a plan or issuer satisfies the out-of-network emergency care copayment or coinsurance limitations in the statute if it provides benefits for out-of-network emergency services in an amount at least equal to the greatest of the following three amounts (adjusted for in-network cost sharing): (1) the median amount negotiated with in-network providers for the emergency service; (2) the amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable (UCR) amount); or (3) the amount that would be paid under Medicare for the emergency service (collectively, minimum payment standards).¹² The Departments' regulations clarify that the cost-sharing requirements create a minimum payment requirement for the plan or issuer. If State law prohibits balance billing, or in cases in which a group health plan or health insurance issuer is contractually responsible for balance billing amounts, plans and issuers are not required to satisfy the minimum payment standards set forth in the regulations, but may not impose any copayment or coinsurance requirement for out-of-network emergency services that is higher than the copayment or coinsurance requirement that would apply if the services were provided in-network.¹³ The cost-sharing requirements do not prohibit a group health plan or health insurance issuer from providing benefits with respect to an emergency service that are greater than the amounts specified in the regulations.

Q4: Is a plan or issuer required to disclose how it calculated the amount under the minimum payment standards, including the method the plan or issuer generally uses to determine payments for out-of-network services (e.g., the UCR amount)?

Yes. For plans subject to the Employee Retirement Income Security Act (ERISA), documentation and data used to calculate each of the minimum payment standards, including the UCR amount, for out-of-network emergency services are considered to be instruments under which the plan is established or operated and would be subject to the disclosure provisions under ERISA section 104(b) and 29 CFR 2520.104b-1, which generally require such information be furnished to plan participants (or their authorized representatives) within 30 days of request.¹⁴

In addition, the DOL claims procedure regulations, as well as the internal claims and appeals and external review requirement under PHS Act section 2719, which apply to non-grandfathered group health plans and issuers of non-grandfathered group or individual coverage, set forth rules regarding claims and appeals, including the right of a claimant (or the claimant's authorized

¹¹ 75 FR 37188, 37194 (June 28, 2010); *see also* 80 FR 72192 (Nov. 18, 2015).

¹² 26 CFR 54.9815-2719A(b)(3); 29 CFR 2590.715-2719A(b)(3); 45 CFR 147.138(b)(3).

¹³ *See* 26 CFR 54.9815-2719A(b)(3)(iii); 29 CFR 2590.715-2719A(b)(3)(iii); 45 CFR 147.138(b)(3)(iii); FAQs about Affordable Care Act Implementation (Part I), Q15, available at www.dol.gov/ebsa/faqs/faq-aca.html and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html.

¹⁴ *See* DOL Advisory Opinion 96-14A (July 31, 1996). *See also* FAQs about Affordable Care Act Implementation (Part XXIX) and Mental Health Parity Implementation, Q12, available at www.dol.gov/ebsa/faqs/faq-aca29.html and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-XXIX.pdf, providing that a plan's or issuer's characterization of information as proprietary or commercially valuable cannot be a basis for non-disclosure.

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.¹⁵ A failure to provide or make payment in whole or in part is an adverse benefit determination.¹⁶

Coverage for Individuals Participating in Approved Clinical Trials

In general, PHS Act section 2709(a)¹⁷ states that if a non-grandfathered group health plan or health insurance issuer offering non-grandfathered group or individual coverage provides coverage to a qualified individual (as defined under PHS Act section 2709(b)), then such plan or issuer: (1) may not deny the qualified individual participation in an approved clinical trial¹⁸ with respect to the prevention, detection, or treatment of cancer or another life-threatening disease or condition;¹⁹ (2) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and (3) may not discriminate against the individual on the basis of the individual's participation in the trial.

Routine patient costs, as defined in PHS Act section 2709(a)(2), include “all items and services consistent with the coverage provided in the plan (or coverage) that are typically covered for a qualified individual who is not enrolled in a clinical trial.” Routine patient costs do not include (i) the investigational item, device, or service being studied in the approved clinical trial; (ii) items and services that are provided solely to satisfy the clinical trial's data collection and analysis needs and that are not used in the direct clinical management of the patient; and (iii) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis. PHS Act section 2709(c) provides that this section shall not be construed to require a group health plan, or a health insurance issuer offering group or individual health insurance coverage, to provide benefits for routine patient care services provided outside of the plan's (or coverage's) health care provider network unless out-of-network benefits are otherwise provided under the plan (or coverage).

