



June 15, 2011

Ms. Janie Miller  
Secretary  
Cabinet for Health and Family Services  
275 E. Main Street  
Frankfort, KY 40621

(Sent via email and regular mail)

Re: Follow-up Comments to Medicaid Managed Care Request for Proposals

Dear Secretary Miller:

The following represents additional information relating to the provision of pharmacy services under the anticipated new managed care structure of the state's Medicaid program. It is a follow-up to previous communications between the pharmacy community and the Cabinet. As the Cabinet moves forward in the implementation of managed care within the Medicaid program we ask that it consider the principles put forth below. As always, we are willing to discuss the pharmacy program and provide input to the Cabinet to make sure that pharmacy services are provided to Medicaid recipients in the most efficient and effective manner.

### **Medicaid Pharmacy Program Best Practices**

Although pharmacy programs in Medicaid are optional services for states, they are recognized as an essential benefit to virtually all other medical interventions. Pharmacy programs are used by over half of the beneficiaries, more in the disabled and chronically

ill but no less important for the children. In Kentucky, gross pharmacy spending in the Medicaid program in 2009 was approximately \$509 million, only about 9% of total Medicaid expenditures. The Medicaid program received \$238 million in drug rebates from pharmaceutical manufacturers in the same period reducing the net outlay for drugs to \$271 million or about 4.7% of total Medicaid expenditures. It is therefore imperative that the benefit is viewed in context of its value to the beneficiary's health as well as its overall value to the state. If not administered appropriately the pharmacy program can not only cost the state more within the pharmacy program but also cost the state more within other silos of Medicaid expenditures.

If the pharmacy benefit is inappropriately restrictive it is probable that a state will increase their cost in other areas of the Medicaid program (i.e. emergency room visits and hospitalizations). If the pharmacy program does not have appropriate safeguards in place it is probable that a state will pay a premium for the service and not see the potential benefits.

The following information is based on a draft best practices principles currently being developed by the National Community Pharmacy Association for managing a Medicaid pharmacy program, modified as we feel appropriate for Kentucky.

### **Principles**

**Access to pharmacy services is a critical component for patients suffering from chronic physical disease. It is even more crucial for those with severe mental illness.**

Pharmacies are generally well distributed in Kentucky. However, access means not only the physical presence of a pharmacy to a patient but the ability of the services at the pharmacy to match the patient's needs. The patient should be able to freely choose the pharmacy that best meets their needs and with whom they have developed a practitioner relationship. The provider should expect to receive a reasonable reimbursement for product, distribution services, and clinical services.

**Adherence to a prescribed drug therapy for chronically ill patients is essential.**

Failure to take medications and take them appropriately will result in poor patient outcomes and increased cost to the state payer. When adherence drops to 80 percent (taking a medication 3 times a day as opposed to 4r, or for 5 ½ days instead of seven) you will see a 2.5 times greater rate of hospitalization for seriously mentally ill patients. Similar impacts occur with patients who have congestive heart failure, diabetes, asthma as well as other chronic diseases.

Adherence should be monitored with tools provided by the Medicaid program. The outcomes of these tools should be available to the practitioner base (prescribers, care coordinators, pharmacists and others engaged in the care and treatment of the patient). Adherence requires the patient to understand what medications he or she is taking and

why, should be a goal of the program. The benefits of adherence will be lower costs to the state and healthier patients.

**Dose optimization lowers pharmacy program costs and results in higher adherence.**

Dose optimization means taking the fewest units of medication the fewest times a day. Many medications are priced essentially the same regardless of the strength. With some of the units costing tens of dollars apiece it is imperative to establish a policy to encourage if not require dose optimization to occur.

**Mail order and 90-day supplies have been touted as a cost savings approach. Mail order has not proven to be of benefit in a Medicaid population.**

Although many states have discussed using mail order and a few have tried (currently two states have optional mail order), there has yet to be significant uptake or benefit realized in this population. Studies have shown because of the increased waste that mail order is of marginal benefit. When given a level playing field patients rarely chose mail order willingly. Providing a 90-day supply of medication to treat stable chronic conditions, especially those medications are available generically, may provide some marginal savings for a public program. However, a recent study in Missouri projected a \$1.4 million dollar savings for an SSI population representing approximately 18% of the total population. Currently approximately 5 states require 90-day supplies of generics used for stable chronic conditions.

**Generic medications are extremely cost effective. Medicaid programs should support generic utilization whenever feasible.**

Generic utilization continues to increase as more trade name products go off patents. Generally a generic prescription will cost approximately 20 percent of the trade name product. A Medicaid pharmacy program should be measuring generic utilization as well as generic efficiency (how many times a generic was used when a generic could be used). In only very rare cases can a case be made for a brand name product over a generic.

**State maximum allowable costs (SMAC) prices should be fairly determined and represent market considerations.**

As noted generics can save the state program millions of dollars. From a cost perspective they typically represent only about 20 percent of the cost of the program. Significant savings are achieved (i) when generics are used and (ii) when brand name products that have no generic equivalent are changed in consultation with the prescriber to a generic therapeutically equivalent product. The program should not create disincentives for the use of generics by having unobtainable pricing or by not responding promptly to price increases in the market place. In many ways generic drug products are “spot market” priced and can fluctuate significantly and often. In some cases it may make sense for the program to offer generic incentives for utilizing generic products.

**Establishing a targeted days supply limit on first prescription fills can save program dollars.**

Selectively requiring no more than a 15-day supply on the first fill of a brand name prescription that will be used chronically can save significant program dollars. Many times medications new to a patient will be changed or discontinued. This may be because the patient cannot tolerate the medication or because the medication turns out not to be efficacious to that patient.

