INTRODUCTION

The use of generic drugs represents a cornerstone in Medicare and Medicaid’s plan to provide coverage of prescription drugs in the most cost-effective manner possible. Increased access to all prescription drugs will come to senior citizens who currently have limited or no prescription drug coverage by reducing their out-of-pocket expenditures through the use of Medicare’s new prescription drug benefit. In addition, all beneficiaries involved in this Medicare Part D benefit, administered through private at-risk plans, will find aggressive pressure applied to encourage the use of generic drugs over branded products.

Mark McClellan, MD, Administrator of the Centers for Medicare & Medicaid Services (CMS), in the Department of Health and Human Services, has noted that although Medicaid has lagged behind the most effective private health plans in terms of generic drug use, the new Medicare Part D benefit is going to build upon the approach of these private plans in encouraging an efficient use of resources.

Even though Medicaid already utilizes generic substitution of chemically equivalent medications, much room exists for growth. In one recent study, it was demonstrated that state Medicaid programs could realize an annual savings of 3.6% of their total drug expenditures and an additional 9.5% in state pharmacy assistance programs with fairly simple generic substitution. Previous studies supported this same position—that state Medicaid programs could achieve significant savings through the increased use of generic substitutions without any adverse effect on clinical outcomes. Most of these unrealized savings were concentrated in a small group of medications that included clozapine (Clozaril®, Novartis), alprazolam (Xanax®, Pfizer), and levothyroxine (e.g., Synthroid®, Abbott).

Generics account for more than half of all prescriptions written in the U.S. According to the Generic Pharmaceutical Association, the average price of a brand-name drug is $84.21, compared with $30.56 for a generic brand. In addition, much greater savings could be realized with substitution via step therapy, in which generic products within a class (nonchemical equivalents) are used before branded products are. Approaches such as this will expand the use of generic medications.

RISING TIDE RAISES ALL BOATS

Signed into law on December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108-173) creates a new drug benefit as Part D of Medicare. Beginning on January 1, 2006, Medicare will begin to pay for outpatient prescription drugs through private plans for beneficiaries who voluntarily enroll in the Part D benefit. Dually eligible patients (those covered by both Medicare and Medicaid) will be automatically enrolled if they do not enroll voluntarily. Beneficiaries can remain in traditional fee-for-service programs, enrolling separately in private prescription drug plans (PDPs), or they can enroll in an integrated Medicare Advantage plan (a managed care plan) for all Medicare-covered benefits, including drugs.

In general, all medications, especially generic drugs because of their cost-effectiveness, will be used to a greater extent because more elderly patients will have lower out-of-pocket expenditures as a result of the introduction of Medicare Part D. As several studies have demonstrated, there is a direct relationship between the use of medications and the lowering of out-of-pocket expenditures through prescription insurance such as that available through Medicare Part D.

SUBSTITUTION OF CHEMICAL EQUIVALENTS

The expanded use of generic medications will come as a result of a section of the MMA that calls for the public disclosure of pharmaceutical prices for equivalent drugs. Under Section 1860D-4(b)(4) of the MMA, Part D sponsors will be required to ensure that pharmacies inform plan enrollees of any differential between the price of a covered Part D drug and the cost of the lowest-priced generic equivalent. As stipulated in the proposed rule, this information must be provided when the enrollee purchases the drug or, in the case of mail orders, at the time of delivery of that drug.

The CMS strongly believes that such disclosure will provide enrollees—many of whom might not know that less expensive generic equivalents are available—with valuable information that will save them money and also save money for the Part D plans and Medicare. According to this information, it is expected that consumers will choose generic medications as a cost-effective alternative to branded products.

DRUG UTILIZATION MANAGEMENT

Section 423.120(b)(vi) and (b)(vii) of the final rule describes the P&T committee’s role in reviewing policies that guide exceptions and other utilization-management processes, including drug utilization review (DUR), generic substitution, prior authorization, quantity limits in step therapy, and “therapeutic interchange” and in evaluating and analyzing treatment protocols and procedures related to the Part D plan’s formulary, at least annually.

The most significant of these processes is the use of therapeutic interchanges, which encourage the use of generic substitution through either a step-therapy approach or beneficial tiered cost-sharing. Some examples of drug classes that would benefit are selective serotonin reuptake inhibitors (SSRIs) and 3-hydroxy-3-methylglutaryl coenzyme A (HMG–CoA) reductase inhibitors (statins). These medica-

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tions are used by a large number of the elderly population and are likely to undergo a shift from branded products to their generic equivalents as a result of the plans’ use of drug utilization-management tools.

**EASED ENTRY OF GENERICS**

Representative Henry Waxman (D-Calif.), coauthor of the legislation that bears his name (the Hatch–Waxman Act), stated that although drug prices have been lowered by as much as two thirds, partly because of generic substitution, the law is not a perfect solution to the problems of high drug prices. As a result, modifications have been made.