A qualified individual as defined under PHS Act section 2709(b) is generally a participant or beneficiary (or enrollee in individual market coverage) who is eligible to participate in an approved clinical trial according to the trial protocol with respect to the treatment of cancer or

¹⁵ 29 CFR 2560.503-1, 26 CFR 54.9815-2719, 29 CFR 2590.715-2719 and 45 CFR 147.136. For additional requirements for the full and fair review standard that applies under PHS Act section 2719, in addition to 29 CFR 2560.503-1(h)(2), see 26 CFR 54.9815-2719(b)(2)(ii)(C), 29 CFR 2590.715-2719(b)(2)(ii)(C) and 45 CFR 147.136(b)(2)(ii)(C), and (b)(3)(ii)(C).

¹⁶ 29 CFR 2560.503-1(m)(4).

¹⁷ There are two sections 2709 in the PHS Act, as amended by the Affordable Care Act. For purposes of these FAQs, “section 2709” refers to the section titled “Coverage For Individual Participating in Approved Clinical Trials” codified at 42 U.S.C. § 300gg-8.

¹⁸ The term “approved clinical trial” means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and is further described in PHS Act section 2709(d). PHS Act section 2709(d).

¹⁹ The term “life-threatening condition” means “any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.” For this purpose, death need not be imminent for a disease or condition to be life-threatening. PHS Act section 2709(e).

another life-threatening disease or condition; and either: (1) the referring health care professional is a participating provider and has concluded that the individual's participation in such trial would be appropriate; or (2) the participant, beneficiary, or enrollee provides medical and scientific information establishing that the individual's participation in such trial would be appropriate.

The Departments stated in a prior FAQ²⁰ that the statutory language of PHS Act section 2709 is self-implementing, and until any further guidance is issued, plans and issuers are expected to implement the requirements of PHS Act section 2709 using a good faith, reasonable interpretation of the law.

Q5: If a plan or issuer generally covers chemotherapy to treat cancer, can the plan or issuer limit coverage of chemotherapy for an individual due to the fact that it is provided in connection with the individual's participation in an approved clinical trial for a new anti-nausea medication?

No. PHS Act section 2709 generally provides that a plan or issuer may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for any items or services furnished in connection with participation in an approved clinical trial. If the plan (or coverage) typically covers chemotherapy for a qualified individual who is not enrolled in a clinical trial, the plan or issuer cannot deny (or limit or impose additional conditions on) the coverage of such item or service on the basis that it is furnished in connection with participation in an approved clinical trial.

Under PHS Act section 2709(a)(2)(B), routine patient costs do not include (i) the investigational item, device, or service being studied in the approved clinical trial; (ii) an item or service provided solely to satisfy the clinical trial's data collection and analysis needs and that is not used in the direct clinical management of the patient; or (iii) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis. These exceptions do not apply to chemotherapy in this case.

However, note that PHS Act section 2709 does not require a plan or issuer to provide benefits for routine patient care services provided outside of the plan's (or coverage's) health care provider network unless out-of-network benefits are otherwise provided under the plan (or coverage).

Q6: If a plan or issuer typically covers items and services to diagnose or treat certain complications or adverse events,²¹ can the plan or issuer deny coverage of such items and

²⁰ FAQs about Affordable Care Act Implementation (Part XV), Q3, available at <http://www.dol.gov/ebsa/faqs/faq-aca15.html> and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs15.html.

²¹ An adverse event is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. HHS Office of the Assistant Secretary for Health, Office for Human Research Protections, *Unanticipated Problems Involving Risks & Adverse Events Guidance*, (Jan 15, 2007), available at <http://www.hhs.gov/ohrp/policy/advevntguid.html> (for examples of adverse events, see Appendices C and D).

services when provided to diagnose or treat complications or adverse events (e.g., side effects) in connection with an individual’s participation in an approved clinical trial?

No. PHS Act section 2709 generally provides that a plan or issuer may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for any items or services furnished in connection with participation in an approved clinical trial. Routine patient costs for items and services to diagnose or treat complications or adverse events arising from participation in an approved clinical trial are items and services furnished in connection with participation in an approved clinical trial, and accordingly, are required to be covered in accordance with PHS Act section 2709, if the plan typically covers such items or services for a qualified individual who is not enrolled in a clinical trial.

