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HOW IMPLEMENTING A PRESCRIPTION DRUG PRIOR AUTHORIZATION PROGRAM CAN DECREASE MEDICARE SPENDING

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Introduction
Rising health care costs have been a hot topic in the U.S. for more than a year. The debate culminated in 2010 with the passage of the Patient Protection and Affordable Care Act (PPACA), modifying many aspects of the U.S. health care system. A major goal of PPACA is to reduce spending on health care. In 2009 alone, 17.6% of the Gross Domestic Product was spent on health care. Pharmaceutical drugs continue to consume a major portion of spending. Brand name drug prices, despite a drop in inflation, continue to increase. Between 2008 and 2009, drug prices increased by 9.3%, while inflation dropped by 0.3%. In general, brand drugs in the United States cost up to twice as much as those in other countries. Medicare and Medicaid together accounted for $823.7 billion spent on health care in 2008, 9% of which was spent on prescription drugs. Prescription drug spending made up 6% of the total Medicaid expenditures in 2008, whereas Medicare spent 11% on prescription drugs that year.

The health care reform debates suggested multiple ways to reduce Medicare prescription drug spending, including offering Medicaid-level discounts for Medicare prescriptions filled by those dually eligible for both Medicaid and Medicare. Ultimately, PPACA focuses primarily on decreasing the cost-sharing burden on beneficiaries by requiring a 50% discount from drug manufacturers for prescriptions filled during the “coverage gap.” A simpler way, however, to cut Medicare’s overall spending on prescription drugs is to rely more on prior authorizations. Targeted prior authorization requirement programs in Medicaid have led to significant savings in many states, and have enormous potential to decrease costs in Medicare as well.

Overview of the Medicaid and Medicare Programs
Medicaid is a joint federal/state program, managed at the state level to provide medical assistance to low-income and disabled individuals. The Medicaid statute outlines mandatory coverage requirements for the program, which include inpatient and outpatient hospital services, laboratory and X-ray services, nursing facility services, and physician services, as well as optional categories of coverage, such as dental services, physical therapy, and prescription drugs. Prescription drugs, although optional, are covered by every state Medicaid program. When a state elects to provide coverage for prescription drugs, the Medicaid statute requires that the program cover all eligible drugs for which a manufacturer agrees to pay a discount. The discount amount is determined by a base percentage of that drug’s average price, with an additional discount tacked on when that drug’s price increases by more than the inflation rate. Medicare, on the other hand, is a purely federal program, providing medical assistance to individuals age 65 and over, and people with permanent disabilities for 24+ months regardless of income. Before 2006, Medicare only covered a small number of outpatient prescription drugs, primarily used in an inpatient setting or to treat a specific disease or disorder. When Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act in 2003, it created a prescription drug benefit for all Medicare enrollees. Under the program, called Medicare Part D, individual health plans provide either a stand-alone prescription drug program (PDP), or a comprehensive health insurance plan that includes prescription drug coverage (MA-PDP). Each Medicare Part D plan has some leeway to determine which drugs will be covered. When enacted, the Medicare statute required at least two drugs in each of the required therapeutic drug classes. The Medicare statute was recently modified by PPACA, and now requires the Centers for Medicare and Medicaid Services (CMS) to determine the criteria for which drugs must be covered under every Part D plan. In addition, the Medicare statute prohibits CMS involvement in the negotiation process between Part D plans and drug manufacturers. As a result, each Part D plan sponsor negotiates with drug manufacturers for discounts on drugs covered under that plan. The plan then uses pricing and clinical data to create a formulary (list of covered drugs). There are no requirements for the amount of discounts that manufacturers are to provide, but plans are only

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allowed to charge patients a maximum of 25% cost sharing.20

