

Utilization Controls for Medicaid Prescription Drugs

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Although it is an optional service, all states have elected to provide outpatient prescription drug coverage in their Medicaid programs.¹ In general, a “covered outpatient drug” is a drug which may be dispensed only upon prescription and which is approved for safety and effectiveness as a prescription drug under the federal Food, Drug, and Cosmetic Act.² Congress established broad coverage requirements to help ensure full access to prescription drugs for low-income Medicaid enrollees.³

States that elect to provide outpatient prescription drug coverage must cover all drugs approved by the U.S. Food and Drug Administration (FDA) that are offered by any manufacturer that agrees to provide rebates.⁴ Rebate agreements allow Medicaid programs to purchase prescription drugs at a lowered cost.⁵ Nevertheless, states have substantial discretion to use utilization control techniques to steer Medicaid beneficiaries toward or away from certain drugs, within limits.⁶ Specifically, federal regulations require states to ensure that prescription drugs are provided in sufficient amount, duration, and scope to reasonably achieve their purpose.⁷ In addition, states may place “appropriate limits” on drugs, as long as they take into account medical necessity or utilization control procedures.⁸ States must ensure that drug coverage is designed in the “best interests” of Medicaid beneficiaries.⁹ States must also ensure that their utilization control policies are consistent with the requirements for behavioral health parity.¹⁰ In practice, states have considerable leeway to restrict access to medications, as described below.

Prior authorization or screening

States can require beneficiaries to obtain prior authorization or pre-screening before they can fill a prescription for a particular medication.¹¹ CMS has stated that the Medicaid Act “affords States broad authority and flexibility to implement a prior authorization program in order to secure cost savings for the Medicaid program.”¹² Justice O’Connor agreed, stating: “Prior authorization is, by definition, a procedural obstacle to Medicaid beneficiaries’ access to medically necessary prescription drugs covered under the Medicaid program. . . . [that] may serve a Medicaid purpose by safeguarding against unnecessary utilization and assuring that payments are consistent with efficiency, economy and quality of care.”¹³ Typically, states subject more expensive

drugs to prior authorization to ensure that they are dispensed only to beneficiaries who truly need them.¹⁴ Many states will negotiate additional discounts from drug manufacturers—known as supplemental rebates—in exchange for removing prior authorization limits on their drugs. CMS has explicitly sanctioned this practice.¹⁵

States' discretion with respect to prior authorization is not unbounded, however. States have an obligation to ensure that all covered drugs are available for their “medically accepted indications.”¹⁶ Thus, CMS has cautioned states that “[p]rior authorization criteria should reflect evidence-based standards for appropriate medical use of the pharmaceutical in question.”¹⁷ CMS has suggested that such evidence-based standards should be consistent with the information contained in the compendia listed in the Medicaid Act.¹⁸ In addition to clinical criteria, states may implement non-clinical requirements in prior authorization. For example, a state could oblige the prescriber to demonstrate that a prescribed drug is part of the beneficiary's treatment plan or that the beneficiary has agreed to comply with the treatment regimen.¹⁹

In all cases, when a state requires prior authorization of a drug, it must provide responses to prior authorization requests by telephone or other telecommunication device within 24 hours.²⁰ In addition, the state must make arrangements that permit pharmacists to dispense at least a 72-hour supply of any covered drug in an emergency situation.²¹ States may require that pharmacists provide a 72-hour emergency supply whenever the drug is prescribed by an authorized prescriber or may allow pharmacists to provide an emergency supply at their discretion.²²

Lock-in & lock-out programs

The Medicaid Act authorizes states to use methods and procedures as needed to safeguard against unnecessary utilization of care and services.²³ States are specifically authorized to restrict the provider or providers from whom a beneficiary can receive items and services for a “reasonable period of time.”²⁴ These restrictions are referred to as lock-in programs or patient review and restriction programs.²⁵

Regardless of the name chosen by the state Medicaid agency, these programs may only apply to beneficiaries who have been found to utilize items or services at a frequency or amount that is not medically necessary, as determined in accordance with guidelines established by the state.²⁶ The state's lock-in restrictions must assure that the affected beneficiary has reasonable access to services of adequate quality, taking into account geographic location and reasonable travel time.²⁷ Restrictions cannot apply to emergency services.²⁸ States have also been enjoined from restricting the entire family unit when only one beneficiary has been determined to be an over-user.²⁹

Individuals must be provided notice and an opportunity for a hearing before being subjected to lock-in restrictions.³⁰ Enrollees in Medicaid managed care programs can be placed into locked-in programs under these same conditions.

Step therapy

Another technique that states use to limit access to prescription drugs is to require beneficiaries to try to use an alternative drug before the state will authorize another, usually more expensive, treatment.³¹ This kind of rule is known as “step therapy,” “fail first,” or “try and fail.” Under such a policy, the state will only allow a beneficiary to receive the desired drug after demonstrating that the person tried an alternative and the alternative drug did not achieve treatment goals.³² Step therapy is often used to require beneficiaries to try a generic equivalent or alternative before the beneficiary can access a brand name drug, as described in more detail below.

