Chapter 9: Pharmacy Services

Executive Summary

Description

In Fiscal Year 2008, Medicaid fee-for-service pharmacy services were provided to 113,446 unique beneficiaries through 745 contracted pharmacies, with nearly 2 million prescriptions dispensed.

Pharmacy program management is aided by a federally mandated Drug Utilization Review (DUR) program to provide education to physicians, mid-level practitioners and pharmacists. In addition to the guidance provided by the DUR board, the Kansas Medicaid Prescription Drug List (PDL) Advisory Board provides direction for the implementation of a PDL, which is a compilation of drugs that are most cost-effective for the State. Of note, medications used for mental health are statutorily excluded from inclusion on the Medicaid PDL in Kansas. The pharmacy prior authorization process operates using a manual prior authorization (PA) system.

Key Points

- Changes in drug spending and population served changed dramatically between FY 2006 and 2007 due, in part, to implementation of Medicare Part D which now covers prescription drugs for low -income seniors eligible for both Medicaid and Medicare. The second significant shift in the fee-for-service (FFS) prescription drug program occurred in January 2007, with the transition of approximately 50,000 beneficiaries from Medicaid fee-for-service to the HealthWave managed care program.

- Significant increases in costs-per-prescription exceed consumer and medical price inflation rates, as well as long-run rates of increases in state revenue. This raises questions about the sustainability of Medicaid prescription drug spending.

- Psychotherapeutic medications comprise a notably higher percentage of expenditures than the next largest classes of medications combined, including central nervous system (CNS) drugs, anti-infectives, gastrointestinal drugs, and anti-asthmatic drugs, in order of expenditures.

- Nearly half of all of the growth in Medicaid prescription drug spending in FY 2008 is attributable to increases in the cost-per-prescription and in the utilization of mental health drugs. In

the last few years, an increasing number of scientific studies have identified serious adverse events associated with use of mental health drugs. In Kansas, two thirds (63%) of mental health drugs are prescribed by general practitioners and other non-psychiatrists. This raises questions as whether beneficiaries have full access to best practices and the current body of knowledge regarding the safety and effectiveness of mental health medications.

These findings indicate the need for increased oversight and active management of the Medicaid pharmacy program, including more aggressive pursuit of market-based price discounts and focused attention on the management of mental health indications. Given the emerging data regarding the use of mental health medications in children, KHPA is especially concerned about the safety of young Kansans. Prior authorization (PA) is the standard tool used by pharmacy benefits management (PBM) and Medicaid programs to improve safety and ensure appropriate dispensing of drugs that are commonly mis-used.

Recommendations

1. Update drug pricing formulas and reimbursement limits for Medicaid fee-for-service (FFS) drugs.

2. Implement an automated prior authorization (PA) system.

3. Remove the statutory limitation on management of mental health prescriptions.

4. Establish a Mental Health Prescription Drug Advisory Committee.

Overview and Background

This review examines trends and activities in the Medicaid fee-for-service (FFS) pharmacy program. The goal of the review is to identify opportunities for program improvements that improve safety and quality of care, generate efficiencies in program administration and yield savings for the state. The Medicaid fee-for-service pharmacy program includes all prescribed medications that are offered to beneficiaries and provided through community pharmacies and physicians' offices. Medications administered in an institutional or inpatient setting are not included in the fee-for-service pharmacy program. Instead, these medications are reimbursed through payment to the facility. Prescription drugs dispensed to Medicaid beneficiaries participating in the HealthWave managed care program are also not specifically addressed in this review since these medications are reimbursed through the HealthWave program, rather than fee-for-service pharmacy.

Program Description

Under the federal rules governing the administration of Medicaid, pharmacy programs are an optional benefit that states may choose to offer. Given the central role of pharmacy in medical care, all states have chosen to provide this service to their beneficiaries. There are many federal requirements for Medicaid pharmacy programs. These include a requirement that all Food and Drug Administration (FDA) approved prescription drugs are available to Medicaid beneficiaries (specifically, those prescription drugs whose manufacturers have a pricing contract with the Centers for Medicare and Medicaid Services; this is essentially all prescription drugs in the U.S.).

In Fiscal Year (FY) 2008, pharmacy services were provided to 113,446 unique beneficiaries through 745 contracted pharmacies, with nearly 2 million prescriptions dispensed. Most of the contracting pharmacies are located in Kansas, but Medicaid also contracts with a small number of additional pharmacies in Colorado, Nebraska, Oklahoma, and Missouri to help serve Kansas Medicaid beneficiaries who live close to state borders. The Kansas Board of Pharmacy reports 836 licensed pharmacies in Kansas. Kansas Medicaid has successfully contracted with a significant majority (89%) of Kansas pharmacies to ensure pharmacy access for Medicaid beneficiaries.

Medicaid rules allow pharmacies to dispense a sufficient quantity of medication for up to 30 days of therapy. Pharmacies are reimbursed for the cost of the drug plus a $3.40 "professional service fee" for each prescription. Billing by pharmacies is unique in comparison to other medical services because pharmacies bill electronically before the drugs are dispensed. In contrast, hospitals, physician offices and other providers file claims after the service has been provided. This pharmacy billing mechanism provides an opportunity for public and private insurers to interact with beneficiaries when the medication is dispensed. Medicaid reimbursement to pharmacies for the cost of the drug is set at 27% below the average wholesale price (AWP) for "multi-source" (generically available) drugs. Medicaid reimbursement is set at 13% below AWP for single source (brand name) drugs. Reimbursement may be further limited by KHPA's maximum allowable cost (MAC) list., a set of prices established by the state through periodic examination of wholesale prices for generically-available drugs. A MAC is established when current reimbursement is greater than actual acquisition cost.

To offset pharmacy costs, states also receive a rebate from prescription drug manufacturers for each prescription dispensed to a Medicaid beneficiary. The federal government secures a substantial rebate on behalf of states from drug manufacturers who have agreed to participate in the Medicaid program (at least 15% of the average price at the manufacturer's level). In addition, states can separately negotiate additional rebates from manufacturers in exchange for listing a drug as "preferred". This means that the state has agreed to a "listed preference" in dispensing that specific drug rather than other therapeutically equivalent drugs. In Kansas, the process of determining therapeutic equivalence is transparent and publicly regulated. That process is described in more detail below.

Pharmacy services for Medicaid beneficiaries enrolled in the two HealthWave managed care organizations (MCOs) are reimbursed through the capitated rate paid to the MCO for each beneficiary. The HealthWave MCOs manage their pharmacy program independently, developing separate agreements with pharmacies and manufacturers to determine reimbursement rates and rebate agreements. The MCOs are allowed to subcontract with a pharmacy benefit management firm for medication management services. For instance, Unicare utilizes WellPoint for management of their pharmacy benefits and Children's Mercy Family Health Partners employs CVS/Caremark. WellPoint and CVS/Caremark use standard formulary management techniques and both operate under the same stipulations required for the fee-for-service pharmacy benefit. This includes requiring coverage of every drug included in the federal rebate program. The pharmacy benefit management programs also adhere to Kansas law which does not allow for any restrictions or "management" of mental health drugs (Kansas Statute 39-7, 121b). Costly medications used to treat hemophilia and acquired immunodeficiency syndrome (AIDS) are carved out of the managed care organization (MCO) capitation rate and are covered under the fee-for-service benefit.

The Medicaid pharmacy program provides administrative support for two additional programs, the AIDS Drug Assistance Program (ADAP) and MediKan. ADAP is jointly administered by KHPA and the Kansas Department of Health and Environment (KDHE). It is funded by a Health Resources and Services Administration (HRSA) grant and state general funds. The program provides coverage of HIV/AIDS treatment medications for program enrollees. These medications can be purchased at the Medicaid price and take advantage of federal rebates. MediKan is a public health insurance program financed entirely by the state of Kansas to provide coverage to citizens applying for federal disability. The MediKan pharmacy benefit package is more limited than Medicaid, but it includes most maintenance medications and other life-sustaining drugs. In the Medikan program, prescription drugs are reimbursed using Medicaid prices. However, no rebates are collected.

Program Management

Drug Utilization Review

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) required each state Medicaid Program to establish a Drug Utilization Review (DUR) program to provide education to physicians, mid-level practitioners and pharmacists. This education is provided through patient profile reviews, population-based interventions, academic detailing visits and a quarterly newsletter. KHPA contracts for academic detailing services, which include visits to approximately 60 providers each year. Visits in FY 2008 covered such topics as hypertension and diabetes. The DUR program is supervised by the DUR Board, which also determines appropriate criteria for medications on prior authorization (as referenced below). By law, the DUR Board is composed of four physicians, four pharmacists, and one Advanced Registered Nurse Practitioner or Physician's Assistant. The Kansas DUR Board convenes every other month in a public meeting.

Preferred Drug List

In addition to the guidance provided by the DUR board, the Kansas Medicaid Preferred Drug List

(PDL) Advisory Board provides direction for the implementation of a preferred drug list. Established in 2002 and authorized by K.S.A. 39-7, 121a, the PDL Advisory Board advises KHPA on the implementation of the Kansas PDL. The PDL is based on safety, effectiveness, and clinical outcome data in order to promote clinically appropriate utilization of pharmaceuticals for high quality, cost-effective treatment. The PDL Advisory Board is composed of practicing physicians and pharmacists who carefully evaluate evidence-based clinical information to determine the relative uniqueness of individual medications within a class of medications. If their evaluation of the evidence allows them to determine that agents in the drug class are therapeutically equivalent, KHPA ascertains which agent is most cost-effective for placement as a PDL preferred drug. The use of a PDL is a standard pharmacy management tool used in both the public and private sectors. However, per Kansas statute, medications used for mental health are excluded from inclusion on the Medicaid PDL. The PDL is established in Kansas regulations and is published on KHPA's website.

