NBER WORKING PAPER SERIES

PERVERSE INCENTIVES IN THE MEDICARE PRESCRIPTION DRUG BENEFIT

David McAdams
Michael Schwarz

Working Paper 12008
http://www.nber.org/papers/w12008

NATIONAL BUREAU OF ECONOMIC RESEARCH
1050 Massachusetts Avenue
Cambridge, MA 02138
January 2006

David McAdams at MIT Sloan School of Management, mcadams@mit.edu. Michael Schwarz at UC Berkeley and NBER, mschwarz@berkeley.edu.

Perverse Incentives in the Medicare Prescription Drug Benefit
David McAdams and Michael Schwarz
NBER Working Paper No. 12008
January 2006
JEL No. I1

ABSTRACT

We analyze some of the perverse incentives that may arise under the current Medicare prescription drug benefit design. In particular, risk adjustment for a stand-alone prescription drug benefit creates perverse incentives for prescription drug plans' coverage decisions and/or pharmaceutical companies' pricing decisions. This problem is new in that it does not arise with risk adjustment for other types of health care coverage. For this and other reasons, Medicare's drug benefit requires especially close regulatory oversight, now and in the future. We also consider a relatively minor change in how the benefit is financed that could lead to significant changes in how it functions. In particular, if all plans were required to charge the same premium, there would be less diversity in quality but also less budgetary uncertainty and less upward pressure on drug prices.

David McAdams
Sloan School of Managment
MIT
mcadams@mit.edu

Michael Schwarz
University of California, Berkeley
Department of Economics
140 Warren Hall MC 7360
Berkeley, CA 947210-7360
and NBER
mschwarz@berkeley.edu

Prescription drug plan (PDP) providers for the new Medicare Part D prescription drug benefit submitted their formularies to regulators at the Centers for Medicare & Medicaid Services (CMS) by a June 6, 2005 deadline. These providers had spent months optimizing the structure of their formularies but, after the deadline, CMS notified a number of plans that their formularies were insufficiently comprehensive. A CMS clarification stated that 'all or substantially all' of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories" must be covered by all formularies.[1] These plans had less than a week to submit new formularies meeting these requirements. One former Medicare official was quoted in the New York Times in June 2005 saying: "Medicare officials are flexing their muscles. They are requiring prescription drug plans to cover more drugs than anyone expected. They are establishing a gold standard for access to drugs in a number of therapeutic classes" (Pear 2005).

Even the formulary of Kaiser's plan – cited as a model of best practice for the Medicare benefit by Bush administration officials in December 2004 – was unacceptable. Kaiser's commercial formulary only includes two brand names for many therapeutic classes. Offering such a limited formulary allows large drug purchasers to negotiate substantial discounts by using formulary placement as leverage over pharmaceutical companies (Frank 2001).[2] As all formularies are required to cover more drugs, PDP providers

[1] CMS web site: http://www.cms.hhs.gov/pdps/formularyqafinalmmrevised.pdf (accessed August 5, 2005).

[2] An insurer's ability to extract price concessions depends on its ability to move volume to a particular drug, which itself depends both on the number of drugs on the formulary and the rate of formulary compliance (Frank 2001). For example, hospital pharmacies that fall under managed care steer large groups of patients to particular drugs more effectively than more traditional pharmacies. According to a 2003 Boston Consulting Group report, hospital pharmacies on average receive a 25% discount relative to retail drug stores.

will be less able to control drug costs.

Why did CMS require formularies to be more extensive than the existing best practice? One reason, we argue, is that a limited formulary will tend to harm Medicare beneficiaries to a much greater extent than the same formulary in an integrated plan like Kaiser's. The extent to which formulary restrictions harm beneficiaries depends crucially on how they are combined with other plan practices. A limited formulary works well for Kaiser patients because Kaiser doctors are aware of those limitations and usually prescribe from the formulary. Furthermore, a seamless exceptions process ensures that medically necessary drugs are covered, even when they are not on the formulary. Since Medicare Part D is a stand-alone benefit, PDPs may not be able to achieve as high formulary compliance nor have as much incentive to provide as seamless an exceptions process.

