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More Guidance on ACA, Mental Health Parity and Women's Health and Cancer Rights

The departments recently issued FAQs addressing a potpourri of topics related to the ACA's market reforms, mental health parity and women's health and cancer rights. Among other things, the guidance covers specific preventive care issues, rescissions, reference-based pricing as it relates to cost-sharing limits, mental health parity disclosure requirements and breast reconstruction.

Background

On April 20, 2016, the Departments of Labor, Health & Human Services and Treasury (departments) issued guidance in the form of Frequently Asked Questions (FAQs) on Affordable Care Act (ACA) market reforms, the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), and the Women's Health and Cancer Rights Act of 1998 (WHCRA).

Affordable Care Act Market Reforms

The FAQs provide helpful guidance and clarification on ACA market reforms, including preventive services, rescissions, out-of-network emergency services and cost-sharing.

Preventive Services

Under the ACA, non-grandfathered group health plans must cover certain preventive services without cost-sharing, as detailed in our August 7, 2015 *For Your Information*.

Colonoscopy-Related Medications. Prior guidance established that a colonoscopy is a preventive procedure when recommended as a screening for colorectal cancer. (See our May 28, 2015 *For Your Information.*) The FAQs clarify that bowel preparation medications prescribed for a colonoscopy performed as a preventive service must be covered without cost-sharing, as an integral part of this procedure.

Contraceptive Coverage. Under earlier guidance, plans must cover, without cost-sharing, at least one form of contraception in each of the currently 18 FDA-approved contraceptive methods — but can use reasonable medical management techniques to control costs and promote efficient care delivery. In doing so, however, plans must accommodate any individual for whom a particular drug would be medically inappropriate; provide an accessible, transparent and expedient exceptions process; and cover a particular contraceptive service or item without cost-sharing if a provider recommends it based on medical necessity. (See our May 28, 2015 *For Your Information.*)

The FAQs permit a plan to create a standard exception form with instructions that an attending provider may use to prescribe a particular service or FDA-approved item. Plans may use the Medicare Part D Coverage Determination Request form as a model.

Rescissions

The ACA prohibits a group health plan from rescinding coverage except in the case of fraud or intentional misrepresentation of material fact. (See our March 31, 2016 *For Your Information.*)

The FAQs clarify that, absent fraud or misrepresentation of a material fact, a plan cannot terminate a teacher's coverage retroactively for the time period following the end of the school year. For example, if a teacher was employed under a 10-month contract from August 1 to May 31, paid premiums for health coverage under the school district's health plan for the plan year August 1 to July 31, and resigned on July 31, the plan cannot terminate health coverage retroactively to May 31.

Generally, a **rescission** is a cancellation or discontinuance of coverage that has a retroactive effect and is not attributable to failure to timely pay premiums.

Out-of-Network Emergency Services

The ACA prohibits non-grandfathered group health plans from imposing cost-sharing (co-payments or co-insurance) on out-of-network emergency services in an amount greater than that imposed for in-network emergency services. The regulations allow for "balance billing," where providers bill patients for the difference between the provider's billed charges and the amount collected from the plan plus the amount collected from the patient in copayments or coinsurance, but generally require plans to satisfy certain minimum payment standards. (See our October 1, 2010 *For Your Information.*)

The FAQs specify that a plan must disclose, upon request, how it calculated the amount under the minimum payment standards, including the method it generally uses to determine payments for out-of-network services (for example, the "usual, customary, and reasonable" amount).

Clinical Trial Coverage

Under the ACA, non-grandfathered employer group health plans and health insurers may not deny a qualifying individual's participation in certain approved clinical trials, deny or limit coverage of routine patient costs for items and services furnished in connection with a trial, or discriminate based on participation in a trial. (See our May 21, 2013 *For Your Information.*)

"**Routine patient costs**" are all items and services provided in the plan that are typically covered for a qualified individual who is not enrolled in a clinical trial. This category excludes the investigational item, device or service being studied in the clinical trial, items and services provided solely to satisfy the clinical trial's data collection and analysis needs, and services that are clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

The FAQs make clear that, if a plan typically covers chemotherapy

and/or items or services to diagnose or treat certain complications or adverse events, the plan cannot deny or limit coverage for such items or services provided in connection with participation in an approved clinical trial.

> **Example**: A plan that covers chemotherapy to treat cancer cannot limit chemotherapy coverage provided with participation in a clinical trial for a new anti-nausea medication.

Cost-Sharing Limits and Reference-Based Pricing

The ACA limits the annual out-of-pocket (OOP) costs that a non-grandfathered health plan can require an enrollee to pay for essential health benefits through cost-sharing. (See our February 27, 2013 *For Your Information*.) If a plan includes a network of providers, it may count an individual's spending for out-of-network items and services toward the OOP limit. Plans that use "reference-based" pricing can treat providers that accept the reference amount as the only in-network providers (and, therefore, all other providers as out-of-network) as long as the plan uses a reasonable method to ensure adequate access to quality providers. (See our November 12, 2014 *For Your Information*.)

Reference-based pricing is a medical management technique in which a plan pays a fixed amount for a particular procedure, such as knee replacement, and contracts with providers who agree to accept the fixed amount as full payment.