Limiting access to generic drugs

States have substantial discretion to use utilization control techniques to steer Medicaid beneficiaries toward generic drugs, within certain limits.³³ One way states do this is by requiring or allowing pharmacists to automatically substitute a generic for a brand name prescription without seeking the prescribing provider’s permission first. CMS has long encouraged state Medicaid programs to use these substitution policies.³⁴ The rationale for substitution rules is that generic drugs are almost always cheaper than their brand name equivalents.³⁵

As of 2014, all state Medicaid fee-for-service programs have a policy that requires or allows pharmacists to substitute generic equivalents without the prescribing provider’s specific authorization or consent in at least some circumstances.³⁶ In 11 states, the substitution can be overridden by a prescriber writing in his or her own handwriting “Brand Medically Necessary.” In the remaining states, the prescriber must take additional steps to prevent substitution at the pharmacy.³⁷ While state policies differ to some degree, substitution without prescriber consent is almost always limited to multiple source drugs—*i.e.*, generic drugs that the FDA has deemed therapeutically equivalent to a brand name drug.³⁸ Substitution without prescriber consent is not permitted for generic alternatives, that is, drugs that are similar to the generic but that differ in some notable way, such as the method of administration or dosing requirements.³⁹

Another technique states impose is to require beneficiaries to obtain prior authorization to use a brand name drug instead of an equivalent or alternative medication. Generally, these rules require the provider to document that the brand name drug is medically

necessary for the beneficiary based on individual circumstances in order for the state to approve the brand name drug. In some states with mandatory generic substitution rules, the only way to get a brand name drug is to go through a formal prior authorization process that evaluates the medical necessity of the brand name drug relative to equivalent therapies.⁴⁰

Another technique that states use to limit access to brand name drugs is through step therapy that requires beneficiary to try an equivalent or alternative drug before the brand name will be authorized.

Quantitative and refill limits

The Medicaid Act authorizes states to “impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste.”⁴¹ Thus, states may, for example, only authorize a prescription for 30 pills or less, permit only 2-week course of a particular prescription treatment, or limit beneficiary’s to one refill per prescription. While states have substantial discretion to impose such limitations, CMS has made clear that states’ discretion with respect to quantity, duration and refill limits is tempered by medical necessity:

States must have the necessary evidence and medical necessity criteria for imposing limits on the duration of these medications. Setting limits on the length of medication-assisted treatment can affect retention and outcomes. Medication-assisted treatment should be continued as long as the treatment is medically necessary and the individual participates in treatment as set forth in their treatment plan.⁴²

Some states have also imposed limits on the number of prescriptions their Medicaid programs will cover in a month. For example, Mississippi has limited beneficiaries to five prescriptions per month, of which no more than two may be for single-source or brand name drugs.⁴³ In practice, most states with per month limits do employ “soft caps” to ensure that beneficiaries receive medically necessary treatment.⁴⁴ In general, courts have allowed quantitative limits as long as they are designed consistent with medical necessity and will ensure that most beneficiaries receive the care they need.⁴⁵

CMS has particularly recommended that states impose quantity, duration, and refill limits on pain medications and drugs used to treat substance use disorders. It has noted that these drugs that are susceptible to “abuse, overdose or diversion of the medications” and that such limits serve an important purpose in avoiding

overprescribing.⁴⁶ According to CMS, these “limits may be useful in verifying that a . . . prescription for pain [medication] is prescribed only for a specified duration, so the prescriber can reassess the recipient periodically.”⁴⁷

Some drugs are subject to rules governing the quantity, duration, or refill of prescriptions that apply beyond Medicaid. For example, a few states impose quantity limits on all prescriptions.⁴⁸ Certain prescription drugs that are classified as controlled substances may also have limits imposed on them by federal law or by the Drug Enforcement Administration (DEA).⁴⁹ States also commonly limit the quantity or refills for all prescriptions for certain controlled substances written in the state.⁵⁰

Formularies

Typically, a prescription drug formulary is a list of outpatient prescription drugs that a state or health plan agrees to cover.⁵¹ The term “formulary” in Medicaid is defined by statute and differs from “formularies” used by other kinds of health plans.