This by itself does not explain why CMS intervention was needed. After all, the Medicare benefit will "give beneficiaries a choice of at least two drug plans that will cover a comprehensive set of both brand name and generic drugs".[3,4] In a typical market, consumers' choices penalize providers of inadequate products. As is well known, however, the standard logic of competition does not apply to health insurance markets. Since insurers prefer to attract less costly patients, each insurer has an incentive to offer *less* generous coverage than its competitors (at a lower price). In some situations, this can create a "race to the bottom" in which a competitive insurance market fails to offer

[3]HHS News, January 21, 2005.

[4]Some seniors may have other options than this stand-alone benefit. Employers who offer drug coverage that meets the minimum standard for Medicare's drug benefit will be given incentive to continue to offer that coverage. HMOs may combine drug coverage with comprehensive health coverage under "Medicare Advantage". Dual Medicare/Medicaid beneficiaries will be automatically enrolled in Medicare Part D and receive additional subsidies.

any insurance product providing meaningful coverage. Indeed, an unsubsidized market for stand-alone prescription drug insurance is unlikely to be viable due to the severity of this problem (Pauly and Zeng 2003). Indeed, private markets have failed to provide meaningful stand-alone prescription drug coverage for seniors.[5]

Three important features distinguish the Medicare drug benefit from private provision of drug coverage. These differences are essential for creating a viable market for prescription drug coverage. First, any formulary must meet a set of minimum standards as mandated in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) and enforced by CMS. Thus, a race to the bottom would not lead to wholesale failure of the benefit but simply to all PDPs offering the minimum formulary allowed by law. Second, the benefit is generously subsidized.[6] Medicare will pay 74.5% of total plan premiums *plus* 80% of all catastrophic costs. (In 2006, catastrophic costs are defined as annual drug costs exceeding $5,100.) Overall, the cost of the benefit to the federal government in 2006 is projected to be over $1750 per beneficiary, or about 68% of the projected total cost for all drugs that will be consumed by beneficiaries in 2006.[7]

[5]With steep premiums and a cap of $3000 for drug reimbursement, even Medigap Plan J provides little protection from catastrophic costs, yet this is the maximum amount of coverage that an individual senior can purchase. This led a 1999 National Economic Council study to conclude that the only meaningful form of private prescription drug coverage is retiree drug coverage, and only 25% of the elderly have this type of coverage.

[6]In addition to these direct subsidies, Medicare will bear much of the risk of cost overruns. Medicare will audit each PDP provider's "spending target" and cushion 75% of any variation from this target from 2.5% to 5% and 80% of any variation more than 5%. (For example, if the target is $100 million but actual spending is $110 million, then Medicare will cut a check for about $5.9 million.)

[7]The drug expenditures for 2006 are projections taken from Stuart, Briesacher, Shea, et al 2005. Among all potential Part D enrollees, average annual per senior drug cost in 2006 will be $2,608. Estimated 14% of enrollees will have catastrophic spending and, among these, average total costs will be $9,106. On a per senior annual basis, then, government payments due to catastrophic coverage will

Third and perhaps most importantly, the premium subsidy that Medicare pays to PDP providers is "risk-adjusted."

This is not a paper about the various transitional challenges that will loom large during the benefit's first months and years. Rather our goal is to identify novel structural problems that we believe will create perverse incentives that will put long-term upward pressure on drug prices and downward pressure on drug plan quality. Unfortunately, the initial plans and prices offered for 2006 coverage are of little use for predicting long-term trends. Plans' widely dispersed bids may simply be due to their initial uncertainty about the extent of competition and about seniors' demand for drugs at subsidized prices.[8] Similarly, prices may be significantly lower than in future years due to switching costs.[9]

Risk adjustment for prescription drugs: a double-edged sword

Risk adjustment is a common practice among employers who offer their employees a choice of health insurance options. Each health insurance plan's payment for providing coverage is adjusted up or down based on the expected cost of the patients who choose its plan. This dampens plans' incentive to discriminate against more costly patients, reducing the likelihood of a race to the bottom.

