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Behavioral Pharmacy Benefit Management: Case Studies

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Introduction: Behavioral Health Pharmacy Issues

Pharmaceutical costs have increased significantly in both the general and the behavioral health care systems in recent years. This paper reviews several of the most promising methods for managing behavioral pharmacy practices and costs while seeking to continue to maintain open access to these drugs. It describes the current situation, defines the practice, outlines a number of specific case studies, offers information about related initiatives, and concludes with some comments about likely trends in the field.

Increases in the Cost and the Benefit of Pharmaceuticals

Triggered by ever increasing demand, as well as rising prices, pharmaceutical costs have been rising rapidly across the entire health care system. Prescription drug costs account for approximately 10 percent of total spending on health care in the U.S.¹ Medicaid spending on outpatient drugs increased by 18.1 percent per year from 1997 to 2000, even as overall healthcare spending increased only 7.7 percent per year during the same time period². Psychotropic and central nervous system drugs account for more than 24 percent of the \$250 billion in pharmaceutical companies' total annual sales³ and represent some of the fastest rising costs in the Medicaid program. While these drugs have helped to revolutionize the treatment of mental illness over the last three decades, state Medicaid officials, health maintenance organizations, and employers have had to seek ways to control their rapidly rising costs.

There are psychotropic drugs for each of the major mental health conditions, including antidepressants and antipsychotics, as well as treatments for bi-polar disorder, ADHD, and other conditions. For every one of these conditions, new groups of drugs have been and are being identified. New drugs for addictive disorders, such as buprenorphine, have extraordinary promise, yet also hold the potential for increased costs in the short term. The new medications have significantly higher costs, but are believed to be more effective and/or to minimize side effects for the individuals being treated.

Virtually everyone is now aware of the extraordinary impact of the new class of antidepressants known as Selective Serotonin Re-uptake Inhibitors (SSRIs); included in this group are brand name drugs Prozac, Zoloft, and Paxil, among others. These drugs are more effective than previous treatments, while they impose fewer side effects. Their impact on the individuals who take them has therefore been remarkable, and they have had a correspondingly impressive impact on the mental health system. However, because the costs of these drugs are significantly greater than the costs of the older drugs, they also have had an impact on expenditures. As the patent for Prozac has expired, Fluoxetine's costs have declined markedly and generic versions are available. However, there are few studies that

¹ Heffler S., et al. "Health Spending Projections for 2001-2011: The Latest Outlook." *Health Affairs*, March/April 2002.

² Bruen B. *States Strive to Limit Medicaid Expenditures for Prescribed Drugs*. Kaiser Commission on Medicaid and the Uninsured, February 2002.

³ Pharmaceutical Research and Manufacturers of America, Annual Report, 1998.

help physicians understand the differential benefits of this drug compared with other antidepressants.

Similarly, the new group of atypical antipsychotics has dramatically lessened the negative side effects of drug treatment for psychosis while, according to many studies, improving efficacy.⁴ However the cost of the new drugs is significantly higher than the cost of earlier ones. For example, treatment of schizophrenia with Haldol, one of the earlier, “typical” antipsychotic drugs, is approximately \$.06 per day, while the daily cost of Zyprexa, one of the “atypicals,” is \$8.⁵ Fueling the controversy over costs and benefits, a new study from the Veterans Administration indicates that the clinical efficacy of Haldol, when it is coupled with an anti-convulsant, is identical to that of Zyprexa.⁶ This study, however, was limited in scope and had difficulties in recruiting subjects. Furthermore, one of the significant differences between the two drugs lay in their impact on clarity of thinking. Although the difference was deemed insubstantial by the researcher, it might be critically important to the consumer. One key question thus becomes, “How should public policy makers evaluate the trade-off between the increased cost of the newer drugs and their benefit?”

These new drugs have significantly altered the delivery of mental health services, reduced stigma, and may have helped, along with managed care, to keep costs down for much of the 1990s. Mark and Coffey have shown that between 1992 and 1999, spending on mental health care dropped from 7.2 percent to 5.1 percent of all private health insurance spending. As these authors state, “new medications such as selective serotonin reuptake inhibitors (SSRIs) and atypical antipsychotic medication have reduced the side effects associated with psychotropic treatment of depression and schizophrenia, allowing for improved compliance and perhaps a reduced need for inpatient care.”⁷ The challenge facing the field is one of controlling the rapid cost growth in behavioral pharmacy benefits while maintaining access to medications that have controlled the costs of services and reduced medication side effects.

Pharmacy Benefit Management

Pharmacy Benefit Management (PBM) refers to a variety of actions taken by or on behalf of a health care purchaser to more effectively control drug costs and improve quality. PBMs often include “the use of prescription drug formularies (lists of drugs available for coverage by the plan), patient cost sharing, case management of high cost beneficiaries and drug utilization management programs intended to influence which drugs patients use and how long they use them.”⁸ Since this paper is primarily focused on Medicaid, patient cost sharing will not be

⁴ Sheitman B., Lee H., Strauss R., and Lieberman J.A. “The Evaluation and Treatment of First-Episode Psychosis.” *Schizophrenia Bulletin*, 1997; 23(4):653-661.