The key distinction in establishing Medicaid formularies is that the cost of a drug may not be considered.⁵² In general, Medicaid formularies can consider only the safety and effectiveness of drugs.⁵³ In addition, if a state decides to exclude an outpatient prescription drug from its formulary, it may only do so after finding the drug does not have a significant, clinical therapeutic advantage over other drugs, and the state must explain the basis for the exclusion in writing.⁵⁴

The Medicaid formulary must be developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor or the state’s drug use review board.⁵⁵ The formulary must include the covered outpatient drugs of any manufacturer which has entered into and complies with a Medicaid rebate agreement (subject to certain exceptions explained below).⁵⁶ Even if a state excludes an outpatient prescription drug from its formulary, the state must still permit coverage of the excluded drug pursuant to a prior authorization program.⁵⁷

Cost-Sharing

States may impose cost-sharing on drugs as a way of limiting access.⁵⁸ In addition, subject to limitations, states may designate “preferred” and “non-preferred” drugs and charge additional cost sharing for non-preferred drugs, similar to a formulary tiering structure.⁵⁹

A Medicaid enrollee's income determines the applicable level of cost sharing (as summarized in the chart below), with some populations and services exempt.⁶⁰

Rules for Medicaid Prescription Drug Cost Sharing			
	≤ 100% FPL	101% - 150% FPL	>150% FPL
Maximum Allowable Copayments (All amounts are subject to a cap of 5% of family income)			
Preferred drugs*	\$4	\$4	\$4
Non-preferred drugs [#]	\$8 (nominal)	\$8 (nominal)	20% agency cost of drug

* The preferred drug copay must be waived if the prescribing physician notes that it is needed.

[#] This cost sharing can also be applied to individuals normally exempt from cost sharing.

Drugs excluded from cost sharing include certain drugs prescribed as part of a preventive service and family planning services and supplies.⁶¹ In addition, some populations are exempt from cost-sharing, including pregnant women; children under age 19, except for infants under age 1 with incomes above 133%; children in federally funded foster care; children with disabilities, except those eligible under the Family Opportunity Act with incomes above 150% FPL; persons in institutions who have only a personal needs allowance, and at state option, persons receiving home and community based services who are subject to share-of-cost; women eligible through the Breast and Cervical Cancer Treatment Program; individuals receiving hospice care; and Indians who have been served through Indian Health Services programs.⁶²

Federally authorized exclusions

States *may* exclude or otherwise restrict certain classes or uses of drugs, including those used for:⁶³

anorexia, weight loss, or weight gain	nonprescription ("over the counter") drugs
fertility	prescription vitamins and minerals (except prenatal vitamins and fluoride preparations)

cosmetic purposes or hair growth	covered drugs which the manufacturer seeks to tie to associated tests or monitoring services
agents used for cough and cold relief	agents when used to treat sexual or erectile dysfunction.

Congress has charged the Secretary of HHS with the responsibility to update the exclusion list from time to time.⁶⁴

Special rules for contraception

The Medicaid Act requires states to cover family planning services and supplies for individuals of childbearing age, including minors.⁶⁵ States receive a 90 percent federal matching rate for offering, arranging, and furnishing family planning services.⁶⁶ As with many other Medicaid benefit categories, states have some flexibility to determine which particular family planning services to cover but must ensure that coverage is “sufficient in amount, duration, and scope to reasonably achieve its purpose.”⁶⁷ CMS has made clear that “medically accepted” contraceptive “methods, procedures, pharmaceutical supplies and devices” qualify as family planning services and are eligible for the enhanced reimbursement rate.⁶⁸

Importantly, federal Medicaid law contains special protections for Medicaid enrollees seeking family planning services. First, states must provide family planning services without cost-sharing.⁶⁹ This means that states are not permitted to charge enrollees a co-pay for contraceptive drugs, supplies, or devices. Second, federal regulations require states to ensure that Medicaid enrollees are “free from coercion or mental pressure and free to choose the method of family planning to be used.”⁷⁰ Recently revised managed care regulations clarify that plans must provide family planning services consistent with this provision.⁷¹ Thus, as CMS recently noted, states and managed care plans may not use utilization controls that “effectively deprive” enrollees of “free choice of equally appropriate [family planning] treatments.”⁷² In particular, states and plans may not use step therapy or adopt policies that restrict a change in method.⁷³ Similarly, “[s]tates and managed care plans should avoid practices that delay the provision of a preferred method or that impose medically inappropriate quantity limits, such as allowing only one long acting reversible contraceptive (LARC) insertion every five years, even when an earlier LARC was expelled or removed.”⁷⁴ However, CMS has left open the possibility that states and plans may require prior authorization to determine that a particular family planning “method is medically necessary and appropriate for the individual, using criteria that may include considerations such as severity of side effects, clinical

effectiveness, difference in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service.”⁷⁵

States must establish an Alternative Benefit Plan (ABP) for adults covered through the Affordable Care Act (ACA) expansion group and may enroll certain other Medicaid beneficiaries in an ABP as well.⁷⁶ States may offer a different benefits package to beneficiaries enrolled in an ABP than they otherwise offer through the Medicaid program, and ABPs must cover prescription drugs.⁷⁷ In addition, ABPs must cover all FDA-approved contraceptive methods, including OTC methods as prescribed, without cost-sharing.⁷⁸ However, federal regulations allow plans to adopt “reasonable medical management techniques.”⁷⁹ The federal government has issued guidance that establishes limitations on the use of medical management with respect to contraceptives, however.⁸⁰ The guidance clarifies that ABPs must cover without cost-sharing at least one product or item in each of the FDA-approved contraceptive methods for women.⁸¹ For example, plans must cover, without cost-sharing, both the copper IUD and at least one progestin-based IUD, as the FDA classifies them as distinct methods. Likewise, plans may choose not to cover brand-name contraceptive drugs that have a generic equivalent.⁸² However, if an enrollee’s provider determines that a particular contraceptive is medically necessary, the plan must defer to the provider’s determination and cover the product without cost-sharing.⁸³

