



Essential Health Benefits Prescription Drug Standard

Issue No.5 – Pharmacy and Therapeutics Committees

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Introduced by the Affordable Care Act (ACA), Essential Health Benefits (EHB) are a set of ten health care service categories that plans must cover.¹ The EHB requirement applies to non-grandfathered health plans offered in the individual and small group markets (both inside and outside the Marketplace).² One of the ten categories of benefits is prescription drugs.

On February 20, 2015, the Department of Health and Human Services (HHS) issued the Notice of Benefit and Payment Parameters for 2016 final rule (Final Rule 2016), which finalized changes to the EHB standard.³ The Final Rule 2016 significantly modified EHB prescription drug requirements.

This fact sheet, focusing on **Pharmacy and Therapeutics (P&T) Committees**, is the fifth in a series of NHeLP fact sheets describing the EHB prescription drug standard. Additional fact sheets in this series examine formulary transparency, the exceptions process, mail-order pharmacies, and the use of the United States Pharmacopeia Classification System to establish minimum coverage standards.

Background – P&T Committees in Federal Health Programs

For the 2014 and 2015 plan years, HHS established the minimum EHB standard for prescription drug coverage at a minimum of one drug per class and category based upon the United States Pharmacopeial Convention (USP) Medicare Model Guidelines a drug classification system which is updated every three years. (For more on the USP Classification System see Issue No. 4 in this series). NHeLP and other health advocates raised concerns that formularies for some Qualified Health Plans (QHPs) failed to provide an adequate array of prescription drugs and lacked appropriate mechanisms to update their formularies.

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In response to these concerns, **beginning in 2017** HHS will require QHPs to establish Pharmacy and Therapeutics (P&T) Committees to review and update plan formularies in conjunction with the USP Medicare Model Guidelines. Although new to QHPs, all Medicare Part D plans and some state Medicaid programs operate P&T Committees.

Medicare P&T Committees

The Social Security Act requires Medicare prescription drug plans, known as Part D plans, to maintain P&T Committees to design and review formularies.⁴ The Centers for Medicare & Medicaid Services (CMS) outlines requirements for P&T Committee membership, responsibilities, conflict of interest policies, and reporting requirements in the Medicare Prescription Drug Benefit Manual.⁵

P&T Committees are one component of Medicare Part D consumer protections in prescription drug formularies and design. Other protections and oversight of plan formularies include:

- Medicare Part D plans must cover six essential classes of drugs which must be offered without step therapy or prior authorization requirements for beneficiaries who are currently taking the drug.⁶
- Part D plans must submit their formularies and utilization management tools to CMS for review.⁷
- CMS conducts compliance reviews and audits of Medicare Part C and D plans, which are [publicly posted on the CMS website](#).⁸
- CMS initiates [enforcement actions](#) against non-compliant plans.

In its 2013 review of Medicare P&T Committees, the HHS Office of the Inspector General (OIG) identified numerous deficiencies in Medicare P&T conflict of interest standards and made recommendations, including: (1) define pharmacy benefit managers as entities that could benefit from coverage decisions (to recognize that they may have a conflict of interest), (2) ensure that safeguards are in place to mitigate improprieties related to employment by the entity managing the P&T Committee, (3) ensure that an objective process is used to determine conflicts, (4) ensure that an objective process is used to manage conflicts, and (5) oversee compliance with the requirement that a specified number of members be independent and free of conflict.⁹

Medicare Part D P&T Committees have rarely raised concerns for advocates, due to safeguards provided under the Part D program, such as protected drug classes and robust reporting and monitoring requirements.

Medicaid P&T Committees

Federal law allows state Medicaid programs to design and update prescription drug formularies using Drug Utilization Review Boards (DURBs) or through separate committees “consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State.”¹⁰ However, unlike the Medicare Part D program, the Medicaid Act and regulations provide little detail on the composition, operations, and procedures of these separate formulary committees, or when DURBs develop formularies in addition to engaging in utilization review.¹¹

A number of states operate stand-alone Medicaid P&T Committees, which vary widely in composition, responsibilities, and structure.¹² For example, California’s P&T Committee holds no in-person meetings; while other states, including Kansas and Washington State, hold regular meetings and provide opportunities for public comment.¹³ In some states, Medicaid P&T Committees establish preferred drug lists (PDLs) and medical utilization management criteria, such as prior authorization, in Fee for Service (FFS) Medicaid.¹⁴

Medicaid Formularies vs. Preferred Drug Lists

Formularies: Under federal law, Medicaid formularies may exclude a prescription drug from coverage only if the “drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary.” The cost of drugs may not be considered in designing a formulary. And, the state must permit access to an excluded drug pursuant to a prior authorization program.

