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Pharmaceutical cost management and access to psychotropic drugs: The U.S. context

Haiden A. Huskamp^{*}

Harvard Medical School, Department of Health Care Policy, 180 Longwood Avenue, Boston, MA 02115, United States

Abstract

In recent years, prescription drug expenditures in the United States have increased rapidly. In 2003, spending on prescription medications totaled \$179.2 billion dollars, or approximately 11% of national health expenditures [Smith, C., Cowan, C., Sensenig, A., Catlin, A., & the Health Accounts Team. (2005). Health spending growth slows in 2003. *Health Affairs*, 24 (1) 185–194]. In response to rapid increases in prescription drug expenditures, both public and private payers of health care services have adopted strategies to try to contain drug costs, including drug formularies, prior authorization programs, cost sharing and utilization management. In this paper, I provide a background on prescription drug spending trends, financing, and access to medications; describe some of the tools used most commonly to manage prescription drug utilization; present results from the literature on the impact of these tools; and discuss some implications of this information for the new Medicare prescription drug benefit to be implemented in 2006 as well as for future prescription drug innovation.

Keywords

Pharmaceutical; Psychotropic drugs; Prescription medications

In recent years, prescription drug expenditures in the United States have increased rapidly. In 2003, spending on prescription medications totaled \$179.2 billion dollars, or approximately 11% of national health expenditures (Smith, Cowan, Sensenig, Catlin, & Health Accounts Team, 2005). Expenditures rose 10.7% from the previous year, and 2003 was the fifth straight year of double-digit growth in prescription drug spending (Smith et al., 2005). In response to rapid increases in prescription drug expenditures, both public and private payers of health care services have adopted strategies to try to contain drug costs, including drug formularies, prior authorization programs, cost sharing and utilization management.

The past few decades have represented a period of rapid innovation for the treatment of mental illness. Several important psychotherapies were developed, but many of the key innovations were psychotropic drugs, including medications used to treat depression, schizophrenia and bipolar disorder. Not surprisingly, these advances have been accompanied by increases in expenditures on psychotropic medications. From 1996 to 2001, spending on psychotropic drugs almost tripled from \$5.9 million to \$14.7 million (Zuvekas, 2005). There is some evidence that spending for psychotropic drugs has increased more rapidly than spending for many other classes. For example, from 2000 to 2001, retail sales for antidepressants grew faster than retail sales for any other therapeutic class (National Institute for Health Care Management, 2002).

^{*}Tel.: +1 617 432 0838; fax: +1 617 432 0173. E-mail address: huskamp@hcp.med.harvard.edu.

Although traditionally payers have been reluctant to restrict access to psychotropic medications because of their importance in the treatment of mental illness and because of clinical literature that suggests that patients often respond differently to different medications, payers are increasingly applying pharmacy cost management techniques to psychotropic medications (Huskamp, 2003). However, there is reason to believe that these techniques, including formularies and prior authorization programs, will be less effective at controlling utilization and spending for psychotropic medications than for many other therapeutic classes (Huskamp, 2003).

There is a growing literature on the impact of some of these techniques on medication use and spending. However, only a small subset of these studies report results for classes of psychotropic medications. Below I provide background on prescription drug spending trends, financing, and access to medications. I describe some of the tools used most commonly to manage prescription drug utilization and I present results from the literature on the impact of these tools. Finally, I discuss some implications of this information for the new Medicare prescription drug benefit to be implemented in 2006 as well as for future prescription drug innovation.

1. Background on drug expenditure trends, financing and access to psychotropic medications

There are three main factors driving the recent increases in prescription drug spending: 1) increases in the number of prescriptions filled; 2) changes in the types of drugs used (i.e., increased use of newer, more expensive drugs instead of older, less-expensive medications); and 3) price increases for existing drugs (Kaiser Family Foundation, 2004). From 1993 to 2003, the number of prescriptions filled increased 70% and the average number of prescriptions per person increased from 7.8 to 11.8 (Kaiser Family Foundation, 2004). Increases in the number of prescriptions filled were considered to be responsible for 42% of the overall increase in prescription drug spending from 1997 to 2002. Retail prescription prices have increased an average of 7.4% a year from 1993 to 2003, which is more than twice the average inflation rate of 2.5% (Kaiser Family Foundation, 2004). Increases in prices for existing drugs were responsible for 25% of the spending increase, while changes in the types of drugs used were responsible for another 34% (Kaiser Family Foundation, 2004).

