Medicaid Outpatient Prescription Drugs

Prepared By: Michelle Lilienfeld[1]
Date: November 30, 2016

Prescription drug coverage is an important facet of the Medicaid program. Although an optional benefit, all states cover outpatient prescription drugs in their Medicaid programs.[2] This fact sheet provides an overview of Medicaid outpatient prescription drug coverage, including: federal minimum requirements, state restrictions on prescription drug access, and special rules applying to managed care and alternative benefit plans.

Federal Minimum Requirements

General Medicaid Coverage Requirements

Under the Medicaid program, states are required to specify the amount, duration, and scope of each service provided for categorically needy and medically needy beneficiaries.[3] States have some discretion in determining the amount, duration, and scope of services. However, each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.[4] Moreover, the care and services must be offered in the "best interests" of beneficiaries.[5] States may place "appropriate limits" on services taking into account medical necessity and utilization control procedures.[6] States must ensure their utilization control policies are consistent with the requirements for behavioral health parity.[7] Additionally, states are required to provide services equal in amount, duration, and scope for all beneficiaries within the categorically needy and medically needy groups respectively.[8]

With limited exceptions, state Medicaid agencies must ensure their state plan is in operation under evenhanded, mandatory standards throughout the entire state.[9] This requirement, however, does not prevent states from contracting with health care organizations and entities that serve specific areas of a state to furnish services to Medicaid beneficiaries.[10] Subject to certain exceptions, state Medicaid plans must allow beneficiaries to obtain Medicaid services from any institution, agency, pharmacy, person, or organization that is qualified and willing to furnish the services to the beneficiary.[11]

Drug Use Review

States are required to implement a drug use review program for covered outpatient drugs to ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes.[12] Drug use review programs consist of prospective and retrospective reviews and also provide educational outreach designed to inform practitioners of common drug therapy concerns.[13] The primary difference between the

prospective and retrospective reviews is not the subject matter of the review, but rather the timing of it.

> *Prospective*: Review of individual drug therapy plans before each prescription is filled or delivered to the beneficiary in order to screen for possible drug therapy issues resulting from duplicate services, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of treatment, drug allergy interactions, and clinical abuse or misuse.[14] The prospective review relies on pharmacists at the point-of-sale to discuss the drug, dosage, and side effects with the beneficiary.[15]
>
> *Retrospective*: Periodic review of claims and other data to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and beneficiaries.[16] The retrospective review is aimed at gathering information about errors that occurred in the past and use that information to help educate providers about proper practices and reduce the likelihood of those errors in the future.

States are required to establish drug use review boards for their Medicaid programs to help assess the appropriateness of prescriptions given to Medicaid beneficiaries.[17] Federal law sets the minimum requirements for drug use review boards, and states are permitted to give the boards additional responsibilities. Among other things, these boards are required to oversee drug use review programs and submit an annual report to the Centers for Medicare & Medicaid Services (CMS), which includes a summary and assessment of the impact of educational interventions on quality of care, and an estimate of the cost savings generated as a result.[18] CMS makes each state's annual report publicly available and produces a summary of those reports every year.[19]

Medicaid Drug Rebate Program

The Medicaid Drug Rebate Program requires prescription drug manufacturers to enter into, and have in effect, a rebate agreement with the Secretary of the Department of Health and Human Services (HHS) in exchange for Medicaid coverage of their outpatient drugs.[20] Approximately 600 drug manufacturers currently participate in the rebate program, which helps offset federal and state Medicaid prescription drug costs.[21] The rebate is collected quarterly from the manufacturers and is based on a specific formula.[22] Rebates are paid to the states, based on their utilization of the manufacturers' covered drugs, and shared with the federal government. The Affordable Care Act (ACA) amended the drug rebate requirements, and CMS released a final rule effective April 1, 2016, which implements the changes.[23]

In addition, drug manufacturers must also enter into agreements with two other Federal programs in order to have their outpatient prescription drugs covered under Medicaid: 1) a pricing agreement for the Section 340B Drug Pricing Program which provides discounts on outpatient prescription drugs to certain safety net providers, and 2) a master agreement with the Secretary of Veterans Affairs (VA) for the Federal Supply Schedule program which supports the health care acquisition needs of the VA and other government agencies.[24]

