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Essential Health Benefits Rules Will Still Burden States

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On Nov. 26, 2014, the Centers for Medicare & Medicaid Services published a proposed rule that includes several changes to the regulations governing the provision of essential health benefits (EHB) in the commercial market. 79 Fed. Reg. 70674.

Background

The Affordable Care Act requires that nongrandfathered 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 is the coverage states generally must provide to the Medicaid expansion population, must also cover EHB. Social Security Act § 1937(b)(5). CMS requires states to replicate the process used on the commercial side in defining EHB for alternative benefit plan purposes. That is, state Medicaid programs must choose a base-benchmark plan, supplement as necessary to create an EHB-benchmark, and ensure the alternative benefit plan coverage is substantially equal to the

EHB-benchmark in the 10 EHB categories. CMS also requires alternative benefit plans to comply with most other commercial EHB regulations, such as the special coverage rules for prescription drugs.

Requiring states to comply with the commercial EHB rules has resulted in an extremely complex alternative benefit plan design process and made it difficult for states to align alternative benefit plans with their state plan. It also means that changes to the commercial EHB rules can have significant implications for states that provide alternative benefit plans to the Medicaid expansion population. Further, for states that wish to keep their alternative benefit plans aligned with their state plan, any change made to the alternative benefit plan must also be made on the state plan side and vice versa.

In both the proposed regulations and the preamble, CMS offers a number of changes to the commercial EHB rules, some of which may impact alternative benefit plans. The proposed changes include allowing states to select a new base benchmark plan, as well as modifications to the rules governing prescriptions drugs and habilitative services.

Selection of New Base-Benchmark Plans

In the preamble to the proposed rulemaking, CMS proposes to allow states the option to select "a 2014 plan that meets the requirements of § 156.110" as a new base-benchmark. 78 Fed. Reg. at 70718. That is, states would be able to replace their current base-benchmark with a 2014 version of one of the base-benchmark options listed in Section 156.100(a), provided the 2014 plan already complies with Section 156.110, which is the regulation requiring that the EHB-benchmark plan cover all 10 EHB categories and supplement the base-benchmark if necessary. See 79 Fed. Reg. at 70718. This rule would effectively eliminate the need for states choosing a 2014 plan as a new base-benchmark to supplement under Section 156.110.

However, CMS is also considering allowing states to select a base-benchmark that does not meet the Section 156.110 requirements, "[i]f a category of base-benchmark plans under § 156.100(a)(1)-(4) does not include a plan that that meets the requirements of § 156.110." 78 Fed. Reg. at 70718. The categories of base-benchmark options in Section 156.100(a) are: (1) the largest health plan by enrollment in any of the three largest small group insurance products; (2) any of the three largest state employee plans; (3) any of the three largest federal employees health benefits program (FEHBP) plans; or (4) the largest commercial non-Medicaid HMO. If a state chose a base-benchmark that did not comply with Section 156.110, it would be required to supplement in the same way states supplemented in developing their current EHB packages. 78 Fed. Reg. at 70718.

CMS specifies that the new base-benchmark plan would apply "for the 2017 plan year." States' current commercial base-benchmark selections apply "for at least the 2014 and 2015 benefit years," 78 Fed. Reg. 12834, 12840 (Feb. 25, 2013), but the preamble does not discuss states' options for the 2016 plan year. It is not clear whether this option to choose a new base-benchmark would apply to alternative benefit plans — Medicaid regulations specify that states' current alternative benefit plans apply until Dec. 31, 2015, 42 C.F.R. § 440.345(e).

Prescription Drug Coverage

As with other categories of EHB, plans subject to the EHB rules must include coverage of prescription drugs that is "substantially equal" to the prescription drug coverage in the EHB-benchmark. See § 156.115(a)(1). 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).

CMS proposes a number of significant changes to 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 standards for P&T committees. The P&T committee would need to ensure that the plan's formulary:

1. cover 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. provide 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).

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 [U.S. Food and Drug Administration]-approved drugs and new uses for existing drugs." Id. § 156.122(a)(2)(iii)(A)-(D).

The proposed rules also include procedural requirements for P&T committees. P&T committees would need 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 percent 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). 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).

In the preamble, CMS notes that Medicare Part D and the National Association of Insurance Commissioners already have standards for P&T committees. CMS seeks comments on whether it should adopt those standards "in lieu of or in addition to" the standards in the proposed rule. 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.

