

# Perverse Incentives in the Medicare Prescription Drug Benefit

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*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 need to regulate formulary composition, less budgetary uncertainty and less upward pressure on drug prices.

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, anti-convulsant, anticancer, immunosuppressant and HIV/AIDS categories” must be covered by all formularies.<sup>1</sup> 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 includes only 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).<sup>2</sup> As all formularies are required to cover more drugs, PDP providers will be less

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

<sup>2</sup>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.

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 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”.<sup>3,4</sup> 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 any insurance product providing meaningful coverage. An unsubsidized market

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<sup>3</sup>HHS News, January 21, 2005.

<sup>4</sup>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.

for stand-alone prescription drug insurance is unlikely to be viable due to the severity of this problem (Pauly and Zeng 2004). Indeed, private markets have failed to provide meaningful stand-alone prescription drug coverage for seniors.<sup>5</sup>

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.<sup>6</sup> Medicare will pay 74.5% of total plan premiums *plus* 80% of all catastrophic costs. (15% of catastrophic costs are covered by PDPs while the remaining 5% are out-of-pocket. 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 \$1700 per beneficiary, or about 65% of the projected total cost for all drugs that will be consumed by beneficiaries in 2006.<sup>7</sup>

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<sup>5</sup>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.

<sup>6</sup>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.)

<sup>7</sup>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 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 during these early years 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.<sup>8</sup> Similarly, prices may be significantly lower than in future years due to switching costs.<sup>9</sup>

## **Risk adjustment for prescription drugs: a double-edged sword**

Risk adjustment for comprehensive health insurance is widely used in the public sector. It is also utilized by some employers who offer their employees a choice of health insurance options.<sup>10</sup> Each health insurance plan’s payment for providing coverage is adjusted up  $\frac{80\% * (\$9,106 - \$5,100) * 14\% \approx \$450}{\$2,608}$ . The direct subsidy received by PDPs per beneficiary is about \$1250. As a percentage of total costs, then, Medicare will pay  $(\$1,250 + \$450)/\$2,608 \approx 65\%$ .

<sup>8</sup>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.

<sup>9</sup>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 initially and then increase prices in later years.

<sup>10</sup>While widely used and well-understood in the public sector, risk adjustment is the exception rather than the rule in the private sector (Keenan et al 2001). Glazer and McGuire (2001), Feldman, Dowd, and Maciejewski (2001), and Frank and Rosenthal (2001) point out that premium negotiations and other informal mechanisms effectively substitute for risk-adjustment in the private sector while Ellis (2001) argues that the market is not in equilibrium.

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. As noted by McClellan, Spatz, and Carney (2000), "Risk adjustment is burdensome but is an essential part of implementing a drug benefit".

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. 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.

Risk adjustment for stand-alone prescription drug coverage has received very little attention. This would be a small concern if the lessons learned from comprehensive health insurance applied to prescription drug coverage. But unfortunately, 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 may act as 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.* Depending on the coarseness of CMS' medical diagnosis categories, seniors having different medical conditions may or may not be lumped together for risk adjustment.<sup>11</sup> In the context of traditional health insurance, more finely-defined patient categories tend to be better, since then one can better estimate expected future

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<sup>11</sup>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](http://www.cms.hhs.gov/healthplans/riskadj) for details (accessed August 5, 2005).

costs (Glazer and McGuire 2000) and reduce insurers' incentive to discriminate against any particular group of patients by providing more accurate risk adjustments.

In the context of prescription drug coverage, on the other hand, finer risk adjustment can have the downside of causing less aggressive price competition among drug manufacturers. As an extreme case to illustrate this point, suppose that drug-level pharmacy claims data were used. This may appear sensible, since past drug usage can be used to predict future drug usage for chronic conditions.<sup>12</sup> Yet using such information for risk-adjustment purposes would effectively create a cost-reimbursement system with tremendously perverse incentives for both PDPs and drug manufacturers.

Consider the clinically similar class of drugs known as proton pump inhibitors. One might expect that PDP providers would force manufacturers of drugs in this class to compete aggressively on price, since PDPs can always threaten to steer patients toward the cheapest drug in the class. However, if drug-level pharmacy claims data were used for risk adjustment, drug manufacturers would have very little incentive to compete on price. To see why, suppose that AstraZeneca were to charge more for its proton pump inhibitor, Nexium. The risk adjustment formula would then predict that any senior taking Nexium is more costly than before, and each PDP provider would receive a larger subsidy from Medicare for such seniors. Consequently, PDPs would have little incentive to drop Nexium or otherwise encourage seniors to switch to a less expensive substitute.