⁵ Callahan P. “Lilly's Zyprexa Acted Similarly To Cheaper Drug,” *The Wall Street Journal*, Dec 2, 2003.

⁶ Rosenheck R., et al. “Effectiveness and Cost of Olanzapine and Haloperidol in the Treatment of Schizophrenia: A Randomized Controlled Trial.” *The Journal of the American Medical Association*, November 26, 2003; 290: 2693-2702.

⁷ Mark T. and Coffey R. “What Drove Private Health Insurance Spending on Mental Health and Substance Abuse Care, 1992 -1999?” *Health Affairs*, January/February, 2003.

⁸ Huskamp H. and Keating N. “*The New Medicare Drug Benefit: Potential Effects of Pharmacy Management Tools on Access to Medications.*” The Henry J Kaiser Family Foundation, July 2004.

discussed though it may become increasingly relevant. There are some examples of cost sharing now being used in Medicaid and the new Medicare Prescription Drug, Improvement, and Modernization Act of 2003 explicitly includes co-insurance provisions for the pharmacy benefit.

Across the country, there have been a variety of attempts to control pharmacy benefit costs in the overall health care market. PBM firms have sought to curtail cost growth using a number of methods that, in one way or another, restrict access. These include formulary management, tiered pricing, co-payments, prescription limits, and utilization review.⁹ However, a growing concern, particularly in the public sector, about whether the quality of care suffers¹⁰ under programs that seek to restrict access has given rise to new approaches. Thus, a number of the more innovative Medicaid pharmacy management approaches focus not just on cost control but also on quality.¹¹

Many of the PBM activities have been in use within Medicaid since the late-1980s and certain requirements were put into law as a part of the Omnibus Budget Reconciliation Act of 1990. Initially, Medicaid focused on retrospective utilization review. Increasingly, states also have adopted prospective pharmacy utilization management approaches, mostly using point of sale devices for pharmacies, though with mixed results.¹² It is important to keep in mind that these efforts seek to reduce spending or control cost growth, but they also focus on quality, patient safety and the use of evidence-based prescribing practices. Polypharmacy, multiple prescribing, and contraindicated dosing are several examples of utilization related reviews that have these multiple goals in mind.

Managing public sector behavioral pharmacy benefits often involves a more complex set of issues than managing pharmaceutical benefits for other conditions. This is due to several factors, including some previously noted:

- The severity of major mental illness.
- New drugs have been brought to the market over the last decade that are extremely costly and yet have dramatically reduced side effects.
- The outcomes of drug and other behavioral treatments are often less clear cut than are those for physical conditions; it thus may be difficult to develop a differential diagnosis, prescribe and subsequently modify the prescription in non-responsive cases.
- The cost per episode of drug treatment tends to be very high for many of those with the greatest disabilities.

⁹ Mercer Human Resource Consulting, "Navigating the Pharmacy Benefits Marketplace." California HealthCare Foundation, January 2003.

¹⁰ Bernasek C., et al. "Case Study: Michigan's Medicaid Prescription Drug Benefit." Kaiser Commission on Medicaid and the Uninsured, January 2003.

¹¹ Henry D., Mendelson D. and Fallierias A. "Clinical Pharmacy Management Initiative: Integrating Quality into Medicaid Cost Containment." Center for Health Care Strategies, April 2003.

¹² Kidder D. and Bae J. "Evaluation Results From Prospective Drug Utilization Review: Medicaid Demonstrations." *Health Care Financing Review*, Spring 1999: 20 (3), 107-118.

- The most seriously ill individuals are often those supported by the public behavioral health system through Medicaid and/or the state behavioral health authority.

In addition, pharmacy benefits, primary care, and behavioral health services are often managed through different payment arrangements. The majority of Medicaid managed care initiatives carve out behavioral health services for the disabled either through a separate managed care plan or leaving it in fee-for-service.¹³ Pharmacy benefits are rarely included in the behavioral health plans. They may become part of the primary care plan; remain in fee-for-service (e.g. Massachusetts); become carved-out from the pharmacy benefit (e.g. California); or provided in a separate benefit (Pennsylvania for Clozaril). The frequent lack of integration of benefits between behavioral health, primary care, and pharmacy adds to the challenges facing states in managing behavioral drugs.