Prior Authorization

Prescription drugs that are non-preferred (not on the PDL) are still available to beneficiaries through a process known as prior authorization. Prior authorization (PA) is a tool used widely by public and private purchasers of health care, including KHPA. Reasons for the use of a non-preferred agent must be provided by the prescribing physician before the drug can be dispensed to a beneficiary. Reasons justifying the use of a non-preferred drug through prior authorization are established by the DUR Board. All PA criteria are reviewed and approved by the DUR Board, the KHPA Board and the Legislative Rules and Regulations Committee prior to implementation.

The current pharmacy prior authorization process is manual. All PA requests are submitted by mail or fax and nurses in the KHPA fiscal agent's PA unit compare submitted documentation against the PA criteria established by the DUR Advisory Board. Requests that fall outside of established criteria are reviewed by a nurse or pharmacist at KHPA. Nearly 6,000, approximately 23 per working day, PA requests are processed annually, making it a labor intensive process. Automated PA systems are available that allow programming of established criteria into a computer database. Using the power of information technology, pharmacy claims can then be screened against the beneficiary's prescription and medication history. Since pharmacies submit claims electronically, this process can be conducted electronically during the transaction at the pharmacy counter. Claims that do not meet criteria are intercepted by the automated PA system at the point of sale, which prompts the pharmacist to begin the manual PA process by contacting the prescriber, while claims that meet evidence-based guidelines are processed instantaneously.

Over the last several years, the Medicaid program has focused on prescription drug spending in several therapeutic classes with the highest expenditures and/or volume. Accordingly, most cardiovascular, gastrointestinal and anti-asthmatic therapeutic classes have been evaluated by the PDL Committee and subsequently placed on the PDL. Several medications in other therapeutic classes, such as the analgesics Actiq and Fentora and anti-infectives Zyvox and Synagis, have been placed on PA due to safety or cost concerns.

Analyses of drugs placed on the PDL or on PA reveal significant decreases in inappropriate use and significant savings to the state whether for an entire drug class or an individual drug. For example, the addition of PA requirements for Byetta an injectable medication for diabetes that is sometimes used off-label for weight loss since February 2007 has resulted in an expenditure decrease from $180,000 to $100,000 and a drop in paid claims from 990 to 515. This illustrates the ability of the PA process to reduce off-label drug use determined to be inappropriate by the Kansas DUR Board.

Provider Education: Behavioral Pharmacy Management System

The Behavioral Pharmacy Management System (BPMS), provided by Comprehensive NeuroScience (CNS) is utilized by KHPA and several other state Medicaid programs to enhance its physician education efforts. The program is a retrospective educational effort focused on mental health drugs. This means that the BPMS project tries to educate prescribers after they have already prescribed a mental health medication/s. BPMS utilizes quality indicators, which are based on clinical evidence and expert input, to identify potentially inappropriate drug therapy. Examples of quality indicators (QIs) utilized by Kansas Medicaid include the use of two or more atypical antipsychotics within 45 days and use of five or more psychotropic medications within a 90 day period.

Prescription claims are collected by Kansas Medicaid on a quarterly basis and submitted to CNS for analysis. Prescribers (physicians or mid-level practitioners) who are found to exceed a threshold of the QI are mailed letters which outline which quality indicators their prescribing behavior has triggered and provides clinical evidence to suggest alternate therapies. These mailings occur four to six months after the triggered prescriptions were written and filled. Prescribers are encouraged to re-evaluate the therapy that triggered the QI. Prescribers targeted by BPMS mailings may request a consultation from one of the program's clinical consultants. Both adult and child psychiatrists are used as consultants. In 2007, BPMS distributed more than 4,000 mailings. However, less than ten prescribers requested a consultation.

Despite consistent and detailed monitoring of prescribing patterns since the program's inception in 2005, data from the BPMS project are inclusive. Prevalence of prescribing behavior triggering some of the Kansas QIs does appear to have fallen over time. However, declines in potentially problematic prescribing behavior were observed for only a portion of the quality indicators. In addition, the timing of BPMS interventions and the observed decline in prescribing behavior is not consistent across quality indicators. Accordingly, it is unclear whether the BPMS project actually caused the changes in prescriber behavior.

A principle focus of the BPMS is a reduction in Kansas polypharmacy — the simultaneous use of multiple drugs in a single class, such as atypical antipsychotics. The BPMS educational efforts are designed to reduce polypharmacy, and to encourage the recommended, clinically appropriate use of a single drug within each class, known as monotherapy. Quarterly reports provided by the Comprehensive NeuroScience staff in support of BPMS projects do suggest a decrease in polyphar-

macy rates. However, the data also demonstrate a drop in the overall number of children in the Kansas Medicaid program using (atypical) antipsychotics, which is not a goal of the BPMS project. This inconsistency suggests that either: (1) other factors are behind the decline in antipsychotic use, such as the publication of new research raising safety concerns in this drug class, or (2) that the BPMS intervention itself was having the unintended effect of reducing overall use of antipsychotics. The questionable effectiveness of the Kansas BPMS and similar retrospective education efforts in other states strongly suggests the need to identify alternative tools to address the significant safety and cost concerns identified in the analysis below. Available studies of such retrospective educational efforts have shown only modest impact (Rascati, Okano and Burch, 1996; Grimshaw, Thomas and MacLennan, 2004; Jamtvedt, Young, Kristoffersen, O'Brien and Oxman, 2006; Lu, Ross-Degnan, Soumari and Pearson, 2008).

Changes in the Program in Fiscal Years 2007 and 2008

In calendar years 2007 and 2008, the pharmacy program implemented several program modifications as a result of new federal and state legislation.

Reimbursement

The 2005 Deficit Reduction Act (DRA) included a provision to change Medicaid prescription drug reimbursement. The change was motivated by long-standing concerns that Medicaid pays too much for pharmaceuticals. Specifically, the law focused on the mechanism used to determine Medicaid price indices, referred to as the Average Whole Price (AWP). The AWP is supposed to represent the manufacturers' average sale price at the wholesale level. These prices form the basis of payment for state Medicaid programs, including Kansas. Kansas reimburses pharmacies at 87% of AWP for brand name drugs and 73% for generically-available drugs. Successful state legal actions against manufacturers demonstrate that the AWP overstates costs, which has undermined the credibility of using AWP as the mechanism for Medicaid payment. The Kansas' Attorney General filed suit in 2008 against dozens of manufacturers to recover Medicaid overpayments caused by mis-reporting of manufacturers' average sale price at the wholesale level.

In the DRA, Congress sought to establish a new basis for Medicaid payments to pharmacies, establishing a statutorily-defined average manufacturer's price (AMP) for this purpose. National studies reveal that the AWP reimbursement exceeds pharmacy costs. Many stakeholders became concerned that the proposed change from AWP to the new AMP would reimburse pharmacists less than the actual cost to purchase pharmaceuticals. Kansas pharmacists and the pharmacy association voiced their concerns to KHPA and the legislature. As a result, the Kansas legislature imposed a temporary measure to protect existing levels of reimbursement and asked KHPA to survey pharmacies to find out their actual inventory costs.

In the Fall of 2007, KHPA surveyed pharmacies to determine their pharmaceutical acquisition costs. Staff analyzed the data to determine the potential impact of the pricing change on Kansas pharmacies. The survey confirmed that Kansas Medicaid often over-compensated pharmacies for

the cost of prescription drugs. A total of 50 surveys were returned which included data on 24,980 paid claims totaling $375,549. On average, pharmacies had a gross profit on ingredient costs of $6.76 per claim. (The largest potential "loss" on a pharmacy claim was $18.87 and the largest potential "gain" was $87.23.) Using the survey data, KHPA examined strategies to ensure that pharmacies would not incur a significant financial loss while providing services to Medicaid beneficiaries. The goal was to maintain the current level of pharmacy access.

Federal action delayed the pricing change implementation so no change in state policy was undertaken. Currently the change to average manufacturer's price (AMP) pricing is still being examined, and implementation is planned for October 2009. As a result of the Congressional delay, the policy issue of pharmacy overpayments has fallen back to the states. KPHA is currently exploring strategies to bring prices back in line with an appropriate standard.

Tamper-resistant Prescriptions

A new federal law (The U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007) requires that prescriptions written for Medicaid recipients be provided on tamper-resistant paper. This upcoming change in requirements was announced to Medicaid providers through bulletins distributed to all providers in September 2007, October 2007, February 2008 and September 2008, as well as via a posting on the KHPA website. Final implementation of the tamper-resistant requirements took place on October 1, 2008. Pharmacies are no longer allowed to fill prescriptions for Medicaid beneficiaries written on prescription pads that do not meet all federal requirements.

National Provider Identifier

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated the adoption of standard "unique identifiers" for health care providers and health plans. The goal was to improve the efficiency and effectiveness of the electronic transmission of health information. The Centers for Medicare & Medicaid Services (CMS) developed the National Provider Identifier (NPI) to accomplish this mandate. The original implementation date for universal use of the NPI was May 2007, but in April 2007 CMS delayed implementation to May 23, 2008. The Kansas legislature passed a law during the 2006 session requiring all pharmacy claims to be submitted with the prescribing providers' NPI. This law was also to become effective in May of 2007, however, it was delayed consistent with the federal change.