Medicaid Preferred Drug Lists
To combat increasing drug costs, most Medicaid state programs now use a Preferred Drug List (PDL) as a way to increase utilization of lower-cost medications, while also offering an incentive to drug manufacturers to provide even deeper discounts. Generally, a PDL is a list of drugs which the state “prefers” for Medicaid recipients. Drugs not listed on the PDL are still available for coverage under Medicaid, but the patient’s physician must first submit a prior authorization (PA) request to the state before the drug will be reimbursed by Medicaid. A PA request is typically granted if the patient has tried and failed on or is allergic to the preferred medications in that therapeutic class. The PA process is generally done via fax or phone, and physicians receive a decision from Medicaid within 24 hours at the most. In the meantime, the patient is able to receive a 72-hour supply of the medication while the PA request is being processed.21

Even though the Medicaid statute only allows a state to exclude a drug from its formulary if there is not a “significant, clinically meaningful therapeutic advantage,” the statute allows states to use a prior authorization process for any covered drug.22 The legality of early efforts to create PDLs and implement PA processes in Michigan, Maine, Florida, Tennessee and California has been upheld by courts.23 In Michigan, for example, the state received approval from CMS to create a PDL and PA program for Medicaid recipients.24 Under the program, a Pharmaceutical and Therapeutics (P&T) Committee, comprised of physicians and pharmacists, reviewed the clinical data for the drugs contained in forty different therapeutic classes, and selected two drugs in each class that were the “best in class.”25 In addition, the P&T Committee also determined which of the “best in class” medications had the lowest price, and any other drug in the class which cost more than that lowest price but did not provide any additional clinical benefit would require a PA.26 Manufacturers of drugs not selected as best in class then had the option of offering a rebate in addition to the federally required rebate (“supplemental” rebate) to ensure that their drug would also be available without a PA.27 As such, all of the preferred drugs in a class without a PA requirement were either clinically superior to the non-preferred drugs, or cost no more than any other preferred drug.

The Michigan Medicaid P&T Committee also created criteria for approval of each non-preferred drug, including factors such as whether the patient is allergic to the preferred options, or whether the patient had previously tried and failed on the preferred options.28 Physicians requesting approval for a non-preferred medication can call a hotline to receive approval, and can discuss their drug recommendation with a pharmacist if it does not fit the required criteria.29 If there is a delay in determining approval, physicians can prescribe a seventy-two hour supply of the medication for the patient while the approval request is being processed.30 In addition, physicians and patients can seek an appeal if the approval is denied.31 The court ultimately validated Michigan’s program, holding that it did not violate the Medicaid statute’s requirement to provide necessary safeguards to assure that the services provided are consistent with the best interests of beneficiaries.32

Currently, forty-seven states have a Medicaid PDL in place,33 and processes like the one in Michigan have proven successful in steering physicians toward writing prescriptions for the state’s “preferred” drugs.34 For example, Georgia and North Carolina had roughly the same number of Medicaid enrollees in 2007, but Georgia had a PDL and North Carolina did not.35 In 2007, Georgia Medicaid spent over $281 million on prescription drugs (or 5.6% of total acute care spending), while North Carolina spent over $707 million (or 10.6% of total acute care spending).36 In addition, according to a 2005 Kaiser study of thirty-seven states, an estimated 3.4% of those states’ Medicaid prescription claims were for drugs requiring a PA.37 Further, the thirty states reporting PA request data approved an average of 10% of all PA requests.38 This shows that, because the PA request takes time to complete—including conducting the adequate research into the patient’s history of previous unsuccessful treatments—and time is money to busy physicians’ offices, physicians are more likely to write a prescription for the preferred drug of that type, unless there is a true medical reason why the patient needs a non-preferred medication. Further, most PDLs are created by a P&T Committee, consisting of physicians and pharmacists, which has examined all clinical data for the drugs in a given therapeutic class and determined which, if any, of the drugs offer superior clinical benefit compared to the others. As such, physicians generally do not have a compelling case for requesting a non-preferred medication, unless the patient is allergic to or has failed on another medication. In those cases, physicians will successfully navigate the prior approval process.

