

Health Care in Motion

Timely, Substantive Updates on Policy Shifts · Actionable Advocacy to Protect Health Care

December 6, 2023

Notice of Benefit and Payment Parameters for 2025 Proposed Rule: Important Potential Changes to Prescription Drug Protections

Every year, the Centers for Medicare and Medicaid Services (CMS) releases its Notice of Benefit and Payment Parameters (NBPP) rule for the following plan year. This regulation sets the rules of the road for Affordable Care Act (ACA) marketplace plans and related ACA programs and protections. In November 2023, CMS released the [NBPP proposed rule for the 2025 plan year](#). It includes many provisions – including several related to prescription drug coverage highlighted below – that could impact people living with HIV and other complex conditions and disabilities. Advocates should consider [submitting public comments](#) to ensure these provisions make it into the final version. Comments are due January 8, 2024.

Prescription Drugs and Essential Health Benefits

Under the ACA’s EHB rules for prescription drug coverage, individual and small group plans must cover either (1) at least one drug in each drug category or class (a concept discussed below), or (2) the same number of drugs per category and class as the state’s EHB benchmark plan, whichever is higher. Plans have always been free to cover more drugs than are required under these rules.

Consumer advocates have argued that some plans try to categorize drugs that the plan covers beyond these low minimum standards as “non-EHB.” This allows the plan to treat “non-EHB” drugs as if they are not subject to EHB protections, including that all cost-sharing for these drugs must count toward an individual plan’s out-of-pocket maximum, and the prohibition on employer plans from applying annual and lifetime limits for these drugs. In response to this practice, CMS proposes to clarify that when a plan covers more than the minimum drugs required under EHB rules, these additional drugs are still considered EHB and are subject to EHB requirements.

Some plans, particularly in the employer-based market, [have been exploiting this EHB loophole](#) in combination with “copy maximizer” or similar programs. Under these programs, plans require patients who take certain

Essential Health Benefits (EHB) Overview

Every individual and small group plan must cover EHB – a set of ten categories of essential services that includes prescription drugs. These plans must also count all cost sharing for EHB toward the plan’s out-of-pocket maximum. While employer plans do not have to cover EHB, they are prohibited from placing any annual or lifetime limits on EHB services.

high-cost medications to enroll in a program where the patient is charged a low monthly copay for their drugs, while the plan collects larger copayments from the drug manufacturer's copay assistance program. Patients are told that they must enroll in these programs or risk owing exorbitant amounts for their medications. They may also face challenges if they have to change plans mid-year. Manufacturers claim that these copay maximizer programs are siphoning charitable funds that are supposed to be used to lower copayments for patients who can't afford them, and some manufacturers [cut off access to their assistance programs](#) to patients enrolled in these programs. Plans, on the other hand, claim that these programs are necessary to combat the ever-rising prices manufacturers charge for brand-name drugs. Under these copay maximizer programs, because the plans have labeled the affected drugs "non-EHB," neither the patient's own copayments nor the copayments made on the patient's behalf by the copay assistance program are counted toward the patient's deductible or out-of-pocket maximum.

The proposed rule only addresses the practice of deeming certain drugs non-EHB. Advocates and the federal government are [continuing to wrestle](#) with the larger question whether payments made by copay assistance programs count towards cost sharing requirements. However, if plans can no longer designate drugs as non-EHB, copay maximizers and similar programs will become less advantageous for the plans, since plans will have to count at least some of the payments made for these drugs toward a patient's out-of-pocket maximum.

Changing the Drug Classification Standard

The proposed rule also asks for comment on a somewhat technical but important change regarding the drug classification system used to enforce the EHB minimum standards for coverage of prescription drugs. As discussed above, plans subject to EHB requirements must cover either (1) at least one drug per category and class, or (2) the same number of drugs per category and class as the state's EHB benchmark plan, whichever is higher. The drug categories and classes are currently defined in the United States Pharmacopeia (USP) [Medicare Model Guidelines \(MMG\)](#).

Many people have argued that this classification system is underinclusive and that because it is developed for Medicare, it is not designed with the commercially insured population in mind. In response to these concerns, CMS is considering whether to replace the USP MMG system with the [USP Drug Classification \(DC\)](#) system. Advocates, including CHLPI, have argued that the USP DC system is updated more frequently than the USP MMG system and that the USP DC system is more transparent and accessible to consumers and advocates.

CHLPI submitted [comments](#) in January 2023 regarding potential improvements to the EHB regulations that included a call for CMS to move to the USP Drug Classification system.

Pharmacy and Therapeutics Committee Standards

CMS is also proposing consumer friendly changes to the standards governing pharmacy & therapeutics (P&T) committees. P&T committees are bodies made up of medical providers, pharmacists, administrators and others. They have a variety of roles within the health care system, but for health insurance plans, they decide what drugs are covered on a plan's formulary.

The ACA has a number of requirements for P&T committees that ensure they are made up of unbiased subject matter experts and that they take into account reputable and up-to-date scientific evidence. CMS is proposing

to add a requirement to the P&T committee membership rules to include that a P&T committee must have a consumer representative as part of its membership for plan years beginning January 1, 2026. This consumer representative would be required to have an affiliation with a consumer or community-based organization (for example, organizations that protect consumer rights via advocacy, research, or outreach efforts). CMS believes that requiring this perspective will help P&T committees better understand the impacts that formulary decisions have on consumers.

Adverse Tiering Enforcement

In its [draft annual letter to issuers](#) for the 2025 plan year – guidance that CMS releases every year to accompany the NBPP – CMS reiterated its commitment to reviewing qualified health plans to ensure plans are not utilizing discriminatory formulary designs. As it did last year, CMS will use an [adverse tiering](#) review to assess whether plans are discriminating against consumers with certain high-cost chronic conditions by placing all drugs that treat those conditions on the plans’ most expensive formulary tiers. For the 2025 plan year, CMS will continue to focus its review on four conditions: hepatitis C virus, HIV, multiple sclerosis, and rheumatoid arthritis.

Comments on the proposed NBPP for 2025 are due January 8, 2024. Advocates should consider [submitting comments](#) highlighting how each provision impacts people who depend on high-cost drugs to stay healthy. Comments may also be submitted on the draft letter to issuers by January 2, 2024.

Subscribe to all Health Care in Motion Updates

Health Care in Motion is written by Carmel Shachar, Health Law and Policy Clinic Faculty Director; Kevin Costello, Litigation Director; Elizabeth Kaplan, Director of Health Care Access; Maryanne Tomazic, Clinical Instructor; Rachel Landauer, Clinical Instructor; Johnathon Card, Staff Attorney; and Suzanne Davies, Clinical Fellow. This issue was written with the assistance of Amy Killelea of Killelea Consulting.

For further questions or inquiries please contact us at chlpi@law.harvard.edu.