State Restrictions on Prescription Drug Access

In addition to the general Medicaid coverage requirements described above, the Medicaid Act applies specific requirements to states' coverage of outpatient prescription drugs. While states must comply with these minimum, mandatory requirements, they have considerable flexibility to influence beneficiaries' access to prescription drugs.[25] For example, states may restrict prescription drug coverage by imposing limits on the minimum or maximum quantities per prescription or on the number of refills when limitations are necessary to discourage waste, fraud and abuse.[26] In addition, states may exclude or restrict coverage of an outpatient prescription drug if the prescribed use is not for a medically accepted indication.[27]

State Drug Formularies

Prescription drug formularies are used by states to restrict access to certain types of drugs and drug classes, largely as a cost control measure for prescription drug coverage. In Medicaid, the cost of drugs may not be considered in designing a formulary. States may establish a Medicaid drug formulary if the following requirements are met:

- It is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the state or the state's drug use review board.
- It includes the covered outpatient drugs of any manufacturer which has entered into and complies with a Medicaid drug rebate agreement (certain exceptions apply).
- A drug may be excluded with respect to a specific disease or condition for an identified population, if based on the drug's labeling, the drug does not have a significant, clinically meaningful therapeutic advantage (for safety, effectiveness, or clinical outcome of such treatment for such population) over other drugs in the formulary, and the basis for the exclusion is explained publicly and in writing.
- The state plan permits coverage of a drug excluded from the formulary pursuant to a prior authorization program.
- The state's coverage meets other requirements the Secretary may impose.[28]

Prior Authorization and Preferred Drug Lists

States may require prior authorization before providing a beneficiary with an outpatient prescription drug. To meet prior authorization requirements, states must:

1. Provide a response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
2. Provide for the dispensing of at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation.[29]

States may also create preferred drug lists (PDLs), which list prescription drugs that do not require prior authorization. States use PDLs to encourage providers to prescribe drugs on the list and to get manufacturers to offer discounts for listing their products.

Prescription Drug Exclusions

States may freely restrict or exclude certain drugs or classes of drugs from their formularies.

Excludable Drugs

- Anorexia, weight loss, or weight gain drugs
- Fertility drugs
- Drugs for cosmetic purposes or hair growth
- Drugs used to relieve the symptoms of coughs and colds
- Drugs used to promote smoking cessation
- Most prescription vitamins and minerals, except prenatal vitamins and fluoride preparations
- Non-prescription drugs (*e.g.*, over-the-counter drugs)
- Outpatient drugs that manufacturers seek to tie to associated tests or monitoring services
- Benzodiazepines
- Barbiturates
- Drugs used to treat sexual or erectile dysfunction, unless such agents are Food and Drug Administration-approved and used to treat a condition other than sexual or erectile dysfunction[30]

Cost-Sharing

States are allowed to impose cost-sharing and premiums on certain eligible individuals within the Medicaid population.[31] Cost-sharing refers to any payment, such as deductibles, co-payments, and co-insurance, made by the beneficiary as a contribution to the cost of their healthcare; whereas, a premium refers to any enrollment fee or similar charge paid for coverage of medical benefits.[32] With respect to prescription drugs, states have the option of establishing cost-sharing at or below the following amounts:[33]

Service	**Maximum Allowable Cost Sharing**	
	Family Income ≤150% Federal Poverty Level	**Family Income >150% Federal Poverty Level**
Preferred Drugs	Up to $4.00	Up to $4.00
Non-Preferred Drugs	Up to $8.00	Up to 20% of the cost the Medicaid agency pays for the drug

Source: 42 C.F.R. § 447.53(b)

In states that do not have fee-for-service payment rates, cost-sharing for prescription drugs at any income level may not exceed the maximum amount established for individuals with income at or below 150% of the Federal Poverty Level.[34]

Managed Care

States are allowed to enter contracted arrangements with managed care organizations; states may require Medicaid beneficiaries to enroll with a managed care plan.[35] A Medicaid managed care organization is a health care entity that provides capitated payments for certain services to enrollees.[36] Roughly 80% of Medicaid beneficiaries are served through managed care delivery systems.[37]

When states and managed care plans enter contracts under which the plans will deliver services to Medicaid beneficiaries, they may exclude some or all covered outpatient prescription drugs from the managed care plans' responsibility. When a drug is excluded from the health plan's responsibility, it is considered to be "carved out."[38] The state is responsible for informing beneficiaries who may enroll in a plan which benefits are covered by the managed care plan, and which are covered by the state.[39]