Pharmacy benefit management firms offer a range of services that they generally bundle together for health purchasers. Many are characterized by restrictions on access, such as prior approval and restrictive formularies. Public mental health systems and health plans with significant enrollments of disabled populations have been slow to adopt many of these cost control approaches in mental health, however the cost growth of behavioral drugs has significantly exceeded other drugs. Needless to say, Medicaid administrators are now noticing the advantages of PBMs. While in many cases, access to behavioral drugs has been deliberately kept open because of quality concerns and pressure from consumers and advocates, virtually everyone recognizes that some forms of targeted cost and quality controls are needed in behavioral pharmacy, especially given the budget constraints most states are now facing. The question is what types of reforms should and will be adopted.

Representatives of consumer organizations, such as the National Alliance for the Mentally Ill (NAMI) and the National Mental Health Association (NMHA) have been outspoken in their support for unrestricted access to behavioral drugs. NAMI recently published a report entitled “Strategies for Responding to Threats to Limit Access to Medications in Medicaid and other Mental Health Financing Systems”¹⁴ and the Board of Directors adopted Policy Recommendations on access to medications on February 21, 2003. In a similar effort, the NMHA approved a policy position on access to medications. NMHA also prepared a series of four issue briefs outlining the case for open access, consumer protections and options that promote the appropriate use of medications.¹⁵

Both organizations are strongly against state policies that might require consumers to “fail first” on a less expensive medication before being authorized for a newer medication. In 2003, 28 state Medicaid programs used a fail first approach for at least some drug classes.¹⁶ Similarly, both organizations seek to exempt all medications for mental illness from formulary

¹³ Stroul B., Pires S. and Armstrong M. “2003 State Survey.” Health Care Reform Tracking Project. February, 2004.

¹⁴ National Alliance for the Mentally Ill. “Strategies for Responding to Threats to Limit Access to Medications in Medicaid and Other Mental Health Financing Systems.” *NAMI State Policy Bulletin*. April 16, 2002.

¹⁵ National Mental Health Association. “Access to Medications for Public Health Programs.” March 7, 2004.

¹⁶ *Medicaid and the Prescription Drug Benefit: Cost Containment Strategies and State Experiences*. Kaiser Commission on Medicaid and the Uninsured, September 2002.

restrictions or prior authorization requirements. In many cases they have been successful at this in states. For instance, Massachusetts, announced their intent to restrict access to certain higher cost drugs for serious mental illness on the Medicaid formulary in 2002. They reversed that position after encountering strong opposition from advocates and practitioners alike. Numerous states have carved out behavioral drugs or certain of the atypical drugs from their capitated benefits (e.g. California). Nonetheless, other states experiencing budget problems continue to explore ways to restrict the behavioral pharmacy benefit.

NMHA and NAMI have concluded restrictions on medication access are not cost effective in the long term. Effective medications have reduced the overall costs of treatment and allowed individuals to live in less restrictive settings. Researchers also have concluded that spending an additional 20-30 percent on the implementation of clinically effective guidelines in mental health could increase the cost effectiveness of mental health care by as much as four times.¹⁷ Prescribing is best left between the physicians and the consumer. Ken Duckworth, MD, a Boston psychiatrist and medical director of the National Alliance for the Mentally Ill, says his patients “must often try several different medications before finding a combination that works. Restricting Medicare's payments to two or three drugs in each category could harm doctors' ability find effective drug combinations.”¹⁸

While rising costs are a concern to most states, many officials are truly concerned about finding strategies that improve health, reduce waste and increase quality of care. NMHA and NAMI have strongly supported methods to review claims data for appropriate prescribing patterns, use case management approaches with primary care physicians, review claims for evidence of polypharmacy (prescribing combination therapy for conditions), and use practice guidelines and medication algorithms.

¹⁷ Wells. K. and Sturm R. *Improving the Quality and Cost-Effectiveness of Treatment for Depression*. RAND, 1998.

¹⁸ Zwillich T. “Mental Illness Drugs Battle Medicare Plan Psychiatrist, Officials Say Restrictions Could Damage Care of Severely Ill.” WebMD Medical News. September 27, 2004.

Case Studies

This paper reviews several of the most promising methods of behavioral pharmacy management. Each of the case studies presented involves a different set of interventions, but all of them aim to improve quality and control costs in public behavioral health. All of them have been able to maintain unrestricted access to needed medications. While the programs described in these case studies have been implemented in a constantly changing marketplace, training physicians in the use of prescribing algorithms, prescriber utilization review methods, and pooled purchasing reflect the latest public sector thinking about how to contain costs while not restricting access.

CalMAP: The California Medication Algorithm Project

The California Medication Algorithm Project (CalMAP) seeks to replicate the efforts and success of the Texas Medication Algorithm Project (TMAP), and to develop implementation guidelines and materials for the unique circumstances that exist in California. CalMAP has been funded by several of the major national pharmaceutical companies¹⁹ with additional support from each of the participating counties. The effort is sponsored by the California Institute for Mental Health, San Diego County Mental Health Services and the Texas Department of Mental Health and Mental Retardation.