In 2003, approximately 46% of prescription drug expenditures were paid for by private insurance, 30% were paid out-of-pocket, 19% were paid by the Medicaid program (the public insurance program that covers more than 50 million low-income individuals in the U.S.), 2% were paid by Medicare (the public insurance program that covers approximately 41 million elderly and disabled Americans) and 4% were paid from other public sources (Smith et al., 2005). In 1996, approximately 23% of nonelderly individuals in the U.S. had no drug coverage. In the fall of 2001, 36% of Medicare beneficiaries had no drug coverage (Kaiser Family Foundation, 2004). Frank (2001) noted that different purchasers pay quite different prices for the same medications in the U.S. Individuals without insurance coverage often pay significantly higher prices than people with private insurance coverage because an individual purchaser has no bargaining power over price, unlike large health plans and pharmacy benefits managers.

Although use of prescription medications seems to be increasing overall, there is evidence that the lack of prescription drug coverage results in reduced utilization among the uninsured. A Kaiser survey found that 37% of those without insurance reported that they did not fill a prescription because of the cost, compared to 13% of individuals with insurance (Kaiser Commission on Medicaid and the Uninsured, 2003a). Another survey of seniors in eight states found that 35% of the seniors without drug coverage reported that they did not fill one or more

prescriptions or they skipped doses of medications over the past year, compared to 18% of seniors with coverage (Kaiser Family Foundation/Commonwealth/Tufts, 2002).

Financing for psychotropic medications is slightly different than financing for prescription medications overall. The public share of psychotropic expenditures and the share paid out-of-pocket are higher than for prescription drug expenditures as a whole, while the private insurance share is lower (Zuvekas, 2005). In 2001, approximately 36% of psychotropic medication expenditures were financed by private insurance, while another 36% of spending was paid for out-of-pocket and 28% was paid for by public programs (Zuvekas, 2005). The recent increases in spending for psychotropic medications are driven by greater prevalence of use as well as by increases in mean spending per user (Zuvekas, 2005). Of the increase in expenditures, 37% was accounted for by new users and 63% by higher spending per user. Approximately 80% of the increased expenditures during the period 1996 through 2001 is explained by two categories of drugs: 1) selective serotonin reuptake inhibitors (SSRIs) and other newer antidepressants (52%); and 2) atypical antipsychotics (28%) (Zuvekas, 2005).

Over the last several years, use of psychotropic medications has increased rapidly. The percentage of individuals using a psychotropic drug increased from 5.9% in 1996 to 8.1% in 2001 (Zuvekas, 2005). Approximately three-quarters of those individuals receiving some type of mental health treatment in 2001 (10.7% of the U.S. population) used a psychotropic medication during that year (Zuvekas, 2005). Use of psychotropic medications has increased particularly rapidly among children. Psychotropic medication prevalence among children increased two-fold to three-fold from 1987 to 1996 (Zito et al., 2003). In 2001, children between the ages of six and 17 had the lowest rate of use (5.8%), compared to adults 18–44 (7.3%), adults 45–64 (12.2%) and adults 65 and older (11.0%) (Zuvekas, 2005). Rates of use were higher for women than men (9.9% versus 6.2%) and for whites (9.8%) than blacks (4.0%) or Hispanics (3.9%) (Zuvekas, 2005).

2. Common strategies for controlling prescription drug use and spending

Private and public payers have adopted a variety of pharmacy cost containment strategies in an attempt to control rising spending on prescription drugs. Tools often used by private plans include three-tier formularies, utilization management programs, and cost sharing. Tools used by the Medicaid program include prior authorization programs, preferred drug lists, fail-first or stepped formularies, generic substitution, limits on number of prescriptions filled, and, to a lesser extent, cost sharing (Kaiser Commission on Medicaid and the Uninsured, 2003b).

