NHeLP
NATIONAL HEALTH LAW PROGRAM

Sunshine & Accountability Project

Issue Brief: Obtaining Information About Medicaid Prescription Drug Denials
Prepared by the NHeLP Sunshine and Accountability Project

February 2010

As federal fund recipients, state Medicaid agencies must implement their programs consistent with federal Medicaid and due process laws and should be held accountable for how government funds are spent. These standards still apply when states contract Medicaid responsibilities over to private entities, such as managed care organizations and insurance companies. The federal law includes important consumer protections when these arrangements are used. Among other things, the State Medicaid agency or contracting managed care entity must provide general information to each potential enrollee and, upon request, more detailed information about covered benefits, including outpatient prescription drugs.[1] This information must be provided in "sufficient detail to ensure that enrollees understand the benefits to which they are entitled."[2]

Medicaid beneficiaries need to understand coverage exclusions and coverage guidelines that will be used before they sign up for a plan; otherwise, they cannot make an informed choice of plan. As a federal district court judge recently noted, it is "essential" for Medicaid beneficiaries—particularly those with special health care needs—to know the limits of coverage so that they can attempt to compensate for gaps in coverage.[3] Medicaid beneficiaries have a particular interest in drug coverage because, compared to other populations, they are more likely to have health problems and chronic or disabling conditions that can be treated or ameliorated with prescription drugs.

Denials of Outpatient Prescription Drug Claims

> "Claims denials are probably the most effective way the industry has to manage medical expenses."
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> ***Source:*** Center for American Progress (quoting Wendell Potter, former senior public relations executive, Cigna Corp.)[4]

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[1] *See* 42 C.F.R. § 438.10(e).
[2] *Id.* at § 431.10(f)(6)(v).
[3] *Salazar v. District of Columbia*, 596 F. Supp. 2d 67, 69 (D.D.C. 2009) (granting motion to compel discovery of company's clinical coverage guidelines).
[4] Scot J. Paltrow, Center for American Progress, *Insurers' Black Box Now-Secret Claims Denial Rates Could Tell Consumers a Lot About Their Insurance Company* (Oct. 21, 2009), *at* http://www.americanprogress.org/issues/2009/10/pdf/insurers_black_box.pdf.
The Center reports that many managed care plans have changed their structures over the last decade so that the medical staff making coverage decisions is no longer reporting to the

The detailed information available to Medicaid beneficiaries and potential enrollees should include information about the policies that a managed care company applies when denying claims for prescription drugs, either electronically or following a request for prior authorization, and its prescription claim denial rates.

Outpatient prescription drugs, perhaps more than any other covered service, offer the possibility for improper denials. There are a great many reasons why a drug claim can be denied. State Medicaid agencies can deny coverage based on eligibility (e.g. the individual is no longer eligible for Medicaid), technical errors (e.g. the claim was submitted under an incorrect number), or for substantive reasons (e.g. lack of medical necessity for the drug). Most States have adopted prescription drug utilization control devices that also will provide a substantive reason for refusing to approve a claim, which may include:

- *Formularies.* A formulary is a list of drugs for which the State will provide reimbursement when prescribed for medically accepted indications. Drugs not on the formulary are not covered.
- *Preferred drug listings.* States can identify drugs as more cost effective and encourage their use by, for example, waiving or reducing cost sharing, allowing pharmacies to substitute for other drugs, or waiving prior authorization for drugs they include on the list.
- *Drug exclusions*. States can exclude a number of categories of drugs, such as prescriptions for weight loss or gain, fertility drugs, barbiturates, and benzodiazepines.[5]
- *Prescription limits*. States can impose limitations, with respect to all drugs in a therapeutic class, on the minimum and maximum quantities per prescription or on the number of refills, *provided* the limits are needed to discourage waste.[6]
- *Prior authorization*. States can require prior approval of a drug before payment is authorized.

In addition to information about a company's policies and practices, its prescription claims denial rates are also a valuable source of comparative information.

Drug claims data need to be closely monitored in order to evaluate the process that a company uses to make drug coverage decisions. With the exception of formal requests for prior authorization, Medicaid prescription coverage and billing decisions occur "on line" and in "real time." The pharmacy computer is linked to the computer system of the state Medicaid agency or its contracting pharmacy benefits manager. The patient will present their doctor's prescription to the pharmacist, who then enters the relevant information in the pharmacy computer. The electronic claim instantly goes to the Medicaid agency's claim processor (the state or a private company) and is then

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medical director but to a business executive who is responsible not only for assuring corporate sustainability and profits but also deciding medical staff pay and promotion. *Id.*

[5] *See* 42 U.S.C. § 1396r-8(d)(1)(B)(ii).

