Overview: Medicaid Outpatient Prescription Drug Coverage

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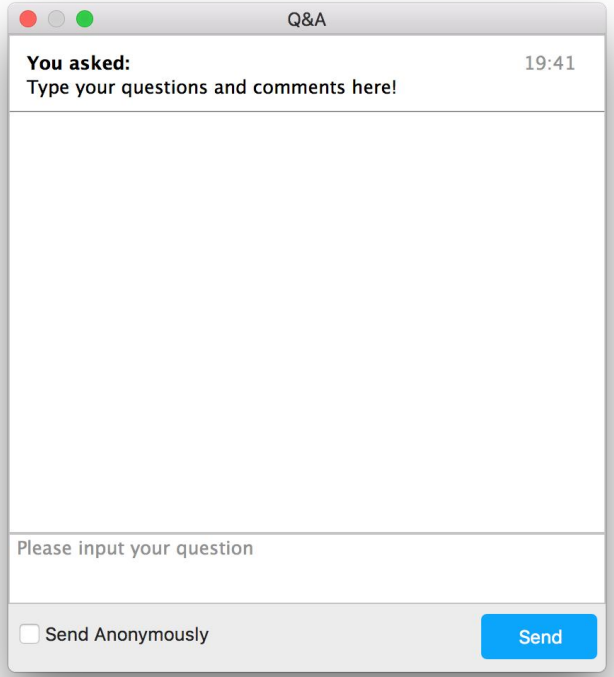
NATIONAL HEALTH LAW PROGRAM

Housekeeping – Q&A and Chat

- Please use the Q&A box for all **questions** to the panelists
  - Click on the Q&A icon at the bottom of the screen
- We will answers questions at each section break and at the end
- Webinar is being recorded. Everyone who registered will receive a link to the recording

- If you have a **technical issue**, please use the chat function



About the National Health Law Program

- National non-profit committed to improving health care access, equity, and quality for low-income and underserved individuals and families
- Federal, State & Local Partners in 50 states, D.C., and P.R.
  - Poverty & legal aid advocates
  - Health Law Partnerships
  - Disability rights and justice and sexual and reproductive health, rights, and justice advocates
- Strategy Areas: Federal Policy, California Policy, Enforcement & Litigation
- Practice Areas: Delivery System Reform, Disability, Eligibility & Enrollment, Services, Sexual & Reproductive Health
- Bluesky: @nhelp.bsky.social | Facebook: @NHeLProgram | Linkedin
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NHeLP's Equity Stance

Health equity is achieved when a person's characteristics and circumstances — including race and ethnicity, sex, gender identity, sexual orientation, age, income, class, disability, health, immigration status, nationality, religious beliefs, language proficiency, or geographic location — do not predict their health outcomes.

Our goal is to continuously examine the health care system and to advocate for health laws and policies that counteract structural barriers, institutional power dynamics, and examples of overt discrimination and implicit bias that create health inequity.

https://healthlaw.org/equity-stance/

Roadmap

- Rx coverage requirements
  - Outpatient vs. inpatient
  - Excludable drugs
- Off-label uses
- Formularies vs. Preferred Drug Lists
- Cost sharing
- Utilization management
- Quantitative limits
- Managed care
- Due process

Medicaid Outpatient Prescription Drugs

Optional service but all states + DC cover
- SSA 1927; 42 U.S.C. § 1396r-8

Fun Facts:
- Rx is 6% of total Medicaid spending
- 84% of Medicaid prescriptions are for generic drugs
- Feds pay 90% of cost of Rx for Medicaid expansion adults

Why Medicaid prescription drug access is important

- Treatment adherence can improve health outcomes and prevent hospitalization/more serious conditions (*e.g.*, HIV, diabetes)
- People with disabilities, chronic illness, and complex medical conditions rely on prescription drugs to maintain health
- Conditions treatable with prescription drugs disproportionately affect BIPoC (e.g., high blood pressure)
- Medicaid enrollees are low income and have no other means to access medication

Medicaid Services Generally

- Statewideness
- Reasonable promptness
- Amount, duration, and scope
  - Reasonable standards
- Comparability
- Providers
  - Freedom of choice
  - Medicaid is payment in full (no balance billing)
    - May have “nominal” cost sharing

Medicaid Rx – the grand bargain

States agree to cover most outpatient prescription drugs

Manufacturers agree to provide generous rebates

"Once a drug manufacturer enters into a rebate agreement, the law requires the State to provide coverage for that drug under its plan unless the State complies with one of the exclusion or restriction provisions in the Medicaid Act."

Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 652, (2003) (citing 42 U.S.C. § 1396r–8(d)).

Is it a covered outpatient prescription drug?

- FDA approved?
  - No distinction between fast track and conventional
  - No coverage requirement for experimental
- Is it outpatient?
  - Contrast inpatient settings (hospitals, hospice, dialysis, nursing facilities)
  - Gray area – physician administered, directly observed treatment (TB, MAT)
- Is it lawfully excluded?
- Medically accepted indication?
  - FDA label/approval
  - Supported off-label uses (more on this in a bit)
- Research tool: Drug Products in the Medicaid Drug Rebate Program

Drugs states may exclude

- anorexia, weight loss (more on this soon), 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.