Per legislative directive, KHPA began requiring NPIs on all claims submitted as of April 1, 2008, approximately seven weeks prior to the federally required date. Between April 1 and May 23, KHPA's fiscal agent, EDS, proactively contacted pharmacies who were receiving a high number of claim denials due to NPI submission issues and provided education. KHPA plans to use the prescriber information related to the NPI, incorporating it into the agency's new data management system, the Data Analytic Interface. One application of this information is an analysis of mental health providers' prescribing patterns by type and specialty. The analysis successfully identified providers for about 90% of prescriptions using the NPI.

National Drug Code

Another requirement of the DRA was aimed at data collection related to drug rebates. The law instructed states to obtain the National Drug Code (NDC), quantity used, and other pieces of data for the purpose of collecting drug rebates, specifically for physician administered medications. This data was required if states wanted to ensure availability of Federal Financial Participation (FFP) funds for physician-administered medications. KHPA began collecting and submitting of utilization data in January 2007. As of January 1, 2008 claims submitted with NDCs that are not rebate eligible are denied. Due to the recent implementation of these policies, the physician-administered drug category was not included in this program review.

Service Utilization and Expenditures

Total spending on fee-for-service pharmacy benefits was $154 million in Fiscal Year (FY) 2007 and $159 million in FY 2008, an increase of 3% (see Table 1). This increase is historically low. In addition, there was a 22% decrease in the number of persons receiving fee-for-serve pharmacy. The reasons for the decrease in fee-for-service pharmacy are described after Table 1.

Table 1- Summary of Medicaid FFS Drug Spending

	FY 2006	FY 2007	FY 2008	% Change 2007-2008
Prescription Expenditures	$254,789,200	$153,716,025	$158,909,440	3%
Prescription Claims	3,698,904	2,027,451	1,911,461	-6%
Cost per Prescription	$68.88	$75.82	$83.14	10%
Persons Served	181,396	144,809	113,446	-22%
Claims per person	20.39	14.00	16.85	20%
Cost per person	$1,404.60	$1,061.51	$1,400.75	32%

Changes in the Population Served

Over the last three years there were several policy changes impacting the number of individuals served by the Medicaid fee-for-service pharmacy program. The most significant change occurred on January 1, 2006 when Congress expanded drug coverage to seniors through the new Medicare Part D program. Prior to that time, State Medicaid programs had been the primary source of payment for prescription drugs for low-income seniors eligible for both Medicaid and Medicare. Beginning in the middle of FY 2007, the number of dual-eligible persons served, claims and total expenditures all dropped significantly. As a result, total fee-for-service (FFS) drug costs dropped by more than $100 million in FY 2007, making it very difficult to compare summary totals from FY 2006 with FY 2007- 2008.

The second major population shift in the FFS prescription drug program occurred in January 2007 with the transition of approximately 50,000 beneficiaries from Medicaid fee-for-service to the

HealthWave managed care program. The beneficiaries who were transitioned into HealthWave were primarily low income young women and children in comparatively good health. This resulted in the FFS prescription drug program having a population with a higher proportion of ill, more costly beneficiaries.

Enactment of another federal policy through the Deficit Reduction Act (DRA), was the imposition of a federal requirement for proof of identity and citizenship in order to become, or remain, eligible for Medicaid services. The policy change was implemented by the Federal government on July 1, 2006. The quick implementation and the resulting backlog of paperwork produced a loss of 20,000 beneficiaries at the beginning of fiscal year 2007. This change primarily impacted low income young women and children. The Kansas legislature provided additional resources to the KHPA to hire temporary and some permanent, staff for the KHPA eligibility clearinghouse and the backlog was resolved by the beginning of January 2008

An additional population shift occurred in FY 2007 with the implementation of the presumptive medical disability (PMD) program. The PMD program screens those applying for federal disability and presumptively enrolls those most likely to become eligible into Medicaid. This program partially replaced the MediKan program, a state-only program that provides limited medical services, as well as general assistance cash benefits, to individuals with disabilities who are applying for federal disability. With the introduction of PMD benefits, many who would otherwise be covered by the state-only MediKan program are now enrolled in Medicaid.

Spending by Population Group

Examination of expenditures by specific populations from FY 2006 - 2008 in Table 2 below reveals diverse spending patterns because of the population shifts mentioned above. This has resulted in large declines in total spending in some groups.

Table 2 – Expenditures by Population: Detailed Eligibility Groups

	Enrollees			Expenditures			Per Member Per Month (PMPM) Expenditures		Percent change in PMPM 2007 to 2008
	FY 2006	FY 2007	FY 2008	FY 2006	FY 2007	FY 2008	FY 2007	FY 2008	
Aged and Disabled									
Supplemental Security Income (SSI) - Aged; 65 and over	5,740	2,361	2,324	$11,157,023	$2,408,535	$2,575,467	$85.01	$92.35	9%
SSI– Disabled; under age 65	28,794	24,705	26,226	$90,650,673	$76,207,830	$87,257,767	$257.06	$277.26	8%
Medically Needy – Aged (SSI)	17,827	10,152	9,886	$39,254,632	$1,341,316	$1,291,451	$11.01	$10.89	-1%
Medically Needy – Disabled (SSI)	12,501	9,014	9,890	$38,798,507	$13,503,873	$16,617,335	$124.84	$140.02	12%
HealthWave-eligible (beg. Jan 2007)									
Temporary Aid to Needy Families – Transitional Medical	3,593	3,368	1,304	$795,250	$602,334	$177,805	$14.90	$11.36	-24%
Low income families with children	35,454	28,040	14,983	$15,453,123	$9,354,246	$3,961,448	$27.80	$22.03	-21%
Pregnant Women under 150% of poverty	9,133	7,714	6,076	$1,590,444	$1,136,933	$706,356	$12.28	$9.69	-21%
Children under 1 below 150% of poverty	9,540	7,704	4,083	$2,470,476	$1,924,495	$941,414	$20.82	$19.21	-8%
Children 1 – 5 under 133% of poverty	17,549	14,763	8,823	$3,506,816	$3,293,540	$2,244,516	$18.59	$21.20	14%
Children 6 – 18 under 133% of poverty	20,844	17,190	10,060	$8,400,694	$6,407,919	$3,068,848	$31.06	$25.42	-18%
MediKan									
General Assistance/ MediKan	5,776	4,779	3,964	$9,708,975	$9,128,059	$7,596,511	$159.17	$159.70	0%
Other Populations									
Foster Care up to 21	5,853	6,246	6,494	$9,736,583	$9,600,467	$10,804,162	$128.09	$138.64	8%
Foster Care-Juvenile Justice Authority custody	1,515	1,307	1,255	$2,700,463	$2,269,902	$2,075,980	$144.73	$137.85	-5%
Children adopted with special needs	3,676	4,035	4,295	$5,316,746	$6,654,622	$7,557,216	$137.44	$146.63	7%

Note: Populations groups with fewer than 1,000 beneficiaries are not included in this analysis.

Expenditures for the Aged and Disabled populations, many of whom are also eligible for Medicare, declined significantly in FY 2007, the year after implementation of Medicare Part D, and resumed growth in FY 2008. Per-capita expenditures, expressed in terms of an average expenditure per member per month (PMPM), grew significantly in FY 2008 in all but the disabled elderly category.

Expenditures for the Temporary Assistance to Families (TAF) and Poverty Level Eligible (PLE) populations declined significantly in both FY 2007 and 2008. This decline reflects the mid-FY 2007 transfer of 50,000 beneficiaries to HealthWave (and out of fee-for-serve pharmacy). Average spending per person (the PMPM) declined in FY 2008, reflecting the short-term and retroactive na-

ture of enrollment in the category following the expansion of HealthWave.

The shift in population out of MediKan beginning in FY 2007 resulted in substantial decreases in volume of that group in both FY 2007 and FY 2008. This is because an increasing percentage of MediKan enrollees were screened for presumptive Medicaid enrollment, resulting in a corresponding increase in the Medicaid Social Security Income Under-65 population. Those individuals moved into Medicaid were those with the clearest indication of disability.

Other populations, which include foster children and children with special health care needs, were not affected by any of the major population shifts described above and show more consistent enrollment and expenditures over time.

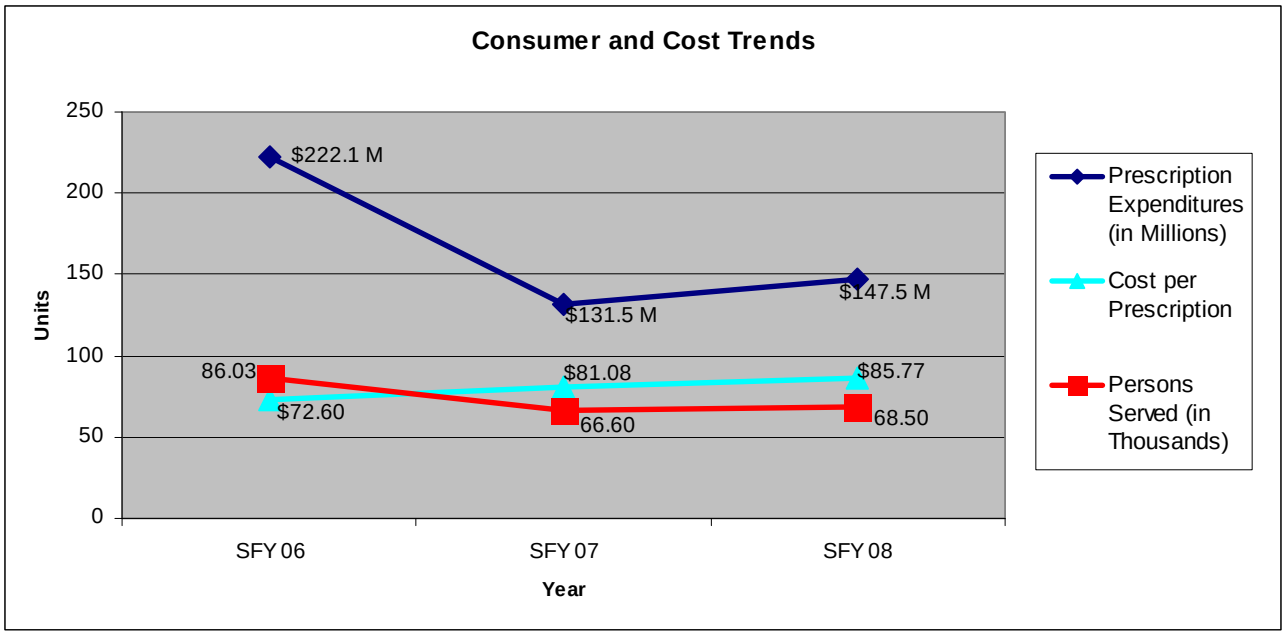
Focused Review of Fee-for-Service Population