The goal of the Texas Medication Algorithm Project, which was started in 1996, was “to improve the quality of care and achieve the best possible patient outcomes for each dollar of resource expended.”²⁰ The project was designed to “develop, implement and evaluate not just a set of medication algorithms, but an algorithm-driven treatment philosophy...”²¹ As a result of its basic goals and design premise, the full implementation of TMAP involves a significant redesign and reframing of the prescribing practice of psychiatrists and other clinicians in the clinic. According to Stephen Shon, MD, Medical Director of the Texas Department of Mental Health and Mental Retardation, twelve states are now implementing pilots of TMAP.

TMAP consists of four major components: evidence based medication algorithms; clinical and technical support for the clinician; patient and family education; and the uniform documentation of care and patient outcomes. Each of these elements involves changes in the practice and procedures that clinicians and adjunct staff have traditionally used for prescribing. First, physicians must be trained extensively so that they learn a new set of prescribing rules that incorporate a new attention to the stages of treatment and to previous medication trials. The explicit methods for documenting the outcomes of treatment require the use of new forms and increased attention to receiving structured feedback from consumers about their symptoms. Collecting outcomes data and systematically documenting treatment

¹⁹ These companies include: Eli Lilly Pharmaceutical Company; Bristol-Meyer-Squibb Pharmaceutical Company; Janssen Pharmaceutical Company; and Astra-Zeneca Pharmaceutical Company.

²⁰ Texas Medication Alogorithm Project Overview, Department of Mental Health and Mental Retardation.

²¹ Ibid.

involve a significant change in the usual approach of many clinicians. These procedures are intended to aid the physician in finding an effective medication, and may provide information that aids in the overall recovery of the consumer. Finally, the education of consumers and family members requires development of appropriate materials and takes a significant amount of time of support staff or peers. One of the unique contributions of the TMAP project was the development of methods for consumer-to-consumer education and peer support.

San Diego County's Adult Mental Health Services (SDMHS) chose to implement the Medication Algorithm Project for adults with schizophrenia within two of its county clinics in late 2002 (resulting in "SanDMAP"). Initial steps involved the development of consensus within the community concerning the use of algorithms; reviewing existing and developing new educational materials; training physicians; and adapting treatment documentation and outcome measurement to the unique requirements of Medi-Cal and the specific clinic. SDMHS recently expanded the program to the county-operated inpatient unit and to a long term care setting for individuals with mental illness.

TMAP, SanDMAP, and CalMAP all seek to ensure that medications are prescribed in a way that truly supports recovery. San Diego Adult Mental Health staff actively sought the collaboration of individuals from the National Alliance for the Mentally Ill in San Diego, and other advocates within the community, to assist with the training and education efforts. Following the guidelines and framework laid out by Texas, these individuals worked with the County to develop peer facilitators and other peer supports to provide education to consumers. Known as the "Roadmap to Recovery," these educational services included ten sessions to help consumers better understand the nature of their disease and the desired effects of the medications. There is a separate program for family members. The efforts of three of the peer facilitators were recognized by the San Diego County Board of Supervisors in an Annual Volunteer Awards ceremony.

CalMAP is particularly challenging, partly because of the size and nature of California's mental health system and partly because of the managed care approach being taken by the state.²² California is geographically vast and diverse. Its mental health services are run by county governments in different ways – some have predominantly county-operated services while others contract with private providers for many services, including administrative services. San Diego is one of the few counties to have contracted with a managed care organization to perform many administrative functions.

²² Medicaid managed mental health care in California is unique because it is based on a fixed level of funding, a global budget or "block grant", for the state share of Medicaid funds. This money is transferred from the state to the county and then each county is responsible for continuing to bill Medi-Cal for services and for the federal match. This strategy limited the state's risk and permitted counties to increase spending and draw down additional federal funds. Contracts between the state and the counties outline a broad range of requirements that are delegated from the state to the county. The California managed care initiative also is unique in that the state has transferred the risk of hospital benefits, but continues to pay the hospitals; the state has carved out atypical antipsychotics and certain other drugs to reduce the risk of restrictions on access. Furthermore, it has retained the Medi-Cal Rehab Option billing requirements that require extensive documentation and quality control.

While most pharmacy benefits in California are included in physical health HMO premiums for individuals eligible for managed care, the higher cost atypical drugs have been carved out of the HMO benefit and remain on fee-for-service.

