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CMS Proposes Changes to Essential Health Benefits Prescription Drug Rules

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Health Care

On November 26, 2014, the Centers for Medicare & Medicaid Services (CMS) published proposed changes to the regulations governing the provision of Essential Health Benefits (EHB) in the commercial market. 79 Fed. Reg. 70674. This proposed rulemaking includes significant changes to the EHB rules governing prescription drug coverage.

Background

The Affordable Care Act (ACA) requires that non-grandfathered health plans in the individual and small group markets cover EHB, which includes items and services in 10 statutory benefit categories.[1] CMS promulgated regulations outlining how States should define EHB for these purposes. *See* 45 C.F.R. Part 156, Subpart B. Under these rules, state insurance regulators must develop an "EHB-benchmark plan" based on the benefits in a "base-benchmark plan," which is either chosen by the State from a list in CMS regulations or, if the State does not choose a base-benchmark, is "the largest plan by enrollment in the largest product by enrollment in the State's small group market." § 156.100. The base-benchmark plan must be supplemented with benefits from one of the other base-benchmark plan options to the extent the base-benchmark does not cover all 10 EHB categories. Health plans in the individual and small group markets are then required to provide coverage that is "substantially equal" to the coverage in the State's EHB-benchmark. § 156.115(a)(1). Medicaid Alternative Benefit Plans, which are the coverage States provide to the Medicaid expansion population, must also generally comply with the EHB rules. 42 U.S.C. § 1396u-7(b)(5).

CMS also imposes additional requirements in the EHB rules specific to prescription drugs. For example, health plans must cover the greater of "(i) one drug in every United States Pharmacopeia (USP) category and class; or (ii) the same number of prescription drugs in each category and class as the EHB-benchmark plan." § 156.122(a)(1). And plans "must have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the health plan." *Id.* § 156.122(c).

[1] The ten categories are: (1) ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) pediatric services, including oral and vision care.

Proposed Changes to the Prescription Drug Rules

In its recent proposed rulemaking, CMS proposes a number of significant changes to the EHB rules governing prescription drugs.

Developing the Drug Formulary

In the preamble, CMS explains the shortcomings of the USP category/class requirement:

> [I]ssuers have often had difficulty developing formularies that conform to the USP drug category and class system. Because the USP system was developed for the Medicare population, some drugs that are likely to be prescribed for the larger EHB population were not reflected. There were also many operational challenges associated with the drug count standard: Newly approved drugs were not counted; some drugs were counted in multiple USP classes; discontinued drugs had to be manually removed from the counting tool; and issuers had to submit justifications to explain their inability to meet the benchmark count due to system issues. We also found that the drug count review did not encourage the inclusion of newly-approved drugs and did not provide an incentive for issuers to cover innovative products or other products that would not be counted using this counting standard.

79 Fed. Reg. at 70719.

As a result, CMS proposes, effective for the 2017 plan year, to replace the USP category/class requirement with a requirement that health plans develop their drug formularies using "a pharmacy and therapeutic (P&T) committee." Proposed § 156.122.

The proposed rules include a number of standards for P&T committees. The P&T committee would need to ensure that the plan's formulary

1. Covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states and does not substantially discourage enrollment by any group of enrollees; and
2. Provides appropriate access to drugs that are included in broadly accepted treatment guidelines and which are indicative of, and consistent with, general best practice formularies currently in widespread use.

Id. § 156.122(a)(2)(iii)(E). It is not clear how CMS or state regulators would interpret these standards or whether, if they are finalized, CMS plans to clarify their meaning with subregulatory guidance.

The proposed rules also include procedural requirements for P&T committees. In making decisions, the P&T committee would be required to "[d]evelop and document procedures to ensure appropriate drug review and inclusion;" "[m]ake clinical decisions based on scientific evidence;" "[c]onsider the therapeutic advantages of drugs in terms of safety and efficacy;" and "[r]eview new FDA-approved drugs and new uses for existing drugs." *Id.* § 156.122(a)(2)(iii)(A)-(D). The P&T committee would be required to meet at least quarterly and maintain written documentation of the rationale for its decisions. *Id.* § 156.122(a)(2)(ii). The proposed rule also

addresses P&T committee membership. A P&T committee would be required to include members that "represent a sufficient number of clinical specialties to adequately meet the needs of enrollees;" have a majority of members practicing as health care professionals; and have at least 20% of the members lack any conflict of interest with respect to the plan issuer or any pharmaceutical company (members with a conflict must recuse themselves from voting on any matter in which they have a conflict). *Id.* § 156.122(a)(2)(i).

In the preamble, CMS notes that Medicare Part D already has standards for P&T committees. Although the Medicare Part D standards are similar to the proposed EHB standards, they have important differences. Most notably, a Medicare Part D P&T committee must ensure that the formulary generally includes at least two drugs from each USP category and class, whereas an EHB P&T committee would need to ensure the formulary complies with the more amorphous substantive standards quoted above. In addition, the Medicare Part D committee membership requirements are different than the membership requirements in the proposed EHB rules. *See* 42 C.F.R. § 423.120(b). CMS seeks comment on whether it should adopt the Medicare Part D standards, or the standards issued by the National Association of Insurance Commissioners (NAIC), in the EHB rules "in lieu of or in addition to" the standards it has proposed. 79 Fed. Reg. at 70719.