In order to interpret the underlying trends in prescription drug spending and utilization, the previously described population shifts must be considered. The impact of Medicare Part D is addressed by focusing on changes that occurred post implementation. The tables and figures below include data from 2006, but the analysis focuses on FY 2007 and FY 2008. The impact of the transition of 50,000 beneficiaries from the fee-for-service (FFS) population to Healthwave (HW) is addressed by excluding this population from the remaining analysis. The resulting population expenditures and trends are re-stated in Table 3 and displayed in Figure 1 below. The non-HealthWave population presented in Table 3 represents more than 85% of Kansas Medicaid drug expenditures in FY 2007 and more than 92% in FY 2008.

Table 3 – Summary of FFS Drug Spending Excluding HealthWave Populations

	FY 2006	FY 2007	FY 2008	% Change 2007-2008
Prescription Expenditures	$222,131,005	$131,537,003	$147,455,386	12%
Prescription Claims	3,059,522	1,622,392	1,719,269	6%
Cost per Prescription	$72.60	$81.08	$85.77	6%
Persons Served	86,030	66,605	68,520	3%
Claims per person	35.56	24.36	25.09	3%
Cost per person	$2,582.02	$1,974.88	$2,152.01	9%

Figure 1



Results in Table 3 and Figure 1 indicate a 12% increase in non-HealthWave pharmacy costs in FY 2008, comprised of nearly equal increases in the total number of prescriptions (6%) and the costs per prescription (6%). Further analysis, also shown in Table 3, indicates that the increase in the number of prescriptions was due to both an increase in number of persons receiving pharmacy services (3%) and an increase in the average number of prescriptions dispensed per person (3%), resulting in a total pharmacy costs per person increase of 9%.

This trend in costs-per-prescription exceed consumer and medical price inflation rates, raising concern about the sustainability of Medicaid prescription drug spending. This analysis does not reveal whether the increase is due to both price inflation as well as shifts in utilization towards more costly drugs, or if the health needs of the population served shifted utilization towards more costly drug categories. Additional analyses below attempt to identify the primary sources of growth in the FFS prescription drug program.

Spending by Type of Medication

Figure 2, and the accompanying Table 4, illustrate trends in spending for the five most expensive drug classes. Psychotherapeutic medications comprise a notably higher percentage of expenditures than the next largest classes of medications combined, including central nervous system (CNS) drugs, anti-infectives, gastrointestinal drugs, and anti-asthmatic drugs. Table 4 also reveals that mental health drugs (psychotherapeutic drugs plus Central Nervous System drugs) comprise 42% of the growth in total non-HealthWave spending on prescription drugs in the Medicaid program in FY 2008.

The percentage of spending among these five categories has remained consistent over the three year period, with the exception of a drop in the percentage of spending attributable to gastrointestinal medications. Psychotherapeutic medications were the dominant drug class as measured by spending in each of the three years.

Figure 2

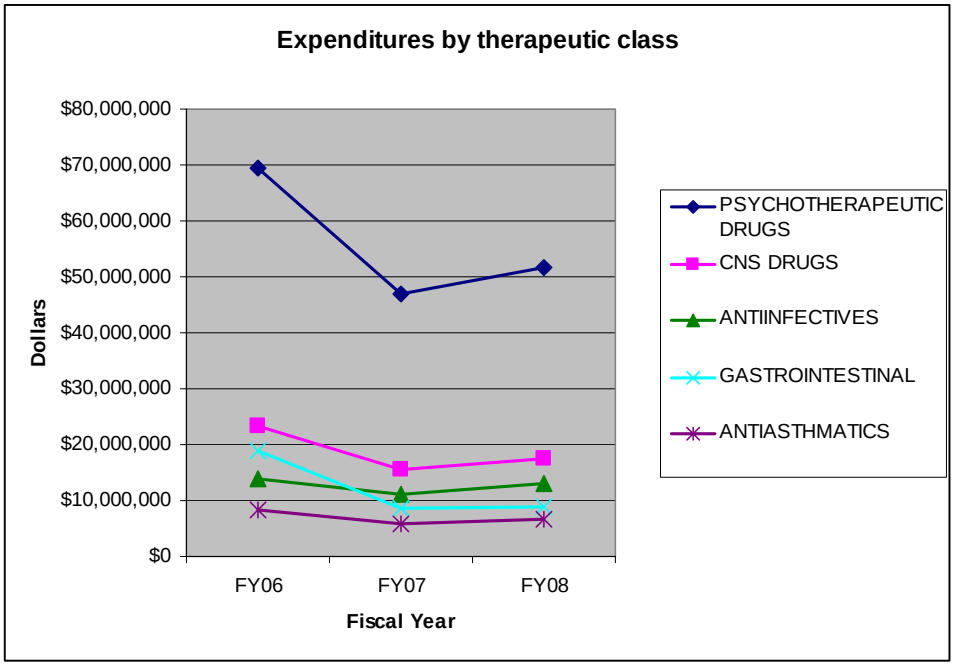


Table 4 – Drug Class Expenditure Trends

Therapeutic Drug Class	FY 2006	FY 2007	FY 2008	Increased Spending in Drug Class from 2007 to 2008	Percent of Total Increased Spending 2007-2008
Psychotherapeutic Drugs	$69,415,638	$46,887,670	$51,572,772	$4,685,102	29%
CNS Drugs	$23,425,960	$15,459,564	$17,490,353	$2,030,788	13%
Anti-infectives	$13,909,624	$11,139,003	$12,935,437	$1,796,434	11%
Gastrointestinal	$18,834,959	$8,601,693	$9,006,524	$404,831	3%
Anti-asthmatics	$8,290,453	$5,806,880	$6,710,627	$903,747	6%
All other drugs	$88,254,371	$43,642,193	$49,739,674	$6,097,480	38%
Total	**$222,131,005**	**$131,537,003**	**$147,455,386**	**$15,918,383**	**100%**

Figure 3 below examines the top five most utilized drug classes in FY 2008. Trends reveal patterns similar to those observed in expenditures, except that the rate of increase is slightly lower. The pattern suggests widespread increases in utilization by drug class.

KHPA data indicates that expenditure increases are due not only to an increased number of beneficiaries served but also to increased cost of the medications utilized. This could be due either to

an overall increase in drug cost or a shift in utilization from less costly medications to more costly. Further examination of this trend will occur in FY 2010.

