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Departments Issue 31st Set of FAQs

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The Departments of Labor, the Treasury, and Health and Human Services (collectively, the "Departments") have issued the 31st set of Affordable Care Act ("ACA") frequently asked questions ("FAQs"). This time, the Departments address a wide range of topics including preventive services, disclosure obligations, coverage in connection with approved clinical trials, reference-based pricing, the Mental Health Parity and Addiction Equity Act, and the Women's Health and Cancer Rights Act. Below is a brief summary of the guidance issued on these topics.

Preventive Care

All non-grandfathered group health plans must cover certain mandated preventive items and services in-network without cost-sharing.

- Colonoscopy. Colorectal cancer screening for adults over age 50 is a mandated preventive care service. This includes required preparation as an integral part of the procedure.

  FAQ 31 clarifies that bowel preparation medications are required to be covered without cost-sharing.

- Contraceptives. Plans that use reasonable medical management techniques ("MMTs") to control costs and promote efficient delivery of contraceptives (e.g., cover generic drugs without cost sharing and impose a copay for equivalent branded drugs) must have an exception process and the plan must defer to the determination of the attending provider.

  FAQ 31 suggests that the Medicare Part D Coverage Determination Request Form3 can serve as a model notice for the exceptions process.

Out-of-Network Emergency Services

Non-grandfathered group health plans cannot impose cost-sharing on out-of-network emergency services (expressed as a copayment or coinsurance rate) in a greater amount than what is imposed for in-network emergency services. A plan must pay a "reasonable amount" before a patient is responsible for any balance billing.

FAQ 31 explains that a plan must disclose how it calculated the reasonable amount as a part of its ERISA plan documents and claims and appeals procedures.

Clinical Trials

Non-grandfathered group health plans may not deny a qualified individual from participating in an approved clinical trial with respect to the prevention, detection or treatment of cancer and certain life-threatening illnesses, including routine patient costs in connection with such participation.

The Departments believe this provision is self-implementing. Unless and until further guidance is issued, plans are expected to implement these requirements using a good faith, reasonable interpretation of the law.

FAQ 31 provides additional guidance with the following clarifications:

- A plan 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 such as a clinical trial for an anti-nausea medication.
- Routine patient costs include items and services to diagnose or treat complications or adverse events (e.g., side effects) arising from participation in an approved clinical trial and must be covered.

Referenced-based Pricing

Non-grandfathered health plans are required to ensure that any annual cost-sharing imposed with respect to essential health benefits is limited to the annual maximum out-of-pocket ("MOOP") limit (for 2016, $6,850 for self-only coverage and $13,700 for other than self-only coverage).

As previously announced, the Departments are concerned with a reference-based pricing structure (or similar network design) because 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. The Department outlined specific factors that will be considered whether evaluating whether a reference-based pricing program (or other similar design) is using a reasonable method to ensure adequate access to quality providers. These factors are restated in the appendix for reference.

Per FAQ 31, 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. If there is not adequate access to quality providers willing to accept the price as payment in full, the plan is required to count an individual's out-of-pocket expenses for the provider who did not accept the reference price toward the MOOP limit.

Mental Health Parity and Addiction Equity Act ("MHPAEA")

MHPAEA applies to:

- Employers with at least 51 employees offering group health plan coverage that includes any mental health and/or substance use disorder ("MH/SUD" benefits,

- Non-grandfathered insured small group and individual health plans, as MH/SUD is considered an essential health benefit.

With respect to MHPAEA, the FAQs provide the following clarifications.

1. Plan-specific data must be used when running the substantially all and predominant tests. The financial requirements and treatment limitations imposed on MH/SUD benefits cannot be more restrictive than the predominant financial requirements and treatment limitations that apply to substantially all medical and surgical benefits. The regulations outline specific requirements to demonstrate compliance with these requirements and permit "any reasonable method" to be used to determine the dollar amount of all plan payments under these tests.

   In performing the substantially all and predominant tests, it is not reasonable to base the analysis on a carrier's (or TPA's) entire book of business. Rather, to the extent group health plan-specific data is available, each self-funded group health plan must use such data. For fully-insured group health plans, the issuer should use group health plan-specific data to make projections, or if none, then data from other similarly-structured group health plans with similar demographics.