With all of the diversity in Medi-Cal coverage and policies across the different counties, and with substantial and yet varied levels of county funding for mental health services and a strong county operated system of care, the process of rolling-out CalMAP is particularly challenging. Taking the lessons learned in San Diego, from their implementation of the algorithm in two clinics, CalMAP staff and consultants are working with two other counties on implementing the program and bringing it to scale. Both Kern and Humboldt Counties have actively embraced the program and implementation is well underway. This is being coordinated by a team of individuals from the California Institute of Mental Health. Several notable features of the effort are:

- **Clinical Peer Training Model:** San Diego medical staff, to the extent they are available, are active participants in the training for Kern and Humboldt Counties. They provide the new medical and other clinical staff with the opportunity to learn from peers who have already implemented the algorithm. This is an invaluable learning tool, keeps costs down, provides benefits to trainer and trainee alike, and permits the development of a statewide support network of clinicians.
- **Fidelity Tools:** Fidelity toolkits were developed for SAMHSA to review the degree to which replications of TMAP have maintained clinical standards and evidence-based activities (similar to the fidelity tools developed for other evidence based practices). These toolkits have proven to be very useful guides for design specification for program implementation. They not only provide a checklist of elements of the program that should be reviewed for fidelity, but also an extremely useful framework for keeping the focus on measurable factors and documentation requirements. Kern and Humboldt counties have greatly benefited from them.
- **Process Mapping:** This is a very useful set of tools for the design, implementation and documentation of the medication algorithm. Clearly TMAP has already outlined many of the decision rules and conditions. However, process maps of existing procedures become useful starting points in planning, and can be used to compare to proposed processes to highlight areas of difference and implementation requirements.
- **Project Management Approach:** While every project of the scope and significance of a medication algorithm requires some form of project management, the need for an explicit management framework for implementation becomes even more important in a replication with the complexity of CalMAP. The explicit use of management tools for the ownership of tasks, development of explicit timelines, and approval of changes, facilitates the subsequent replication of the project in future counties.

CNS Behavioral Prescriber Management

The Behavioral Pharmacy Management Systems (BPMS) group of Comprehensive Neuroscience, Inc. (CNS) provides enhanced behavioral drug utilization review and education services to state Medicaid agencies and health plans. CNS employs evidence-based algorithms to analyze pharmacy claims and provides educational interventions to help improve the quality of prescribing practices and to enhance consumer adherence. It is one of the few private sector pharmaceutical research and consulting organizations devoted exclusively to Neuroscience products. For its Behavioral Pharmacy Management product, CNS developed a series of consensus guidelines for appropriate behavioral pharmacy prescribing practices. These guidelines formed the basis, in fact, for the Texas Medication Algorithm. CNS used these guidelines to build the best practice algorithms to analyze claims data. BPMS monitors clinically and cost effective prescribing practices at the health plan, physician and patient levels. Through retrospective claims analyses, CNS identifies physician “outliers” whose prescribing practices fall outside the consensus guidelines and would benefit from information and education on behavioral pharmacy practices and the review of treatment guidelines.

Funded through a series of grants from several of the major behavioral pharmaceutical manufacturers, the BPMS product has been offered to state Medicaid agencies at no added cost. The work is consistent with other retrospective drug utilization review approaches to pharmacy benefit management, though CNS’ focus on mental health and educational approaches differentiates the service from other efforts that have generally focused on claims denial or recovery. As of the beginning of 2004, BPMS had been implemented in 16 states and they continue to market the program directly to additional states. The program is perhaps best known for its early work in its 2002 beta site in Philadelphia, Pennsylvania, with Ameri-Choice Health Plan, and Missouri beginning in 2003.

BPMS includes a series of 34 cost and quality edits that it uses for its claims analysis, including:

- Therapeutic duplication of atypical antipsychotic drugs
- Excess dosing for atypical antipsychotics
- Inadequate dosing for atypical antipsychotics
- Children receiving three or more behavioral drugs concurrently
- Use of two or more drugs from the same chemical class
- Evidence of excessive switching of atypical antipsychotic
- Antipsychotic prescriptions from multiple physicians (concurrent)
- Use of sedatives/hypnotics for greater than 60 days
- Discontinuance of any antipsychotic drug
- Children receiving ADHD, plus mood stabilizing, plus sedative/hypnotics
- Therapeutic duplication of anti-convulsant and mood stabilizing drugs.

Using these and other edits, BPMS provides to all interested public purchasers, a one-time Opportunity Analysis, documenting the scope and breadth of quality issues found in a one-

year retrospective analysis of their pharmacy claims. Following this analysis, BPMS offers interested states a comprehensive, full-service, multi-year intervention.

Data from Missouri suggest the scope of issues that might be found in other states. Out of 481,000 enrollees (average monthly), 31 percent of all drug expenditures were for behavioral pharmacy and 43 percent of these costs, or 13 percent of the total, were for atypical antipsychotics. Nine percent (43,159) of the total average monthly enrollment had received prescriptions for atypicals in the previous 90 days, while 8,430 or 1.8 percent received typical antipsychotic drugs. Joseph Parks, Medical Director, Missouri Department of Mental Health, reported at a conference in August, 2003 that a total of 37 percent of the claims for psychotropic drugs were flagged as deviating from the indicators, affecting 26 percent of the patients. As analyses of other systems have found, Missouri determined that five percent of the prescribers accounted for 50 percent of the total cost, providing a focus for the Department's educational and quality efforts.

