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Potential Effects of the New Medicare Drug Benefit on Pricing for Psychotropic Medications

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The new Medicare Part D prescription drug benefit created by the Medicare Modernization Act of 2003 (MMA) will have sweeping effects on how prescription drugs, including psychotropic medications, are financed for seniors and individuals with disabilities. The MMA relies on private Part D plans to control benefit costs by negotiating discounted prices with drug manufacturers and using pharmacy management tools common in the private sector, such as tiered formularies, to control drug use and spending. However, the MMA may not result in large overall price discounts or cost savings for psychotropic medications because of unique characteristics of many of these drugs. Also, concern exists that the legislation could result in higher Medicaid prices for those not in Medicare and lower investment in research and development for psychotropic drugs in the future. In this column we describe key features of the new benefit and discuss these concerns.

Key features of Medicare Part D

The Part D benefit will be administered by private Part D plans for Medicare fee-for-service enrollees and by Medicare Advantage plans for managed care enrollees, under contract with the Department of Health and Human Services. A minimum of two plans must compete to enroll beneficiaries in each of 34 prescription drug plan (PDP) regions, and at least one of these plans must be a private drug-only plan.) PDP regions vary in size from an estimated 182,651 Medicare beneficiaries in Region 33 (Hawaii) to an estimated 4,257,579 beneficiaries in Region 32 (California) (1). Unlike current private-sector plans, Medicare shares financial risk with most Part D plans for the cost of prescription drugs used by enrollees; thus plans have some incentives to control drug use and cost. The level of risk passed to plans is relatively low for the first two years of the program but will increase over time. In regions without two or more approved plans, enrollees can enroll in a “fallback” drug plan that places no financial risk for drug costs on the plan sponsor.

The legislation allows plans considerable flexibility in structuring pharmacy management tools, such as formularies, that will be used to negotiate prices and control drug use and expenditures (1). A key goal of formularies in this context is to stimulate price competition between different drugs that treat the same condition. If a plan can demonstrate the ability to move market share across competing drugs within a therapeutic class on the basis of price, manufacturers may be willing to negotiate sizeable discounts or rebates. Plans are required to cover only two drugs in each therapeutic category and class, although recent guidance from the Centers for Medicare and Medicaid Services (CMS) states that plans should cover a majority of antidepressants, antipsychotics, and anticonvulsants. However, CMS is silent about the generosity of coverage for these drugs.

Although Part D enrollment is voluntary for most Medicare beneficiaries, the approximately 7 million individuals who are dually eligible for both Medicare and Medicaid—a significant proportion of whom have a mental illness—will automatically receive drug coverage through a Part D plan instead of through the Medicaid program beginning January 2006. [See *Open Forum*, p. 1143.]

Competition and prices under Part D

The extent to which plans are able to negotiate low prices with manufacturers and to control drug expenditures will depend on a variety of factors, including the number and type of plans that participate in each region, the number of enrollees in each plan and the types of medications they use, and the impact of pharmacy management tools used by plans.

In general, larger plans should have greater bargaining power with manufacturers over price. However, a plan's bargaining power will likely vary across therapeutic classes or manufacturers. For example, if a plan has a limited number of enrollees with schizophrenia, the plan may not be able to extract discounts from manufacturers of antipsychotic drugs, because the plan will not be able to provide enough prescription volume to compensate for a lower price.

Plan incentives to control drug spending through the use of pharmacy management tools will vary by type of plan and over time on the basis of the level of financial risk that plans must assume. For example, fallback plans may exist in some regions, such as rural areas, where the size of the market or characteristics of the beneficiaries do not attract enough PDPs. Because fallback plans bear no risk, these plans have little incentive to negotiate low prices with manufacturers or control drug expenditures through pharmacy management tools. By contrast, as the level of financial risk passed down to PDPs increases over time, the incentive to control costs will increase and plans may strengthen pharmacy management.

The fewer psychotropic medications in a class that a plan places on its formulary, the more likely a manufacturer is to negotiate larger rebates. For example, if only two drugs in a class are placed on the formulary, a manufacturer may be willing to offer sizeable rebates because of the prescription volume likely to result from the listing. However, use of formularies may be less effective in controlling costs for psychotropics than for many other types of medications. Finding an appropriate pharmaceutical treatment for some patients can be difficult, so patients and their clinicians may be less willing to switch psychotropic medications in response to financial incentives, such as lower copayments, that are created by tiered formularies (2). As a result, use of formularies may do little to encourage price competition for psychotropic medications or may not result in large rebates.

Costs for non-dual-eligible Medicaid beneficiaries

Many state Medicaid programs have adopted a variety of strategies to control drug spending, including prior authorization programs, preferred drug lists, stepped formularies, and generic substitution policies (3). By using preferred drug lists and prior authorization programs, states hope to negotiate lower prices from manufacturers in exchange for preferred status—and no prior authorization—for their medications. Evidence on the use of various strategies suggests that these tools result in lower Medicaid drug expenditures, although the evidence is somewhat mixed on whether some of these savings are offset by other health care costs, and there is little evidence on the effects on psychotropic classes specifically (unpublished manuscript, Huskamp HA, 2005).