Figure 3

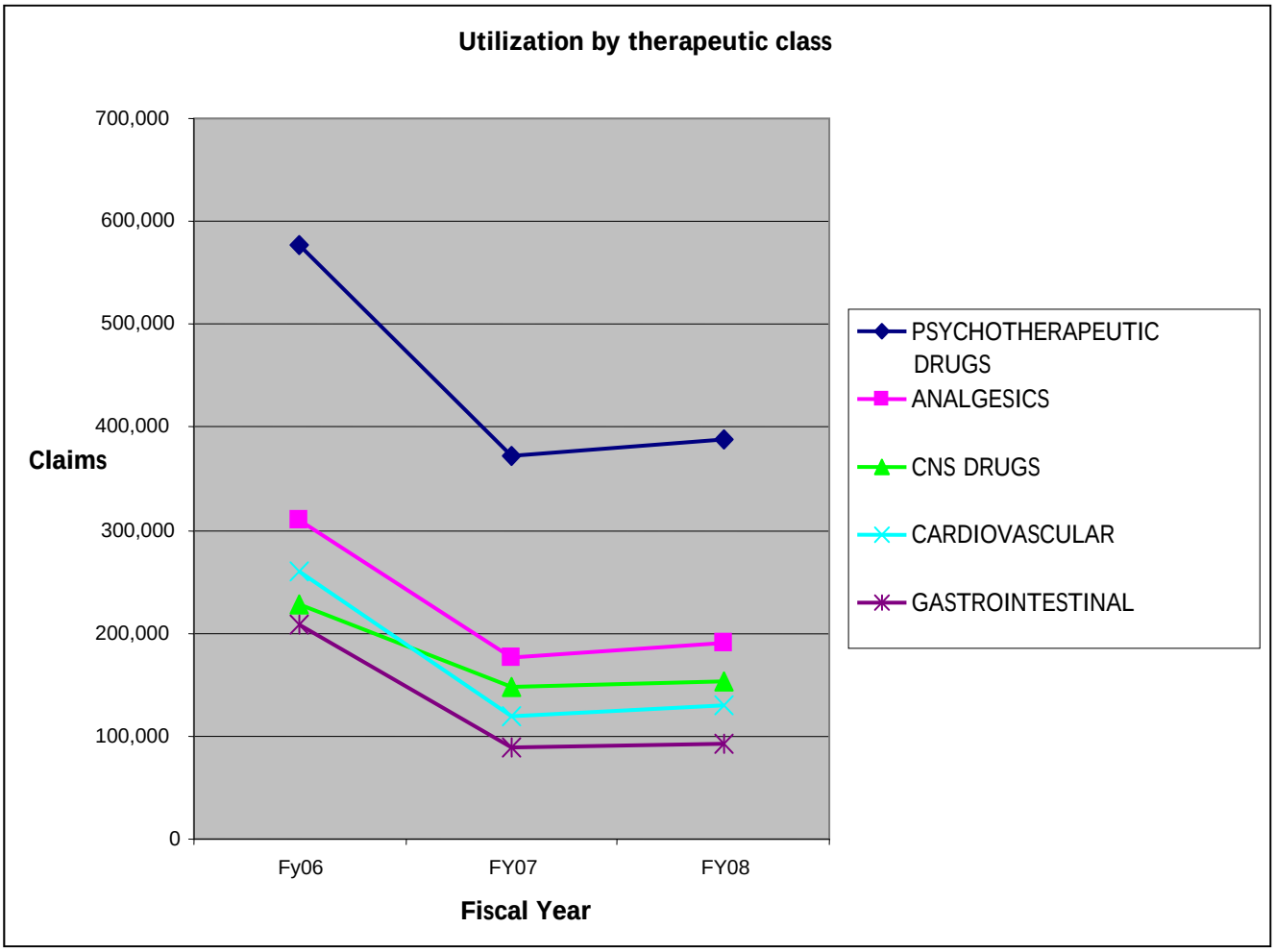
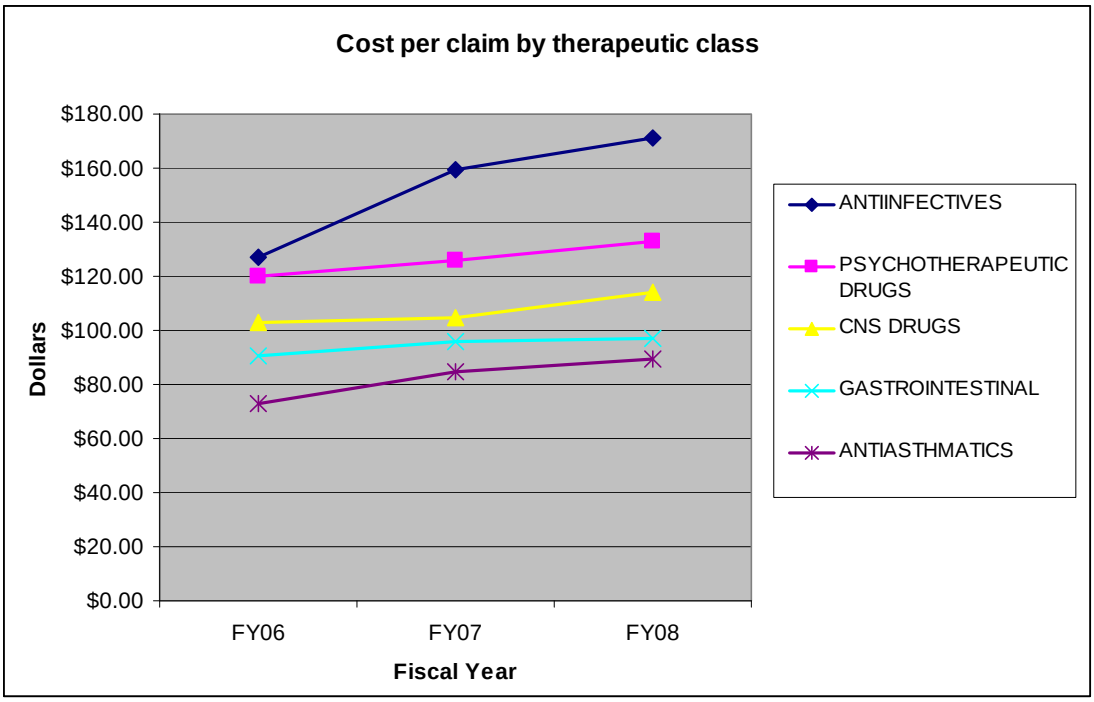


Figure 4 displays costs per prescription by therapeutic class, and indicates that costs rose consistently across each major class of drug prescribed, with the exception of a small rate of growth in gastrointestinal drugs. The growth rate reduction is attributed to recent program management activities. The Proton Pump Inhibitor class, which as class of drugs generally taken once daily to treat gastroesophageal reflux disease, has been on the PDL for several years. An additional PA edit added in February 2008 related to twice-daily dosing. Although clinically appropriate in some cases, twice-daily dosing is frequently used without sufficient evidence of necessity. Using criteria developed by the DUR board, unnecessary twice-daily use was reduced over 75 percent, with an estimated $1.2 million of associated savings. The restrictions are thought to have produced a nearly flat cost-per-prescription curve from FY 2007 to FY 2008 in the gastrointestinal class (see Figure 4).

Except for gastrointestinal drugs, spending in each class grew by the overall average, 12% (plus or minus 2%). The consistency between FY 2007 and FY 2008 in the growth of both drug spending and utilization across major drug classes suggests that changes in the health needs of the population

were not a factor. Possible explanations for increased costs-per prescription include broad increases in drug prices and/or a broad trend towards prescribing of more expensive drugs within each therapeutic class. The anti-infective drug class provides an example of increased cost per claim due to increased drug prices. The anti-infective cost per claim trend has been on a steady, fairly steep increase for the last decade as the prices of newly discovered antibiotics have been set at higher costs by their manufacturers. Due to factors such as antibiotic resistance, the relatively small utilization of antibiotics, generally used only for a short period of time while other medications such as those that treat high blood pressure are used continuously and stiff regulatory challenges imposed by the Federal Drug Administration (FDA), the profitability of producing new anti-infectives is limited and therefore prices of new antibiotics are set high to offset the expense of new drug discovery and approval.

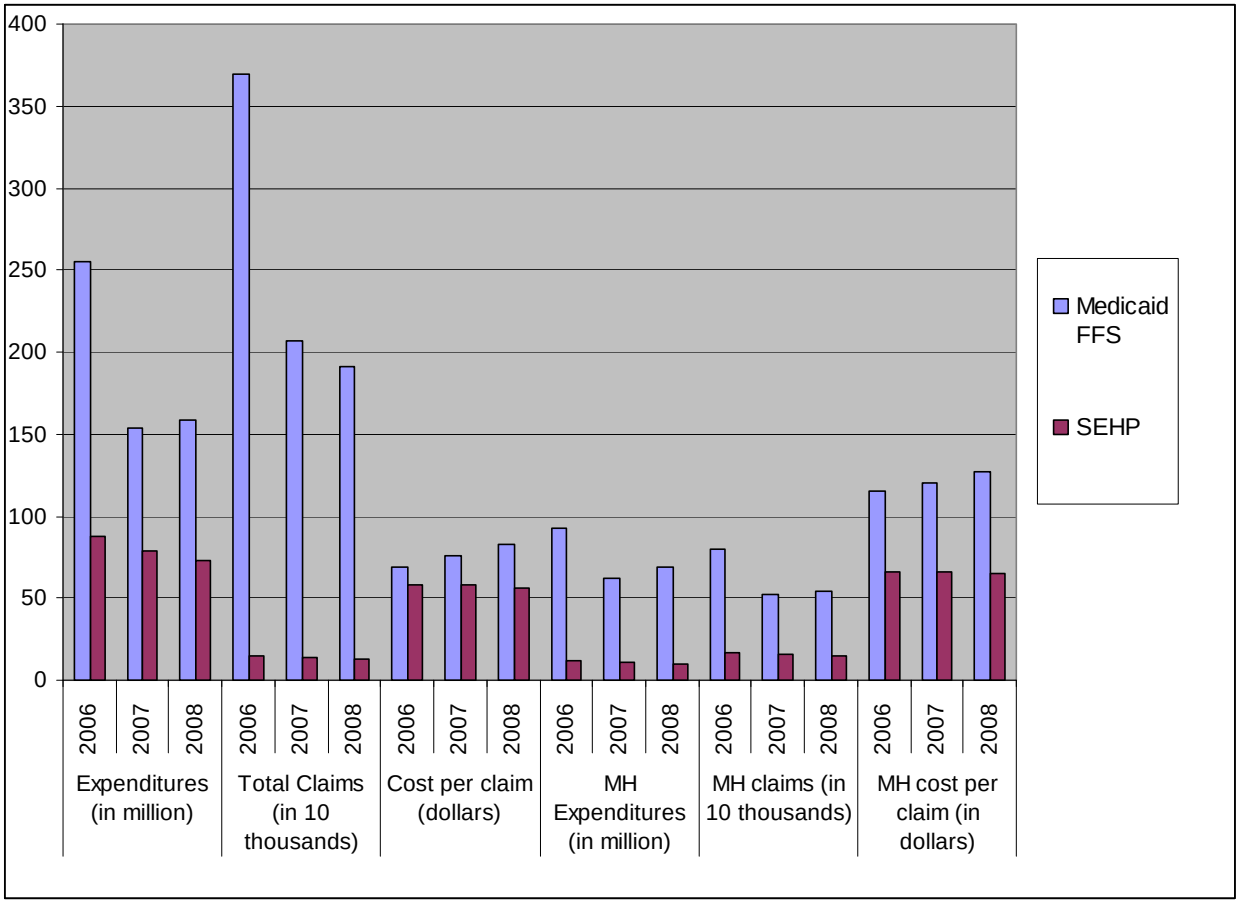
Figure 4



Factors potentially contributing to the increased costs per prescription can be examined through trend comparisons of the Medicaid program and the privately-insured population, whose drug purchases are conducted at more competitive market rates. Figure 5 below includes information for the past three years from the Medicaid FFS pharmacy program and the state employee health plan (SEHP). The SEHP provides health insurance to approximately 90,000 state and other public employees and their dependents across the state of Kansas. The SEHP contracts with private insurance companies who secure competitive market prices through networks of pharmacies. Pharmacy benefits in the SEHP are managed by a private pharmacy benefits management (PBM) firm, currently CVS Caremark. The comparison in Figure 5 presents trends in total expenditures, numbers of claims and costs per claim. The comparison includes data on all pharmacy costs — the left

-most columns in the figure - and information on expenditures for the most costly class of drugs in Medicaid, mental health (MH) drugs.