Limitations on Cost-Sharing under the Affordable Care Act

PHS Act section 2707(b) provides that a non-grandfathered group health plan shall ensure that any annual cost-sharing imposed under the plan does not exceed the limitations provided for under section 1302(c)(1) of the Affordable Care Act. Under section 1302(c)(1), an enrollee’s cost sharing (as defined in section 1302(c)(3)) for EHB is limited.²²

For plan or policy years beginning in 2014, the maximum annual limitation on an individual’s cost sharing under Affordable Care Act section 1302(c)(1) (sometimes called the maximum out-of-pocket limit or MOOP limit) was set by reference to section 223(c)(2)(A)(ii) of the Code. For plan or policy years thereafter, the MOOP limit is increased by the premium adjustment percentage described under Affordable Care Act section 1302(c)(4). The MOOP limit has been as follows for plan/policy years beginning in the applicable calendar years: for 2015, \$6,600 for self-only coverage and \$13,200 for other than self-only coverage; for 2016, \$6,850 for self-only coverage and \$13,700 for other than self-only coverage; and for 2017, \$7,150 for self-only coverage and \$14,300 for other than self-only coverage.

Previous FAQs provided guidance on the MOOP limit under PHS Act section 2707(b).²³ The FAQs clarified that if a plan includes a network of providers, the plan may, but is not required to, count an individual’s out-of-pocket spending for out-of-network items and services toward the MOOP limit. The FAQs also addressed reference-based pricing for non-grandfathered large group insurance market and self-insured group health plans,²⁴ under which the plan pays a fixed

²² The annual limitation on cost sharing established under section 1302(c) of the Affordable Care Act also applies to non-grandfathered individual and small group market plans that are required to provide the essential health benefits package under PHS Act section 2707(a).

²³ See FAQs about Affordable Care Act Implementation (Part XII), Q2, available at <http://www.dol.gov/ebsa/faqs/faq-aca12.html> and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html; FAQs about Affordable Care Act Implementation (Part XVIII), and Mental Health Parity Implementation, Q2-Q5, available at <http://www.dol.gov/ebsa/faqs/faq-aca18.html> and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18.html; FAQs about Affordable Care Act Implementation (Part XIX), Q2-Q4, available at <http://www.dol.gov/ebsa/faqs/faq-aca19.html> and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19.html.

²⁴ The FAQ stated that, for non-grandfathered health plans in the individual and small group markets that must provide coverage of the essential health benefit package under section 1302(a) of the Affordable Care Act, additional requirements apply. Section 1302(a) of the Affordable Care Act and PHS Act section 2707(b) do not apply to grandfathered health plans.

amount for a particular procedure (for example, a knee replacement), which certain providers will accept as payment in full.²⁵ In the Departments' reference-based pricing FAQ, the Departments expressed concerns that such a pricing structure could be a subterfuge for the imposition of otherwise prohibited limitations on coverage, without ensuring access to quality care and an adequate network of providers. Subsequently, the Departments issued an FAQ outlining what specific factors the Departments will consider when evaluating whether a non-grandfathered large group market or self-insured group health plan that utilizes reference-based pricing (or similar network design) is using a reasonable method to ensure that it provides adequate access to quality providers at the reference-based price under PHS Act section 2707(b).²⁶ Among other things, the FAQ stated that the Departments will consider all the facts and circumstances when evaluating whether a plan's reference-based pricing design (or similar network design) that treats providers that accept the reference-based price as the only in-network providers and excludes or limits cost-sharing from counting towards the MOOP limit for services rendered by other providers is using a reasonable method to ensure adequate access to quality providers at the reference price.

Q7: If a non-grandfathered large group market or self-insured group health plan has a pricing structure in which the plan pays a fixed amount (sometimes called a reference price) for a particular procedure, but the plan does not ensure that participants have adequate access to quality providers that will accept the reference price as payment in full, is the plan required to count an individual's out-of-pocket expenses for providers who do not accept the reference price toward the individual's MOOP limit?

Yes. The Departments' previous guidance explained that, for purposes of PHS Act section 2707(b), a plan that utilizes a reference-based pricing design (or similar network design) may treat those providers that accept the reference-based price as the only in-network providers and not count an individual's out-of-pocket expenses for services rendered by other providers towards the MOOP limit only if the plan is using a reasonable method to ensure adequate access to quality providers at the reference price.²⁷ A plan that merely establishes a reference price without using a reasonable method to ensure adequate access to quality providers at the reference price will not be considered to have established a network for purposes of PHS Act section 2707(b).