*(B) Coarse risk adjustment.* Medicare avoids this sort of problem by using medical diagnoses to determine each senior's risk adjustment, regardless of which drugs he may have taken to treat his medical conditions. Diagnosis-based risk adjustment promotes price competition among drug manufacturers as long as the drugs used to treat seniors

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<sup>12</sup>More broadly, pharmacy claims data have been used to predict future health care expenditures (Zhao, Ash, Ellis, et al. 2005; Lamers 2001).

with a given diagnosis are close substitutes. In this case, PDP providers have an incentive to drop from their formularies all but the cheapest drugs that can treat each given medical condition, which in turn induces drug manufacturers within each therapeutic class to compete more aggressively on price. On the other hand, for diagnoses that are closely associated with unique drugs, diagnosis-based risk adjustment becomes equivalent to pharmacy claims-based risk adjustment, and drug manufacturers again have little incentive to compete on price.

Diagnosis-based risk adjustment can also lead to a perverse incentive for PDPs to discriminate when a given diagnosis code is associated with several drugs that are not close substitutes.<sup>13</sup> In that case, risk adjustment based on the average cost of patients with this diagnosis would be too generous for patients who take the cheapest drugs and inadequate for patients who need the most costly drugs. As a result, all PDP providers would have an incentive to discourage seniors who need the most costly drugs 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 who want a particular drug from subscribing, a PDP provider only needs to move that drug onto a different tier, add it to a pre-approval list, and/or tighten its approval process.

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 cate-

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<sup>13</sup>Drugs associated with a given diagnosis code may not be close substitutes for several reasons. For example, the diagnosis code might be defined broadly enough to include several distinct medical conditions treated by different drugs, or the drugs that treat a given medical condition may not all be suitable for each senior.

gory and class”.<sup>14</sup> 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 also will seek “to avoid drug selection and cost-sharing that discriminate against specific disease groups”. 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.

One way to reduce the need for close regulatory oversight is to modify the design of the benefit. For instance, we argue below that eliminating price competition among PDPs (by fixing premiums) may actually strengthen quality competition among PDPs, thus reducing the need for regulation. A more radical approach is advocated by Huskamp et al. (2000), who propose eliminating consumer choice. Under their system, a single PDP would be awarded a contract for each region. This proposal has a number of advantages relative to the current design of the Medicare drug benefit. In particular, adverse selection disappears when there is just one PDP per region, formulary compliance is likely to be high, and seniors will not have to agonize over a complex decision.

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<sup>14</sup>“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).

## 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. By offering seniors such choice, Congress 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. However, an unintended drawback of this design is that PDP providers may have more incentive to discriminate against seniors with high expected drug costs. As already discussed, 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 an incentive to offer less generous formularies at lower total premiums, regardless of the subsidy scheme.

Indeed, given that subsidies are set at 74.5% of the national average total premium, 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” (the very healthiest seniors) who are likely to choose the cheapest plan. Each PDP provider will attempt to offer a plan whose total premium equals 74.5% of the national average, with a correspondingly less generous formulary, so that enrolling seniors pay nothing. If 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.<sup>15</sup>

Seniors will have little meaningful choice if plans cluster at the minimal legal coverage. In this case, the quality and cost of the benefit will effectively be dictated by

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<sup>15</sup>While perhaps counter-intuitive, such extreme race-to-the-bottom behavior has been well documented in similar economic experiments (Nagel 1995). In the experiments, each participant guesses a number and is rewarded if his guess is close to three-quarters of the average guess.

CMS regulators through their implementation of a minimum standard. PDPs may also be motivated to include on their formularies the cheapest drugs that meet the legal requirement, which need not be the most cost-effective. For instance, consider a hypothetical example in which PDPs are required to cover at least two of three drugs, each of which has no therapeutic substitutes and treats a different chronic condition. Suppose that these drugs increase life expectancy by three months, six months and one year and cost \$10,000, \$15,000, and \$20,000, respectively, but they are lumped together for risk-adjustment purposes. Seniors with no pre-existing conditions would prefer a plan covering the most expensive drugs, since these are the most cost-effective in terms of extending life. However, since these drugs treat chronic conditions, plans that cover the most expensive drugs will suffer from an adverse selection. For example, they will pay \$20,000 per senior with the third condition but receive a risk adjustment for that senior based on the average cost of all seniors having any of the three conditions, which will be strictly less than \$20,000. For this reason, all plans will have an incentive to exclude the most expensive drug in spite of the fact that it is the most cost-effective.