Based on these claims analyses, multiple interventions are implemented and phased in over the course of the multi-year intervention. These include the preparation by CNS of quality reports for the health plan or state agency and distribution of quality letters to physicians informing them of the practice patterns detected and suggesting alternative approaches and considerations. Peer-to-peer telephonic consultations and/or group consultations are scheduled with selected prescribers and BPMS staff are available to work with state officials on appropriate follow-up activities.

BPMS represents a "non-invasive" approach to improving the quality and cost-effectiveness of prescribing practices through educational interventions. Missouri and others have experienced reductions in cost growth and sometimes even reduced costs as a result of BPMS efforts. More importantly, prescribing error rates and practice variation are reduced and the quality of care is improved. Through this type of claims-based analysis, health plans and public agencies can better understand the factors that drive their behavioral pharmacy claims. The approach taken in BPMS is fully consistent with and expands upon, drug utilization management approaches within Medicaid. The major differences are that this is a prescriber education effort, rather than a claims review process, and through their extensive research and specialization in behavioral health drugs, BPMS includes a more comprehensive set of guidelines and claims edits than has been generally available to state Medicaid agencies through existing PBMs.

Pooled Purchasing Initiatives: California, Maine and the Medicaid Multi-State Pool

In the fall of 2003, California implemented Senate Bill 1315 with the goal of reducing behavioral pharmacy prices for General Fund purchasing through use of a tiered purchasing method. This effort covers behavioral pharmacy purchasing by the Departments of Mental Health, Developmental Disabilities, Prisons, the California Youth Authority, and state universities. It does not include the cost of prescriptions paid by Medicaid as these are incorporated into managed care for many of the counties.

To implement the pricing method, the Department of General Services convened a Common Drug Formulary Committee (CDFC) that focused on usage and prescribing for the five major atypical antipsychotic drugs in the state's formulary. These included Abilify, Zyprexa, Risperdol, Geodon, and Seroquel. These five drugs accounted for approximately 80 percent of the budget. The challenge facing the committee was how to maintain open access to these drugs and constrain costs. Efficacy studies for these drugs demonstrate clinical equivalence among them, and to some degree with earlier classes of antipsychotics. However clinicians frequently report that consumers experience different clinical responses and tolerance for the various drugs.

The CDFC reviewed each of the drugs for usage, dosage, and pricing. Because of similar clinical efficacy, the committee deemed the costs of these drugs to be a critical factor that should influence prescribing practice. In theory, physicians and psychiatrists would have to exhaust all options in Tier One before prescribing Tier Two drugs. This required protocol would be subject to documentation requirements and retrospective review.

Each of the manufacturers was informed of the state's intent to develop a tiered prescribing system. Manufacturers were given the opportunity to reduce prices and provide rebates to the state to keep their drugs in Tier One, thus maintaining open access. After the first round of discussions, four of the five drugs were placed by the CDFC in Tier One, with Seroquel in Tier Two. However, several months later, Astra Zeneca responded with a lower pricing and rebate proposal and Seroquel was moved to Tier 1.

As with many other bulk pharmacy purchasing efforts, California received discounts for pharmaceuticals through rebates provided by the manufacturers. By combining purchasing across several state agencies, California's Department of General Services was able to exert significant leverage on drug manufacturers to bring their net pricing for state funded purchases into line with "Medicaid Best Price."²³ While counties should be able to participate in the purchasing, all or most have not done so to date. This may be partly due to

²³ Drug pricing is generally determined by rebates, or discounts, on the "average wholesale price" of a drug. Medicaid Best Prices are the lowest price (including rebates) paid by other companies. These are documented in reports filed by the pharmaceutical manufacturers to the federal government under the Medicaid Drug Rebate statute.

complications with distribution of the state's rebates and with the uses of rebates already received by counties.

Concerned about discounts that would lower the "Average Wholesale Price," drug manufacturers use these rebates to lessen the cost to purchasers. This pricing method is confusing both to purchasers and consumers, since the rebates are generally not offset directly against the price. Virtually all reviews of drug pricing and pharmacy benefit management firms have decried the lack of transparency of the net pricing after rebate for health purchasers. The California effort demonstrates the importance of market leverage on pharmacy pricing and it highlights the lack of transparency in pharmacy pricing that results from the interaction of Average Wholesale Price, Medicaid Best Price, Federal Acquisition Cost and rebates. As Gary Claxton, Vice President at the Kaiser Family Foundation, noted recently in discussing consumer perspectives on drug pricing, "It is virtually impossible for any of us to tell what the price of drugs are. ... The manufacturer may have given the rebate to the third party pharmacy benefit manager. The PBM may have passed some, or all of the rebate, on to the employer. You will never know what that is."²⁴

California has plans to expand the tiered pharmacy effort to other drug classes for other conditions. These other drugs, however, represent a significantly smaller portion of state spending, and recent changes in the California administration have slowed down their purchasing efforts. In a related trend, California and other states are beginning to talk to drug manufacturers about developing episode based pricing for drugs. This proposal holds the promise of controlling costs, and potentially of by-passing the complex rules concerning Average Wholesale Price and Medicaid Best Price.