Preferred Drug Lists: Federal law allows states to designate “preferred drugs” and charge Medicaid enrollees cost sharing, subject to limitations.¹⁵ Unlike formularies, PDLs can consider cost when determining if a prescription drug is a preferred drug.¹⁶ PDLs are considered a prior authorization program rather than a formulary.¹⁷ States also use PDLs to obtain supplemental manufacturer rebates.¹⁸

The lack of federal regulations or guidance on Medicaid P&T Committees has created challenges for advocates and stakeholders seeking restrictive criteria for prior authorization and other utilization controls or to add new medications to PDLs.¹⁹ (Note - Medicaid requirements for DURBs and P&T Committees do not apply to prescription drugs subject to 340B discounts and provided through Medicaid managed care.)²⁰

P&T Committees in Health Plans Providing EHBs

In public comments submitted to HHS, NHeLP and other health advocates supported P&T Committees as a needed complement to using a published drug classification system when establishing minimum EHB prescription drug coverage. Since the USP Medicare Model Guidelines are updated every three years, P&T Committees provide a mechanism to expeditiously update prescription drug formularies and medically indicated uses. To help ensure that P&T Committees fill the gaps in formularies and provide enrollees with prescription drug access that meets their needs, advocates urged HHS to:

- Require a broad spectrum of providers and expertise on the P&T Committees, including practicing physicians who are up-to-date on current practice standards;
- Clarify conflict of interest and disclosure requirements, as well as robust federal monitoring, and compliance reviews, including corrective action plans;
- Establish minimum transparency requirements, including holding public meetings, providing public notice of meeting times, posting the meeting agenda and minutes on the plan's website so that they are readily and easily accessible for consumers and other stakeholders. Committee by-laws, membership, terms of appointment, and financial disclosure information should all be posted on the plans' websites and be publicly available;
- Require P&T Committees to provide opportunities for stakeholder involvement, including public comment periods; and
- Broaden the scope of P&T Committees to include reviewing the appropriateness of medical management techniques such as prior authorization, pill quantity limits, and step therapy.²¹

Change/Clarification

HHS adopted P&T Committee standards based largely on the Medicare Part D standards, which include requirements for membership, meetings, responsibilities, and conflicts of interest.²² However, states have the primary responsibility for the oversight and enforcement of EHB P&T Committee standards.²³ Among the requirements established for EHB P&T Committees:

- Meet at least quarterly and review new drugs or new indications within 90 days of Food and Drug Administration (FDA) approval, and make a decision within 180 days of its release onto the market. If this timing is not met, the committee must justify the delay in writing;

- Base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data;
- Include a majority of individuals who are practicing physicians, practicing pharmacists and other practicing health care professionals who are licensed to prescribe drugs;
- Include members with clinical specialties to address the needs of enrollees, including persons with chronic conditions and disabilities who are expected to consult with outside experts;
- Ensure the formulary covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all states of a disease, and does not discourage enrollment by any group of enrollees;
- Have procedures for reviewing medications and documenting their formulary review; and
- Make the committees' recommendations on which drugs to include in the formularies binding on the plans.²⁴

HHS also established conflict of interest requirements for EHB P&T Committees, including:

- Members can be affiliated with the issuer or pharmaceutical manufacturer but must recuse themselves when voting on a matter where a conflict arises;
- A minimum of 20% of the membership must have no conflict;
- Conflict of interest statements must be filed at least annually;
- Committees establish definitions of conflict and procedures to monitor and enforce.

Advocacy Opportunities

The Final Rule 2016 falls short in a number of areas where NHeLP and other advocates urged for more robust requirements. For example, states, not federal authorities, are primarily responsible for establishing and monitoring EHB P&T Committees. In addition, the Final Rule 2016:

- Fails to include transparency requirements, such as public posting of P&T meeting times, minutes, by-laws, and conflict of interest disclosure statements. Instead HHS encourages committees to publicly post information for consumers;²⁵
- States that committee recommendations on utilization activities, such as prior authorizations, step therapy, and quantity limits are not binding on plans;²⁶

- Does not require monitoring of appeals and exceptions to identify inadequate formularies; and
- Does not include protections such as the Medicare Complaint Tracking Module, protected drug classes, and rigorous federal monitoring, and will likely result in piecemeal and sporadic oversight.²⁷

The Final Rule 2016 provides minimum standards that do not preclude states from requiring more rigorous standards for EHB P&T Committees. Advocates should consult with their state's insurance commissioner and push for a stakeholder process to establish and monitor EHB P&T Committees.

Conclusion

Although the Final Rule 2016 did not fully address all of the concerns raised by health advocates, the introduction of P&T Committees for EHBs is a significant step forward. Even though QHPs are not required to have P&T Committees until 2017 (or sooner in some states), health advocates and consumers have a new tool to ensure that EHB formularies meet the needs of enrollees. Moreover, the new P&T Committees demonstrate the importance of advocacy efforts and lay the groundwork for future improvements in EHB prescription drug standards.

¹ The ten EHB statutory categories of benefits are: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services (including chronic disease management); and pediatric services, including oral and vision care. The EHB requirement applies to non-grandfathered health plans offered in the individual and small group markets (both inside and outside the Marketplace). This fact sheet focuses on EHBs as they apply to the private market.

² See 42 U.S.C. § 300gg-6(a); 45 C.F.R. § 147.150. See also 29 C.F.R. § 2590.715-1251(c)(1). This fact sheet focuses on EHBs as they apply to the private market.