> "Risk adjustment is burdensome but is an essential part of implementing a drug benefit" – CMS Administrator Mark McClellan (McClellan, Spatz, and

be 80% * ($9,106 - $5,100) * 14% ≈$450. The direct subsidy received by PDPs per beneficiary is about $1250. As a percentage of total costs, then, Medicare will pay $(\$1,250 + \$450)/\$2,608 \approx 65\%$.

[8]The cheapest PDP available in Maine for 2006 requires beneficiary contributions of $19.60 per month while Minnesota's cheapest plan costs only $1.87 per month.

[9]Seniors' confusion and slow enrollment into the benefit suggests that their switching costs between plans may be high. If so, plans have an incentive to set low prices in the first year and then increase prices in later years.

Carney 2000).

CMS will use a conventional approach for risk-adjustment in which each senior's expected next-year drug spending will be predicted on the basis of such observable characteristics as age, sex, new or continuing status in the program, and past medical diagnoses.[10] The subsidy that a PDP provider receives for each senior is then adjusted up or down to reflect how that senior's expected total cost differs from the average.

While widely used and well-understood for traditional health insurance coverage, risk adjustment for stand-alone prescription drug coverage has received very little attention. This would be small concern if the lessons learned from comprehensive health insurance applied to prescription drug coverage. Unfortunately, this is not the case. Indeed, as we shall argue, risk adjustment methods that work well for traditional health insurance could be disastrous if used for the Medicare drug benefit.

More broadly, we argue in general that risk adjustment in the context of stand-alone prescription drug coverage is a far less robust tool for discouraging discrimination than in the context of comprehensive health insurance. This is due to two unique features of prescription drugs. (A) Pharmaceutical companies with drugs still on patent are protected from competition and hence are monopolists. In contrast, providers of other medical services are rarely monopolists. (B) PDP providers have far more precise tools than health insurers for discouraging targeted groups of patients from enrolling in their plans.

(A) "Fine" risk adjustment causes upward pressure on drug prices. How much information about seniors should be used when computing risk-adjusted premiums? In the context of traditional health insurance, it is best to use as much information as possible,

[10]CMS has published the diagnosis codes that will be used for risk adjustment. See "CMS-HCC Risk Adjustment Models" at www.cms.hhs.gov/healthplans/riskadj for details (accessed August 5, 2005).

since then one can better estimate expected future costs (Glazer and McGuire 2000). This allows for more accurate risk adjustment so that insurers have less incentive to discriminate against any particular group of patients. For instance, pharmacy claims data can be used to predict future health care expenditures (Zhao, Ash, Ellis, et al 2005). Such pharmacy claims data would of course also help predict future drug spending. If this sort of data is used for risk adjustment purposes, however, drug manufacturers may have a perverse incentive to raise prices.

Currently, past pharmacy claims data is not available to CMS and hence is not being used for risk adjustment purposes. In the future, however, risk adjustment based on pharmacy claims data will be possible. For instance, suppose that Medicare's risk adjustment formula were to account for whether each senior is currently prescribed to Nexium or Prevacid, two of several clinically similar "proton pump inhibitors". This is useful information when predicting future drug costs, since these drugs are frequently taken for chronic conditions, e.g. any senior currently taking Nexium is likely to continue to do so in the future. AstraZeneca, the manufacturer of Nexium, now has more incentive to raise its price. After doing so, the risk adjustment formula will predict that any senior taking Nexium will be more costly than before, and each PDP provider will receive a larger subsidy from Medicare for such seniors. Consequently, PDP providers have little incentive to drop Nexium or otherwise encourage seniors to switch to Prevacid, even if it is significantly less expensive. For this reason, the cost for drugs associated with chronic illness will skyrocket if risk adjustments are computed using such detailed drug-level information.