Figure 5
A Comparison of Pharmacy Trends in Medicaid and the State Employee Health Plan (SEHP)



Contrasting the Medicaid FFS pharmacy program and the SEHP reveals conflicting trends in total spending and costs per claim for both the full pharmacy program and for mental health (MH) drugs.

Costs increased for Medicaid in 2008, while overall use, spending, and costs per claim have remained flat or declined in the state employee health plan over the last three years. During this time, the pharmacy benefits management (PBM) contract was re-bid and the state negotiated a new, lower-cost contract price for prescription drugs on behalf of employees and their dependents. This comparison demonstrates that the cost trends affecting the Medicaid program are not driven by similar trends in the Kansas health care marketplace. Increasing costs per prescription in Medicaid appear to be driven by: (1) an increase in the Medicaid price index, an increase that does not appear to be in line with prices charged to Kansas state employees in the private marketplace, or (2) a Medicaid-specific trend towards the prescribing of more expensive drugs within each drug class. Both of these explanations may be correct. In order to help identify underlying

trends in the use and costs of prescription drugs, below we further examine the largest class of drugs prescribed in Medicaid, psychotherapeutic and central nervous system (CNS) drugs.

Mental Health Medications

KHPA data indicates that psychotherapeutic drugs account for both the largest expenditure and the greatest volume of prescription medications utilized by the Medicaid fee-for-service (FFS) population. They are also are responsible for the largest percentage of growth in the fee-for-serve pharmacy program. For the non-HealthWave population, FY 2008 expenditures for Psychotherapeutic and Central Nervous System Drugs (together frequently referred to as "mental health drugs") were $69 million; representing 47% of total spending on drugs. Atypical antipsychotics drugs are the largest unit of spending in this category at $37.5 million, accounting for over 50% of spending in this category. Addressing the costs and growth of mental health medications is a central issue in reducing the rate of growth in the Medicaid FFS prescription drug program.

This analysis has focused solely on cost and utilization of prescription drugs and has not included an examination of the impact of medications on beneficiary health or total medical spending. Mental health professionals and research literature emphasize significant advances in mental health treatments over the past decades, as psychotherapeutic medications have improved patient functioning and replaced more restrictive treatments. However, over the past few years, there have been increasing numbers of news reports of serious adverse events associated with the use of some mental health drugs. Use of antidepressants in adolescents received attention in 2004 when the FDA added a black box warning to antidepressants. The FDA cautioned prescribers and consumers that adolescents may be at higher risk of suicide while taking an antidepressant (FDA, 2004). An Archives of General Psychiatry study reports that those warnings resulted in a 9.6% decrease in antidepressant prescribing to children and adolescents – a sharp contrast to the previous trend of a 36% per year increase (Olfson, Marcus and Druss, 2008).

More recently, there has been a focus on atypical antipsychotics and potential health risks of psychotherapeutic drugs. Advances produced by this broad class of antipsychotic drugs include improved function, reduced inpatient hospitalization and reduced use of outpatient treatments for individuals with schizophrenia and other psychoses. Newer generation antipsychotics have demonstrated a reduction in some side-effects associated with older classes of antipsychotics. However, evidence of long-term safety and efficacy has lagged behind the increasingly common use of these medications. Recent studies have raised questions about the effectiveness of the newer antipsychotics over the older generations of antipsychotics (Sikich, Frazier and McClellan, 2008). There is also mounting safety concerns related to atypical antipsychotics. These drugs, frequently used off-label in children, have repeatedly been associated with significant weight gain as well as negative changes in cholesterol, insulin, and liver enzymes. New long-term studies of atypical antipsychotic use in adolescents and children are showing higher incidence of obesity, type II diabetes, cardiovascular conditions and cholesterol disorders among children prescribed an atypical antipsychotic versus a similar population of children not prescribed an atypical antipsychotic. In chil-

dren prescribed multiple psychotropic medications, the incidence is even greater (McIntyre and Jerrell, 2008).

Analysis of KHPA claims data reveals that 6,197 unique Medicaid fee-for-service beneficiaries under the age of 18 received a prescription for an atypical antipsychotic in FY 2008, which is 12% of the roughly 50,000 eligible beneficiaries under the age of 18. Aggregate use of atypical antipsychotics increased by 6% from FY 2007 to FY 2008 in children less than 18 years of age, with an alarming increase in 3-6 year olds, where there was a nearly 2.5 fold increase in beneficiaries prescribed an atypical antipsychotic. This increase does not reflect use among children enrolled in HealthWave managed care plans, and occurred despite a decline in the number of children participating in the fee-for-service program between FY 2007 and FY 2008.

Analysis of the entire Medicaid and SCHIP population – which includes roughly 160,000 beneficiaries enrolled in the HealthWave managed care system – shows that approximately 4% of beneficiaries under age 18 were prescribed a psychotherapeutic medication in SFY 2008. That includes 1.2% of beneficiaries under age 5, some less than 1 year old. Additionally, 0.5% of beneficiaries under age 5 were prescribed an atypical antipsychotic, even though no such drugs are FDA approved for use in children under age 5 for any indication.

Only one atypical antipsychotic, risperidone (Risperdal®), is FDA approved for use in young children and adolescents (ages 5-17). Approved pediatric indications for taking risperidone are schizophrenia, short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder, and irritability associated with autistic disorder. Aripiprazole (Abilify®) is also approved for treatment of schizophrenia in adolescents (ages 13-17). The National Institutes of Mental Health (NIMH) reports the incidence of schizophrenia in children to be 1 in 40,000 (0.0025%). An NIMH sponsored study reports that the incidence of bi-polar disorder in children is 1%, and the American Academy of Pediatrics reports the incidence of autism spectrum disorders to be 1 in 150 (0.06%) (Nicolson and Rapoport, 1999; Lewinsohn, Klein and Seely, 1995; American Academy of Pediatrics, 2008). It is expected that Medicaid would be the primary insurer of a greater proportion of children with these conditions than is found in the general population because severe mental disability can itself be a qualification for Medicaid services. However, the greater percentage (17% vs. 0.0025-1%) of children receiving atypical antipsychotics can not be explained by this population characteristic alone.

Additional analyses of KHPA fee-for-service data indicates that use of multiple psychotropic medications is common among children enrolled in Kansas Medicaid. From April to June of 2008, 214 children under 18 years of age were prescribed 5 or more different psychotropic medications within a 90 day period. In the same time period, 201 children under 18 years of age were prescribed two atypical antipsychotics simultaneously. Scientific evidence supporting the use of multiple psychotropic medications simultaneously is lacking. Reasons for these potentially inappropriate prescribing patterns have not been isolated.

These concerns have also received attention from the federal government. Starting in FY 2009, the US Health and Human Service (HHS) Office of Inspector General (OIG) will be placing a larger focus on prescribing patterns that do not follow approved uses. The FY 2009 OIG Work Plan lists "Medicaid payments for drugs not approved for use by children" as a category that will be reviewed. The Social Security Act states Medicaid will pay for outpatient drugs if prescribed for indications approved by the FDA or if supported by official drug compendia, such as DrugDex, as standard-of-care therapy. The OIG plans to review paid claims from 2007. The OIG does not specifically mention psychotherapeutic drugs, but high-profile news reports of off-label use of these drugs in other states suggest that this may be one motive for their new focus on off-label use.

Off-label use and potential misprescribing of atypical anti-psychotics among children has garnered increasing attention in the press, in the scientific literature and among medical experts. An external panel of experts convened to review the oversight practices of the FDA recently chastised the agency for acting too slowly to improve prescribing patterns for these drugs among children. The New York Times reported that

> "The committee's concerns are part of a growing chorus of complaints about the increasing use of antipsychotic medicines in children and teenagers. Prescription rates for the drugs have increased more than fivefold for children in the past decade and a half, and doctors now use the drugs to settle outbursts and aggression in children with a wide variety of diagnoses, even though children are especially susceptible to their side effects." (Harris, 2008)

Safety concerns are reinforced by recent reports of the marginal value of the newer anti-psychotics. A large-scale meta-analysis of 150 scientific (double-blind) trials conducted by a team of experts working on a grant from the National Institutes of Mental Health concluded that the newer generation of anti-psychotics as a group carried no clear advantage in effectiveness in the treatment of schizophrenia, were associated with significant new risks, and in comparison to most of the older anti-psychotic drugs, did not improve on the pattern of side effects observed in the older drugs (Leucht, 2008).

Concerns have been raised in a number of states about the high rate of use of mental health medications among children in the foster care system. Children in foster care are eligible for Medicaid services in all 50 states. In FY 2008, over half of children in the Kansas foster care system (52%) were on mental health medications. Overall use has fallen from 71% in 2004, when the FDA's black-box warning was placed on antidepressants for children. Among children in the state's foster care system, 20% are on an atypical antipsychotic medication, and 20% are on an antidepressant with some children on both. The use of anti-psychotic medications has fallen slightly from a high of 24% of foster care children in FY 2005, but payments for antipsychotics have increased from $2 million in FY 2002 to $4.2 million in FY 2004 and $5.5 million in FY 2008. This increase coincides with an increased use of the newer generation of atypical anti-psychotics.