We argue that the market might be more capable of delivering a benefit of reasonable quality at an affordable price if drug plans were allowed to compete on quality but not on price. More precisely, we consider an alternative to the current financing design. Under the current design, the average beneficiary premium is 25.5% of the average total premium. Now consider an alternative 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. Plans would still be allowed to compete by offering different formularies, different pharmacy networks, etc., and seniors would still have the ability to choose among plans.

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 indirectly determined by regulators when they set minimum formulary requirements and by the price-setting decisions of pharmaceutical companies. Fixing premiums may reduce the diversity of PDPs on quality dimensions, but it has the obvious advantage of insuring that the cost of the benefit is predictable.

Less obvious but no less important is that fixing premiums can reduce the need to regulate formularies and decrease the upward pressure on drug prices. Since seniors pay the same premium regardless of which plan they choose, any plan that offers a less generous formulary will become less attractive to *all* seniors, not just to those who are less healthy or more affluent. To attract seniors, all PDPs will aim to assemble the most generous formulary that is possible within their fixed budgets. This promotes price competition between drugs, within and across therapeutic classes. PDPs having a limited budget will only include the most cost-effective drugs, so pharmaceutical companies will have to price aggressively enough that their drugs are not excluded. 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 need to regulate the benefit.

Of course, if the funds provided by Congress are insufficient to cover all useful drugs, some drugs that are less cost-effective will not be covered. Yet this is inevitable under the current benefit design as well. Indeed, as we have discussed, under the current system plans may have an incentive to exclude some drugs that are more cost-effective. A system with fixed premiums also might be vulnerable to political meddling, since PDPs and pharmaceutical companies would have an incentive to lobby Congress to increase the

budget. Under the current system, however, these interest groups have an incentive not only to lobby Congress but also to influence how CMS regulators implement the benefit.

A potential drawback to setting the same premium for all seniors is that the quality of the benefit might vary regionally. However, it is unclear whether our proposal or the status quo would lead to greater regional inequity. Unlike many other health care services, most drugs are not produced locally and hence production costs do not vary by region. Indeed, if resale across regions were seamless, the price of drugs would be the same in all regions. In this case, our proposal of setting the same subsidy in all regions would ensure equity while the current system of setting the subsidy in each region equal to 74.5% of the average total premium in that region would lead to inequity. For example, if seniors in relatively more wealthy areas demand more drugs, these wealthier seniors will receive a larger subsidy.

## **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 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 may 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 pressure on prices of 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, but 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.

Broadly speaking, Congress’ intent appears to be that people with a particular disease or condition should not be put in a position where the drugs that they need are not covered. Still, it is unclear where to draw the line. For instance, recent research suggests that metastatic colorectal cancer may be most effectively treated by a combi-

nation of Avastin, Eloxatin, and Xeloda, three of the very few drugs approved to treat this disease.<sup>16</sup> Avastin alone costs about \$50,000 for one year's supply and, on average, prolongs life by several months. Does refusal to cover Avastin constitute illegal discrimination against colon cancer patients for whom this drug (perhaps in combination with others) is their best hope? When PDPs submitted their formularies, the answer to this question was not clear to all plans. Afterwards CMS clarified its requirement, insisting on "inclusion on all formularies of all or substantially all of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories."<sup>17</sup>

Once all formularies are required to carry a particular drug, we can expect the price of that drug to explode. Indeed, as argued by Newhouse (2004), 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 twenty times as high.

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.

Other potentially 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 its bottom line. In contrast, CMS audits plans' cost projections for the purpose of "risk-sharing". Medicare

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<sup>16</sup>Bendell J, Yu D, Hurwitz H, et al. (2005) argue that 94% of patients in their sample achieved a clinical benefit under this combination treatment (dubbed XeloxA).

<sup>17</sup>CMS web site: <http://www.cms.hhs.gov/pdps/formularyqafinalmmrevised.pdf> (accessed August 5, 2005).

will pay up to 80% of any difference if these projections are wrong, so 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.

