



WORKING PAPER:

**Fifty Concerns about the Medicare Law, and
Ideas on How To Fix Them**

July 22, 2004

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One of the few statements accepted across the political spectrum is that the implications of the new Medicare law are enormous. Clearly, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) is important because it adds a long-overdue drug benefit to the program that costs between \$400 and \$535 billion over ten years. Beyond this, the delivery system and design of the drug benefit; its interactions with the renamed and reinvigorated Medicare Advantage (formerly the Medicare+Choice program); and other changes have similarly profound implications. Many of the changes are clear in the structure of the legislation,¹ but others are in its details and their impact depends on their implementation.

This paper aims to both catalogue the important issues associated with the new law and suggest how they could be addressed. The 50 highlighted issues are both serious and solvable. They focus on concerns of beneficiaries -- particularly those with low income or high health care needs² -- rather than those of health care providers, health plans, potential drug insurers, or drug manufacturers. Each is described succinctly, including references to both the section of the law where the issue arises and the page number in the *Conference Report to Accompany H.R. 1*.³ The regulatory and legislative fixes are brief suggestions rather than full-blown proposals. Some require further policy development and involve tradeoffs. For example, increasing consumer protections may discourage private plan participation; limiting potentially overly-aggressive cost management tools may increase Federal costs. The intent is to encourage discussion and debate about policies to ensure affordable, meaningful drug coverage, and basic benefits, for the Medicare population.

This paper places a special emphasis on potential regulatory changes to the new Medicare law. The law delegates numerous and significant policy decisions to the regulatory process and the Secretary of Health and Human Services. For example, the regulations could create a simplified appeals process for beneficiaries who lose access to preferred drugs when a plan changes its formulary midyear; they could create standards the limit employer "dropping" of their contributions to retiree drug coverage. These regulatory improvements are especially important since the odds are low that legislative changes can be enacted in the near term. The President has indicated that he will veto major legislative changes,⁴ and has declined to send to Congress a list of technical corrections as required by law.⁵ As such, the forthcoming proposed regulations represent an important moment in Medicare policy making.

Fifty Concerns About the Medicare Law

Issue	Can Be Improved through Regulation (X=Yes)
Drug Cost Containment	X
1 Creates interim discount card that benefits few	X
2 Effectively blocks reimportation of U.S.-made prescription drugs	X
3 Prohibits Secretary from negotiating prices for Medicare	X
4 Allows potentially unlicensed insurers to set drug prices for Medicare	X
5 Does not prohibit financial ties between drug industry and drug plans	X
6 Creates incentives for lowering access as well as prices	X
7 Does not require that drug plans pass through all discounts to enrollees	X
8 Selects drug plans solely on their willingness to accept financial risk	X
9 Limits access to and viability of non-risk "fallback" plans	
10 Limits government oversight over the prices Medicare pays	X
Drug Benefit Eligibility and Enrollment	
11 Entitles beneficiaries to access to a drug plan – not a drug benefit	X
12 Limits enrollment opportunities	X
13 Guarantees minimal information prior to plan choice	X
14 Provides plans with personal information to use in marketing	X
15 Provides false sense of choice of drug plans	X
16 Locks beneficiaries into drug plans which could change during the year	
Drug Benefit Premium	
17 Lets private plans, not Medicare, set annual premiums	X
18 Does not protect Social Security benefit increases from drug premiums	X
19 Increases premiums for those who do not enroll when they should	X
20 Does not ensure that low-income enrollees pay low or no premium	
21 Charges late enrollment fee to low-income beneficiaries	
Drug Benefit Cost Sharing and Coverage	
22 Lets plans define what classes of drugs are covered	X
23 Permits formulary to be developed by people with financial conflicts	X
24 Allows plans to change formularies during the year	X
25 Allows plans to change alter standard cost sharing	X
26 Allows preferred drug cost sharing to differ across classes of drugs	X
27 Allows drug cost sharing to be higher at out-of-network pharmacies	X
28 Places no explicit limits on cost management tools	X
29 Includes a vague appeals process	X
30 Does not count payments for off-formulary drugs toward catastrophic benefit	X
31 Allows drug cost sharing to increase faster than income	
Benefit Gap and Supplemental Insurance	
32 Does not require clear notice as to when the "gap" will begin	X
33 Defines "out-of-pocket" spending to discourage supplemental coverage	X
34 Prohibits Medicaid from covering drugs for Medicare beneficiaries	
35 Prohibits sale of Medigap coverage for drugs	
36 Creates incentive that could lower retiree drug coverage	X
37 Allows drug plans to sell unregulated supplemental coverage	X
38 Could limit options for state programs to fill in the gap	X