[6] *Id.* at § 1396r-8(d)(6).

electronically processed for compliance with state or managed care contactor prescribing rules. The result is an electronic response to the pharmacist indicating whether the claim will be reimbursed and, if so, at what amount. If the claim is rejected, the response will include a claim rejection code, indicating the reason for the rejection. The process takes less than a minute.

These kinds of electronic denials are increasingly common in the case of failures to obtain prior authorization. Most prescribing health care providers are working under multiple competing insurance systems (e.g. Medicare, Medicaid, managed care, private insurance), each with their own preferred drug lists and prior authorization rules. Prescribers cannot readily track which drugs require prior authorization under which plan at any given time. As a result, they routinely write prescriptions for drugs that require prior authorization without first requesting such authorization or even checking to see if prior authorization is needed. The problem is uncovered only after the patient presents the prescription to the pharmacy and the electronic claim review denies the prescription because prior authorization has not yet been sought.

In many if not most states, an individual whose pharmacy claim is electronically rejected for any reason will leave the pharmacy empty handed, without any prescription. If this happens to a person who is covered by Medicaid, then their "due process" rights are implicated. Specifically, due process requires that, when a pharmacy claim is denied, including at the pharmacy counter based on information provided electronically by the Medicaid agency or its contractor, the individual is to be provided a timely and adequate written notice explaining the basis and legal support for the denial and an opportunity for a hearing to challenge the denial.[7] Due process also requires continued benefits—an immediate and ongoing supply pending the outcome of a requested fair hearing if the rejected prescription is for a continuing refill.[8] The Medicaid Act also includes provisions that require a 72-hour supply of the drug in emergency situations.[9]

Finally, the sheer volume of the Medicaid prescriptions offers unparalleled opportunity for mistakes to occur. For example, data produced by the Florida Medicaid agency in a lawsuit, Hernandez v. Medows, showed that, in 2002, prescriptions could be denied for 70 different reasons. While the vast majority of denials were for technical reasons (e.g. typographical errors, mistaken coding), a number of claims were denied for substantive reasons, such as a failure to comply with prescription limit, prior authorization, or generic or preferred drug list requirements. Over 58,000 recipients in one month were denied their medications because they exceeded the quantitative limit or were not on the preferred drug list. The length of the delay which occurred between initial denial and any eventual coverage is unknown. Ultimately, 25% of recipients who were initially denied (13, 681) received either a generic substitute or a different brand

[7] *See* 42 U.S.C. § 1396a(a)(3); 42 C.F.R. § 431.200 et seq.; *Goldberg v. Kelly*, 397 U.S. 254 (1970).
[8] *Id.* Medicaid and Constitutional laws require a pre-termination hearing, meaning that benefits must be continued pending review of the denial of a claim for ongoing services, in this case a prescription refill. *Id.*
[9] *See* 42 U.S.C. § 1396r-8(d)(5).

name drug, but over 20,000 recipients, or *more than a third of all denials*, failed to receive any medication in the same therapeutic class as the prescription. The denied medicines covered the range of diseases and conditions, including for tuberculosis, gastrointestinal reflux, cholesterol-lowering drugs, and fungal conditions. None of these recipients received due process—notice of the reason for the denial/delay and the opportunity to appeal the denial.[10]

Similarly, in Karen L v. Health Net, a case in Connecticut several years ago against the state Medicaid agency and Health Net, discovery revealed that, for a population of about 90,000 low-income children and their caretaker relatives, about 3,000 drugs were denied electronically at the pharmacy counter each month, specifically for lack of prior authorization. No notices of denial were issued based on these denials of Medicaid coverage at the pharmacy.

Claim denial information is not readily accessible to the public

The NHeLP Sunshine and Accountability Project sought to obtain prescription denial information from Medicaid participating managed care plans. In December 2008 and January 2009, our partners from Florida, Missouri, New Mexico, Virginia and Washington sent uniform requests for information to the managed care organizations operating in their states that asked them to provide information about:

> the number of requests for payment of a prescription drug covered under the plan's Medicaid contract for which payment was (1) electronically approved at point of service; (2) electronically rejected at point of service even though the drug was not on an excluded drug list; and (3) for those included in (2), the number that were later approved after initial payment rejection.