Of course, this problem is easily solved for drugs like proton pump inhibitors which have several close substitutes. Rather than using pharmacy claims data at the drug level, one could code for the class of drug or the illness for which it was prescribed.

PDP providers would then have a strong incentive to encourage patients to switch to a relatively inexpensive drug within the class, and drug manufacturers would have relatively little incentive to boost prices. Less obvious is how to deal with unique patented drugs that are closely associated with the treatment of particular medical conditions. The only way to eliminate a drug manufacturer's extra incentive to raise prices in this case is to lump together seniors with a variety of conditions for risk adjustment purposes, i.e. to use a "coarser" set of information to determine subsidies. Unfortunately, this also has a serious drawback.

(B) "Coarse" risk adjustment creates perverse incentives for PDPs. Suppose that seniors with two somewhat different pre-existing conditions are lumped together and receive the same risk adjustment. As long as one of these pre-existing conditions is more costly, all PDP providers will have an incentive to discourage seniors having the more costly condition from joining their plans. Making matters worse, PDP providers have an enormous array of instruments at their disposal to make their plans less attractive to highly targeted groups of seniors. To discourage seniors with a particular pre-existing condition from subscribing, a PDP provider only needs to move a specific drug onto a different tier, add that drug to a pre-approval list, and/or tighten its approval process.

Plans are not allowed to discriminate in this way, but in its formulary guidelines CMS explains that it identifies discriminatory plans by first searching for "outliers". If all plans seek to provide poor quality to the same patients because of coarse risk adjustment, no plan will be an outlier. For this reason, it is unclear how CMS will be able to detect or correct systematic discrimination against certain groups of patients.

CMS' current approach for dealing with this problem is to impose a high "lowest bar" for plans. In this way, CMS can limit the extent to which discriminatory practices can harm groups of seniors with certain pre-existing conditions. "The minimum statutory

requirement is that a formulary must include at least two drugs in each approved category and class".[11] Indeed, according to CMS formulary guidelines, much more than the statutory minimum may be required of plans: CMS may insist on inclusion of drugs that "present unique and important therapeutic advantages" and/or those that are "most commonly used by the Medicare population". A variety of checks will also seek "to avoid drug selection and cost-sharing that discriminate against specific disease groups".

Regulating formularies will be a major challenge for CMS. As we have seen, simply looking for "outliers" will not be sufficient. Monitoring other plan practices such as the exception procedure will pose another challenge.

Will exception procedures be as fair as in current best practice? PDP providers are required by law to set up a procedure for granting exceptions for patients who need a medication not on the formulary. This is a standard practice in most HMOs. Medicare Part D coverage differs importantly from HMO coverage, however, as it offers drug coverage separately from the rest of health insurance. Consequently, some of the best practices used by HMOs to control drug costs may be ill-suited for Part D.

HMOs develop and maintain a reputation for providing a certain standard of care, but it is unclear if a PDP provider will be able to develop a reputation for offering a fair exception procedure. Any senior who takes a PDP provider's reputation for granting costly exceptions into account is more likely to be a bad risk. For this reason, it might actually be desirable for a PDP provider to establish a reputation for denying medi-

[11] "Medicare Modernization Act Final Guidelines – Formularies", January 2005, at http://www.cms.hhs.gov/pdps/FrmUpldInstGdncMatrl.asp (accessed January 10, 2006). When defining drug categories and classes, PDP providers may use their own classification system, but the system developed for CMS by U.S. Pharmacopeia is a "safe harbor". See "Medicare Model Guidelines" at http://www.usp.org/healthcareInfo/mmg (accessed August 5, 2005).

cally necessary exceptions because that could deter unprofitable patients from choosing its plan. Consequently, market discipline is unlikely to force PDP providers to adopt reasonable exception rules. The burden of monitoring exception procedures may fall on the Medicare bureaucracy. Without active pressure from Medicare, PDP's exception procedures may deteriorate into automatic denial of most costly requests.

