Essential Health Benefits Prescription Drug Standard

Issue No. 3 – Mail-Order Pharmacies

Prepared By: Wayne Turner and Shyaam Subramanian
Date: June 22, 2015

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] One of the ten categories of benefits is prescription drugs.

On February 20th, 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.[2] The Final Rule 2016 significantly modified the EHB prescription drug requirements.

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

Background – Mail-Order Pharmacies

Depending on their medical condition and prescription drug needs, individuals may prefer to obtain prescription drugs via mail-order or at a retail (brick and mortar) pharmacy. Health plans providing EHBs are permitted to provide covered prescription drugs through mail-order or retail pharmacies. However, health plans may require an enrollee to obtain a particular covered drug through mail-order only. For example, enrollees may be required to obtain certain types of drugs or certain quantities of drugs through mail-order instead of at a retail pharmacy.[3] Health plans implement mandatory mail-order programs for a variety of reasons, including because of the reduced cost to dispense drugs in this manner.

In comments to HHS' Notice of Benefit and Payment Parameters proposed rule for 2016 (HHS' Proposed Rule), consumer groups raised concerns about health plans' use of mandatory mail-order programs, including:[4]

- Gaps in treatment and lack of access to medications

- Enrollees may immediately need medications, for example pain relievers or antibiotics, and cannot wait for medications to arrive in the mail;
  - Enrollees may run out of a medication before it can be refilled, and gaps in treatment can lead to serious health consequences, including enrollees developing resistance to the prescribed medication;[5]
  - Medications may be lost or stolen in the mail; and
  - Many individuals—including people experiencing homelessness, those without a permanent mailing address, or people who move frequently—may not receive medications or may experience delays if limited to receiving prescription drugs via mail-order only.
- Drug adherence and adverse health effects
  - An enrollee's repeated face-to-face interaction with a pharmacist can build trust and lead to better adherence to the prescribed drug regimen;
  - Enrollees may be able to ask questions about medication side effects and dosage requirements and receive other counseling at a retail pharmacy, including from a pharmacist who is familiar with the enrollee's medical history; and
  - A retail pharmacist who repeatedly serves an enrollee in-person is in the best position to identify potentially dangerous or deadly drug interactions and address side effects, some of which can only be detected visually.[6]
- Enrollee privacy
  - Enrollees may want to keep their medical conditions confidential and not have prescription drugs regularly delivered to their home or workplace where neighbors, co-residents, or co-workers can come to know of their condition or medication needs.
    - Privacy issues may be particularly critical for women experiencing intimate partner violence. These women may need access to confidential sexual and reproductive health care, including contraception and prescription drugs for sexually transmitted infections.
    - Individuals diagnosed with HIV/AIDS who are forced to receive antiretroviral medications at their workplace may be subject to stigmatization from co-workers and supervisors.[7]

Contrary to the ACA's goal of improving access to health care, enrollees in mandatory mail-order programs may be unable to obtain prescription drug benefits in a manner that is appropriate for them and their medical conditions. In comments to HHS' Proposed Rule, NHeLP and other advocates urged HHS to address these and other concerns by requiring health plans to:

- Provide enrollees with the option of accessing covered prescription drugs through in-network retail pharmacies;
- Ensure that enrollees can access retail pharmacies within a short distance from where they live;
- Ensure enrollees are not penalized with prohibitively high cost-sharing for obtaining drugs at a retail pharmacy; and
- Comply with these requirements no later than the 2016 plan year.

Many, but not all, consumer concerns were addressed in the Final Rule 2016.

Change/Clarification

In response to consumer concerns, HHS in the Final Rule 2016 prohibited health plans providing EHBs from offering covered prescription drugs to enrollees only through mail-order.