**Limiting the number of prescriptions per month for recipients is a very harsh approach for saving program dollars.**

Establishing an arbitrary monthly prescription limit infrequently resolves program cost issues. It increases overhead for the program, confusing and frustrates providers and patients alike. One only needs to look at the variety of limits that have been tried to see the lack of evidence in the process. Targeted, evidence based precertification programs utilizing the best technology are far more financially productive.

**The use of over-the-counter (OTC) drugs in public programs is a two-edged policy.**

OTC medications are optional in Medicaid programs and may be cost effective only with well considered coverage policies. OTCs can be used effectively in step therapy. They should require a prescription. They should always be accompanied by a rigid formulary indicating dosage forms, strengths and quantity limits. Alternatively, a limited formulary of drugs that could be dispensed directly by the pharmacist without a prescription based on his or her professional judgment could be considered.

**Prospective program edits are essential to save costs, maintain quality and assure appropriate program utilization.**

Program edits should all have the same basic qualities to assure provider understanding, acceptance and support. The following are some essential edits not yet discussed and basic criteria for their appropriate use.

Edits should be transparent. They should be established on the basis of best medical evidence and in the context of the patient's diagnosis and condition. Transparency means if a transaction is blocked, it should be apparent why and under what conditions it can be overridden. If this is not the case, the program appears to make arbitrary coverage decisions. Edits should be administered electronically and in real time. They should require little human intervention (at least 85 percent should be totally handled in the background of the transmission, but a call center should be available in a timely manner if needed).

Medications should have quantity limits set per unit of time. Those medications most prone to abuse should be set first.

Step therapy should be used to incentivize generics first, then preferred drugs, and lastly innovator medications.

Other general transparent edits:

- Quantity limits
- Maximum dosage limits
- Limits on therapeutic duplication
- Early refill limits

## **Specialty Drugs**

Specialty drugs and specialty pharmacies are difficult to define both in scope and practice. The medications covered by these pharmacies are generally considered to be those requiring specialized handling or training and as such are not generally available in the community setting. In many cases the definition of “specialty drug” has been unnecessarily expanded to include some medications that are generally available in the community setting with no other characteristic than high cost. The Cabinet should assure that “specialty drugs” are narrowly defined and the specialty pharmacy is providing a service not generally available in the community setting before allowing them to be designated as a sole provider of a drug.

With or without a specialty pharmacy presence in a state, the agency should establish a state maximum allowable cost for many of the products distributed through this channel. (See SMAC )

## **Physician Administered Drugs**

All pharmaceuticals except those used as an adjunct to a physician service or treatment (i.e. a numbing agent, an antiseptic, lubricant) should be billed through the pharmacy program. This aggregates rebates and allows for appropriate editing. The base reimbursement should be the same among providers with the service fees separate.

## **Provider Advisory Board**

An advisory board of pharmacy practitioners can be helpful to fine-tune policy, establish cost savings opportunities and understand industry issues. The meetings should be no more than quarterly unless an unusual need arises. They should be totally advisory, have an agenda, and set time for meeting and include practitioners from independent, chain, and specialty practices.

## **Preferred Drug List (PDL)**

A preferred drug list is used to promote clinically appropriate utilization of pharmaceuticals in a cost-effective manner. A “first line drug” should be established for each therapeutic class of interest and its use mandated if it is consistent with best medical evidence. The agency “bids” these products by therapeutic class to establish the priority

of coverage. There was some speculation that this process would diminish the Affordable Care Act and the new rebate structures. To date, this does not appear to be happening. All states should avail themselves of these additional revenue streams.

### **Formulary Issues**

As Kentucky Medicaid moves to managed care, the Cabinet should carefully consider how managed care organizations deal with formulary issues. It is especially important since the state's plan may result in the regionalization of the Medicaid program with multiple managed care organizations operating in each region. Requiring a common formulary statewide among all managed care organizations with identical prior authorization rules is in the best interest of the patient as it would guarantee continuity of therapy as patients move from region to region or switch between managed care organizations.

### **Medication therapy management (MTM), care coordination and related nondistributive services of pharmacists.**

Since the passage of Medicare Part D, there is much more public awareness of the benefit of pharmacist services in choosing, balancing, administering and adjusting medication therapy. Pharmacists are highly trained individuals specializing in medication therapy. They add safety, efficacy and cost savings to programs that use them in conjunction with prescribers and in multidisciplinary teams. The cost savings varies by service and patient population but is routinely a multiple of the cost to provide the services.

### **When a state decides to contract out or “carve out” pharmacy services**

If the decision is made to contract the pharmacy benefit to a pharmacy benefit manager or contract the whole benefit to a managed care entity, there are considerations that should be addressed. Some of those considerations are:

- These principles still apply. The procurement should contain at least the minimum detail of these principles.
- The encounter data from the patients or MCO should be validated and sufficient to afford state monitoring, coordination of benefits and rebate collections.
- The procurement would best ask for a per member per month capitated rate for pharmacy alone by the same patient stratification used in the remainder of the bid. This should also be compared to the experience the state effort achieved as well as being actuarially sound.
- A sample of the provider contract should be provided.

- Access by location and service level should be requested and monitored as should any patient charges.
- Reimbursement for providers should be uniform and based on provider cost of dispensing.
- Required results of all drug utilization review should be made available for review (at contract level).
- All medications should be part of the contract, no exclusions or stopgap measures for clotting factor, protease inhibitors, anti-viral or similar targeted medications.
- A stipulation for disclosing provider contractor terms and all collected rebates including non-cash rebates should be included.
- A clear statement on how physician administered drugs and specialty drugs are handled and reimbursed along with rebate terms should be disclosed.
- Sufficient reporting to allow monitoring of all benchmarks should be required.
- Access to patients' specific utilization information should be made available to the agency and monitoring contractors on a near real-time basis.

Sincerely,

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