2.1. Tools used commonly by private plans

2.1.1. Three-tier formularies—Approximately two-thirds of privately insured workers and their dependents had prescription drug coverage that used three-tier copayment structures in 2004 (Kaiser and Health Research and Educational Trust, 2004). Three-tier formularies provide financial incentives to consumers in the form of lower copayments if they choose drugs that are less expensive for the plan. Consumers using generic drugs – the first tier – pay the lowest out-of-pocket costs (e.g., \$10) for a prescription; users of preferred brand-name drugs – the second tier – pay a higher out-of-pocket price (e.g., \$20) and users of non-preferred brand-name drugs – the third tier – pay the highest level of cost sharing (e.g., \$35).

There are two primary goals of three-tier formulary adoption. First, three-tier formularies encourage patients and their physicians to consider the relative costs of different drugs in a therapeutic class by providing financial incentives (in the form of lower patient cost sharing) to choose drugs that are lower cost for the plan. Second, adoption of a three-tier formulary may allow plans to negotiate price discounts or rebates from manufacturers. If a plan can demonstrate the ability to move prescription market share on the basis of price through the use

of a three-tier formulary, manufacturers may be willing to negotiate lower prices in order to have preferred formulary status (e.g., a tier two listing with a lower patient copayment instead of a tier three listing with a higher copayment) for their medication.

2.1.2. Utilization management—Utilization management (UM) programs typically focus on influencing utilization patterns for particular medications or therapeutic classes. UM programs may have multiple goals, including improving patient safety and quality of care (e.g., detecting dangerous medication interactions) as well as encouraging patients to use lower-cost medications. Under a utilization management program, an enrollee may be required to obtain approval before receiving coverage for a particular medication or dosage.

2.1.3. Cost sharing/benefit limits—Private health plans often use cost sharing as a means of controlling utilization and spending for prescription drugs. There is an extensive literature on the effect on prescription drug use and spending of cost sharing such as standard copayments. This literature shows that increasing the out-of-pocket price for medications results in reduced use and spending for prescription drugs (e.g., Liebowitz, Manning, & Newhous et al. 1985). The Medicare program offers beneficiaries the option of selecting a qualified managed care plan offered by a private health care organization instead of enrolling in the traditional fee-for-service Medicare program. The managed care plans (now referred to as Medicare Advantage plans, formerly called Medicare+Choice plans) often offer supplemental benefits not covered under the fee-for-service program, including some level of prescription drug coverage. These plans typically use cost sharing in the form of copayments, deductibles and benefit caps for prescription drugs.

2.2. Tools commonly used by Medicaid

2.2.1. Prior authorization—In 2003, 95% of the 43 state Medicaid programs responding to a survey by the Kaiser Commission on Medicaid and the Uninsured used prior authorization for at least some medications (Kaiser Commission on Medicaid and the Uninsured, 2003b). Under prior authorization, a physician is required to obtain administrative approval from the Medicaid program to prescribe a particular medication to a given patient before that patient can receive coverage for the drug. Some state programs exempt psychotropic medications from prior authorization requirements. For example, in 2003, 27 states exempted typical antipsychotics, 26 exempted atypical antipsychotics, 25 exempted SSRIs and 16 exempted stimulants (Managed Care, November 2003).

2.2.2. Preferred drug lists—Eighteen of the 43 states responding to the Kaiser Commission survey reported using preferred drug lists for a subset of drug classes (Kaiser Commission on Medicaid and the Uninsured, 2003b). A preferred drug list is a list of drugs in each affected class that are preferred by the State. Use of these medications does not require prior authorization by the patient and their physician; use of medications not on the preferred list does require authorization.

2.2.3. Other strategies—Several states have adopted a number of other cost containment techniques for their Medicaid programs. Approximately two-thirds of states responding to the Kaiser Commission survey (28 of 43) reported using “fail-first” policies for selected medications (Kaiser Commission on Medicaid and the Uninsured, 2003b). Under a fail-first or stepped formulary policy, a patient must try one or more of a subset of medications in a drug class (often the generic drugs) and fail to respond appropriately to this drug (or drugs) before the patient is able to receive approval for a higher-cost medication. For example, a fail-first or stepped formulary policy for selective serotonin reuptake inhibitors (SSRIs) might require a patient to fail to respond appropriately to paroxetine and fluoxetine (generic versions of Prozac and Paxil) before receiving approval for coverage of a brand-name SSRI.