This guidance does not affect the Departments' previously issued FAQ²⁸ regarding specific factors that the Departments will consider when evaluating whether a non-grandfathered plan that utilizes reference-based pricing (or similar network design) is using a reasonable method to

²⁵ FAQs about Affordable Care Act Implementation, Part XIX, Q4, available at <http://www.dol.gov/ebsa/faqs/faq-aca19.html> and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19.html.

²⁶ FAQs about Affordable Care Act Implementation (Part XXI), available at www.dol.gov/ebsa/pdf/faq-aca21.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Reference_Pricing_FAQ_101014.pdf.

²⁷ FAQs about Affordable Care Act Implementation (Part XXI), available at www.dol.gov/ebsa/pdf/faq-aca21.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Reference_Pricing_FAQ_101014.pdf.

²⁸ FAQs about Affordable Care Act Implementation (Part XXI), available at www.dol.gov/ebsa/pdf/faq-aca21.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Reference_Pricing_FAQ_101014.pdf.

ensure that it provides adequate access to quality providers at the reference-based price. Under the standards set out by the Departments, it continues to be the case that, under PHS Act section 2707(b), a non-grandfathered plan that utilizes reference-based pricing (or similar network design) may treat providers that accept the reference based-price as the only in-network providers for purposes of determining what counts towards an individual's MOOP limit as long as the non-grandfathered plan uses a reasonable method to ensure that it provides adequate access to quality providers at the reference-based price.

This FAQ addresses only group health plans' and group health insurance issuers' obligations under section 2707(b) of the PHS Act. For non-grandfathered health plans in the individual and small group markets that must provide coverage of the EHB package under section 1302(a) of the Affordable Care Act, additional requirements apply.

Mental Health Parity and Addiction Equity Act of 2008

Generally, MHPAEA 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.

With regard to any nonquantitative treatment limitation (NQTL),²⁹ the MHPAEA final regulations 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.³⁰

Financial Requirements and Quantitative Treatment Limitations

A type of financial requirement (such as copay or coinsurance) or quantitative treatment limitation (such as day or visit limits) 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 the limitation does not apply to at least 2/3 of medical/surgical benefits in a classification, it cannot apply to MH/SUD benefits in that classification. If the type of limitation does apply to at least 2/3 of medical/surgical benefits in a classification, the predominant level that may be applied to MH/SUD benefits in the classification is the one that applies to more than one half of medical/surgical benefits within the classification subject to the financial requirement or treatment limitation. The determination of the portion of medical/surgical benefits subject to the financial requirement or treatment limitation is based on the dollar amount of all plan

²⁹ NQTLs generally are limits on the scope or duration of benefits for 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, applying the requirements of §146.136 to individual market coverage.

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

payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year.

Under the MHPAEA regulations, “any reasonable method” may be used to determine the dollar amount of all plan payments for the substantially all/predominant analysis.³¹

Q8: When performing “substantially all” and “predominant” tests for financial requirements and quantitative treatment limitations under MHPAEA, may a plan or issuer base the analysis on an issuer’s entire overall book of business for the year?

No. Basing the analysis on an issuer’s entire overall book of business expected to be paid for the year or book of business in a specific region or State is not a reasonable method to determine the dollar amount of all plan payments under MHPAEA. To the extent group health plan-specific data is available, each self-insured group health plan must use such data in making their projections. For large fully-insured group health plans, for which the premiums are determined on an experience-rated basis, the issuer should generally have group health plan-specific data to make projections. If a large, fully-insured plan does not have sufficient group health plan-specific data to make projections, data from other similarly-structured group health plans with similar demographics can be utilized for the analysis.

For insured small group and individual market plans, the health insurance issuer should use data at the “plan” level (as opposed to the “product” level) to perform the substantially all and predominant analyses, as such terms are defined in 45 CFR 144.103.³² If an issuer does not have sufficient data to calculate the substantially all and predominant tests at the plan level, it can use data at the product level to inform its projections of expected spending in the benefit classification at issue (provided that the issuer can demonstrate the validity of the projection method based on the best available data).