Drug coverage for dually eligible beneficiaries has customarily been through Medicaid. One key question is how enrollment of these individuals in Part D plans will affect the bargaining

power of Medicaid programs on behalf of beneficiaries who are not dually eligible. For some classes of psychotropic medications, such as antipsychotics, a sizeable number of Medicaid beneficiaries who use the medications are dually eligible—they qualify for Medicare because of a mental disability. Because these individuals will now be served by Part D plans, state Medicaid programs attempting to negotiate discounts through the use of strategies such as preferred drug lists or prior authorization programs could find their bargaining power reduced. Manufacturers may be less willing to negotiate discounts on the basis of these strategies, because the potential prescription volume at stake is lower without the dually eligible population. As a result, states could find that the prices they pay for certain psychotropic drugs increase for their non-dually eligible Medicaid populations. However, a number of states exempt certain psychotropics from some of these drug cost containment tools. In 2003, for example, 27 states exempted first-generation antipsychotics, 26 exempted second-generation antipsychotics, 25 exempted selective serotonin re-uptake inhibitors, and 16 exempted stimulants from prior authorization (3). In these states, moving dually eligible individuals, many of whom use these medications, to Part D plans may not have much effect on Medicaid pricing of psychotropic medications for the non-dually eligible populations, because the states do not currently take advantage of their bargaining power to negotiate discounts.

Effect on research and development investment

Another key question is how the changes to the Medicaid program resulting from the MMA will affect incentives to conduct research and development for drugs used to treat mental illness. There has been dramatic innovation in the prescription drug industry over the past several decades, particularly for medications used to treat mental illness (4). To achieve this innovation, the pharmaceutical industry invests heavily in research and development. Currently, the industry ranks third behind the computer and electronics industries in self-funded expenditures on research and development, with the top four drug companies investing 14 percent of net sales (5). Although the pharmaceutical industry faces large upfront research and development costs, the marginal cost of manufacturing each pill is very low. According to economic theory, competition between manufacturers will ultimately drive prices down to the marginal manufacturing cost. If manufacturers could charge only this amount, they may be unable to recover research and development costs and may have little incentive to invest in future efforts in these areas. To provide incentives for investment, U.S. law provides patent protection for new drugs for a fixed period, which gives the manufacturer the exclusive right to market the product and allows the firm to charge a higher price.

An important issue in regard to the MMA's effect on pricing of psychotropic medications is the fact that Medicaid is the dominant payer for certain classes of psychotropic drugs, particularly antipsychotic medications. In 2001 Medicaid was responsible for 52 percent of spending on antipsychotic drugs and approximately 67 percent of antipsychotic prescriptions (6). Once the dually eligible beneficiaries are moved to Medicare Part D plans, Medicare Part D will control a large proportion of the market for certain drug classes, such as antipsychotics. The combined Medicaid and Part D share of antipsychotic prescriptions will likely be even higher than the current Medicaid share. The resulting negotiating power that state Medicaid programs and Part D plans have with manufacturers will not be nearly as great as it would be if the government were unilaterally negotiating prices on behalf of all Medicaid and Medicare beneficiaries. However, large national Part D plans that serve multiple PDP regions will have significant bargaining power. Also, the National Governors Association has recently called for increased rebates to state Medicaid programs, the ability to restrict the drugs available to Medicaid beneficiaries, and the option to use reference pricing, defined as setting an upper limit on a state's payment for a drug (7,8). In theory, if stringent pharmacy management tools are adopted by Medicaid and Part D plans, incentives for future research and development

investments for medications used to treat mental illness could be affected, although no empirical evidence on this issue is available.

Conclusions

Medicare is relying on large price concessions from manufacturers in addition to private-sector drug management strategies to help control the costs of the new Part D drug benefit. However, the new program may not result in large discounts and rebates for psychotropics and could possibly have unintended effects for psychotropic medications.

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References

1. Huskamp HA, Keating NL. The new Medicare drug benefit: formularies and their potential effects on access to medications. *Journal of General Internal Medicine*, in press
2. Huskamp H. Managing psychotropic drug costs: will formularies work? *Health Affairs* 2003;22(5): 84–96. [PubMed: 14515884]
3. Kaiser Commission on Medicaid and the Uninsured: Medicaid Outpatient Prescription Drug Benefits: Findings From a National Survey, 2003. Available at www.kff.org/medicaid/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=30030 Accessed Jan 20, 2005
4. Mental Health: A Report of the Surgeon General. Rockville, Md, US Department of Health and Human Services, 1999
5. National Patterns of Research and Development Resources: 2003. NSF pub 05-308. Arlington, Va, National Science Foundation, Division of Science Resources Statistics, 2003
6. Frank RG, Conti R, Goldman HH. Mental health policy and psychotropic drugs. *Mil-bank Quarterly* 2005;83:271–298.
7. Young J. Drug industry at odds with GOP on Medicaid spending. *The Hill*, June 21, 2005. Available at www.hillnews.com/thehill/export/thehill/news/frontpage/062105/drug.html Accessed June 21, 2005
8. Pear R. Governors' association proposes Medicaid curbs. *New York Times*, June 16, 2005, p A18