Approximately 70% of responding states required substitution of a generic version of a brand-name drug when a brand-name drug with a generic alternative available is prescribed (Kaiser Commission on Medicaid and the Uninsured, 2003b). Fourteen of the 43 states responding to the Kaiser Commission survey reported limiting the number of prescriptions that each Medicaid enrollee is permitted to fill each month, while the vast majority of states (42 of 43) reported limiting the quantity of a drug that can be dispensed at one time.

Finally, although use of cost sharing for Medicare beneficiaries is limited by federal regulation, 35 of the 43 state Medicaid programs responding to the Kaiser Commission survey reported using minimal cost sharing (\$0.50 to \$3.00 per prescription) for prescription drugs in 2003 (Kaiser Commission on Medicaid and the Uninsured, 2003b).

3. What we know about the effects of these strategies

Although these tools are now used widely for classes of psychotropic medications by health plans and public sector insurance programs in the U.S., there is reason to believe that the tools may not be as effective at controlling the costs of psychotropic medications as they may be in controlling costs of many other therapeutic classes of drugs (Huskamp, 2003). Characteristics of mental disorders, psychotropic medications and the current structure of the mental health care financing system are likely to reduce the effectiveness of these tools at reducing the costs of psychotropics (Huskamp, 2003). First, because of the substantial biological heterogeneity within most mental disorders, patients with a given condition often respond differently to different psychotropic medications. For example, many randomized trials have found that various SSRIs have similar effectiveness overall (Simon, 2001). However, clinical experience suggests the various medications may not be equally effective for an individual patient (Simon, 2001). For most patients, there are no biological markers to indicate that a particular medication will work best for a given patient. As a result, finding the right treatment match can be difficult, and patients and their physicians may be less willing to switch medications in response to financial incentives or administrative procedures than they might be for medications that treat more biologically homogeneous conditions.

Second, one of the most common financing mechanisms for mental health services, the managed behavioral health carve-out, creates no incentives for controlling prescription drug costs (Huskamp, 2003). Under a managed behavioral health carve-out, a health plan or employer separates out the risk for specialty mental health services from the risk for other health care services and contracts with a specialty managed care vendor to manage the mental health benefit only. Because the carve-out contracts typically place the vendor at no financial risk for psychotropic medication use (i.e., the vendor is only at risk for mental health inpatient and outpatient care), the vendor has no incentive to control psychotropic medication costs or to facilitate use of pharmacy management tools. To the extent that psychotropic medications and outpatient specialty behavioral health services (e.g., psychotherapy) may be substitutes in mental health treatment, carve-out contracts may provide vendors financial incentives to encourage providers to use psychotropic medications instead of psychotherapy. There is some evidence of increased psychotropic prescribing after carve-out adoption (e.g., Busch, 2002; Ling, Berndt, & Frank, 2003).

3.1. Three-tier formularies

Over the past several years, a number of studies have examined the effect of three-tier formulary adoption on medication utilization and spending patterns in private health plans. These studies have shown that three-tier formulary adoption is associated with a shift from use of tier three nonpreferred brand medications toward the use of tier two preferred brand drugs (Rector, Finch, Danzon, Pauly, & Manda, 2003; Huskamp et al., 2003). Studies have also documented a shifting of costs from the plan to the patient, with enrollee spending increases and plan spending