Advantages of a drug benefit with fixed subsidy and premium

Seniors face an important trade-off when selecting a prescription drug plan, since plans can vary in both price *and* formulary extensiveness. It might seem that giving seniors more choice is unambiguously good for them, but this need not be the case. Indeed, the market might be more capable of delivering a benefit of reasonable quality at an affordable price if all drug plan premiums were the same.

More precisely, consider an alternative to the current design in which Medicare's subsidy is fixed at the amount budgeted for it by Congress and each beneficiary pays 25.5% of the total premium received by plans.[12] (Plans would still be allowed to compete by offering different formularies, different pharmacy networks, etc.) This relatively minor change in the way that the benefit is financed would significantly change the way that the benefit functions. The crucial difference is that the total cost of the benefit in this alternative is determined ahead of time based on the amount budgeted by Congress. Under the current design, the total cost of the benefit is determined through the market by PDPs and, indirectly, by price-setting decisions of pharmaceutical companies.

Fixing premiums will reduce diversity of PDPs on the quality dimension, but also has the obvious advantage of insuring that the cost of the benefit does not explode. Under the current design, prices, premiums, and government liabilities may turn out to be far

[12]Under the current design, the average beneficiary premium is 25.5% of the average total premium.

higher than currently projected. Fixing premiums could have several other significant advantages.

(i) Less upward pressure on drug prices. Under our alternative design, seniors pay the same premium regardless of which plan they choose. To attract seniors, then, all PDPs will aim to assemble the most generous formulary that is possible within their (fixed) budgets. This in turn puts pressure on pharmaceutical companies to keep their prices competitive so that their drugs are covered. In this way, setting the same premium for all plans even promotes competition among drugs that are not therapeutic substitutes.[13] Indeed, if the per person budget of the drug benefit is not sufficient to cover all valued medications, PDPs would face a difficult decision regarding what drugs to leave off the formulary. Since the least cost-effective drugs are most likely to be excluded, each pharmaceutical company has less incentive to raise the prices for its drugs.

(ii) Less downward pressure on formulary quality. The 74.5% premium subsidy was intended to create a self-regulating system in which the size and quality of the benefit are determined by seniors themselves via their participation in a market. An unintended drawback of this design, however, is that PDP providers may have more incentive to discriminate against seniors with high expected drug costs. As we have already discussed at length, any sensible risk adjustment approach will be imperfect so that some seniors will be more profitable to PDP providers than others.

If healthier seniors are more profitable (as one might expect), all plans will have

[13]Setting the same premium for all plans promotes competition among therapeutic substitute drugs for a more obvious reason. Given a limited budget, plans will only include the cheapest of these drugs, so each drug will need to be priced very aggressively not to be excluded. On the other hand, when seniors compare plans on both price *and* formulary extensiveness (as now), more expensive plans may opt to include all drugs from this class regardless of relative prices.

an incentive to offer less generous formularies at lower total premiums, regardless of the subsidy scheme. When subsidies are set at 74.5% of the national average total premiums, however, a race to the bottom becomes more likely, in which all plans offer the minimum formulary allowed by law. To see the point most starkly, suppose that all plans want to attract "good risks" (very healthiest seniors) who are likely to choose the cheapest plan. Each PDP provider will therefore attempt to offer a plan whose total premium equals 74.5% of the national average (with a correspondingly less generous formulary). When every plan attempts to be cheaper and less comprehensive than the average plan, the only possible stable outcome is for all plans to offer the minimal coverage allowed by law. While perhaps counter-intuitive, such extreme race-to-the-bottom behavior has been well documented in similar economic experiments (Nagel 1995).[14]

In contrast, when beneficiary premiums are fixed, any plan that offers a less generous formulary will become less attractive to *all* seniors, not just to those who are less healthy. Indeed, competition among plans could put upward rather than downward pressure on the quality of the benefit. For this reason, fixing the subsidy and beneficiary premium could have the extra advantage of decreasing the extent to which CMS will have to regulate the benefit.