One factor that may be contributing to the potential misuse of psychotherapeutic medications in Kansas is the relatively small and unevenly distributed supply of psychiatrists and other trained mental health professionals across the state. The Medicaid population is served by Kansas Health Solution (KHS), a unified network of mental health professionals organized under a managed care entity owned and operated by the state's community mental health centers. Mapping KHS's network of mental health providers to KHPA Medicaid fee-for-service (FFS) beneficiary demographic information reveals that there is one mental health provider for each 175 FFS beneficiaries. That number drops significantly when examining mental health providers that have prescriptive authority. There is only one prescriber for approximately 2,000 FFS beneficiaries.

When coverage is broken down by county, 43 Kansas counties (41%) have no mental health providers, and in Pratt, Jackson, Wilson and Osage counties, the ratio of beneficiaries to providers is greater than 1000 to one. However, Community Mental Health Centers (CMHCs) in Kansas are by statue required to serve all Kansans, regardless of ability to pay for services and CMHC catchment areas include all 105 Kansas counties. Sixty-five Kansas counties (62%) have no mental health professionals that can prescribe medication, and an additional 11 counties have a prescriber to beneficiary ratio of greater than 1000 to one. Figures 6 and 7 are graphical representations of the breakdown of mental health professionals to beneficiaries by county. Figure 6 is the ratio of mental health providers (i.e. psychiatrists, psychologists, psychiatric nurse practitioners, social workers, counselors, marriage, and family therapists) to each FFS beneficiary. Figure 7 is the ratio of mental health providers who can prescribe medications (i.e. psychiatrists, psychiatric nurse practitioners, and psychiatric physician assistants) to each FFS beneficiary.

Figure 6

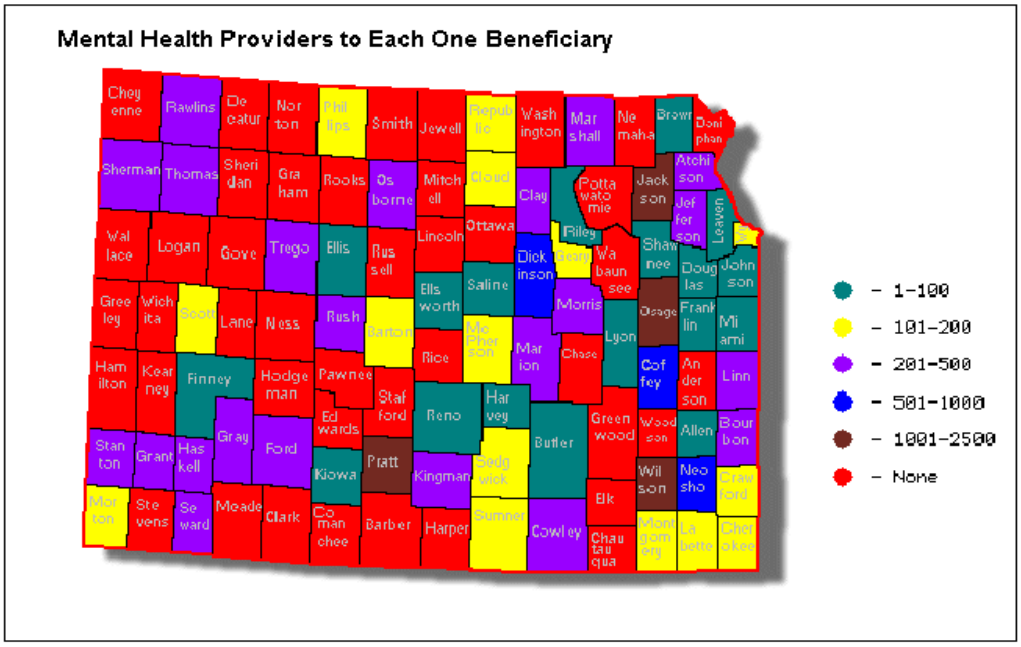
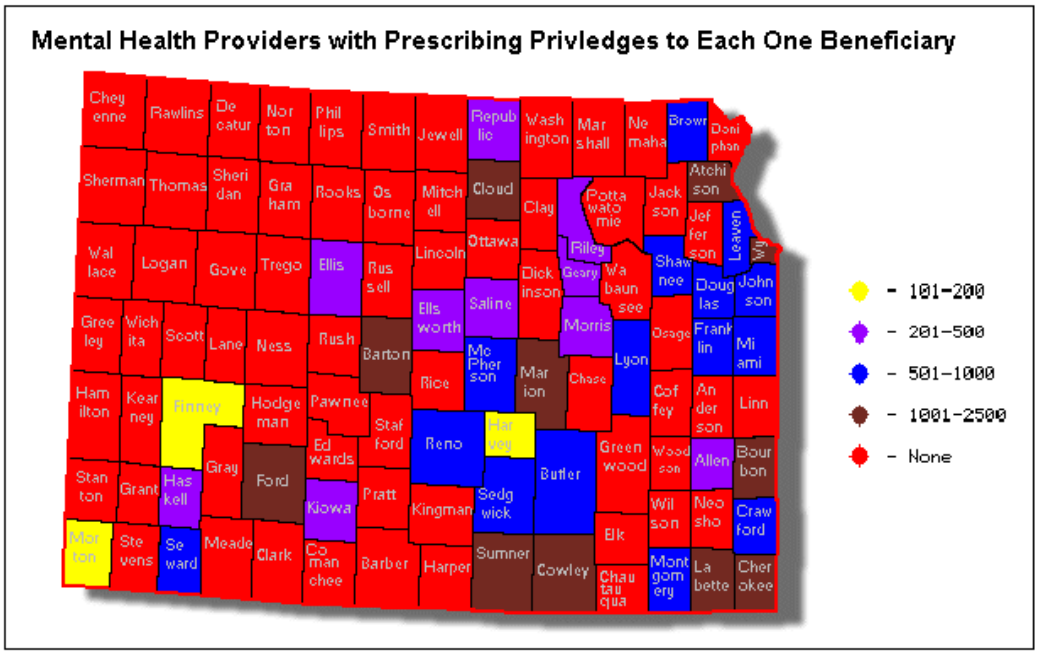


Figure 7



With the uneven statewide distribution of specifically trained mental health prescribers, anecdotal and claims information suggests that families seek services from primary care physicians, advanced registered nurse practitioners and physician assistants for treatment of mental health conditions. Statewide, most prescriptions for psychotherapeutic medications for Medicaid fee-for-service beneficiaries are written by primary care providers, not mental health professionals. An analysis of Medicaid FFS drug claims in FY 2008 using the newly required NPIs to identify prescribers revealed that just over one-third (37%) of mental health prescriptions were written by a psychiatrist, while a combination of general practitioners (35%), nurse practitioners (14%), and physician assistants (3%) wrote half.

A significant concern, given the increasing safety issues raised for several mental health drugs, is how to assure high-quality mental health treatment statewide. As mentioned previously, KHPA has engaged in physician education through the BPMS program, but with unknown results. Another strategy would be to apply electronic mechanisms to ensure that prescriptions dispensed for Medicaid beneficiaries are consistent with quality guidelines established by mental health professionals.

Conclusions

This review of the Medicaid FFS pharmacy program has documented substantial changes over the past three years, has identified an unsustainable pattern of increases in utilization and spending and has raised a number of safety concerns in the use of mental health medications, especially among children. Key findings include:

- Expenditures on fee-for-service pharmacy benefits totaled $154 million in FY 2007. This total increased to $159 million in FY 2008, an increase of 3.4% despite a 22% decrease in the number of persons served.
- Costs per prescription rose 6% in FY 2008, a rate that significantly exceeds consumer and medical inflation. In addition, a recent comparison of reimbursements and costs at the pharmacy level suggests that Medicaid over-compensates pharmacies, on average, for the ingredient costs of Medicaid drugs.
- Increasing costs per prescription in Medicaid appear to be driven by either an increase in the Medicaid price index, an increase that does not appear to be in line with prices charged to Kansas state employees in the private marketplace, or a Medicaid-specific trend towards the prescribing of more expensive drugs within each drug class.
- Over 40 percent of the growth in Medicaid prescription drug spending in FY 2008 is attributable to increases in the cost-per-prescription and in the total utilization of mental health drugs, as illustrated in Figure 3 and Figure 4.
- In the last few years, an increasing number of scientific studies have identified serious adverse events associated with use of mental health drugs.
    - Atypical antipsychotics, frequently used off-label in children, have repeatedly been associated with significant weight gain, as well as negative changes in cholesterol, insulin, and liver enzymes.
    - New studies with more long-term data of atypical antipsychotic use in adolescents and children are showing higher incidence of obesity, type II diabetes, cardiovascular conditions, and cholesterol disorders among children.
    - Federal panels of experts have questioned whether existing labels provide sufficient warning of these safety concerns.
    - In Kansas, two thirds (63%) of mental health drugs are prescribed by general practitioners and other non-psychiatrists, raising questions as to whether beneficiaries have full access to best practices and the current body of knowledge regarding the safety and effectiveness of mental health medications.

These findings indicate the need for increased oversight and active management of the Medicaid pharmacy program, including more aggressive pursuit of market-based price discounts and focused attention on the management of mental health medications.

Given the emerging data regarding use of mental health medications in children, KHPA is especially concerned about the safety of young Kansans. However, at this time safety precautions commonly employed by insurance plans and other state Medicaid agencies are prohibited by Kansas Statute 39-7, 121b which states that:

> *"no requirements for prior authorization or other restrictions on medications used to treat mental illnesses such as schizophrenia, depression or bipolar disorder may be imposed on Medicaid recipients*."