Issue	Can Be Improved through Regulation (X=Yes)
Low-Income Drug Benefit and State Issues	
39 Includes somewhat arbitrary limits on eligibility for low-income assistance	X
40 Creates difficult and complicated enrollment process	X
41 Provides important but still potentially insufficient assistance	X
42 Does not ensure that nursing home residents have affordable access to drugs	X
43 Creates a "clawback" that could cause state budget problems	
44 Shifts costs to states though administrative costs and Medicare cost sharing	
Other Issues	
45 Saves more through cost shifting than cost containment	
46 Overpays Medicare Advantage plans	X
47 Creates "slush fund" to attract regional preferred provider organization	X
48 Launches premium support demo that has troubling implications	X
49 Creates new trust fund accounting that could result in radical legislation	
50 Creates Health Savings Accounts that could undermine group insurance	

DRUG COST CONTAINMENT

1. **Creates interim discount card that benefits few.** The law creates a temporary program that will operate from June 1, 2004 through January 1, 2006 to offer assistance to Medicare beneficiaries for the cost of prescription drugs. The discount card system consists of two parts: negotiated price discounts offered to individuals who lack other types of coverage; and \$600 in subsidies per year for certain low-income individuals (1860D-31, p. 68-86). The discount card aims to reduce drug prices by having card sponsors negotiate for group discounts to pass along to enrollees. Evidence is mixed on how much savings such discount cards may produce.⁶ Some concerns have arisen about the information about the card programs being too confusing. As of July 15, 3.9 million Medicare beneficiaries have enrolled in the program;⁷ of these, about 2.4 million were automatically enrolled though their Medicare Advantage (managed care) plan.⁸

Transitional assistance: Discount card enrollees meeting certain income criteria who are not eligible for Medicaid, group health, military or Federal health benefits qualify for up to \$600 towards prescription drug spending. Income is self declared and eligibility is determined through the mail and internet. If applicants report income inaccurately, they are at risk of a penalty of perjury or similar sanctions for false statements (1860D-31(f)(2), p. 77). States may automatically enroll individuals into discount cards with the \$600 credit from state pharmaceutical assistance programs, but are not permitted to do so for individuals in Medicare cost sharing programs (programs that pay for Medicare premiums and, in some cases, cost sharing but that do not pay for prescription drugs or other non-Medicare benefits).⁹

Regulatory fixes: Require the full amount of discounts to be passed through to enrollees; have Medicare give plans ratings based on their levels of discounts (e.g., 5 stars for the plans with the best prices across the most commonly-used drugs, etc); allow states to automatically enroll low-income beneficiaries in the Medicare cost sharing program into the transitional assistance program.

Legislative fixes: Require the full amount of negotiated discounts to be passed along to enrollees in discount card plans; limit the private drug card offering to the 3 or so per region that offer the best discounts; give beneficiaries the option of accessing state Medicaid drug prices and/or the VA price discounts as an option in addition to the privately-negotiated drug discount card prices; require states to automatically enroll eligible individuals in Medicare cost sharing programs into the transitional assistance program.¹⁰