The managed care plans in these states did not provide the requested information. Some plans, UnitedHealthcare in Florida and the Molina plan in Missouri, refused to provide the information without a court order or subpoena.[11] It must be stressed that this information is stored electronically by the state Medicaid agency or its contractors and is readily available.[12]

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[10] *See Hernandez v. Medows,* No. 02-20964 (S.D. Fla.), Plaintiffs' Memorandum of Law in Support of Motion for Partial Summary Judgment at 22-23 (Dec. 13, 2002) and Plaintiffs' Supplemental Memorandum of Law in Support of Class Certification at 2 (June 7, 2002) (on file with NHeLP).

[11] Letter from Max Ramsey, Assoc. Gen. Counsel, UnitedHealthcare, to Miriam Harmatz (Jan. 21, 2009) (refusing to provide information without a subpoena "or citation of legal authority") (on file with NHeLP); Letter from Joann Volovar, Molina Healthcare, to Joel Ferber (Feb. 11, 2009) (referring state partner to state Medicaid agency and adding it "considers much of the information you requested, confidential and protected …. The information is only available by court order or subpoena….") (on file with NHeLP).

[12] For example, this information was provided without fight or cost in response to a discovery request in the *Hernandez* case in Florida.

Apparently, the refusal to reveal claim denial information is business as usual. In 2009, the Center for American Progress asked seven of the largest for-profit health insurers—Aetna, Anthem Blue Cross Blue Shield, Cigna, Coventry, HealthNet, Humana, and UnitedHealthcare—to disclose their overall rates of claims denials and breakdowns by reason for the denials. All of the companies declined or did not respond to the request.[13] As noted by J.D. Kleinke, when discussing problems getting information from insurers and pharmacy benefit managers, "obfuscation pays."[14]

Recommendations

1. The federal Centers for Medicare & Medicaid Services (CMS) should issue guidance to state Medicaid programs, their pharmacy benefit managers and participating managed care plans reminding them of their obligations to inform enrollees and prospective enrollees and to follow due process obligations under federal law. The guidance should stress the need to provide general and, upon request, more detailed information about drug coverage and that due process (notice and hearing) protections apply whenever an individual's prescription claim is denied or unreasonably delayed.

2. CMS should periodically audit states to determine the extent of pharmacy approvals and rejections, including electronic denials at the pharmacy, and how patients are being informed when their prescriptions are rejected.

3. State Medicaid agencies should use a patient-friendly ombudsprogram to help individuals navigate the system when a claim rejection occurs.

4. State Medicaid agencies must assure that beneficiaries receive adequate due process when their prescription claims are rejected, including electronic rejections that occur at the pharmacy. For example, the Connecticut Attorney General has recognized that the Constitution and Medicaid law require individuals to be mailed a notice explaining the pharmacy denial on the day of the denial.[15] Medicaid-participating pharmacies in Florida are supposed to post signs and distribute individualized pamphlets advising Medicaid recipients why the denial occurred and how to resolve the problem, including through a hearing.

5. State Medicaid agencies should take steps to ensure that their electronic pharmacy benefit management systems properly monitor claims experience and are programmed to provide user-friendly summary data about the numbers of denied claims and the reasons for the denials. Informed and

[13] Center for American Progress, *surpa* n. 4, at 2.
[14] J.D. Kleinke, *Dot-Gov: Market Failure and The Creation of a National Health Information Technology System*, 24 Health Affairs 1246, 1252 (Sept./Oct. 2005).
[15] Letter to Michael Starkowski, Comm'r, Conn. Dep't of Social Services, from Richard Blumenthal, Conn. Attorney General, and Jeanne Milstein, Conn. Child Advocate at 2 (Jan. 22, 2008) (on file with NHeLP).

open discussions about pharmacy coverage and denials cannot occur without the type of information requested by the NHeLP Sunshine and Accountability Project.

The Importance of Prescription Medications

54% of Americans take prescription medications, and 19% take at least 4 Rxs/day.
Source: Kaiser Family Foundation, 2008.

States where access to newer medications increased the greatest in Medicare and Medicaid between 1991 and 2004 had the biggest increases in life expectancy.
Source: Washington Post, July 11, 2007.

Adults without coverage are more than twice as likely as insured adults to forgo filling a prescription, to cut pills, or to skip doses of medicine because of the cost.
Source: Kaiser Family Foundation, 2008.

Adherence to medication regimens has been associated with lower health care costs for AIDS, Alzheimer's disease, osteoporosis, asthma, diabetes, hypertension, high cholesterol, and heart disease.
Source: AARP Public Policy Institute, 2008.

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