Before 2010, drug manufacturers were not required to pay rebates on drugs delivered through Medicaid managed care arrangements, and thus states had a financial incentive to carve drugs out of their managed care contracts.[40] The ACA changed this rule and requires manufacturers to pay rebates on *all* drugs provided to Medicaid beneficiaries, regardless of whether they received the drug through a managed care plan or a fee-for-service arrangement.[41] Today, the majority of states do not carve drugs out of their managed care contracts, though some carve out particular drugs or drug classes.[42]

Alternative Benefit Plans

Alternative Benefit Plans (ABPs) are the benefit packages offered to the Medicaid expansion population (childless, non-disabled adults whose incomes fall below 133% of the Federal Poverty Level). The amount, duration, and scope of benefits under an ABP, including prescription drugs, are determined by Section 1937 of the Social Security Act (42 U.S.C. 1396u-7). To design ABP coverage, states must 1) select a Section 1937 coverage option that serves as the basis for the ABP, 2) ensure the ABP includes the Essential Health Benefits (including prescription drugs), and 3) ensure other ABP service requirements are met.[43] Nonetheless, the drug rebates and other non-coverage provisions of Section 1927 (42 U.S.C § 1386r-8) discussed in this fact sheet apply to ABPs.[44]

In January 2016, CMS released an informational bulletin outlining, among other things, the prescription drug benefit changes made to the Essential Health Benefits and their impact on ABPs.[45] Per the Bulletin, in most circumstances states will satisfy the required changes through the Medicaid standards already in place.

Conclusion

This fact sheet provides an overview of Medicaid outpatient prescription drug coverage. For in-depth information, advocates should check federal transmittals and guidance documents, state law, and court decisions that address how the Medicaid requirements have been interpreted and state efforts to expand or restrict Medicaid prescription drug coverage and access. Please visit our website at healthlaw.org for further Medicaid prescription drug publications and updates.

---

[1] Galen Williams, former NHeLP law fellow and Emmanuela Jean-Etienne, a third-year law student at the University of Michigan Law School, contributed to the preparation of this Fact Sheet.
[2] *Prescription Drugs*, MEDICAID.GOV, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/prescription-drugs.html (last visited November 26, 2016).
[3] 42 U.S.C. § 1396(a); 42 C.F.R. § 440.230(a).
[4] 42 C.F.R. § 440.230(b).
[5] *Alexander v. Choate*, 469 U.S. 287, 303 (1985). *See also Pharm. Research Mfrs. Of America v. Thompson*, 362 F.3d 817 (D.C. Cir. 2004) (Here, the court endorses HHS' interpretation of "best interests" to mean "further[ing] the goals of the Medicaid program").
[6] 42 C.F.R. § 440.230(d).
[7] ELIZABETH EDWARDS, NAT'L HEALTH LAW PROG. MENTAL HEALTH PARITY AND ADDICTION EQUITY ACT OF 2008 (2014), http://www.healthlaw.org/publications/issue-brief-mhpaea2008.
[8] 42 C.F.R. § 440.240.
[9] 42 C.F.R. § 431.50.
[10] *Id*.
[11] Free choice of providers, 42 C.F.R. § 431.51(b)(1). Apart from this requirement, state agencies may establish fees it will pay providers for Medicaid services, set reasonable standards relating to the qualifications of providers, or restrict beneficiary freedom of choice in accordance with other regulations.
[12] 42 U.S.C. § 1396r-8(g)(1)(A).
[13] 42 U.S.C § 1396r-8(g)(2)(D).
[14] 42 U.S.C. § 1396r-8(g)(2)(A)(i). States are required to assess data on drug use against compendia (American Hospital Formulary Service Drug Information; United States Pharmacopeia-Drug Information; and the DRUGDEX Information System), and peer-reviewed medical literature.
[15] 42 U.S.C. § 1396r-8(g)(2)(A)(ii)(I).
[16] 42 U.S.C. § 1396r-8(g)(2)(B).
[17] 42 U.S.C. § 1396r-8(g)(3)(A).
[18] 42 U.S.C. § 1396r-8(g)(3)(D).
[19] Centers for Medicare & Medicaid Services, Drug Utilization Review Annual Report, *available at* https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/drug-utilization-review-annual-report.html.
[20] 42 U.S.C. § 1396r-8(a)(1).
[21] *Medicaid Drug Rebate Program*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html (last visited Nov. 28, 2016).
[22] 42 U.S.C. §§ 1396r-8(k)(8), (c).
[23] *See* Medicaid Program Covered Outpatient Drugs Final Rule, 81 Fed. Reg. 5,170 (Feb. 1, 2016) (to be codified at 42 C.F.R. pt. 447) *available at* https://www.gpo.gov/fdsys/pkg/FR-2016-