- 2. Effectively blocks reimportation of U.S.-made prescription drugs.** The new Medicare law allows the importation of drugs from Canada -- but only if the Administration permits it. Specifically, the Secretary of Health and Human Services must certify to Congress that reimportation "will pose no additional risk to the public's health and safety; and result in a significant reduction in the cost of covered products to the American consumer" (Sec. 1121, in Sec. 804(l)(1)). To date, the Administration has refused to take action. At a U.S. Senate Budget Committee hearing on February 12, Secretary Thompson stated, "The law requires me to certify that drugs coming in from another country are safe. This is a hurdle I can't meet." The former Commissioner of the Food and Drug Administration (FDA), in reference to Members of Congress supporting reimportation, stated, "...these members are out of touch with the realities of keeping our drug supply safe, and the clear and present dangers to America's drug supply that their bills would create."¹¹

Regulatory fixes: Have the Secretary use some of the \$1 billion discretionary funds for implementation of the law (Sec. 1015, p. 389) to develop safety protocols to implement reimportation; allow states with plans to reimport U.S.-made drugs safely to implement such programs.

Legislative fixes: Permit individuals, pharmacies, and wholesalers to import drugs from Canada with a phase-in to some European Union countries; require the FDA to adopt safety provisions such as guaranteeing that drugs produced abroad meet FDA standards of production and labeling; require wholesalers and pharmacies to register with the FDA; prevent pharmaceutical manufacturers from shutting off supply to countries involved in reimportation.¹²

- 3. Prohibits Secretary from negotiating prices for Medicare.** The law states that the Secretary of Health and Human Services "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors" (1860D-11(i), p. 35-36). This provision prevents Medicare from negotiating

prices that it pays for its beneficiaries. It may also limit the ability for Medicare to monitor what it pays for drugs and setting up rules for relationships between drug manufacturers and insurers, further eroding the program's ability to ensure that the beneficiaries and tax payers are getting appropriate discounts for drugs.

Regulatory fixes: Direct the Attorney General or Federal Trade Commission to monitor negotiations between drug manufacturers and pharmacies and PDP sponsors to ensure adequate prices (the prohibition affects only the Secretary of Health and Human Services).

Legislative fixes: Strike the provision and replace it with language that allows the Secretary to negotiate minimum price discounts available to all plans (allowing private plans to negotiate supplemental rebates if possible); allow the Secretary to negotiate Medicare drug prices if private plans fail to achieve sufficient discounts; have The Secretary negotiate for prices for drugs with few alternatives.¹³ Legislation could also allow Medicare to offer its own drug plan option in which prices are negotiated by the Secretary.¹⁴

4. Allows potentially unlicensed insurers to set drug prices for Medicare.

The drug benefit will be delivered by stand-alone insurers called prescription drug plans (PDPs) and Medicare managed care plans called Medicare Advantage-prescription drug plans (MA-PDs). These organizations will set prices and manage the drug benefit, being paid primarily on a capitated or risk basis (see Appendix for payment details). These organizations must be insurers -- that is, licensed to sell insurance in a state (1860D-12(a)(1), p. 36). However, the Secretary can contract with unlicensed sponsored that meet the Secretary's own solvency standards (1860D-12(c), p. 36-37). This could result in organizations circumventing state law through the Secretary's licensing provision, or the Secretary setting a "low bar" and undermining state standards.

Allows a PDP to operate nationally: The law explicitly allows a single PDP to be offered nationwide (1860D-11(a)(3), p. 29). It could offer different benefits and charge different premiums in the different regions. It could also offer multiple plans in a single region, although one "entity" cannot offer all PDPs in the area without the "fallback" plan being invoked (see # 9). This could allow a monopoly situation where one or two drug insurers set prices for the entire Medicare population, with little incentive to keep prices low.

Regulatory fixes: Ensure that the Secretary's alternative standards for unlicensed organizations are not less than those in any state.

Legislative fixes: Limit the Secretary's authority to approval of only those unlicensed organizations with a pending state license application for a one-year period; prevent any single organization from setting prices for a majority or significant minority of Medicare beneficiaries.