42 U.S.C. § 1396r-8(d)(2)

Example: Coverage of GLP-1s

- Can be excluded for when covered for “weight loss” for adults age 21+
- Must be covered under EPSDT and for other medically-accepted indications, e.g., diabetes, chronic kidney disease
- Questions:
  - Medical diagnosis of “obesity” or “chronic weight management”?
  - Covered for obesity/overweight + another condition?

What's not a covered outpatient drug?

- Vaccines
- Drugs administered in inpatient settings like hospitals, hospice, nursing facilities
- Laboratory and x-ray services
- Dialysis
- Durable medical equipment

Physician administered drugs

- May be considered an outpatient prescription drug if billed separately and state claims the rebate per the Medicaid Drug Rebate Program (MDRP)
- May be provided under “physicians services” with a bundled payment
  - No rebate!

Off-label uses

Supported by citation in any of the following compendia:

- American Hospital Formulary Service Drug Information
- U.S. Pharmacopeia-Drug Information (or its successor publications)
- the DRUGDEX Information System

➢ See NHeLP's More Transparency Needed to Ensure Medicaid Beneficiaries Have Access to Necessary Off-Label Prescription Drugs

➢ Due process question – does the administrative record show the Medicaid agency reviewed the compendia before denying a request for off-label use?

Medicaid formularies

- Defined by statute – 42 U.S.C. § 1396r-8(d)(4)
- Developed and approved by committee of experts (physicians, pharmacists) appointed by Governor
- Based on safety and efficacy; not cost
- Drugs can be excluded only upon a finding that a "drug does not have a significant, clinical therapeutic advantage over other drugs"
- State must explain the basis for the exclusion in writing
- Allow access to non-formulary drugs via prior authorization

Preferred Drug Lists (PDLs)

- More like a traditional formulary
- Cost can be considered
- States often require prior authorization for non-preferred
- Generally developed by Pharmacy & Therapeutics (P&T) Committees
- Federal statute limits cost sharing
- Can provide basis for supplemental rebates (more on this in a bit)

Rules for Medicaid Prescription Drug Cost Sharing

	≤ 150% FPL	>150% FPL
Preferred drugs	$4	$4
Non-preferred drugs[#]	$8	20% agency cost of drug

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

Cites: 42 U.S.C. § 1396o-1(c)

Prior authorization

- Use reasonable standards for prior authorization criteria
- Must respond within 24 hours of request
- Provide at least a 72-hour supply in emergency situations

- Note – 2026 CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule
  - Standards for Application Programming Interfaces (APIs)
  - Public reporting of prior authorization approvals, denials, and appeals
  - Applies to Medicaid/CHIP, Federally-Facilitated Marketplace plans, Medicare Advantage

Other utilization management

- Step therapy
- Refill limits
- Prescriber limits (e.g., HCV treatment)

Other state tools to curb Rx spending

- Generic substitution (when permissible under state law)
- Value based purchasing
- Subscription model
- Supplemental rebates
- Purchasing pools

Quantitative limits

Alabama - limit of 5 prescriptions per month for adults

Arkansas - limit of 3 prescriptions per month for adults with extension of benefits for up to 6 prescriptions

Mississippi - limit of 6 prescriptions per month with no more than 2 brand-name drugs for adults

Texas - limit of 3 prescriptions per month for adults

Source: KFF, How State Medicaid Programs are Managing Prescription Drug Costs Results from a State Medicaid Pharmacy Survey for State Fiscal Years 2019 and 2020 (April 2020)

Managed care

- In general, Medicaid Managed Care must follow the same rules as FFS when it comes to drugs
- States may permit Managed Care plans to negotiate their own supplemental rebates
- States may permit Managed Care plans to establish their own preferred drug lists

Hot Topics: Aid paid pending for Rx

Aid Paid Pending (APP) must be requested before current prescription runs out (based on last fill date)

- Scope of APP: dosage adjustments?
- Length of APP: one fill or multiple fills until hearing is held?
  - *Compare* 42 CFR 438.420(c) (managed care) *with* 42 CFR 431.230(a) (FFS)

Hot topics: Due process

What due process rights when a Medicaid enrollee is denied a prescribed drug at the pharmacy?

"Some initial written notice of the reason for the denial will reasonably apprise the plaintiff of the denial, provide him with information that will assist him in deciding whether to invoke his procedural rights, and allow him to prepare for a hearing should he choose to invoke those rights."

N.B. v. District of Columbia, 244 F. Supp. 3d 176, 182 (D.D.C. 2017).

Resources

- MACPAC: Medicaid Payment for Outpatient Prescription Drugs
- KFF: How State Medicaid Programs are Managing Prescription Drug Costs: Results from a State Medicaid Pharmacy Survey for State Fiscal Years 2019 and 2020

- NHeLP: Fact Sheet: Medicaid Outpatient Prescription Drugs
- NHeLP: Fact Sheet: Utilization Controls for Medicaid Prescription Drugs
- NHeLP: Coverage of Over-the-Counter Drugs in Medicaid
- NHeLP: More Transparency Needed to Ensure Medicaid Beneficiaries Have Access to Necessary Off-Label Prescription Drugs

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