Utilization Review in Medicaid Managed Care

Medicaid Managed Care Plans have substantial discretion to use utilization control techniques with respect to prescription drugs. When a Medicaid plan uses utilization control techniques to limit access to covered outpatient drugs, it must comply with the requirements set forth in 42 U.S.C. § 1396r-8.⁸⁴ Specifically, when a plan covers prescription drugs for Medicaid enrollees, the amount, duration, and scope of drugs provided by the plan must also be “sufficient . . . to reasonably achieve the[ir] purpose.”⁸⁵ Plans must abide by the laws governing prior authorization of drugs in Medicaid, including rules that require a response to prior authorization requests by telephone or other telecommunication device within 24 hours.⁸⁶

In addition, federal regulations require each plan to ensure that drugs are provided in an amount, duration, and scope “that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under FFS Medicaid” and is consistent with EPSDT.⁸⁷ Plans must also define “what constitutes ‘medically necessary services’ in a manner that. . . [i]s no more restrictive than that used in the State Medicaid program, including quantitative and nonquantitative treatment limits, as indicated in State statutes and regulations, the State Plan, and other State policy and procedures.”⁸⁸ But the

regulations also permit plans to place “appropriate limits” on drugs, as long as they are either based on “criteria applied under the State plan, such as medical necessity,” or “for the purposes of utilization control.”⁸⁹ When a plan limits drugs for utilization control reasons, it must nevertheless comply with the prior authorization and amount, duration and scope rules set forth above. In addition, the plan must make sure that services for people with ongoing or chronic conditions are authorized in a manner that reflects their ongoing need and must ensure that family planning services are available consistent with the regulation requiring that enrollees are free from coercion, as described above.⁹⁰

Reading these provisions together, plans have a choice with respect to utilization review: they may either use the same criteria and process that the state uses in FFS Medicaid, **or** they may develop their own criteria and processes for determining whether a particular drug is medically necessary for an individual, as long as they are not more restrictive than those used by the state in FFS Medicaid. CMS has provided little guidance to states and plans, however, as to how to determine whether a plan’s particular criteria or process is “more restrictive.” In the new rules, CMS added the phrase “including quantitative and nonquantitative treatment limits” to help states and plans make this assessment.⁹¹ This phrase is borrowed from the context of Behavioral Health Parity, where plans are required to ensure parity between behavioral health services provided and medical-surgical services provided.⁹² In the parity context, quantitative limits are those expressed numerically, such as a 30 pill per prescription limit, and nonquantitative limits are those that otherwise limit the scope or duration of benefits for treatment under a plan or coverage, such as medical management standards or exclusions for failure to complete a course of treatment.⁹³

Conclusion

States have considerable discretion to limit access to prescription drugs in their Medicaid programs, as long as they take into account medical necessity and appropriate utilization control procedures.⁹⁴ Advocates should evaluate the techniques and methods that their states are using to limit access to covered drugs to ensure that the state is not using undue limitations. Advocates should keep in mind that state Medicaid programs must ensure that drug coverage is designed in the “best interests” of Medicaid beneficiaries.⁹⁵ In addition, while states have discretion to limit drug coverage, they must make certain that covered drugs are provided in sufficient amount, duration, and scope to reasonably achieve their purpose.⁹⁶ Prescription drugs are a crucially important component of treatment for many illnesses and conditions. Advocates should work closely with their states to ensure that Medicaid beneficiaries have appropriate access to necessary prescription drugs.

¹ 42 U.S.C. § 1396d(a)(12). 42 C.F.R. §§ 440.120(a), .90, .100

² 42 U.S.C. § 1396r-8(k)(2)(A).

³ H.R. Rep. 101-881, 101st Cong. 2nd Sess. 1990, 1990 U.S.C.A..A.N. 2017.

⁴ 42 U.S.C. § 1396r-8(k)(2)(i).

⁵ *Id.* § 1396r-8(a)(1).

⁶ See 42 C.F.R. § 440.230(d).

⁷ *Id.* § 440.230(b).

⁸ *Id.* § 440.230(d).

⁹ *Alexander v. Choate*, 469 U.S. 287, 303 (1985).

¹⁰ 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>.