- 5. Does not prohibit financial ties between the drug industry and drug plans.** Nothing in the new law precludes a prescription drug plan (PDP) from being owned by or affiliated with a drug manufacturer. These relationships would be subject to Federal anti-trust laws, and there has been some the recent actions to break the link between pharmaceutical benefit managers (PBMs) and drug manufacturers. However, since the law establishes new types of contracts (and Congress excluded from the final law the provision explicitly precluding these types of relationships), it may be difficult to prevent these relationships.

Regulatory fixes: Define organizations allowed to deliver the drug benefit ("entities", in 1860D-3(a)(2), p. 18) as organizations independent from pharmaceutical manufacturers; enlist the Federal Trade Commission, attorneys general who have addressed this issue in the private sector, and others to issue guidelines on avoiding financial conflict; under the Secretary's discretion about the bid submission, require plans to disclose all financial arrangements with drug manufacturers, similar to those required in a recent settlement between a major PBM and state drug programs.¹⁵

Legislative fixes: Explicitly prohibit ownership and similar conflicting relationships between drug plans and drug manufacturers; require full disclosure of financial relationships between drug plans and drug manufacturers to ensure transparency of transactions; ¹⁶ create strong penalties for violation of this law.

- 6. Creates incentives for lowering access as well as prices.** Prescription drug plans and MA-PDs get paid based on what they bid. Bids are based on expected prices, utilization, and administrative expenses (1860D-11(b)(2)(C)(iv), p. 30). The idea is for competition among PDPs and MA-PDs to reduce prices as plans compete for enrollees. However, this may also create an incentive to reduce appropriate use of prescription drugs. While there is some overutilization in the system that should be reduced, there is also evidence of underutilization.¹⁷ The law provides no incentive for plans to address underutilization since doing so will increase costs and decrease profits. In addition, because stand-alone insurers reap no benefit from increased drug spending that decreases hospital or other service use, they have little incentive to make this kind of investment.¹⁸

Regulatory fixes: Require plans to submit performance data on the use of specific drugs for which there is evidence of under-use, as part of the annual data reporting on quality and performance (1860D-1(c)(3)(iii), p. 11).

Legislative fixes: Move away from a blunt capitation model that creates a financial incentive for under-use toward a pay for-performance model where incentives are aligned to encourage use of appropriate prescription drugs.

- 7. Does not require that drug plans pass through all discounts to enrollees.** As with the discount card program, the prescription drug plans offering the Medicare benefit beginning in 2006 can keep part of the price discounts that

they get from drug manufactures. The “negotiated prices” that they must offer to enrollees in their plans “shall take into account” discounts, subsidies, rebates and other remunerations” (1860D-2(d)(1)(B), p. 16). In addition to allowing plans to build their cost and profits into their premiums’ administrative load, the law allows them to “skim” financial reward from the price discounts that they negotiate.

Regulatory fixes: Define “take into account” to mean providing most if not all of the price concessions achieved to enrollees in the plans, reducing costs to consumers and Medicare.

Legislative fixes: Change the law to read “shall provide all discounts,” etc., eliminating the ambiguity and assuring that drug insurers are acting on behalf of enrollees and the program (similar to #1).

8. Selects drug plans solely on their willingness to accept financial risk.

The Secretary must accept all PDPs bearing full risk that meet the requirements of the law and whose design and benefits are not likely to significantly discourage enrollment of certain part D eligible individuals (1860D-11(e), p. 31-32). The Secretary is prohibited from limiting the number of full-risk contracts (1860D-11(f)(3), p. 32). Limited-risk plans are only approved in areas to ensure the minimum access requirements and those bearing more risk are accepted over those bearing less risk (except that the overall level of the bid may be taken into account) (1860D-11(f)(3), p. 32). No other criteria (e.g., quality, ability to manage utilization) can be used to disapprove of plans.

Allows reduced risk payments to PDPs in areas with few options: Secretary may approve limited risk plans to ensure access. This means increasing the amount that Medicare pays if costs exceed what was included in the bid (1860D-3(b), p. 18). Each plan, not Medicare, sets the level of risk that it is willing to assume; it can ask for lower risk corridor thresholds and/or a higher percent in the risk corridor that Medicare pays. These changes must be symmetrical (e.g., if the plan wants to lower the initial risk corridor threshold to 0, it will not only receive a risk corridor payment for any cost overrun, but will pay back any savings) (1860D-11(b)(2)(E), p. 30). The Secretary may assume 99.99 percent of risk from limited risk plans in underserved areas (1860D-11(f)(2)(C), p. 32).