2. Disclosure requirements. A plan administrator or issuer must disclose the criteria for medical necessity determinations with respect to MH/SUD benefits upon request and the reason for denial of reimbursement or payment for services. Such disclosure must be made to any current or potential participant, beneficiary, or contracting provider and must include the reason for any denial of reimbursement or payment for services with respect to MH/SUD benefits.

   FAQ 31 clarifies that, upon request, a group health plan must make available to any current or potential enrollee or contracting provider the criteria for medical necessity determinations.

   Additionally, a provider acting as a plan participant's authorized representative can request the following documents with respect to the plan's compliance with MHPAEA:
   - The summary plan description ("SPD") or other summary information;
   - The specific plan language regarding the imposition of the nonquantitative treatment limitation ("NQTL") (i.e., preauthorization requirement);
   - The specific underlying processes, strategies, evidentiary standards, and other factors considered by the plan in determining that the NQTL would apply to this particular MH/SUD benefit;
   - Information regarding the application of the NQTL to any medical/surgical benefits;
   - The specific underlying processes, strategies, evidentiary standards, and other factors considered by the plan in determining the extent to which the NQTL would apply to any medical/surgical benefits within the classification; and
   - Any analysis performed by the plan as to how the NQTL complies with MHPAEA.

3. MHPAEA applies to opioid use disorder benefits. Group health plans that offer any medication assisted treatment ("MAT") benefits for opioid use disorder must comply with MHPAEA, including the special rule for multi-tiered prescription drug benefits. The behavioral health services component of MAT should be treated as outpatient and/or inpatient benefits as appropriate.

Women's Health and Cancer Rights Act (WHCRA)

WHCRA provides protection for individuals who elect breast reconstruction in connection with a mastectomy. If a group health plan covers mastectomies, it must provide coverage for certain services in a manner determined in consultation with the attending physician.

FAQ 31 clarifies that such coverage must be provided for all stages of breast reconstruction, including coverage for nipple and areola reconstruction and repigmentation. Plans may impose deductibles and coinsurance for these benefits if consistent with those established for other benefits.

Appendix

The 21st set of ACA FAQs specifies the following factors will be considered as to whether the reference-based price structure (or similar network design) is a reasonable method:

1. **Type of service.** Plans should have standards to ensure that the network is designed to enable the plan to offer benefits for services from high-quality providers at reduced costs. For this purpose:
    a. In general, reference-based pricing should apply only to those services for which the period between identification of the need for care and provision of the care is long enough for consumers to make an informed choice of provider.
    b. Limiting or excluding cost-sharing from counting toward the Maximum Out-of-Pocket ("MOOP") is not reasonable with respect to emergency services.

2. **Reasonable access.** Plans should have procedures to ensure that an adequate number of providers that accept the reference price are available to participants and beneficiaries.

3. **Quality standards.** Plans should have procedures to ensure that an adequate number of providers accepting the reference price meet reasonable quality standards.

4. **Exceptions process.** Plans should have an easily accessible exceptions process, allowing services rendered by providers that do not accept the reference price to be treated as if the services were provided by a provider that accepts the reference price if:
    a. Access to a provider that accepts the reference price is unavailable (for example, the service cannot be obtained within a reasonable wait time or travel distance).
    b. The quality of services with respect to a particular individual could be compromised with the reference price provider (for example, if co-morbidities present complications or patient safety issues).

5. **Disclosure.** Plans should provide the following disclosures regarding reference-based pricing (or similar network design) to plan participants free of charge.
    a. Automatically. Plans should provide information regarding the pricing structure, including a list of services to which the pricing structure applies and the exceptions process. (This should be provided automatically, without the need for the participant to request such information, for example through the plan's Summary Plan Description or similar document.)
    b. Upon Request. Plans should provide:
        i. A list of providers that will accept the reference price for each service;
        ii. A list of providers that will accept a negotiated price above the reference price for each service; and
        iii. Information on the process and underlying data used to ensure that an adequate number of providers accepting the reference price meet reasonable quality standards.