¹¹ See 42 U.S.C. § 1396r-8(d)(5); see also, e.g., CMS, Dear State Medicaid Director Letter (Sept. 18, 2002) [hereinafter SMDL #02-014], <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd091802.pdf>; *Pharm. Research & Mfrs. Of Am v. Meadows*, 304 F. 3d 1197, 1211 (11th Cir. 2002) (noting that a state's prior authorization policy "may not exclude coverage for any Medicaid eligible drugs" but is permissible as long as it "merely conditions coverage for non-preferred drugs on whether the prescribing physician has followed the prior authorization procedure") (emphasis in original). Note that, as part of each state's mandatory drug utilization review process, a state must "provide for a review of drug therapy before each prescription is filled or delivered . . . typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse." 42 U.S.C. 1396r-8(g)(2)(A)(i).

¹² SMDL #02-014, *supra* note 11, at 2.

¹³ *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 685 (2003) (O'Connor, J. concurring in part and dissenting in part).

¹⁴ See, e.g., CMS, Dear State Medicaid Director (Sept. 9, 2004) [hereinafter SMDL #04-006], <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd090904.pdf> ("A prior authorization program is intended to balance the interests of beneficiaries in receiving medically necessary drugs and the interests of states in ensuring that Medicaid pays for prescription drugs in an efficient and economical manner.")

¹⁵ *Id.* at 1. While drug manufacturers must enter basic rebate agreements in order to participate in Medicaid, states have authority to negotiate additional rebates to lower the cost of the drugs they provide. CMS has sanctioned states' using prior authorization as a bargaining tool in these negotiations. See *id.*; SMDL #02-014, *supra* note 11, at 2-3; see also CMS, SAFE AND EFFECTIVE APPROACHES TO LOWERING STATE PRESCRIPTION DRUG COSTS 3-4 (2004) [hereinafter CMS, SAFE AND EFFECTIVE APPROACHES] (on file with NHeLP-LA) (describing as a "best practice" Florida's policy of subjecting drugs to prior authorization if their manufacturers do not enter a supplemental rebate agreement with the State).

¹⁶ See 42 U.S.C. § 1396r-8(d)(5); see also *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1329 (S.D. Fla. 2006) ("The Medicaid Act does not authorize a state to use . . . [a] prior authorization program to deny coverage for a covered drug; it can only condition reimbursement upon a prescribing doctor first . . . obtain[ing] approval for the drug.")

¹⁷ CMS, INFORMATIONAL BULLETIN: MEDICATION ASSISTED TREATMENT FOR SUBSTANCE USE DISORDERS 7 (2014) [hereinafter CMS, MEDICATION ASSISTED TREATMENT], <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-11-2014.pdf>.

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- ¹⁸ See CMS, INFORMATIONAL BULLETIN: BEST PRACTICES FOR ADDRESSING PRESCRIPTION OPIOID OVERDOSES, MISUSE AND ADDICTION 6 (2016) [hereinafter CMS, OPIOID OVERDOSES], <https://www.medicaid.gov/federal-policy-guidance/downloads/cib-02-02-16.pdf>.
- ¹⁹ See *id.* at 6-7 (describing with approval such requirements in Virginia).
- ²⁰ 42 U.S.C. § 1396r-8(d)(5)(A).
- ²¹ *Id.* § 1396r-8(d)(5)(B); see also *Frew v. Hawkins*, No. 3:93-CA-065 WWJ, 2007 WL 2667985, at *24 (E.D. Tex. Sept. 5, 2007) (describing implementation of the 72-hour emergency supply requirement).
- ²² See *Grier v. Goetz*, 402 F. Supp. 2d 876, 907 (M.D. Tenn. 2005), *order clarified*, 421 F. Supp. 2d 1080 (M.D. Tenn. 2006). Cf. *Pharm. Research & Mfrs. Am. v. Thompson*, 362 F.3d 817, 826 (D.C. Cir. 2004).
- ²³ See 42 U.S.C. § 1396a(a)(30)(A).
- ²⁴ See *id.* § 1396n(a)(2); see also 42 C.F.R. § 431.54; CMS, STATE MEDICAID MANUAL ¶ 2103.D (including lock-in as an exception to 42 U.S.C. § 1396a(a)(23), the Medicaid freedom of choice requirement).
- ²⁵ For a more detailed discussion of these programs, see JANE PERKINS, NAT'L HEALTH L. PROG., WHY ARE MEDICAID LOCK-IN PROGRAMS USED AND HOW CAN THEY BE IMPROVED (2016), <http://www.healthlaw.org/publications/LockIn-JP-Issue-Brief>.
- ²⁶ 42 U.S.C. § 1396n(a)(2)(A).
- ²⁷ *Id.* § 1396n(a)(2)(B); 42 C.F.R. § 431.54(e)(2).
- ²⁸ 42 C.F.R. § 431.54(e)(3).
- ²⁹ See *Matthews ex rel. Matthews v. Ibarra*, 703 F. Supp. 68 (D. Colo. 1989) (holding such restrictions violate Medicaid lock-in statute and regulation); *Tripp v. Coler*, 640 F. Supp. 848 (N.D. Ill. 1986) (same; also enjoining policy that restricted all over-users in a unit to the same provider rather than allowing each over-user to designate his provider).
- ³⁰ 42 U.S.C. § 1396n(a)(2)(A).
- ³¹ See, e.g., *Doe v. Beal*, 523 F.2d 611, 621 (3d Cir. 1975), *rev'd on other grounds*, 432 U.S. 438 (1977) (“[P]ursuant to the congressional interest in economization, the state might require doctors to prescribe generic drugs rather than brand names, provided, of course, that this would, in the particular instance, be consistent with sound medical practice.”).
- ³² See, e.g., Nat'l Psoriasis Found., *Physician helps change Utah Medicaid policies*, <https://www.psoriasis.org/accessing-health-care/provider-advocacy/utah-medicaid-policies> (last visited April 27, 2016) (describing 2016 change to eliminate a restrictive “fail first” policy in Utah that limited access to biologic treatments for psoriasis). Most “fail first” policies do allow beneficiaries to bypass generic alternatives and equivalents in cases of clinical contraindication or documented allergy.
- ³³ See 42 C.F.R. § 440.230(d).
- ³⁴ See, e.g., U.S. COMPTROLLER GENERAL, PROGRAMS TO CONTROL PRESCRIPTION DRUG COSTS UNDER MEDICAID AND MEDICARE COULD BE STRENGTHENED 25 (1980), <http://www.gao.gov/assets/140/131865.pdf> (describing support by CMS's predecessor agency for state rules permitting drug substitution); CMS, SAFE AND EFFECTIVE APPROACHES, *supra* note 15, at 1 (recommending that state Medicaid programs implement “Aggressive Generic Substitution Policies”).
- ³⁵ U.S. Food and Drug Administration, Facts about Generic Drugs (“On average, the cost of a generic drug is 80 to 85 percent lower than the brand name product.”), <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understanding-genericdrugs/ucm167991.htm> (last visited Nov. 30, 2016).
- ³⁶ CMS., MEDICAID DRUG UTILIZATION REVIEW STATE COMPARISON/SUMMARY REPORT FFY 2014