decreases after three-tier adoption (Huskamp et al., 2003; Joyce, Escarce, Solomon, & Goldman, 2002; Kamal-Bahl & Briesacher, 2004). Several studies have also documented lower rates of medication continuation after three-tier adoption and the accompanying copayment increases (Goldman et al., 2004; Huskamp et al., 2003; Motheral & Fairman, 2001). For example, Huskamp et al. (2003) found that one large employer's move from a one-tier formulary (i.e., same copayment required for all drugs) to a three-tier formulary with substantial copayment increases resulted in higher rates of medication discontinuation relative to a comparison group for three classes of medications used often to treat chronic conditions (ACE inhibitors, often used to treat hypertension and congestive heart failure; proton pump inhibitors (PPIs), used for acid reflux; and statins, used to lower serum cholesterol). Using administrative data on a large cross section of employers with different pharmacy benefit designs, Goldman and colleagues (2004) simulated the effect of pharmacy benefit changes on medication use. They found that a doubling of copayments was associated with decreased use of eight therapeutic classes. The largest decreases, approximately 45% fewer days of medication supplied, were found for antihistamines and non-steroidal anti-inflammatory drugs (or NSAIDs, used for pain relief and treatment of osteoarthritis), which are medications often used intermittently to treat symptoms. They also found significant reductions in use of medications used to treat chronic conditions, ranging from a 34% decrease in use of antihyperlipidemics, a 26% decrease in use of antihypertensives and a 26% decrease in use of antidepressants. Huskamp and colleagues recently completed a study of the effect on use and spending for medications used to treat attention-deficit/hyperactivity disorder (ADHD) in children of one employer's move from a one-tier to a three-tier formulary (Huskamp et al., 2005). They found that three-tier adoption resulted in a 17% decrease in the monthly probability of using an ADHD medication (relative to the comparison group), a substantial shifting of costs from the plan to the patient, increased likelihood of switching to a lower-tier medication and no effect on medication continuation over time.

3.2. Preferred drug lists

Two recent studies have assessed the effects of preferred drug lists, although neither focused on psychotropic medications. Wang, Pauly, & Lin (2003) used a before-/after-approach to study the effect of Maine Medicaid's preferred drug list for PPIs, which lists a single PPI (pantoprazole) as a preferred agent. Wang and colleagues found that adoption of this program resulted in a large increase in use of pantoprazole among the state's Medicaid enrollees as well as increased use of the drug by cash payers and those with private insurance. Virabhak and Shinogle (2005) studied preferred drug lists for several cardiovascular medication classes (e.g., ACE inhibitors, angiotensin receptor blockers (ARBs), beta blockers, calcium channel blockers) that were adopted by two state Medicaid programs, Illinois and Louisiana. They found that preferred drug list adoption was associated with decreases of between six and nine percentage points in the share of restricted cardiovascular drugs (i.e., those not on the preferred list).

3.3. Prior authorization

There have been several studies evaluating the impacts of prior authorization programs on costs and utilization patterns. These studies have generally shown substantial cost savings for the medications affected resulting from use of prior authorization and somewhat mixed results on prior authorization's impact on use and spending for other types of medical care. Using a time series design, Smalley, Griffin, Fought, Sullivan, & Ray (1995) found that Tennessee Medicaid's prior authorization program targeting NSAIDs resulted in an immediate 53% decrease in NSAID spending. This decrease was primarily attributed to increased use of generic NSAIDs and a 19% decrease in overall use of NSAIDs. The prior authorization program did not result in increased Medicaid spending for other types of services for NSAID patients. In an interrupted time series analysis, Delate, Mager, Sheth, and Motheral (2005) found that one

state's preferred drug list for PPIs resulted in reduced use of PPIs (particularly among those patients without at least one diagnosis of a gastrointestinal condition) and increased use of lower-cost H2 blockers (medications also used to treat acid reflux), with no effect on ambulatory or inpatient medical service use for the management of gastrointestinal conditions among patients that did not receive a PPI. Kotzan, McMillan, Jankel, and Foster (1993) found that Georgia Medicaid's prior authorization program resulted in decreased costs for H2 blockers and NSAIDs, which were not offset by increased costs for other medical services. However, using a pre-/post-design, Bloom and Jacobs (1985) found that West Virginia Medicaid's program requiring prior authorization for cimetidine (an H2 blocker) resulted in an 84% decrease in use of cimetidine among patients with peptic ulcer disease and increased hospitalizations associated with the condition. McCombs, Mulani, and Gibson (2004) found that California Medicaid's removal of prior authorization requirements for three atypical antipsychotic medications resulted in increased average monthly costs of treating patients prescribed antipsychotics across a variety of types of services, although savings resulting from reductions in future use of nursing home and psychiatric hospital care offset the increased costs associated with use of the three medications.