The FAQs provide that a plan using reference-based pricing may treat providers that accept the reference-based price as the only in-network providers — and thereby avoid having to count an individual's OOP expenses for services delivered by other providers toward the OOP limit — only if the plan uses a reasonable method to ensure adequate access to quality providers at the reference price. Otherwise, the plan must count toward the OOP limit an individual's OOP expenses for providers who do not accept the reference price.

Mental Health Parity

The Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) requires group health plans that offer mental health and substance use disorder (MH/SUD) benefits to cover those benefits on terms that are no more restrictive than those for medical and surgical (M/S) benefits. This requirement applies to financial provisions (such as coinsurance) as well as quantitative (such as visit limits) and nonquantitative (such as medical management techniques like prior authorization) treatment limitations. (See our January 14, 2014 *For Your Information*.)

Plans must provide parity in each of the following six classifications: inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care; and prescription drugs.

Financial Requirements and Quantitative Treatment Limitations

A plan may not apply any financial requirement or treatment limitation to MH/SUD benefits in a classification that is more restrictive than the predominant (more than one-half) financial requirement or treatment limitation of that type applied to substantially all (at least two-thirds of) M/S benefits in the same classification. The determination of the portion of M/S benefits subject to the financial requirement or treatment limitation is based on the dollar amount of all plan payments for M/S benefits in the classification expected to be paid for the plan year. Plans may use "any reasonable method" to make this determination.

The FAQs establish that basing the analysis on an issuer's entire book of business for the year is not a reasonable method for purposes of the "predominant" and "substantially all" tests. Rather, a self-insured group health plan must

use available plan-specific data. Large fully insured group health plans that determine premiums on an experience-rated basis should generally have plan-specific data available to make projections. If not, they can use data from other group health plans similar in structure and demographics.

> **Comment.** Prior testing could come into question if the plan previously based its analysis on the issuer's entire book of business. A self-insured plan claiming it lacks available plan-specific data should be prepared to substantiate this assertion.

Disclosure

MHPAEA regulations require plans to make available to participants or beneficiaries, upon request, the criteria for medical necessity determinations for MH/SUD benefits and to provide the reason for any denial of reimbursement or payment. DOL claims procedure regulations and ACA claims and appeals rules also require certain disclosures, upon request.

Documents. The FAQs state that the following documents and information could be helpful to an authorized provider representative wishing to evaluate the plan's MHPAEA compliance — for example, where the plan requests a pre-authorization form after a participant's ninth visit for depression treatment:

- A Summary Plan Description (SPD), or similar summary information provided by non-ERISA plans
- Specific plan language imposing the nonquantitative treatment limitation (NQTL) (such as a pre-authorization requirement)
- Specific underlying processes, strategies, evidentiary standards and other factors the plan considered in applying the NQTL to a particular MH/SUD benefit
- Information on the application of the NQTL to any M/S benefits within the benefit classification at issue
- Specific underlying processes, strategies, evidentiary standards and other factors the plan considered in determining the extent to which the NQTL will apply to any M/S benefits within the benefit classification at issue
- Any analyses performed by the plan on how the NQTL complies with MHPAEA

The plan must also produce documentation of how it applies the NQTL factor, evidentiary standard and analysis in the outpatient, in-network classification for M/S benefits to demonstrate that it does not apply the NQTL to MH/SUD more stringently than to M/S benefits.

> **Comment.** This past March, the Senate Health Education Labor and Pensions (HELP) Committee released a draft of the Mental Health Reform Act of 2016. This bipartisan bill would, among other things, require a mandatory audit for any plan with five or more findings of non-compliance with mental health parity rules. (See our March 14, 2016 *Legislate*.)

Potential Enrollees. Additionally, the FAQs explain that a plan must make the criteria for medical necessity determinations on MH/SUD available not only to current enrollees, but also to potential enrollees (meaning, those currently not enrolled in coverage) and contracting providers, upon request.

Medication Assisted Treatment for Opioid Use Disorder

The FAQs provide that the MHPAEA applies to benefits a plan offers for Medication Assisted Treatment (MAT) for opioid use disorder, a treatment that uses FDA-approved medication for detoxification or maintenance together with

behavioral health services. Because opioid use disorder is a substance use disorder and MAT is a substance use disorder benefit under the MHPAEA, a plan that offers MAT benefits must do so on terms that are no more restrictive than those for M/S benefits. The behavioral health component should be treated as outpatient or in-patient, as appropriate, and the rule for multi-tiered prescription drug benefits applies to the medication component — meaning a plan that applies different levels of financial requirements to different tiers of prescription drug benefits must base the financial requirements on reasonable factors like cost, efficacy or generic versus brand name.

Women's Health and Cancer Rights Act

Under the WHCRA, if a plan covers mastectomies, it must also cover certain related services such as reconstruction of the breast on which the mastectomy was performed, surgery and reconstruction of the other breast to achieve a symmetrical appearance, prostheses, and treatment of physical complications of the mastectomy. The FAQs clarify that this requirement includes coverage for nipple and areola reconstruction, including re-pigmentation, to restore the physical appearance of the breast.

In Closing

In these FAQs, the departments addressed a number of practical questions on ACA market mandates, the MHPAEA, and the WHCRA. Plan sponsors should review their plans in light of this guidance to ensure compliance and make any necessary changes.

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