Title XI (Access to Affordable Pharmaceuticals) of the MMA modifies certain provisions of the Food, Drug and Cosmetic Act (the Hatch–Waxman Act). These revisions will affect the relationship between innovators and generic pharmaceutical companies by reducing the time and difficulty of the process by which generic medications are introduced into the U.S. market. As a result, generic drug manufacturers will gain increased access to the U.S. market for prescription drugs, and innovator companies will gain restoration of their products’ patent life—time that was lost during the Food and Drug Administration’s (FDA’s) approval process.

**BIOLOGICAL AGENTS**

In the near future, more than $10 billion worth of biological products will be coming off their patents. Although there is no regulatory infrastructure for the development of generic biopharmaceutical products, it can be assumed that such a structure will be forthcoming because of both market demands and the federal government’s desire to control expenditures for biological products. As a result of the current political and economic environment, an infinite patent life for biotech products is not feasible. In addition, because the government is assuming a major role in paying for biological agents, the CMS will probably move quickly to permit the entry of these generic medications into the market.

It is noteworthy that U.S. Pharmacopeia (USP) has offered a set of guidelines for formulary design that includes most of the medications in six key formularies. In its guidance on formulary design, the CMS added that formularies must include most of the medications in six key classes; one of these is the antidepressant class.

**MEDICARE PART D FORMULARY REQUIREMENTS**

Not all of the pressure being applied via the MMA toward encouraging generic drug use is positive. An example of the CMS’s power through Medicare Part D in encouraging the use of generics is the exclusion of escitalopram (Lexapro®, Forest) from the required list of medications included in formularies. In its guidance on formulary design, the CMS added that formularies must include most of the medications in six key classes; one of these is the antidepressant class.

On June 10, 2005, however, the CMS issued a document informing the plans that escitalopram did not need to be included on their formularies because another drug, citalopram (Celexa®, Forest), could be used as an alternative—even though escitalopram is the most widely used antidepressant in the long-term care (LTC) setting and is currently being taken by hundreds of thousands of LTC residents. Unfortunately, citalopram is not the generic equivalent of escitalopram. The two drugs differ in structure and exert different clinical effects.

The FDA has stated that escitalopram is approved for the treatment of anxiety, whereas citalopram is not indicated for that purpose. In clinical studies, citalopram was less effective and was associated with more adverse drug effects (ADEs).

The CMS has stated that formularies should follow clinical guidelines. However, established mental health treatment guidelines for depression, such as those developed by the American Psychiatric Association, unequivocally state that drugs to treat depression are not interchangeable.

It is safe to say that exclusion of escitalopram from PDP formularies will be problematic and disruptive to health care. As the CMS becomes more involved in formulary management, these types of actions that encourage generic agents over branded products are likely to increase in number as a means of controlling costs. It is not entirely clear how plan beneficiaries will respond to this move beyond generic substitution to therapeutic interchanges.

In a letter to Dr. McClellan, dated July 5, 2005, The American Society of Consultant Pharmacists urged the CMS to amend Attachment I of the June 10 formulary guidance to delete the bulleted item that stated: “All formularies must include either citalopram or escitalopram.”

Clearly, not all pushes to use generic medications are going to be viewed favorably.

**CONCLUSION**

Tremendous opportunities are possible for the expanded use of generic medications. This growth in the use of generic products will come as a result of:

- lowering of out-of-pocket expenditures for pharmaceutical agents by introducing the Medicare Part D benefit
- the MMA’s requirement for public disclosure of drug prices for chemical equivalents
- the MMA’s adoption of utilization-management tools (generic substitution, therapeutic interchanges, and step therapy)
- the eased entry of generic drugs into the market through provisions of the MMA enabling access to affordable pharmaceuticals
- the potential expansion of biopharmaceutical generic products as a result of greater federal responsibility for these products in an environment of increasing financial constraints
- Medicaid’s budget constraints, encouraging the widening role of generic substitution

Despite the pressure from payers in encouraging the increased use of generic medications, generic prescribing can happen only as a result of educational programs aimed at pharmacy providers, prescribers, and patients. This fact is supported by studies that demonstrate the effectiveness of education.
The CMS is prepared to spend $300 million on outreach education to inform the public about the Medicare PDP benefit, which will include instructing beneficiaries on how to use generic medications to lower their drug costs. It appears that all of the forces discussed in this article are converging to provide a “tipping point” that will raise the rate of generic drug dispensing above 50%. As with any tipping point, however, only time will tell what the long-term consequences will be. The real questions will be whether the public accepts therapeutic interchanges and, more important, whether these educational efforts result in a positive effect on health care outcomes.

REFERENCES