Disclosure

The Departments have issued multiple rounds of guidance to address disclosure obligations under MHPAEA and other laws. The MHPAEA final regulations expressly provide that the plan administrator or the health insurance 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.³³ In addition to these disclosure obligations under MHPAEA, 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.³⁴ If an ERISA plan or administrator fails to provide these documents, a court may hold it liable for up to \$110 a day from the date of failure to provide

³¹ 26 CFR 54.9812-1(c)(3)(i)(E); 29 CFR 2590.712(c)(3)(i)(E); 45 CFR 146.136(c)(3)(i)(E) and 147.160.

³² 45 CFR 144.103 states “product means a discrete package of health insurance coverage benefits that a health insurance issuer offers using a particular product network type within a service area” and “plan” means, with respect to an issuer and a product, the pairing of the health insurance coverage benefits under the product with a particular cost-sharing structure, provider network, and service area.”

³³ 26 CFR 54.9812-1(d); 29 CFR 2590.712(d); 45 CFR 146.136(d) and 147.160.

³⁴ ERISA section 104(b), 29 CFR 2520.104b-1.

these documents.³⁵ Instruments under which the plan is established or operated include documents with comparative 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.

The DOL claims procedure regulations, as well as the internal claims and appeals and external review requirement under section 2719 of the PHS Act, which apply to non-grandfathered group health plans and issuers of non-grandfathered group or individual health insurance coverage, 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.³⁶ This includes documents with comparative 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.

Additionally, employers and issuers sometimes contract with Managed Behavioral Health Organizations (MBHO) or similar entities to provide or administer MH/SUD benefits under the plan or coverage. The preamble to the MHPAEA final regulations clarifies that the coverage as a whole must still comply with the applicable provisions of MHPAEA, and the responsibility for compliance rests with the group health plan and/or the health insurance issuer, depending on whether the coverage is insured or self-insured. This means that the plan or issuer will need to provide sufficient information in terms of plan structure and benefits to the MBHO to ensure that the MH/SUD benefits are coordinated with the medical/surgical benefits for purposes of compliance with the requirements of MHPAEA.³⁷

Q9: I am a provider acting as an authorized representative for an ERISA group health plan participant. The health plan has requested that I complete a pre-authorization form after the patient's 9th visit for the treatment of depression. I understand that there are a number of documents that plans must provide upon request. Which of those documents would generally be most helpful for me to request regarding the plan's compliance with MHPAEA?

You may request the following documents and plan information, which could be helpful in evaluating the plan's compliance with MHPAEA. While it may not be necessary to review all of the following documents and plan information, the plan must provide any of these documents and plan information to you if requested, when you as a provider are acting as an individual's authorized representative:

1. A Summary Plan Description (SPD) from an ERISA plan, or similar summary information that may be provided by non-ERISA plans;

³⁵ ERISA section 502(c)(1).

³⁶ 29 CFR 2560.503-1; 26 CFR 54.9815-2719; 29 CFR 2590.715-2719; 45 CFR 147.136.

³⁷ 78 FR 68239, 68250 (Nov. 13, 2013).

2. The specific plan language regarding the imposition of the NQTL (such as a preauthorization requirement);
3. The specific underlying processes, strategies, evidentiary standards, and other factors (including, but not limited to, all evidence) considered by the plan (including factors that were relied upon and were rejected) in determining that the NQTL will apply to this particular MH/SUD benefit;
4. Information regarding the application of the NQTL to any medical/surgical benefits within the benefit classification at issue;
5. The specific underlying processes, strategies, evidentiary standards, and other factors (including, but not limited to, all evidence) considered by the plan (including factors that were relied upon and were rejected) in determining the extent to which the NQTL will apply to any medical/surgical benefits within the benefit classification at issue; and
6. Any analyses performed by the plan as to how the NQTL complies with MHPAEA.

For example, if the plan can demonstrate that it imposes pre-authorization requirements for both MH/SUD and medical/surgical benefits in the outpatient, in-network classification when the length of treatment for a condition exceeds the national average length of treatment by 10% or more, it has identified a factor on which the NQTL is based. Furthermore, to the extent the plan can document, via studies, schedules or similar documents that contain relevant information or data, that the national average length of outpatient treatment for depression is eight visits, it has identified an evidentiary standard used to evaluate the factor. Finally, by applying the eight visit standard to the case at hand, it demonstrates how the evidentiary standard is applied and the result.