In addition to steering physicians toward lower-cost drugs, the PDL process also provides incentives to manufacturers to offer larger rebates. Of the twenty-five states that reported PDL data to Kaiser in 2005,
The most important factor in the Medicaid PA process is that the burden is placed on manufacturers and physicians—and not on the patient. If a physician believes that a non-preferred or more expensive medication is appropriate for the patient, he must do the work to receive advance approval. In contrast, traditional private insurance plans generally steer patients toward lower-cost drugs through a tiered co-payment system—the more expensive the drug, the higher the patient cost-sharing. Generally, Tier 1 contains generic drugs, with patient average co-pays of $11; Tier 2 contains lower-cost brand drugs, with average co-pays of $25; and Tier 3 generally contains the more expensive brand drugs, with average co-pays of $43. This system requires that patients bear a portion of the cost of selecting a higher-cost medication. Some argue that cost-sharing is a valuable tool in containing health care costs by encouraging patients to select lower-cost care and deterring less-effective treatment choices. Increased cost-sharing, however, has also been shown to cause patients to stop taking medications for chronic conditions. In addition, higher cost-sharing has resulted in worse physiologic outcomes, more emergency room visits and, in some cases, increased mortality. In contrast, reductions in co-pays result in greater prescription drug adherence.

Drug manufacturers have created programs to help ease the burden on private insurance patients by offering co-payment subsidies in the form of rebates. However, while these efforts help relieve the overall financial burden on patients, they diminish effectiveness of a tiered co-payment structure in encouraging use of lower-cost medications.

Medicare Part D Cost Containment

Last year, PPACA made some changes to the way outpatient drugs are paid for under Medicare. Manufacturers are now required to accept some of the burden for patients who have reached the coverage gap. Under the current system, beneficiaries reach the coverage gap (also called the “doughnut hole”) after they have incurred $2,700 in total drug costs. During the coverage gap, beneficiaries are responsible for 100% of their drug costs, until they have reached the catastrophic coverage period. Beneficiaries reach the doughnut hole after paying $866.25 cost-sharing for their drugs, and do not reach the catastrophic coverage level until they have paid an additional $3,453.75.

Under the changes implemented by PPACA, during the doughnut hole, manufacturers will pay 50% of the drug’s cost at the pharmacy, the plan will pay 25% and the patient will pay the remaining 25%.