ANNUAL REPORT: PRESCRIPTION DRUG FEE-FOR SERVICE-PROGRAMS 15 (2015), <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/2014-dur-summary-report.pdf>.

³⁷ *Id.*

³⁸ See DANIEL R. LEVINSON, U.S. DEP'T HEALTH & HUM. SERVS., OFFICE OF INSPECTOR GENERAL, GENERIC DRUG UTILIZATION IN STATE MEDICAID PROGRAMS 3 (2006), <http://oig.hhs.gov/oei/reports/oei-05-05-00360.pdf>; see also Jesse C. Vivian, *Generic-Substitution Laws*, 6 U.S. PHARM. 30, 33 (2008), <http://www.uspharmacist.com/content/s/44/c/9787>.

³⁹ See Vivian, *supra* note 38, at 33.

⁴⁰ See CMS, SAFE AND EFFECTIVE APPROACHES, *supra* note 15, at 2 (describing as “best practices,” policies in Minnesota and Idaho that require beneficiaries to receive prior authorization for drugs that have generic equivalents).

⁴¹ 42 U.S.C. § 1396r-8(d)(6). In 1998, CMS issued guidance recommending, with respect to medications that treat sexual dysfunction, that states consider limiting “the number of refills or the quantity per prescription to discourage waste, fraud and abuse.” CMS, DSMDL (Nov. 30, 1998), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD113098.pdf> (last visited >>). The Medicaid Act was subsequently amended to allow states to exclude these drugs from coverage. See 42 U.S.C. § 1396r-8(d)(2)(K).

⁴² CMS, MEDICATION ASSISTED TREATMENT, *supra* note 17, at 8.

⁴³ MISS. CODE. ANN. § 43-13-117(9)(a).

⁴⁴ See Kaiser Family Found., Medicaid Benefits: Prescription Drugs – 2012, <http://kff.org/medicaid/state-indicator/prescription-drugs/> (last visited Nov. 30, 2016).

⁴⁵ See, e.g., *Grier v. Goetz*, 402 F. Supp. 2d 876, 909 (M.D. Tenn. 2005), *order clarified*, 421 F. Supp. 2d 1080 (M.D. Tenn. 2006) (upholding “a five-prescription-per-month limitation pursuant to which at least three prescriptions must be generic. . . . [with] a major exemption to this five-prescription-per-month limit [in the form of] a ‘shortlist’ encompassing approximately 188 drugs that do not count toward either the five-prescription-per-month limit or the two-brand-per-month limit,” since it would meet the needs of most beneficiaries); see also *Curtis v. Taylor*, 625 F.2d 645, 653 (5th Cir. 1980) (upholding a “limitation on the ‘amount, scope or duration’ of a required service as reasonable [as long as] the coverage provided is adequate to serve the medical needs of most of the individuals eligible for Medicaid assistance”).

⁴⁶ CMS, MEDICATION ASSISTED TREATMENT, *supra* note 17, at 7.