02-01/pdf/2016-01274.pdf. Also, in November 2016, HHS released a proposed notice updating the National Drug Rebate Agreement that HHS and manufacturers will use under the drug rebate program; Announcement of Medicaid Drug Rebate Program National Rebate Agreement Proposed Notice, 81 Fed. Reg. 78,816 (Nov. 9, 2016) *available at* https://www.gpo.gov/fdsys/pkg/FR-2016-11-09/pdf/2016-26834.pdf.

[24] 42 U.S.C. § 1396r-8(a)(1). *See also Medicaid Drug Rebate Program*, *supra* note 21, *VA Federal Supply Schedule Service*, VA.GOV, http://www.fss.va.gov/ (last visited Nov. 28, 2016.)

[25] *Weaver v. Reagan*, 886 F.2d 194, 197 (8th Cir. 1989), *reh'g denied* (Nov. 6 1989).

[26] 42 U.S.C. § 1386r-8(d)(6).

[27] 42 U.S.C. §§ 1396r-8(d)(1)(B), (k)(6) (Medically accepted indication means: (1) any covered outpatient drug which is approved by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.); or (2) the use of which is supported by one or more citations included or approved for inclusion in any of the following compendia: American Hospital Formulary Service Drug Information; United States Pharmacopeia-Drug Information; and DRUGDEX Information System). For additional discussion see, *Edmonds v. Levine*, 417 F. Supp. 2d 1323 (S.D. Fla. 2006).

[28] 42 U.S.C. § 1396r-8(d)(4).

[29] 42 U.S.C. § 1396r-8(d)(5).

[30] 42 U.S.C § 1386r-8(d)(2).

[31] 42 U.S.C. § 1396o(b); 42 C.F.R. § 447.50.

[32] 42 C.F.R. § 447.51. *See also* David Machledt and Jane Perkins, *Medicaid Premiums and Cost Sharing* NHELP n.2 (Mar. 26, 2014), http://www.healthlaw.org/component/jsfsubmit/showAttachment?tmpl=raw&id=00Pd000000ANrCpEAL (providing in-depth review of premiums and cost sharing in Medicaid).

[33] Beginning October 1, 2015, maximum allowable cost-sharing will increase each year by the percentage increase in the medical care component of the Consumer Price Index-Urban Consumers (CPI-U) for the period of September to September of the preceding calendar year, rounded to the next higher 5-cent increment. 42 C.F.R. §447.53(b).

[34] 42 C.F.R. §447.53(c).

[35] 42 U.S.C.§ 1396u-2(a)(1)(A)(i); 42 U.S.C. §1396b(m)(1)(A).

[36] *Id.*

[37] *Managed Care*, MEDICAID.GOV, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/managed-care/managed-care-site.html (last visited Nov. 28, 2016).

[38] *See, e.g.,* 81 Fed. Reg. 27552 (describing the practice).

[39] 42 C.F.R. § 438.10(e)(1)(v).

[40] *See* CMS, DSMDL 2 (Apr. 22, 2010), https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD10006.pdf.

[41] *See id.*; *see also* 42 U.S.C. §§ 1396b(m)(2)(A)(x), 1396r-8(b)(1)(A).

[42] *See* VERNON K. SMITH *ET AL.,* MEDICAID REFORMS TO EXPAND COVERAGE, CONTROL COSTS AND IMPROVE CARE: RESULTS FROM A 50-STATE MEDICAID BUDGET SURVEY FOR STATE FISCAL YEARS 2015 AND 2016 23-24 (2015), http://files.kff.org/attachment/report-medicaid-reforms-to-expand-coverage-control-costs-and-improve-care-results-from-a-50-state-medicaid-budget-survey-for-state-fiscal-years-2015-and-2016.

[43] 42 U.S.C.§ 1396u-7(b).

[44] 42 C.F.R. § 440.345(f).

[45] Centers for Medicaid & CHIP Services Informational Bulletin, Alternative Benefit Plan Conforming Changes, (Jan. 28, 2016), *available at* https://www.medicaid.gov/federal-policy-guidance/downloads/cib-01-28-16.pdf.