Although these mechanisms will help contain some of the rising drug costs of Medicare and lessen the financial burden on beneficiaries, they do not focus on decreasing drug costs before and after the coverage gap. In addition, requiring manufacturers to pay a large discount for prescriptions filled by patients during the doughnut hole may deter them from offering larger discounts for prescriptions filled outside the doughnut hole period. For example, if a drug is priced at $100 per prescription, and the manufacturer provides a 25% discount to the plan, the manufacturer pays a discount of $25 for every prescription filled. However, when the patient receives that same prescription during the doughnut hole, the manufacturer pays the $25 discount, plus 50% of the amount the pharmacy charges the Part D plan for the prescription. So, if the plan pays the pharmacy $75 for that prescription, the manufacturer will be required to pay an additional $37.50 discount, totaling $62.50 in discounts. Such a large discount may make manufacturers less likely to increase their negotiated discounts, particularly for drugs used to treat conditions for chronically ill beneficiaries who are more likely to reach the coverage gap.
Outside of the coverage gap period, most Medicare Part D plans rely on the tiered co-pay structure typically used in traditional private insurance plans to steer utilization to less expensive drugs. Like in the private insurance market, an increased financial burden is placed on patients who have been prescribed higher cost medications. Most common is a three-tiered plan, under which patients pay on average $5 for Tier 1 drugs, $25 for Tier 2 drugs and $53 for Tier 3 drugs, which is higher than the average co-payments for private insurance plans. According to a 2006 survey of over 16,000 senior citizens with various types of health care coverage, those persons with Part D coverage spent more money on prescription drugs than those enrolled in employer health plans. Of the Part D enrollees who participated in the survey, 7.8% reported spending over $300 a month for prescription drugs, while only 4.8% of those enrolled in an employer plan did. The Part D enrollees also delayed filling or did not fill prescriptions more often than those in employer plans, even though both groups averaged five prescriptions per month. The numbers were similar for chronically ill seniors: 24.8% of Part D enrollees reported delaying or not filling a prescription, whereas only 11.9% in an employer plan did. Although the Medicare statute does require that plans cover a certain number of drugs within particular therapeutic categories, plans are not prohibited from using utilization management tools such as quantity limits, step therapy, and prior authorization. CMS, however, has noted that, when approving a plan’s formulary proposal, it will consider whether the proposed utilization management strategies are consistent with current best practices. Some Part D plans rely upon utilization management tools, but such tools appear to be used more often for the poorest Part D enrollees: those persons eligible for a low-income subsidy (LIS) to help cover their expenditures. Of the seniors surveyed in 2006, 12.9% of Part D enrollees who received a LIS reported needing “special permission” to get a prescription filled, which is nearly twice the rate reported by those who did not. Part D plan sponsors claim that they are not in the position to demand high discounts from brand drug manufacturers. According to plan sponsors, negotiations are hindered when a particular drug has few competitors, or when a particular high-cost drug does not have a large amount of utilization. A key motivator for manufacturers to offer increased discounts is to achieve better or equal placement on a formulary than competitor drugs. Few competitors or low utilization could diminish manufacturer motivation. In addition, plans claim that with competing drugs, CMS may require that all or most of the drugs in that particular therapeutic class be covered. Such requirements decrease the ability of plans to negotiate increased discounts.

If plans had more leeway in restricting access to those more expensive drugs with no proven clinical advantage over others in the therapeutic class, plans could drive utilization toward less expensive drugs—saving money throughout the program, not just during the coverage gap. Like the plan in Michigan Medicaid, a Part D plan could review the clinical data, select best in class drugs, and require prior authorization for those drugs with prices higher than the lowest-priced best in class drugs. This system would also meet the original Medicare requirement of covering two drugs in each therapeutic class. Further, if combined with a tiered co-pay structure, patients would still be required to pay the appropriate cost-sharing for the drugs, but more prescriptions would be written for the lower cost drugs—saving money for both the beneficiaries and the Medicare program overall.

Consider the example of the Medicaid systems in Georgia and North Carolina discussed earlier. Georgia Medicaid spent 60% less on prescription drugs than North Carolina Medicaid. If the Medicare Part D program could reduce costs by only 30%, the entire Medicare program would save up to $27 billion. Possibly more importantly, such measures would reduce the financial burden on individual Part D enrollees, potentially allowing more enrollees to utilize the benefits that they were once deterred from because of the cost.

Critical to the above scheme is the careful administration of PA procedures to ensure that patients who truly need a specific drug are not barred from receiving it. In addition, provisions should cover patients who were taking a drug prior to a PA requirement, and a clear appeals process should be established for patients who have been denied a prescription. Most Part D plans have the resources already in place to support a comprehensive PA program. According to the Academy of Managed Care Pharmacy, most Part D plans currently utilize P&T Committees in creating formularies based on safety and clinical data, as well as cost. All that would be required is additional leeway provided to the plans to utilize those tools. PPACA
has created an excellent opportunity for such a change by requiring that CMS recommend in which therapeutic classes Part D plans may restrict access to drugs without major clinical consequences for enrollees.\textsuperscript{70} If a strict PA program has been deemed by courts as consistent with the best interest of Medicaid recipients, and is currently in use for low-income Part D enrollees, surely it can be effective for the remaining Part D enrollees.

\begin{itemize}
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    \item Id. at 826.
    \item Id.
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