⁴⁷ CMS, OPIOID OVERDOSES, *supra* note 18, at 7.

⁴⁸ See, e.g., FLA. ADMIN. CODE 64B15-18.002 (“Pharmacists may order the medicinal drug products set forth in each rule subject to the following terms and limitations: . . . (3) In any case of dispensing hereunder, the amount or quantity of drug dispensed shall not exceed a [thirty-four]-day supply or standard course of treatment unless subject to the specific limitations in this rule.”); see also CNTRS. DISEASE CONTROL, PRESCRIPTION DRUG TIME AND DOSAGE LIMIT LAWS 1-2 (2015) [hereinafter CDC, TIME AND DOSAGE LIMIT LAWS], http://www.cdc.gov/phlp/docs/menu_prescriptionlimits.pdf.

⁴⁹ See, e.g., 21 U.S.C. § 829(a), (b) (drugs designated as Schedule II controlled substances may not be refilled, and those designated III and IV controlled substances “may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner”); 21 C.F.R. § 1306.22 (DEA rules on duration and refill limits for drugs classified as Schedule III or IV controlled substances).

⁵⁰ See, e.g., MO. ANN. STAT. § 195.080 (“The quantity of Schedule II controlled substances prescribed or dispensed at any one time shall be limited to a thirty-day supply. The quantity of Schedule III, IV or V controlled substances prescribed or dispensed at any one time shall be

limited to a ninety-day supply.”); CAL. HEALTH & SAFETY CODE § 11200 (limiting refills on Schedule III and IV drugs); see also CDC, TIME AND DOSAGE LIMIT LAWS, *supra* note 48, at 2-4, 7-8 (cataloging such laws).

⁵¹ See HHS HealthCare.Gov Glossary, Entry for “Formulary,” <https://www.healthcare.gov/glossary/formulary/> (last visited Nov. 30, 2016).

⁵² *Pharmaceutical Research and Mfrs. of America v. Meadows*, 304 F.3d at 1203.

⁵³ 42 U.S.C. § 1396r-8(d)(4)(C).

⁵⁴ *Id.*

⁵⁵ *Id.* § 1396r-8(d)(4)(A). These are often called Pharmacy and Therapeutics (P&T) committees. See also National Academy for State Health Policy (NASHP), *State Experience in Creating Effective P&T Committees* (March 2006), http://www.nashp.org/sites/default/files/medicaid_pandt.pdf.

⁵⁶ 42 U.S.C. § 1396r-8(d)(4)(B).

⁵⁷ 42 U.S.C. § 1396r-8(d)(4)(C); see also *Pharmaceutical Research and Mfrs. of America*, 304 F.3d at 1207-08.

⁵⁸ For a more detailed discussion of cost-sharing as a utilization control, see DAVID MACHLEDT & JANE PERKINS, NAT’L HEALTH LAW PROG., MEDICAID PREMIUMS AND COST SHARING (2015), <http://www.healthlaw.org/publications/search-publications/Medicaid-Premiums-Cost-Sharing>. See also DAVID MACHLEDT, NAT’L HEALTH LAW PROG., A PRIMER ON REFERENCE PRICING & VALUE-BASED INSURANCE DESIGN (2016), <http://www.healthlaw.org/issues/medicaid/services/Reference-Pricing-VBID-IB>.

⁵⁹ 42 U.S.C. §§ 1396o, 1396o-1.

⁶⁰ See *id.* §§ 1396o, 1396o-1(c); 42 C.F.R. § 447.53.

⁶¹ 42 U.S.C. 300gg-13(a) (preventive service exemption); See *id.* § 1396o(a)(2)(d) (exemption for family planning services); 42 C.F.R. § 447.56(a)(2).

⁶² 42 U.S.C. § 1396o; 42 C.F.R. §§ 447.56(a)(1).

⁶³ 42 U.S.C. § 1396r-8(d)(2).

⁶⁴ *Id.* § 1396r-8(d)(3).

⁶⁵ *Id.* §§ 1396d(a)(4)(C), 1396a(a)(10)(A).

⁶⁶ *Id.* § 1396b(a)(5).

⁶⁷ 42 C.F.R. § 440.230(b).

⁶⁸ CMS, STATE MEDICAID MANUAL § 4270.

⁶⁹ 42 U.S.C. § 1396o(a)(2)(D); 42 C.F.R. § 447.56(a)(2)(ii).

⁷⁰ 42 CFR § 441.20. Prevailing medical standards of care require that individuals have access to the contraceptive method that they prefer. The American College of Obstetricians and Gynecologists instructs providers that “in the absence of contraindications, patient choice should be the principal factor in prescribing one method of contraception over another.” AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR WOMEN’S HEALTH CARE: A RESOURCE MANUAL 183 (3rd ed. 2007).

⁷¹ 42 C.F.R. § 438.210(a)(4)(ii).