Accordingly, to be in compliance with the MHPAEA and ERISA disclosure requirements, the plan must furnish to the provider sufficient documentation of the NQTL factor, evidentiary standard and the analysis outlined above. Additionally, it must produce documentation of how the factor, evidentiary standard and analysis is applied in the outpatient, in-network classification for medical/surgical benefits to demonstrate that the NQTL is not being applied to MH/SUD benefits more stringently than to medical/surgical benefits in the classification. As the Departments indicated in prior guidance, the fact that any information (including factors and evidentiary standards used for medical/surgical benefits) may be characterized as proprietary or commercially valuable is not legitimate grounds for not providing the information.³⁸

The information outlined in 1-6 above must also be provided by non-grandfathered health plans under PHS Act section 2719 in instances of internal claims and appeals related to the application of an NQTL to a MH/SUD benefit.

Q10: I'm reviewing my individual market health insurance coverage options. I requested a copy of the medical necessity criteria for coverage of mental health conditions from an issuer, but was told that because I was not enrolled in its coverage, the issuer did not have to provide the criteria to me. Is this correct?

³⁸ See FAQs about Affordable Care Act Implementation (Part XXIX) and Mental Health Parity Implementation, Q12, available at www.dol.gov/ebsa/faqs/faq-aca29.html and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-XXIX.pdf.

No. Under MHPAEA, the criteria for medical necessity determinations under a group health plan or health insurance coverage with respect to MH/SUD benefits must be made available to any current or potential enrollee or contracting provider upon request.

Medication Assisted Treatment for Opioid Use Disorder

Q11: Does MHPAEA apply to any benefits a plan may offer for Medication Assisted Treatment for opioid use disorder?

Yes. Medication Assisted Treatment (MAT) is any treatment for opioid use disorder that includes medication that is FDA-approved for detoxification or maintenance treatment in combination with behavioral health services.³⁹ The Departments' final 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 which must be defined to be consistent with generally recognized independent standards of current medical practice.⁴⁰ Opioid use disorder is a type of substance use disorder and MAT is a "substance use disorder benefit" within the meaning of the term as defined by MHPAEA.

Group health plans and issuers that offer MAT benefits must do so in accordance with the requirements of MHPAEA and, accordingly, any financial requirements and treatment limitations may not be more restrictive than the predominant financial requirements and quantitative treatment limitations that apply to substantially all medical and surgical benefits in a classification. In addition, the special rule for multi-tiered prescription drug benefits also applies to the medication component of MAT.⁴¹ The behavioral health services components of MAT should be treated as outpatient benefits and/or inpatient benefits as appropriate for purposes of MHPAEA.

The Women's Health and Cancer Rights Act

WHCRA provides protections for individuals who elect breast reconstruction in connection with a mastectomy. Under WHCRA, if a group health plan or health insurance issuer offering group or individual health insurance coverage covers mastectomies, the plan or issuer must provide coverage for certain services, in a manner determined in consultation with the attending physician and the patient. Required coverage includes all stages of reconstruction of the breast on which the mastectomy was performed, surgery and reconstruction of the other breast to produce a symmetrical appearance, prostheses, and treatment of physical complications of the mastectomy, including lymphedema.

Q12: Are group health plans and issuers offering group or individual health insurance coverage that cover mastectomies required to provide coverage for nipple and areola reconstruction as a required stage of breast reconstruction under WHCRA?

³⁹ 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.

⁴⁰ 26 CFR 54.9812-1(a); 29 CFR 2590.712(a); 45 CFR 146.136(a).

⁴¹ 26 CFR 54.9812-1(c)(3)(iii)(A); 29 CFR 2590.712(c)(3)(iii)(A); 45 CFR 146.136(c)(3)(iii)(A).

Yes. If a group health plan or health insurance issuer offering group or individual coverage provides medical and surgical benefits with respect to a mastectomy, the plan or issuer is required to provide coverage for all stages of reconstruction of the breast on which the mastectomy was performed, in a manner determined in consultation with the attending physician and the patient.⁴² This includes coverage for nipple and areola reconstruction, including nipple and areola repigmentation to restore the physical appearance of the breast, as a required stage of reconstruction. Under WHCRA, plans and issuers may impose deductibles and coinsurance for these benefits only if such cost-sharing requirements are consistent with those established for other benefits under the plan or coverage.

⁴² ERISA section 713; PHS Act sections 2727 and 2752; Code section 9815 (incorporating PHS Act section 2727).