3.4. Limiting number of prescriptions

Using an interrupted time series regression analysis, Soumerai, McLaughlin, Ross-Degnan, Casteris, and Bollini, (1994) examined the effect of New Hampshire Medicaid's policy of reimbursing only three prescriptions per beneficiary per month on use of psychotropic medications and acute mental health services by patients with schizophrenia. They found that the cap resulted in reductions ranging from 15% to 49% in the use of several classes of psychotropic medications, including antipsychotics, antidepressants, lithium, and anxiolytics. The policy also resulted in an increase in the number of visits to community mental health centers of one to two visits per month and increases in the use of emergency mental health services and partial hospital services, contributing to an overall increase in mental health costs of \$1530 per patient after the policy was adopted. After the cap was removed, use of medications and most mental health services dropped back to pre-policy levels.

3.5. Stepped formularies

Motheral et al. (2004) examined the effect of a large employer's use of stepped formularies for new users (i.e., prior users were not subject to the program) of three classes of medications: PPIs, NSAIDs, and SSRIs. The stepped formulary program required patients to try an H2 blocker before receiving coverage for a PPI, at least two generic NSAIDs before receiving coverage for a brand-name NSAID, and either fluoxetine or fluvoxamine maleate before receiving coverage of a brand-name SSRI. The authors found that the program resulted in substantial savings for the employer for the three classes as a whole (i.e., a decrease of \$0.83 per member per month in net costs while the comparison group experienced an upward trend of \$0.10 per member per month for the same classes). However, there were no statistically significant savings for SSRIs, just for NSAIDs and PPIs.

3.6. Benefit caps

Tseng, Brook, Keeler, Steers, and Mangione (2004) surveyed enrollees of Medicare managed care plans who had high medication costs and prescription drug benefits that were capped annually at some maximum level (e.g., \$800 in covered benefits per year). They found that patients whose prescription drug expenditures exceeded the benefit cap were more likely to report that they reduced their use of prescribed medications than controls but were not more likely to report that they stopped medication use entirely. Patients whose expenditures exceeded the cap were more likely to switch to lower-cost medications than controls.

The evidence on the use of pharmacy management tools as a whole suggests evidence of savings in the form of lower prescription drug costs resulting from the use of these tools. The evidence is somewhat mixed on whether some or all of these savings are offset by other health care costs. Although only a few studies have examined the effect of these tools on medication continuation, there is evidence that selected tools may negatively impact continuation. Unfortunately, only a small subset of these studies present results for classes of psychotropic medications, so it is impossible to compare the effects of pharmacy management tools on psychotropic classes and other therapeutic classes in most cases. The evidence that is available on the effect of selected pharmacy management tools on psychotropic use and spending suggests some reason for concern. Goldman et al. (2004) and Huskamp et al. (2005) find that use of increased cost sharing and three-tier formularies resulted in lower use of antidepressants and ADHD medications. Soumerai et al. (1994) found that a limit on the number of prescriptions that could be filled resulted in lower use of several classes of psychotropic medications and greater use of acute mental health services.

4. Potential implications for new Medicare drug benefit and future innovation

Increased use of pharmacy management tools may have important implications for two key areas: 1) the new Medicare drug benefit; and 2) incentives for future pharmaceutical innovation.

4.1. New medicare drug benefit

The Medicare fee-for-service program, which serves approximately 90% of all Medicare enrollees, has historically not included coverage of outpatient prescription medications. In December 2003, the U.S. Congress passed the Medicare Prescription Drug, Improvement and Modernization Act, which represents the most significant expansion of the Medicare program in almost 40 years. The law created Medicare Part D, a voluntary prescription drug benefit to be implemented in 2006. A primary goal of Part D is to increase access to medications for seniors and Medicare enrollees with disabilities, particularly those with low incomes and/or catastrophic drug expenses.