Other pharmacy purchasing initiatives have been initiated over the last several years though they do not focus exclusively on behavioral pharmacy. Maine Rx, is one such pooled purchasing effort. Citing concerns that the federal government had not taken action to control rising prescription drug costs, Maine sought to use the state's purchasing power to bring prices down for Maine citizens. Maine Rx was enacted into law in 2000 and the pharmaceutical industry fought the law in court, delaying its implementation. In May 2003 the U.S. Supreme Court ruled that the Plan neither violated the Constitution's Commerce clause nor conflicted with federal Medicaid Law, and allowed the plan to proceed. Maine Rx Plus, announced in December 2003 with some minor changes from the original plan, permits all residents of Maine to receive discount pricing on drugs if they are not insured for pharmacy benefits. Maine Rx realized significant savings in drug pricing through the leverage state officials exercised with the Medicaid formulary. It was this use of the Medicaid formulary that the drug industry found most controversial.

Building on the attention created by Maine Rx, First Health Services Corporation, one of the first Medicaid PBM firms, has collaborated with five (now seven) of its states to implement the first multi-state pharmacy purchasing arrangement. In approving the plan in April 2004, Secretary Thompson said "By using the proven technique of negotiating lower

²⁴ Loyd L. "A Medicine Maze." *Philadelphia Inquirer*, May 2, 2004.

prices, states will reap important savings on their drug costs. “ As a part of this plan, all the states have signed agreements with First Health to allow the firm to negotiate drug prices on behalf of the states. States can maintain their own preferred drug lists, including behavioral drugs, and they can have clinical oversight of the lists to maintain access to pharmacy. The PBM achieves cost savings for the states by negotiating additional rebates from the pharmaceutical manufacturers resulting in a net cost below the Medicaid Best Price. Through their waiver approvals, CMS has supported states’ use of these techniques.²⁵

A 2003 survey conducted by the National Conference of State Legislatures found that 38 states will consider measures to control prescription drug costs, through such methods as pooled purchasing, preferred drug lists, prior authorization, and PBMs. For instance, the Commonwealth of Massachusetts recently released a Request for Information (RFI) from Pharmacy Benefit Management companies. The RFI sought information concerning the benefits that the state might realize if it pooled all the pharmacy purchasing for state programs, including Mass Health (Medicaid), Prescription Advantage (Medicare cards) Group Insurance (state employees) and the Department of Public Health, Office of Pharmacy Services.

All of these efforts are happening in the context of increasing scrutiny by federal and state officials. For instance, two recent national settlements (May 2004) require pharmaceutical companies Bayer Corporation and Glaxo SmithKline to pay millions of dollars in damages and penalties to federal and state Medicaid programs for not accurately reporting best price information to federal officials.²⁶ Both companies were found to have offered drugs to a large HMO under a private label for substantially lower cost than reported as “best price.” This action had the effect of reducing the rebates that the companies had paid to state and federal agencies. The complexities of the pricing methods and the extraordinary competition in the marketplace give rise to these problems.

These many efforts will continue to put pressure on the pharmaceutical industry to reduce prices and to make their pricing practices more transparent. Drugs used for the treatment of behavioral conditions, which fuel some of the fastest growing costs in pharmacy benefits, will continue to be a prime focus of these pooled purchasing efforts.

²⁵ NGA Center for Best Practices. “State Purchasing Pools for Prescription Drugs: What’s Happening and How Do They Work?” August 2004.

²⁶ State of New Jersey. Press release: “New Jersey to Get \$4 Million to Settle Medicaid Charges Against Two Pharmaceutical Companies.” May 5, 2003.

Future Directions

In addition to the methods outlined in this report, CMS is disseminating information about other approaches to lower state prescriptions drug costs.²⁷ These include aggressive generic substitution policies, negotiation of supplemental rebate agreements, implementation of successful disease management programs and electronic prescribing. Each of these efforts, taken together with some of the other approaches presented above has the promise of reducing cost growth.

California's interest in episode based pricing for behavioral drugs is a new approach that may help control costs and change practices in the future. As with other efforts to shift the risk in services through case rates or DRGs, the use of episode based pricing in pharmacy services has the advantage of making the pricing more transparent and mitigating the need for confusing rebates.²⁸ In establishing these rates, the "devil is in the details", but it seems likely that some purchasers will want to move in this direction.