Regulating a stand-alone drug benefit

To anticipate where and why CMS may have to play an active regulatory role, it is useful to classify restrictions on PDP behavior into "bright-line" versus "fuzzy-line" rules and "binding" versus "non-binding" rules. A bright-line rule provides a clear test for determining prohibited conduct. For instance, the requirement that "a formulary must

[14]In the experiments, each participant guesses a number and is rewarded if his guess is close to three-quarters of the average guess.

include at least two drugs in each approved category and class" is a bright-line rule. On the other hand, the requirement that all drugs presenting "unique and important therapeutic advantages" be included is a fuzzy-line rule. Enforcing bright-line rules requires minimum regulatory oversight, while verifying compliance with fuzzy-line rules requires interpretation and discretion.

A fuzzy-line rule is binding if most participants have an incentive to violate it and/or negotiate its interpretation with CMS, and non-binding otherwise. PDPs facing binding fuzzy-line rules will push the envelope as far as they can, and enforcing such rules may turn CMS into a heavy-handed regulator. To understand what sort of regulator CMS will likely become, it is important to consider which fuzzy-line rules are likely to be binding.

The requirement that PDPs must include "drugs most commonly used by the Medicare population" might seem straightforward, but it is a fuzzy-line rule since CMS will likely exercise discretion when applying it. For instance, Nexium is one of the most frequently used medications. Does this mean that Nexium must be included on every Medicare formulary? Probably not, since Nexium does not provide "unique and important therapeutic advantages", the other fuzzy-line rule for drug inclusion on formularies. (Prilosec is virtually clinically indistinguishable from Nexium and likely to be available in generic form.) As discussed in the introduction, these rules have already been binding on those offering coverage for 2006, as CMS officials have insisted on more extensive formularies. Unfortunately, by setting minimum requirements for a particular therapeutic class, CMS increases the upward price pressure for drugs in that class.

Perhaps the most important binding fuzzy-line rule is the requirement that formularies should not discriminate against specific groups of patients. "Non-discrimination" in this context is far from being an innocuous platitude. Excluding a drug or setting a high co-pay discriminates against patients whose doctors prescribe this drug. Congress

did not intend to require that all drugs must be covered by all plans. In fact, Congress required plans to use best private market practices to control costs. Consequently, some amount of "discrimination" is necessary. It is not obvious when excluding a drug constitutes illegal discrimination. For instance, Avastin (a drug approved to treat metastatic colon cancer) costs about $50,000 for one year's supply. On average, Avastin prolongs life by several months. Does refusal to cover this drug constitute illegal discrimination against colon cancer patients for whom the drug is the last hope? When PDPs submitted their formularies, the answer to this question was not clear to all plans. *After* all bids with formularies were submitted, CMS extended the deadline for submitting bids and required "inclusion on all formularies of 'all or substantially all' of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories."[15] If all formularies are required to carry a particular drug, we can expect the price of that drug to explode (Newhouse 2004).[16]

We expect the non-discrimination requirement to remain binding in the future. Indeed, as we have discussed earlier, unique features of stand-alone prescription drug coverage suggest that *any* sensible risk adjustment mechanism will give PDP providers the incentive to favor certain groups of patients and not others. (See the section "Risk-adjustment: a double-edged sword".)

The law makes it relatively easy for PDP providers to drop drugs from their formu-

[15]CMS web site: http://www.cms.hhs.gov/pdps/formularyqafinalmmrevised.pdf (accessed August 5, 2005).