CMS is also considering, "[a]s an alternative to[] or in combination with" the P&T committee proposal, replacing the USP category/class test "with a standard based on the American Hospital Formulary Service (AHFS)," which CMS describes as "a widely used formulary reference system in the private insurance market." *Id.* at 70720. CMS seeks comment on this question, as well as "how to use AHFS to develop a minimum standard" and "any other standards that may be appropriate for this purpose." *Id.*

Accessing Drugs Not on the Formulary

As mentioned above, health plans subject to the EHB requirements "must have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the health plan." § 156.122(c). These procedures must include a process for "request[ing] an expedited review" (*i.e.*, within 24 hours) "based on exigent circumstances," which exist "when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug." *Id.* § 156.122(c)(1).

CMS believes that the exceptions process would benefit from "clearer and more uniform standards for issuers that receive an exception request" and that "additional parameters are . . . needed to better ensure that enrollees can obtain drugs that we believe should be covered as prescription drugs under the definition of EHB." 79 Fed. Reg. at 70720. Accordingly, CMS proposes a number of changes to the exceptions process in Section 156.122(c).

First, the proposed rules clarify that if the exception request is granted, "the plan must treat the excepted drug(s) as an essential health benefit, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing under § 156.130 and when calculating the plan's actuarial value under § 156.135." Proposed § 156.122(c).

The proposed rules also outline two different exceptions processes for "standard" and "expedited" requests. *Id.* § 156.122(c)(1)-(2). As in the current rules, the plan would need to

decide a standard request within 72 hours and an expedited request within 24 hours, and expedited requests would only be available for exigent circumstances.

Finally, CMS proposes to require that plans subject exceptions process decisions to external review. *Id.* § 156.122(c)(3). Specifically, plans would be required to allow parties who are denied an exception to seek "an external exception review by an independent review organization." The external review decision would be required within 72 hours for standard requests and within 24 hours for expedited requests. CMS does not indicate whether it plans to apply the external review process requirement to Medicaid Alternative Benefit Plans.

Method for Providing Covered Drugs

Under current rules, plans subject to the EHB requirements can dictate how enrollees access prescription drugs, including by requiring the use of mail-order pharmacies. CMS believes mail-order may be inappropriate in some circumstances, such as when the enrollee has an unstable living situation or needs the drug immediately.

Accordingly, CMS proposes to add a requirement that health plans "allow enrollees to access prescription drug benefits at in-network retail pharmacies, unless: (i) the drug is subject to restricted distribution by the U.S. Food and Drug Administration; or (ii) the drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy." Proposed § 156.122(e)(1). The health plan would be able to charge higher cost sharing for drugs at retail pharmacies, as compared to mail-order drugs, but the higher cost-sharing would count towards the plan's annual limit on cost-sharing and its actuarial value. *Id.* § 156.122(e)(2).

Publication of the Formulary

The proposed rules would add a requirement that health plans subject to the EHB rules publish their drug formularies, "including any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained." *Id.* § 156.122(d). The formularies would need to be published "in a manner that is easily accessible," which means (1) located on the plan's website "through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number" and (2) in a format in which "an individual can easily discern which formulary drug list applies to which plan" offered by the issuer. *Id.*

Prohibition on Discrimination

CMS's existing EHB rules provide that "[a]n issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions." § 156.125(e).

In the preamble to the proposed rulemaking, CMS warns plans against benefit design features that violate this prohibition on discrimination. CMS explains that it has become aware of a number of discriminatory practices, some of which have an impact on prescription drug coverage. CMS cites the following examples:

- Limiting access to hearing aids to enrollees who are under age 6 is discrimination based on age.

- Refusing coverage of "a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen" might constitute discrimination against individuals with chronic conditions.
- Placing most or all drugs that treat certain conditions on higher cost tiers is discrimination against individuals with those conditions.

79 Fed. Reg. at 70723. Although CMS does not propose any rule changes with respect to discrimination, this discussion in the preamble sheds light on CMS's view about the breadth and importance of the existing prohibition on discriminatory plan design.

Other Proposed Changes to the EHB Rules

In addition to the changes specific to prescription drug coverage, CMS proposes a number of other changes to the EHB rules, including:

- Allowing States the option to select "a 2014 plan that meets the requirements of § 156.110" as a new base-benchmark for the 2017 plan year. 79 Fed. Reg. at 70718.
- Changing the requirements for coverage of habilitative services in situations where the base-benchmark does not cover habilitation and the State does not define the benefit. Proposed § 156.115(a)(5).
- Clarifying that the annual limitation on cost sharing applies to plans that operate on a non-calendar year "beginning on the date the plan begins and ending one year later." Proposed § 156.130(b).
- Requiring that employer-sponsored plans "include substantial coverage of inpatient hospital services and physician services" to provide "minimum value." Proposed § 156.145(a).

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Health Care group:

Anna Kraus	+1 202 662 5320	akraus@cov.com
Joan Kutcher	+1 202 662 5206	jkutcher@cov.com
Philip Peisch	+1 202 662 5225	ppeisch@cov.com