The legislation specifies that the benefit will be administered by private health care organizations under contract with the U.S. government. The Congress is relying on these organizations to control the costs of the new benefit using pharmacy management tools used commonly in the private sector, including three-tier and other types of formularies, cost sharing and drug utilization management programs. The legislation and accompanying regulations give plans substantial flexibility in how they design and use these tools.

There is some concern that the application of these tools could restrict access to needed medications for some beneficiaries or that plans could use these tools to discourage high-cost enrollees from joining the plan (Huskamp & Keating, 2005). Because multiple plans will compete for enrollees within a particular region and plans face some financial risk for drug costs incurred by their enrollees, plans have an incentive to try to attract individuals likely to have lower drug costs to their plan and discourage those likely to have higher drug costs. Plans could use pharmacy management tools in an effort to try to attract lower-cost enrollees, which could result in favorable selection for the plan. Adverse selection is a particular problem for health care goods and services for which use is highly predictable from year to year, such as prescription drugs used to treat chronic conditions (Ellis, 1985; Pauly & Zeng, 2003; Stuart, Ahern, Rabatin, & Johnson, 1991; Wrobel, Doshi, Stuart, & Briesacher, 2003–2004). Traditionally, adverse selection has been particularly problematic for mental health care because of the high expenditures incurred by people with mental illnesses and the predictability of spending from year to year due to the chronic nature of the conditions (Huskamp, 2003). Also, adverse selection is more likely to be an issue for drug classes that treat illnesses where treatment matching often involves trial and error, including psychotropic medications

(Huskamp, 2003). The reason is that once a patient finds a good treatment match, the patient and his or her clinician may be less willing to consider switching medications, and the patient may be more likely to seek a plan with generous coverage of those drugs. For example, a patient with schizophrenia who responds well to olanzapine, perhaps after unsuccessfully trying other antipsychotic medications, will be more likely to avoid a plan with a formulary that excludes coverage of olanzapine, all else equal. To try to avoid patients with chronic mental illness who may be likely to use one or more high-cost psychotropic medications as well as other high-cost medications on an ongoing basis, plans could make formulary coverage of psychotropic medications relatively restrictive.

The Centers for Medicare and Medicaid Services (CMS) have the responsibility to monitor plans' use of pharmacy management tools such as formularies to ensure that the design and use of these tools does not discourage enrollment by certain types of enrollees. How plans use these tools could have a substantial impact on the generosity of the coverage, the out-of-pocket burden faced by Part D beneficiaries and, ultimately, the long-term stability of the program (Huskamp & Keating, 2005).

4.2. Future innovation

There is some concern that increased use of pharmacy management tools to control prescription drug spending may ultimately reduce incentives for pharmaceutical companies to invest in research and development (R&D) efforts for new medications. With prescription drugs, R&D often requires large, sunk costs upfront, while the marginal cost of producing a unit of the medication may be quite low after a drug is developed (Berndt, 2004). There is some concern that manufacturers may feel they will be unable to fully recover the sunk costs of R&D and possibly decide not to invest in particular drugs if they expect these medications to be targets of stringent pharmacy management or price setting. This issue is particularly relevant when one purchaser buys a large proportion of the medication in the market. Consider the case of Medicaid and antipsychotic medications. Medicaid is responsible for a large proportion of total spending for certain psychotropic drug classes. For example, Medicaid was responsible for 52% of spending on antipsychotic drugs and approximately 67% of antipsychotic prescriptions in 2001 (Frank & Conti, 2003). For therapeutic classes where Medicaid pays for a large proportion of drugs sold in the market like antipsychotics, the use of pharmacy management tools or price-setting policies may have a significant effect on manufacturers' R&D investment decisions. Manufacturers may be less interested in investing substantial resources in R&D for future antipsychotic agents if Medicaid uses stringent cost management techniques or price setting strategies that could reduce potential revenue from a new drug in the class (Huskamp, 2003).

Thus, public and private payers may ultimately have to balance the goals of controlling rising prescription drug costs and stimulating future pharmaceutical innovation. Payment systems of the future may have to consider this key tradeoff.

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