[16]There are other important reasons why drug manufacturers have additional incentives to raise price within the Medicare drug benefit. For drugs without close substitutes, the fact that beneficiaries only pay a fraction c of the cost means that drug manufacturers' profit-maximizing prices will be $1/c$ times as high. For drugs associated with catastrophic spending, $c = 5\%$ so this effect would predict prices 20 times as high (Newhouse 2004).

laries or change co-payments.[17] While beneficiaries can only change plans once a year, a PDP provider can drop a drug from its formulary any time after giving thirty days notice to subscribers. This rule might appear dangerously one-sided, but it is not unusual in commercial insurance markets.[18] The ability of PDPs to change prices after seniors commit to a plan has already become a concern for legislators. During the open enrollment period, seniors can consult the web-based 'Medicare Plan Finder' to learn more about plans. After entering all of their prescription information, the site provides an estimate of their annual out-of-pocket costs for every drug plan available in their state. These estimations are not binding. Consequently, a senior who is locked into a plan for a year may end up incurring a far greater out of pocket cost than the quote given to him by his PDP. This possibility led Senator Richard Durbin of Illinois propose a Truth in Pricing Act that will require PDPs to stick with their original price estimates (unless the price declines). In a November 29, 2005 letter to congressional colleagues, Senator Durbin illustrated the need for this law by citing the experience of one of his constituents who is taking Arthrotec, Fosamax, K-Tabs, Lasix, Prevacid, and Trental: "The Medicare Plan Finder on November 17, 2005 offered a list of appropriate prescription drug plans, including Medicare Rx Rewards Premier, which had an estimated annual cost of $2,691.69. My staff re-checked the same drug list on the Plan Finder less than a week later, on November 22, 2005, and found the same plan was then estimated to have an annual cost

[17] "CMS will accept changes to formulary drugs on a regular basis, within 30 days ... These submitted changes will be reviewed by CMS to ensure that formularies remain nondiscriminatory and meet other minimum standards", quoted from "Medicare Modernization Act Final Guidelines – Formularies", January 2005.

[18] We speculate that this provision serves a dual purpose: to prevent insolvency of plans that find themselves in financial distress and to allow plans to react to sudden changes in drug prices, as after generic entry.

of $3,844.49, an increase of $1,152.80 from a week before.". At this time, systematic data on fluctuations in co-pays is not available. However, significant weekly and even daily price changes for the same list of drugs were not uncommon during November 2005.

Additional important binding fuzzy-line rules relate to CMS auditing of plans' cost projections. In commercial audits, a financially healthy business typically has little incentive to game auditors, since the outcome of the audit has no direct impact on the bottom line. In contrast, CMS audits plans' cost projections for the purpose of "risk-sharing". Since Medicare will pay up to 80% of any difference if these projections are wrong, biased projections could have a real and significant impact on a PDP's bottom line and on government liabilities. Deciding on permissible methods for producing cost projections may prove to be a binding fuzzy-line rule since anticipating patients' needs is notoriously difficult. Yet another potentially binding fuzzy-line rule related to auditing is that each PDP's formulary must result in an average beneficiary co-pay of 25% (when cumulative annual drug costs are from $250 to $2250). Predicting patients' response to formulary incentives is critical for estimating the average co-pay. Yet understanding the impact of formulary structure on patients' choices is on the frontier of academic research (Goldman, Joyce, Escarce, et al 2004, Huskamp, Deverka, Epstein, et al 2003). There is no standard or generally accepted approach for producing such estimates.

One is left with a system that, we believe, will require continuous and intense long-term regulatory oversight of PDP providers at every level, from formulary design to methods for projecting plan costs.

Conclusion

Where private insurance markets have failed, Medicare may succeed in providing meaningful and sustainable stand-alone prescription drug coverage. Three key features of the

Medicare benefit make this possible: the Medicare benefit is subsidized, the premiums that drug plans receive are "risk-adjusted", and CMS can impose mandatory minimal quality standards.

Both the subsidy and risk adjustment are intended to create a self-regulating market, in which the size and quality of the benefit are determined by seniors themselves via their participation in a market. Our analysis suggests, however, that CMS regulation will ultimately determine the cost and comprehensiveness of the benefit. CMS will likely exercise its discretion in regulating many aspects of the benefit, from dictating the comprehensiveness of permissible formularies to closely overseeing exceptions processes.