³ HHS Notice of Benefit and Payment Parameters for 2016 Final Rule, 80 Fed. Reg. 10,750 (Feb. 27, 2015) (to be codified at 45 C.F.R. pts 144, 147, 153, 154, 155, 156, and 158), available at <http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-03751.pdf> [hereinafter Final Rule 2016].

⁴ 42 U.S.C. § 1395w-104(b)(3)(A), 42 C.F.R. § 423.120(b)(1).

⁵ CMS, MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL, CH. 6, SEC. 30 FORMULARY REQUIREMENTS (July 2008), available at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf>.

⁶ 42 U.S.C. § 1395w-104(b)(3)(G).

⁷ See e.g., CMS, Solicitation for Applications for Medicare Prescription Drug Plan 2016 Contracts New Medicare Prescription Drug Plan (PDP), Medicare Advantage-Prescription Drug (MA-PD) (with and without EGWP), and Expansion of an Existing Contracts with CMS for PDP and MA-PD (including CCP, PFFS, RPPO, Cost Plan, SNPs and EGWPs), 2016 Contract Year, available at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2016-Part-D-Application.pdf>.

⁸ 42 C.F.R. § 423.272.

⁹ HHS Office of the Inspector General, *Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions* (2013), available at <https://oig.hhs.gov/oei/reports/oei-05-10-00450.pdf>.

¹⁰ 42 U.S.C. § 1396r-8(d)(4)(A).

¹¹ DURBs establish state education programs for physicians and pharmacists, identify fraud and abuse, and reduce unnecessary care. 42 U.S.C. § 1396r-8(g)(1)(A); 42 C.F.R. §§ 456.700-719.

¹² National Academy for State Health Policy (NASHP), *State Experience in Creating Effective P&T Committees* (March 2006) available at http://www.nashp.org/sites/default/files/medicaid_pandt.pdf.

¹³ *Id.*

¹⁴ 42 U.S.C. § 1396r-8(d)(4)(D), see also 42 C.F.R. § 440.230(d), 42 C.F.R. § 447.51

¹⁵ 42 U.S.C. §§ 1396o, 1396o-1. See also David Machledt and Jane Perkins, NHeLP, *Medicaid Premiums and Cost Sharing* (March 26, 2015), available at

<http://www.healthlaw.org/publications/search-publications/Medicaid-Premiums-Cost-Sharing>.

¹⁶ See *Pharmaceutical Research and Mfrs. of America v. Meadows*, 304 F.3d 1197, 1203 (11th Cir. 2006) (Florida's PDL was not a formulary under 42 U.S.C. 1396r-8(d)(4) and instead a prior authorization program under (d)(5), because state could consider economic factors). See also *U.S. ex rel. King v. Solvay S.A.*, No. 06-2662, 2015 WL 338032 (S.D. Tex. 2015).

¹⁷ *Id.*

¹⁸ See NASHP, *supra* note 12.

¹⁹ See e.g., Letter from Health Consumer Alliance to Neal Kohatsu MD, MPH, Medical Director, Julia S. Logan MD, MPH, Quality Officer, Office of the Medical Director, California Department of Health Care Services (June 2, 2015) (on file with NHeLP)

²⁰ 42 U.S.C. § 1396r-8(j)(1). However, under proposed changes to Medicaid managed care regulations, DUR would apply to Medicaid managed care. See proposed 42 C.F.R. § 438.3(s), HHS, Medicaid and Children's Health Insurance (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability Proposed Rule, 80 Fed. Reg. 31,098, 31,257 (June 1, 2015).

²¹ National Health Law Program, Comments - Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016 (Dec. 22, 2014), available at <http://www.regulations.gov/#!documentDetail;D=CMS-2014-0152-0276>. See also American Cancer Society Cancer Action Network, Re: CMS-9944-P – Patient Protection and Affordable Care Act: HHS Notice of Benefit and Payment Parameters for 2016 (Dec. 22, 2014) available at <http://www.regulations.gov/#!documentDetail;D=CMS-2014-0152-0209>; California Chronic Care Coalition, Comments on Notice of Benefit and Payment Parameters for 2016 (Dec. 19, 2014) available at <http://www.regulations.gov/#!documentDetail;D=CMS-2014-0152-0071>; HIV Health Care Access Working Group, Comments on Notice of Payment and Benefit Parameters for 2016 Rule; Ohio Consumers for Health Coverage, Comments on Benefit and Payment Parameters for 2016 (Dec. 22, 2014) available at <http://www.regulations.gov/#!documentDetail;D=CMS-2014-0152-0257>;

²² Final Rule 2016, *supra* note 3, at 10,816. Note - the EHB conflicts of interest standards differ from the Part D's standards to make them more suitable for the private market, according to HHS.

²³ *Id.* at 10,815.

²⁴ *Id.* at 10,816.

²⁵ *Id.*

²⁶ *Id.* at 10,817.

²⁷ See, e.g., CMS, Part C and Part D Compliance and Audits – Overview, available at <http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/index.html>.