Protecting Medicaid Patient Access to Prescription Drugs

Under a Medicaid PDL, there are protections that should be built into the program to minimize potential health problems for patients. These are listed below with possible regulatory language that could be used:

1. Grant the prescribing physician and/or pharmacist the ability to override the PDL limitation. When a patient needs access to a medication not on the PDL, this provision would ensure immediate access for the patient without having to undertake the prior authorization process. This language also enables health care providers to put an individual patient's medical needs first.

Notwithstanding any other provision of law, a practitioner may prescribe any drug that the practitioner indicates is medically necessary for a Medicaid beneficiary as being the most effective available.

Where the prescriber has indicated on the face of the prescription "dispense as written" in handwriting, or other appropriate form for electronic prescriptions—
the pharmacy shall not substitute another drug without the express permission of the prescriber, and notwithstanding any other provision of law, the pharmacy shall receive payment for a drug dispensed pursuant to a "dispense as written" order without seeking prior authorization of the state or any benefit administrator, and without telephone or other confirmation that the physician does not wish to substitute another medication.

2. Ensure that a patient stable on a specific drug therapy can continue on that therapy when the PDL is implemented. Essentially, this concept "grandfathers in" existing treatments that are already successfully keeping patients healthy. Patients will not have to change medicines because administrative changes to the Medicaid program have occurred.

In the state's Medicaid fee for service program, provided that a drug is safe and effective for a medical condition, it is unlawful for a payer or benefit manager to limit or exclude coverage for such drug when prescribed for the medical condition of an enrollee if the drug previously has been approved by the payer for such enrollee's medical condition.

3. Deliberations and considerations of the DUR Board or a P&T Committee should be open to all stakeholders and subject to Iowa's Administrative Procedures and Open Meetings provisions.

It shall be unlawful for the State Medicaid agency to implement any formulary or preferred drug list where the selection of drug products has not meet the requirements of the administrative procedure act, including prior notice of proposed restrictions, an opportunity for hearing, and response to public comments.

4. Medicaid patients should have access to new drug therapies until they can be reviewed by the DUR Board or P&T Committee.

Notwithstanding any other provision of law, a covered outpatient drug shall not be subject to restriction or prior authorization prior to the first regularly scheduled meeting of the pharmacy and therapeutics committee at which evidence is presented to support any such restriction on use of the drug in treating program beneficiaries.

5. If the State should elect to contract with a pharmacy benefits manager or other entity to administer the PDL, there should not be a financial incentive in this arrangement that encourages restricting access and cutting costs. Drug efficacy and safety and patient health should come first-not cost cutting.

A state agency contracting for a pharmaceutical benefit management services to administer, develop, manage or implement any aspect of the Medicaid prescribed drug benefit offered under its State plan or to develop a formulary or preferred drug list for such benefit shall establish the fee paid to any program contractor based on the reasonable cost of services provided. A State agency may not offer or pay directly or indirectly any material inducement, bonus, or other financial incentive to a program contractor based on the denial or administrative delay of medically appropriate prescription drug therapy, or on the decreased usage of a particular drug or class of drugs, or a reduction in the proportion of beneficiaries who receive prescription drug therapy under the Medicaid program. Bonuses cannot be based on percentage cost savings of program.

"Program contractor" means any person contracting with the State agency to provide pharmaceutical benefit management services for outpatient prescription drugs.

"Pharmaceutical benefit management services" includes, but is not limited to negotiating or collecting rebates, implementing, managing or developing a formulary, preferred drug list, treatment protocol or guideline, step therapy or other use of prior authorization.)

6. The PDL development and implementation should be based primarily on efficacy and safety.

It is unlawful for a payer or benefit manager to employ a care management technique (including but not limited to implementation of a formulary, treatment protocol or guideline, step therapy or other use of prior authorization) without assuring that its clinical foundation is consistent with quality patient care. Such assurances include evidence of:

(a) clinically-based definitions for each "therapeutic class" of drugs;

(b) reliance on scientific and clinical data in updating formularies, protocols or treatment guidelines;

(c) for any drug subject to prior authorization, a specific set of clinical criteria, available to physicians and patients, specifying when that drug is authorized for coverage.

7. After the PDL is fully operational, the state should plan to conduct a study to assess the PDL's impact on patient quality of care and state costs.

In order to judge the effectiveness of any prescription drug cost-containment program, (including but not limited to implementation of a formulary, preferred drug list, treatment protocol or guideline, step therapy or other use of prior authorization) the State Medicaid Agency shall submit to the legislature a report on the effects of the program on quality of care and cost effectiveness. The report shall be conducted in consultation with health care providers, pharmacists and case managers with specialized expertise in the treatment of chronic conditions of individuals (including children and the aged) with special health care needs. The report shall include at a minimum:

a) the rate of hospitalization and utilization of physician office visits following use of a item preferred by the program vs. a non-preferred item for the same indication;

b) any adverse side effects or interactions and therapeutic contraindications that are encountered from use of the preferred product;

c) the incidence of patient non-compliance and missed dosages for a preferred item whose dosing is more complex than a non-preferred item, including a separate evaluation of the effect on patients being treated for mental illness;

b) any additional burden on providers associated with obtaining prior authorization, including waiting times for approval;

c) the percentage of providers who are denied prior authorization to prescribe medications;

d) the cost of program development;

e) the cost of processing each authorization request;

f) the per patient average cost of the item for which authorization was requested and denied;

g) the per patient average cost of the item that was authorized;

h) the number of authorization requests that resulted in no alternative therapy being obtained; and

i) recommendations, including safeguards (if any) that may be needed to ensure that the health care needs of individuals with special health care needs and chronic conditions are adequately met.