Perverse incentives for PDP providers also arise from the fact that Medicare's premium subsidy is computed as a percentage of the average total premium. Fixing the subsidy at the amount that was budgeted by Congress (while allowing plans to compete on quality) would decrease budgetary uncertainty, could reduce upward price pressure on drug costs, and could somewhat diminish the need for CMS to play an active regulatory role.

Issues with risk adjustment are more fundamental and unavoidable. Risk adjustment is intended to avert a "race to the bottom" and discrimination against particular groups of patients. It has proved successful in accomplishing just that in the market for health insurance. Due to unique features of stand-alone drug coverage, however, PDP providers' incentives to discriminate against patients with certain pre-existing conditions can not be eliminated without creating other serious problems. In particular, PDP providers will have an incentive to discriminate against some groups of patients unless CMS can sufficiently fine-tune its risk adjustment formula. Yet pharmaceutical companies' incentive to raise prices becomes stronger as risk adjustment is taken over finer and finer scales.

In the end, implementation of the benefit will require active regulatory involvement

that controls drug prices and/or controls PDP formularies and plan practices. Understandably, CMS has had to take an active regulatory role during the benefit's well-publicized 'birth pains'. The point of our analysis is to suggest that CMS will have to continue to closely regulate the benefit, especially formulary design, for the foreseeable future.[19] Any minimum standard that CMS imposes on formularies, however, will put additional upward pressure on drug prices. Ultimately, this could jeopardize the drug benefit's budgetary viability.

References

Boston Consulting Group (2003): *Changing Environment for the U.S. Pharmaceuticals*. BCG, Boston, April.

Frank, R. (2001): "Prescription Drug Prices: Why Do Some Pay More than Others Do," *Health Affairs*, 20(2), 115–128.

Glazer, J., and T. McGuire (2000): "Optimal Risk Adjustment in Markets with Adverse Selection: An Application to Managed Care," *American Economic Review*, 90(4).

Goldman, D., G. Joyce, J. Escarce, J. Pace, M. Solomon, M. Laouri, P. Landsman, and S. Teutsch (2004): "Pharmacy Benefits and the Use of Drugs by the Chronically Ill," *Journal of the American Medical Association*, 291(19), 2344–2350.

HHS News (2005): "HHS takes major step to prescription drug benefit," January 21.

[19]The law explicitly prohibits CMS from negotiating prices.

Huskamp, H., P. Deverka, A. Epstein, R. Epstein, K. McGuigan, and R. Frank (2003): "The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending," *New England Journal of Medicine*, 349(23), 2224–2232.

McClellan, M., I. D. Spatz, and S. Carney (2000): "Designing A Medicare Prescription Drug Benefit: Issues, Obstacles, and Opportunities," *Health Affairs*, 19(2).

Nagel, R. (1995): "Unraveling in Guessing Games: An Experimental Study," *American Economic Review*, 85(5), 1313–26.

Newhouse, J. (2004): "How Much Should Medicare Pay For Drugs?," *Health Affairs*, 23(1), 89–102.

Pauly, M., and Y. Zeng (2003): "Adverse Selection and the Challenge to Stand-Alone Prescription Drug Insurance," *NBER Working Paper*, 9919.

Pear, R. (2005): "Medicare Insists on Wider Choice in Drug Benefits," *New York Times*, June 15.

Stuart, B., B. A. Briesacher, D. G. Shea, B. Cooper, F. S. Baysac, and M. R. Limcangco (2005): "Riding the Rollercoaster: The Ups and Downs In Out-of-Pocket Spending Under the Standard Medicare Drug Benefit," *Health Affairs*, 24(4).

Zhao, Y., A. S. Ash, R. P. Ellis, J. Z. Ayanian, G. C. Pope, B. Bowen, and L. Weyuker (2005): "Predicting pharmacy costs and other medical costs using diagnoses and drug claims," *Medical Care*, 4, 34–43.