For plan years beginning on or after January 1, 2017, a health plan providing EHBs must allow enrollees to access prescription drug benefits at in-network retail pharmacies, with some exceptions.[8] Health plans *may* restrict access to a particular drug if 1) the drug is subject to restricted distribution by the U.S. Food and Drug Administration or 2) the drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.[9] For health plans that do not have a network, HHS indicated that enrollees should be able to go to any retail pharmacy to access the benefit.[10]

HHS clarified that health plans may charge enrollees a different cost-sharing amount for obtaining a covered drug at a retail pharmacy than the enrollee would pay for obtaining the same covered drug at a mail-order pharmacy.[11] However, the plan must count all cost-sharing for an approved drug towards a plan's annual limitation on cost-sharing and when calculating the plan's actuarial value.[12]

Advocacy Opportunities

- Ensure your state adopts the new federal mail-order pharmacy requirements, and identify state laws and/or regulations that may need to be amended to comply with the federal requirements.

- Monitor health plan compliance with the mail-order requirements, including the cost-sharing requirements. Although HHS permits health plans to charge enrollees a different cost-sharing amount for obtaining a covered drug at a retail pharmacy, health plans are still prohibited from imposing cost-sharing for drugs that are considered preventive services under the ACA.[13]

- Monitor the exceptions to the mail-order requirements to ensure health plans are not arbitrarily restricting access to prescription drugs. In the preamble to the Final Rule 2016, HHS provided the following guidance:
    - The fact that a health plan restricts access to a drug is not, in and of itself, a justification for the health plan to apply utilization management techniques to that drug.[14]
    - If the health plan finds it necessary to restrict access to a drug, it must indicate this restricted access on the formulary drug list that it must make publicly available.[15] For more information on formulary transparency, please see NHeLP's Formulary Transparency fact sheet.

- If possible, advocate for health plans to comply with the mail-order requirements no later than the 2016 plan year, rather than wait until the 2017 plan year which is when health plans must comply with the new requirements.

- Let NHeLP know if you see issues with mail-order pharmacies or any other prescription drug access issues.

Conclusion

Beginning in 2017, health plan enrollees will have the option of obtaining prescription drugs at in-network retail pharmacies, with some exceptions. This change is a significant step forward, but advocates will have to monitor health plan compliance with the new requirements to ensure enrollees can obtain the prescription drugs they need in a manner that is appropriate for them. The new restrictions on mandatory mail-order programs demonstrate the importance of advocacy efforts, so it will be important to track any issues 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] 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].

[3] Specialty drugs—typically expensive and used to treat complex, chronic conditions—are often provided via mail-order.

[4] *See, e.g.*, AARP, RE: CMS-9944-P (Dec. 19, 2014) *available at* http://www.regulations.gov/#!documentDetail;D=CMS-2014-0152-0117; American Cancer Society 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; HIV Health Care Access Working Group, Comments on Notice of Benefit and Payment Parameters for 2016 (Dec. 22, 2014), *available at* http://www.regulations.gov/#!documentDetail;D=CMS-2014-0152-0144; 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.

[5] *See* Matthew L. Maciejewski et al., *Copayment Reductions Generate Greater Medication Adherence in Targeted Patients,* 29 Health Affairs 2002 (2010); *See also* National Institutes of Health, HIV Medication Adherence (Apr. 2015), https://aidsinfo.nih.gov/education-materials/fact-sheets/21/54/hiv-medication-adherence.

[6] *See* Complaint at 3, *Doe v. Cigna Health and Life Ins. Co. et al.*, No. 15-60894 (S.D. Fla. filed Apr. 27, 2015).

[7] *See* Complaint at 5-6, *Doe v. Aetna, Inc. et al.*, No. 14-2986 (S.D. Cal. Filed Dec. 19, 2014).

[8] *See* 45 C.F.R. § 156.122(e)(1).

[9] *See* 45 C.F.R. § 156.122(e)(1)(i)-(ii).

[10] Final Rule 2016, *supra* note 2, at 10,820.

[11] 45 C.F.R. § 156.122(e)(2).

[12] *Id.*

[13] 42 U.S.C. § 300gg-13(a).

[14] Final Rule 2016, *supra* note 2, at 10,821.

[15] *Id.* Also, *see* 45 C.F.R. § 156.122(d) for new federal requirements around formulary transparency.