⁷² Medicaid and Children’s Health Insurance Program (CHIP) Programs, Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, 81 Fed. Reg. 27,498-27,901, at 27,634 (May 6, 2016), <https://www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-09581.pdf>.

⁷³ *Id.*; CMS, Dear State Health Official Letter 2 (June 14, 2016), <https://www.medicaid.gov/federal-policy-guidance/downloads/sho16008.pdf>.

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ 42 U.S.C. § 1396u-7.

⁷⁷ *Id.* § 1396u-7(b)(2)(A)(iv).

⁷⁸ *Id.* § 300gg-13(a)(4); Health Res. and Servs. Admin., *Women’s Preventive Services Guidelines*, <http://www.hrsa.gov/womensguidelines/> (last visited May 11, 2016) (establishing contraceptive coverage requirement); 42 C.F.R. § 440.347(a); 45 C.F.R. §§ 156.115(a)(4); 147.130(a)(1)(iv) (imposing requirement on ABPs).
⁷⁹ 45 C.F.R. § 147.130(a)(4).

⁸⁰ See U.S. DEP’T OF LABOR, HEALTH & HUMAN SERVS., & TREASURY, FREQUENTLY ASKED QUESTIONS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART XII, at 7-8 (2013), <http://www.dol.gov/ebsa/faqs/faq-aca12.html#5>; U.S. DEP’T OF LABOR, HEALTH & HUMAN SERVS., & TREASURY, FREQUENTLY ASKED QUESTIONS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART XXVI, at 3-6 (2015) [hereinafter ACA FAQ PART XXVI], http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

⁸¹ ACA FAQ PART XXVI, *supra* note 80, at 4. The FDA has approved the following 18 contraceptive methods for women: (1) sterilization surgery; (2) surgical sterilization implant; (3) implantable rod; (4) copper IUD; (5) IUD with progestin; (6) shot/injection; (7) combined oral contraceptives; (8) progestin only oral contraceptives; (9) extended/continuous use oral contraceptives; (10) patch; (11) vaginal contraceptive ring; (12) diaphragm with spermicide; (13) sponge with spermicide; (14) cervical cap with spermicide; (15) female condom; (16) spermicide alone; (17) Plan B,/Plan B One Step/Next Choice emergency contraception; and (18) ella emergency contraception. See FOOD & DRUG ADMIN., OFFICE OF WOMEN’S HEALTH, BIRTH CONTROL GUIDE, <http://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM517406.pdf> (last visited Nov. 30, 2016).

⁸² ACA FAQ PART XXVI, *supra* note 80, at 4. The guidance, which applies to all plans subject to the ACA’s contraceptive coverage requirement, notes that plans may impose cost-sharing on particular items or products within a contraceptive method to encourage use of those items or products. *Id.* However, as noted above, federal Medicaid law requires ABPs to cover family planning services without any cost-sharing.

⁸³ *Id.* A provider’s determination that a particular contraceptive product is medically necessary “may include considerations such as severity of side effects, difference in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service.” *Id.*

⁸⁴ Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, 81 Fed. Reg. 27498, 27553 (preamble to final rule, stating that “states may allow managed care plans to use their own formularies, as well as their own utilization management tools to the extent they are consistent with the requirements of [42 U.S.C. § 1396r-8]”).

⁸⁵ *Id.* § 438.210(a)(3)(i).

⁸⁶ *Id.* §§ 438.3(s)(1), 438.210(d)(3) (effective for contracts beginning on or after July 1, 2017). The prior regulations did not specifically apply 42 U.S.C. § 1396r-8(d)(5)(A) to plans, but CMS has long interpreted plans to be subject to that provision. See Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, 81 Fed. Reg. 27498, 27544-45, 27552-54, 27635-36 (May 6, 2016) (describing CMS’s interpretative history).

⁸⁷ 42 C.F.R. § 438.210(a)(2) (effective for contracts beginning on or after July 1, 2017). The prior regulation is similar, but does not specifically mention EPSDT. See *id.*

⁸⁸ *Id.* § 438.210(a)(4).

⁸⁹ *Id.* § 438.210(a)(5) (effective for contracts beginning on or after July 1, 2017). The prior regulation is similar, but does not specifically mention quantitative and nonquantitative limits. See *id.*

⁹⁰ *Id.* § 438.210(a)(4)(ii)(B)-(C).

⁹¹ 81 Fed. Reg. 27634.

⁹² See EDWARDS, *supra* note 10 (overview of parity laws and rules); see also The Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children's Health Insurance Program (CHIP), and Alternative Benefit Plans, 81 Fed. Reg. 18389 -18445 (Mar. 30, 2016) (federal rules on application of parity to Medicaid).

⁹³ Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, 78 Fed. Reg. at 68246, 68287, 68292 (Nov. 13, 2013).

⁹⁴ 42 C.F.R. § 440.230(d).

⁹⁵ *Alexander*, 469 U.S. at 303.

⁹⁶ 42 C.F.R. § 440.230(b).