This statute prevents KHPA from employing pharmacy management tools that could identify excessively high doses or the combination of multiple drugs, prevent the inappropriate dispensation of medications to young children and alert pharmacists and prescribers that the therapy prescribed may be inappropriate. Given the scale of potential misuse of mental health medications identified in this review, the statutory restriction on the direct management of those medications requires examination. Current management tools have been ineffective and more direct measures merit review.

Direct, point-of-sale management is the standard approach in both the public and private marketplace to address safety issues and introduce market forces in drug pricing.

- Pharmacy edits are commonly used to place limits on the number or combination of drugs dispensed to prevent misuse, fraud, and abuse.
- Prior authorization (PA) is the standard tool used by Pharmacy Benefit Management firms and Medicaid programs to improve safety and ensure appropriate dispensing of drugs that are commonly misused.
- Prior authorization is also the most effective tool in public insurance programs (where limits on cost-sharing prevent the use of financial incentives) to direct beneficiaries towards less expensive drugs that are considered by mental health experts to be therapeutically equivalent, or even preferable to more expensive alternatives.

Concerns over the potential misuse of such direct management tools for prescription drugs led to the exemption of mental health drugs when Kansas first authorized the use of these tools in 2002. Kansas Statute 39-7, 121a provides for the establishment of a preferred drug list in the Medicaid program, and establishes a PDL committee to advise the Medicaid program in the determination of appropriate edits and therapeutic equivalency. Based on the PDL committee's recommendations, the federally mandated DUR committee then uses these recommendations to determine prior authorization criteria for certain drugs. The DUR committee is comprised of physicians, pharmacists and an advance practice nurse practitioner and is currently chaired by a practicing psychiatrist. The PDL committee's recommendations also facilitate competitive pricing within classes of drugs by confirming that the drugs are indeed therapeutically equivalent. KHPA staff use the PDL committee's recommendations to negotiate with drug makers within an established therapeutic class and, based on that competition, place the least cost-effective drugs on prior authorization. In

this way, the clinical decisions regarding medical edits and therapeutic equivalence are made by experts on the PDL committee before the specific economic impact is known. The criteria used for prior authorization is approved by the DUR committee based on the medical judgment of the PDL committee and their own medical evaluation of the evidence. The PDL and DUR committees' recommendations for the establishment of therapeutic equivalence and prior authorization criteria is then reviewed and approved by both the KHPA Board and the Legislative Rules and Regulations Committee before being recorded in the Kansas Regulation 129-5-1 and implemented.

Despite the multiple protections and transparency offered by this established process, if prior authorization and a PDL are to be applied to classes of mental health drugs as well, there are concerns that the expertise and clinical approaches required to treat mental illnesses will not be addressed. Theses concerns led to the establishment by KHPA of a new Mental Health Prescription Drug Advisory committee. This committee is to be used foremost to advise KHPA and the DUR committee in establishing a PDL for the MediKan program.

The motivation behind the establishment of a new advisory committee is two-fold: to recognize the unique expertise and clinical strategies prevalent in the treatment of mental illness, and to establish a mechanism to extend mental health professional expertise to all Medicaid beneficiaries. With limited access to mental health professionals, guidance from a panel of experts, using the tools available with the removal of the statutory restrictions established in 2002, will help assure that patients with mental health conditions are treated according to best practice guidelines.

Another concern in the application of standard tools of pharmaceutical management to the dispensing of mental health medications is the potential delays for critical medications at the point of sale. Current methods for obtaining a prior authorization entail the pharmacist notifying the prescriber of the prior authorization requirement, the prescriber completing the necessary documentation, EDS staff reviewing of submitted documentation and, finally, notifying of the pharmacy/prescriber of the determination. Delays caused by these administrative hurdles could, in some cases, cause a several day lag between the presentation of the prescription at the pharmacy and the actual dispensation of the medication. However, federal Medicaid rules protect beneficiaries from some such delays, allowing the dispensation of a 72-hour supply of drugs when the pharmacy is unable to confirm or reject the request for a prior authorization. Even with these protections, delays could disrupt treatment and undermine the motivation for direct management.

To address concerns about timely dispensing of mental health and other medications, many insurers and some states employ a system of electronic guidelines that are applied at the point of sale to ensure compliance with dispensing criteria established by the PDL and DUR committees. These systems, referred to as "electronic prior authorization," enable real-time management at the point of sale, thus providing a potential technologic solution to concerns over delays, and offering the promise of a reduction in administrative costs for pharmacies already burdened with manual prior authorizations for non-mental health drugs reimbursed through Medicaid.

Recommendations

To address the concerns over the unsustainable rise in the use and cost of Medicaid FFS drugs, KHPA recommends the following:

1. *Update drug pricing formulas and reimbursement limits for Medicaid FFS drugs.*

This program review has identified costs-per-prescription as a key contributor to the 12% increase in pharmacy costs in FY 2008. Based on recent data, Kansas Medicaid often over compensates pharmacies for the costs of prescription drugs and a comparison to trends in the private marketplace in Kansas indicates that per-prescription costs are rising much faster in Medicaid. Mechanisms to be explored and addressed in FY 2009 include a review of the maximum allowable cost (MAC) established by KHPA to limit reimbursement for generically-available drugs to observed market prices.

2. *Implement an automated prior authorization (PA) system.*

Approximately 80% of submitted prior authorization requests are approved, many of which could be achieved through point of sale screening against a guideline database by an automated PA system. Time saved by clinical pharmacists and nurses could allow for expansion of the current PDL, and results in greater savings and efficiency within the Medicaid program, without an increased administrative burden. Currently, all PA requests are submitted on paper, reviewed by a nurse and/or pharmacist and notification provided to the pharmacy via phone if the PA is approved. With the implementation of an automated PA system, prescriptions will be screened at the point of sale against prescription and medical claims history to quickly determine if the claim is appropriate. Streamlining of the PA process will allow for:

- Nearly instantaneous approval of appropriate therapies based on guidelines.
- Enhanced real-time application of drug use protocols to improve patient access and safety.
- Increased efficiency of the PA unit in reviewing requests.
- Reduced burden of completing the documentation required for PAs on pharmacists and physicians.
- Savings through the expanded use of PA and PDL, which facilitates more intensive utilization management and targeted purchasing.

3. *Remove the statutory limitation on management of mental health prescriptions*

Current language prohibits management of mental health prescriptions at the point of sale, which limits KHPA's ability to protect beneficiaries and to take advantage of market pricing, where appropriate. Concerns about direct management of mental health management, raised in 2002,

when the statutory limits were put in place, can be addressed by protecting beneficiaries with established drug regimens, by convening a group of experts to guide the management of mental health drugs, and by ensuring timely access to mental health drugs at the pharmacy. In conjunction with the other recommendations in this review, KHPA is recommending a new and transparent approach to the administration of the pharmacy program that brings mental health expertise to each beneficiary across the state, but these tools will not be effective without a change in the state law which bars their application.

4. Establish a Mental Health Prescription Drug Advisory Committee.

KHPA firmly believes that the treatment of mental illness is vitally important, allowing the mentally ill to lead more mentally and physically healthy, socially integrated, and productive lives. Recent developments in medical research have suggested that some mental health medications are over-used, particularly in young children and adolescents, sometimes with grave adverse health effects. Currently the only mechanism available to Medicaid designed to influence prescribing patterns for mental health drugs is the BPMS program. However, the BPMS program is retrospective, educating prescribers often months after the medication has been provided to the beneficiary. Moreover, the impact of the program is inconclusive at best. More direct mechanisms for changing physician prescribing practices and addressing current deviations from the QI targets for specific beneficiaries are prohibited by the Kansas statute restricting direct management of mental health drugs. These facts, combined the concern that current expenditure trends on mental health drugs is growing at an unsustainable rate, has led KHPA to the proposition of developing a mental health PDL. Guidance from mental health experts about appropriate utilization of mental health drugs will allow for improved treatment of mentally ill Kansans, as well as provide significant reductions in expenditures of tax payer dollars on therapy that is not appropriate. KHPA recommends:

a. Convening a Mental Health Prescription Drug Advisory Board that is composed of experts in the mental health field such as Psychiatrists, Psychologists, Psychiatric Pharmacists, and other stakeholders, including consumers, who have extensive experience in understanding the health care needs of the mentally ill and understand the complex picture of a mentally ill individual.
b. The Mental Health Prescription Drug Advisory Committee would work to ensure the safe use of medications across the state. Serious concerns about the safety and efficacy of atypical antipsychotic use in children requires a more direct approach to management of mental health drugs. Many Kansans receive prescriptions for mental health medications from primary care providers and mid-level practitioners. The Advisory Committee would work to identify new clinical edits to address the most serious safety issues, bringing mental health expertise directly to all beneficiaries across the state through point-of-sale management.
c. The advisory board will have the sole ability to determine which medications should be placed on the preferred drug list, which should require PA (if any), and

what limits should be incorporated into the billing system in order to flag usage that may be inappropriate.

d. Beneficiaries would maintain the ability to access all medically necessary medications; only inappropriate therapy would be limited through the application of pharmacy edits and PAs.
e. Beneficiaries already stable on a medication regimen would be grandfathered into the new PDL, ensuring that no disruption of therapy occurs.
f. Access to mental health professionals, particularly those who can prescribe medications, is limited in some parts of Kansas. Guidance from the advisory panel of experts will help assure that patients are treated according to best practice guidelines in all areas of Kansas, including the rural and underserved.

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