It is not clear whether the P&T committee system or a standard based on the AHFS would be an improvement over the USP category/class requirement for beneficiaries, plan issuers or Medicaid Alternative Benefit Plans. However, we assume that adding a standard based on the AHFS to the P&T committee system would make the process even more burdensome than it already is for Medicaid Alternative Benefit Plans and make it harder for states to develop alternative benefit plans that align with the state plan.

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 toward 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 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 pharmacy. 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) [t]he drug is subject to restricted distribution by the U.S. Food and Drug Administration; or (ii) [t]he 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.

Coverage of Habilitative Services

One of the 10 categories of EHB is "[r]ehabilitative and habilitative services and devices." As with prescription drugs, CMS' current regulations have special rules for the habilitation benefit. If the base-benchmark does not include habilitative services, instead of supplementing the plan with the habilitative benefit from another base-benchmark option, the state can define the habilitative benefit itself. See § 156.110(f). If the state chooses not to do so, the issuer can cover habilitative services either in a similar amount, duration and scope as it covers rehabilitative services or in an amount determined by the issuer and reported to CMS. § 156.115(a)(5).

CMS now believes that "[i]n some instances," its regulations "have not resulted in comprehensive coverage for habilitative services." 79 Fed. Reg. at 70717. To rectify this, CMS proposes to require that, if the base-benchmark does not cover habilitation and the state does define it, "the plan must: (i) [c]over health care services that help a person keep, learn, or improve skills and functioning for daily living;[2] *and* (ii) [p]rovide coverage of habilitative services in a manner no less favorable than coverage of rehabilitative services." Proposed § 156.115(a)(5) (emphasis added). CMS plans to continue to defer to those states that choose to define habilitative services when the base-benchmark is missing the benefit, "as long as the State definition complies with EHB policies including non-discrimination." 79

Fed. Reg. at 70717.

This proposed rule change could result in more generous EHB packages with respect to habilitation in states that choose a base-benchmark that lacks habilitative services compared to states with a base-benchmark that actually covers habilitation. For example, if a state chooses a base-benchmark with limited habilitative services, plans in the individual and small group markets would only need to have a habilitative benefit that is "substantially equal" to that limited benefit in the base-benchmark plan. In contrast, if the state's base-benchmark lacks habilitation, and the state declines to define the benefit itself, plans would need to cover "health care services that help a person keep, learn, or improve skills and functioning for daily living ... in a manner no less favorable than coverage of rehabilitative services."

We think it is unlikely this proposed change will impact alternative benefit plans. Under the current commercial rules, the state has the option to define the benefit itself under Section 156.110(f) if the base-benchmark does not cover habilitation. As we understand CMS' policy, this means that state Medicaid programs can similarly define the habilitative benefit for alternative benefit plans if the base-benchmark does not cover habilitation, even if that results in a different definition of habilitative services than the definition used in the state's commercial market. Accordingly, the new habilitative services provision would only apply to alternative benefit plans if the base-benchmark does not include habilitation and the state Medicaid program voluntarily declines to define the benefit itself.

Prohibition on Discrimination

CMS 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 notes that it "has become aware of benefit designs that [it] believe[s] would discourage enrollment by individuals based on age or based on health conditions, in effect making those plan designs discriminatory, thus violating this prohibition." 79 Fed. Reg. at 70722. For example:

- 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. Id. at 70723.

Notably, CMS states that the prohibition on discrimination in Section 156.125 "does not apply to the Medicaid and CHIP programs, including EPSDT, and Alternative Benefit Plans." Id.

Other Proposed Changes

Other proposed changes to the EHB rules include:

- Clarifying that the annual limitation on cost sharing applies to plans that operate on a noncalendar year "beginning on the date the plan begins and ending one year later." Proposed § 156.130(b). This proposal would not impact alternative benefit plans, which are only subject to Medicaid cost sharing rules.

- Requiring that employer-sponsored plans "include substantial coverage of inpatient hospital services and physician services" to provide "minimum value." Proposed § 156.145(a). Under current rules, plans must cover 60 [percent] of the cost of benefits to offer "minimum value." CMS proposes to add this new coverage requirement because it believes that a plan that omits "substantial coverage for inpatient hospital and physician services is not a health plan in any meaningful sense and is contrary to the purpose of the [minimum value] requirement to ensure that an employer-sponsored plan ... offer coverage with minimum value at least roughly comparable to that of a bronze plan offered on an Exchange." 79 Fed. Reg. at 7025. This proposal will not impact alternative benefit plans because they are not subject to the minimum value rules.

CMS will accept comments on the proposed rules until 5 p.m. on Dec. 22, 2014.

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[1] The 10 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.

[2] This definition of habilitative services comes from CMS' Glossary of Health Coverage and Medical Terms.