In a similar trend, a number of emerging companies have begun to develop comprehensive approaches to the management of specific conditions with the goal of improving quality and reducing overall costs of care. These Disease Management (DM) approaches have been pioneered in efforts for diabetes, asthma, congestive heart failure and, increasingly, major depression. The focus on depression, in particular, has gained "traction" following the 2001 release of the World Health Organization's landmark study on the "burden of disease" and the related mental health report.²⁹ This report and the underlying analysis showed that depressive disorders are the fourth leading cause of disease burden for all ages and ranked second for 15-44 year olds. Five of the top ten conditions for 15-44 year olds were related to behavioral health.

Disease management is gaining attention in Medicaid and increasingly for behavioral health. Using a bundled pricing strategy (monthly or per episode rates), DM programs generally manage chronic diseases or conditions employing comprehensive interventions that include the use of evidence based practices, pharmacy benefits, primary and specialty health care, care coordination, and a focus on consumer education. Pharmacy benefit management within DM programs is primarily based upon the use of evidence based prescribing algorithms (similar to TMAP for specific conditions), but may also include the use of formularies and novel pricing methods and in all cases is carefully coordinated with medical practice. As a primary means of controlling overall expenditures for the identified conditions, many of these

²⁷ "Safe and Effective Approaches to Lowering State Prescription Drug Costs: Best Practices among State Medicaid Drug Programs." Centers for Medicare and Medicaid Services, September 2004.
<http://www.cms.hhs.gov/medicaid/drugs/strategies.pdf>

²⁸ Medicare's shift in 1983 to prospective pricing based upon Diagnosis Related Groups (DRGs) represented an initial step in this direction, although psychiatric diagnoses were exempt from the original regulations. Twenty years later, in late 2003, the Centers for Medicare and Medicaid Services published a proposed rule for a per diem Prospective Payment System for psychiatric inpatient services, finally seeking to shift away from cost-based pricing rules but falling short of an episode based pricing method.

²⁹ World Health Organization. "Mental Health: New Understanding, New Hope." The World Health Report 2001.

programs, such as those for asthma and diabetes, have put a major focus on medication compliance and standardizing prescribing practices. DM efforts also can help with the integration of primary and specialty consultation and treatment services.

While a complete review of behavioral health disease management approaches is beyond the scope of this paper, the integration of pharmacy prescribing and management practices into a full continuum of services for certain diseases and chronic conditions warrants close attention by public health officials as a strategy for the future. Interestingly, Missouri DMH officials have recently announced that Comprehensive Neuroscience is beginning a disease management initiative in Missouri for individuals with chronic schizophrenia. It uses many of the same approaches in BPMS but with a focus on the consumer rather than the prescriber – claims review, identification of high cost consumers by diagnostic category, review of services according to certain algorithms, notification of providers and educational interventions.

Finally, consumer directed health care also is attracting increased attention nationally and behavioral health services have been no exception to this trend. At the heart of consumer direction in health care is the use of health savings or health benefit accounts through which individuals can authorize purchasing for specific services and medications. Catastrophic coverage for Medicaid would be provided by the health plan or purchaser and clearly the federal portion of funds that remain in the accounts would not be likely to revert to the benefit of the recipient. While it is unclear whether it would be desirable to provide full coverage for pharmacy benefits through such a mechanism, consumer direction initiatives have some similar requirements to disease management and medication algorithms:

- They all rely on significant improvements in consumer education, to help consumers better understand symptoms, medication options, anticipated outcomes, and side effects;
- Both need standardization in prescribing practices to provide information to consumers; and
- Both efforts provide transparency in pricing so that consumers will pay market driven prices for their medications.

Summary

This brief review of a variety of approaches to behavioral pharmacy management has identified several promising efforts at controlling costs and improving quality for the public sector that aim to continue to provide open access to the most effective medications. The field is evolving rapidly and the pressure on states and health insurers to control costs and increase quality has never been greater.

Any state that is trying to develop a comprehensive effort to constrain pharmacy prices should focus on:

- **Efforts to standardize prescribing practices using evidence-based guidelines**, such as those developed in the Texas Medication Algorithm Project and California's replication effort (CalMAP);
- **Using administrative claims data to review prescribing practices according to consensus guidelines, and to identify opportunities for provider education and other quality efforts.** Comprehensive Neuroscience's efforts represent one of several potentially promising ways of achieving this goal; and
- **Pooled purchasing efforts** such as California's Common Drug Formulary or the National Medicaid Pooling Initiative that increase the market leverage of states to reduce pharmacy prices and, ultimately, that increase the transparency of pharmacy pricing for all purchasers.

As the discussion of the above examples suggests, to achieve long-term success at controlling pharmacy benefits and costs while maintaining access, health officials must focus on changing the behavior of both consumers and physicians, reducing variation in prescribing practices with evidence based approaches, and controlling pricing and integrating behavioral health services across primary and specialty providers. With the trends in the industry all heading in the same direction, drug manufacturers, professionals, providers, and purchasers should actively seek to align their efforts over the coming years.