The law makes it relatively easy for PDP providers to drop drugs from their formularies or change co-payments.<sup>18</sup> 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.<sup>19</sup> 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

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<sup>18</sup>"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.

<sup>19</sup>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 their annual out-of-pocket costs for every drug plan available in their state. These estimates 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 by his PDP.

This possibility led Senator Richard Durbin of Illinois to 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 of \$3,844.49, an increase of \$1,152.80 from a week before.”

Such problems may be due, at least in part, to “start-up issues” beyond the scope of this paper. Yet the perverse incentives that we have identified here will not go away in the future. Drug makers will tend to respond to their incentives to increase the price of drugs that must be covered, and PDP providers will tend to seek out ways in which they can profitably push the regulatory envelope. One is left with a system that, we believe, will require continuous and intense long-term regulatory oversight of PDP providers.

## **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. However, our analysis suggests that CMS regulation will ultimately determine the cost and comprehensiveness of the benefit through their implementation of a minimum standard. 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. As an alternative, we argue that 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 modestly 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 cannot 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". Our analysis suggests that CMS will have to continue to closely

regulate the benefit, especially the formulary design, for the foreseeable future.<sup>20</sup> Yet any minimum standard that CMS imposes on formularies will put additional upward pressure on drug prices. Ultimately, this could jeopardize the drug benefit's budgetary viability.

## References

Bendell, J.C., D. Yu, H. Hurwitz, et al. 2005. Capecitabine and oxaliplatin (XELOX) in combination with bevacizumab in the treatment of metastatic colorectal cancer: results of a phase II trial. *Proceedings from the European Cancer Conference (ECCO 13)*.

Boston Consulting Group. 2003. Changing Environment for the U.S. Pharmaceuticals". Boston: BCG.

Ellis, R. 2001. Formal Risk Adjustment by Private Employers. *Inquiry* 38(3): 299-309.

Feldman, R., B. Dowd, and M. Maciejewski. 2001. A Demand-Side View of Risk Adjustment. *Inquiry* 38(3): 280-289.

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

Frank R., and M. Rosenthal. 2001. Health Plans and Selection: Formal Risk Adjustment vs. Market Design and Contracts. *Inquiry* 38(3): 290-298.

Glazer, J., and T. McGuire. 2000. Optimal Risk Adjustment in Markets with Adverse Selection: An Application to Managed Care. *American Economic Review* 90(4): 1055-1071.

Glazer, J., and T. McGuire. 2001. Private Employers Don't Need Formal Risk Adjust-

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<sup>20</sup>The law explicitly prohibits CMS from negotiating prices.

ment. *Inquiry* 38(3): 260-269.

Goldman, D., G. Joyce, J. Escarce, et al. 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, January 21. HHS takes major step to prescription drug benefit.

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

Huskamp, H., M. Rosenthal, R. Frank, and J. Newhouse. 2000. The Medicare Prescription Drug Benefit: How Will the Game Be Played. *Health Affairs* 19(2): 8-23.

Keenan, P.S., M. Beeuwkes Buntin, T. McGuire, and J. Newhouse. 2001. The Prevalence of Formal Risk Adjustment in Health Plan Purchasing. *Inquiry* 38(3): 245-259.

Lamers, L. 2001. Health-Based Risk Adjustment: Is Inpatient and Outpatient Diagnostic Information Sufficient? *Inquiry* 38(4): 423-431.

McClellan, M., I. Spatz, and S. Carney. 2000. Designing A Medicare Prescription Drug Benefit: Issues, Obstacles, and Opportunities. *Health Affairs* 19(2): 26-41.

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. 2004. Adverse Selection and the Challenge to Stand-Alone Prescription Drug Insurance. *Frontiers in Health Policy Research* 7: 55-74.

Pear, R. 2005, June 15. Medicare Insists on Wider Choice in Drug Benefits. *New York*

*Times.*

Stuart, B., B. Briesacher, D. Shea, et al. 2005. Riding the Rollercoaster: The Ups and Downs In Out-of-Pocket Spending Under the Standard Medicare Drug Benefit. *Health Affairs* 24(4): 1022-1031.

Zhao, Y., A. Ash, R. Ellis, et al. 2005. Predicting pharmacy costs and other medical costs using diagnoses and drug claims. *Medical Care* 4: 34-43.