Regulatory fixes: Expand on the sole basis for plan disapproval to define “discourage enrollment of certain individuals” (1860D-11(e)(2)(D), p. 32) to include criterion like the absence of quality improvement programs, disease management programs, and other program characteristics beyond cost sharing and formulary design.

Legislative fixes: Provide the Secretary with greater ability and specific criteria for disapproving plans to increase the quality and lower the cost of participating plans; eliminate the option of having extremely limited risk plans since they are likely to cost more than fallback plans (see #9); allow the Secretary to

disapprove plan offerings in certain regions to prevent such plans from gaining a monopoly.

- 9. Limits access to and viability of non-risk “fallback” plans.** Fallback plans are entities that deliver the prescription drug benefit but are not paid based on risk or capitation (similar to how most insurers contract with pharmacy benefit managers (PBMs) today). Fallback plans can only operate in areas where there are not enough full-risk or limited-risk PDPs to meet the minimum access guarantee (1860D-3(a)(1), p. 18). Fallback plans operate under a restricted set of rules that could discourage organizations from being interested in offering them. Although there can be a national prescription drug plan, there cannot be a national fallback plan (1860D-11(g)(1)(B)(v), p. 33). Within the regions set for prescription drug plans, there may be areas where the fallback will not operate. Specifically, if an area has one PDP and a fallback in a region, counties within the region with local MA-PD plans would not be served by the fallback (1860D-11(g)(3), p. 34; 1860D-3(a)(1), p. 18). Fallback plans are prohibited from marketing or branding, although their information appears in the comparative information provided to beneficiaries (1860D-11(g)(7)(C), p. 35). The Secretary is required to submit a report describing use of such plans and make recommendations how to “limit the need for the provision of such plans and to maximize the assumption of financial risk” (1860D-11(h), p. 35).

Benefits and premium for fallback plans: Fallback plans must offer standard coverage and cannot offer supplemental coverage. Premiums are set by the Secretary. They are based on the estimated fallback area costs of coverage plus an amount for administration (1860D-11(g)(6), p. 35). The amount for administration would be based on similar expenses for prescription drug plans, whose administrative costs are likely to be much higher due to marketing costs, risk premiums, etc. The administrative expenditure adjustment artificially raises premiums for fallback plans since beneficiaries will be paying for costs not incurred by such plans.

Limits fallback plan contracting: Fallback plans cannot also be prescription drug plans or have a subcontract with a PDP in its first year as a fallback plan (they may have subcontracts with MA organizations) (1860D-11(g)(2)(B), p. 34). This effectively means that PBMs will have to make a choice of whether they want to be part of the PDP system or fallback system – they cannot do both. In addition, fallback plans cannot contract with a PDP that submitted a bid to be or is a fallback in any region and was a fallback in the specific region in the previous year (1860D-12(a)(2), p. 36-37).

Regulatory fixes: --

Legislative fixes: Create a level playing field by allowing fallback plans to operate under the same set of rules applied to prescription drug plans; lift the restriction on pharmacy benefit managers to allow them to competitively bid to be fallback plans as well as part of a prescription drug plan (so long as they do

not gain monopoly market share); eliminate the administrative adjustment to the fallback plan premiums which handicaps them relative to local prescription drug plans and MA-PDs.

10. Limits government oversight over the prices Medicare pays. The law's requirements for PDPs' submission of data appear weak. As part of their bid submissions, plans have to disclose to the Secretary only "aggregate negotiated price concessions" (1860D-2(d)(2), p 17). Reinsurance payments made to PDPs will be based on "average" rebates (1860D-15(b)(2), p. 51-52). Data are also required to be submitted to develop risk adjusters (1860D-15(c)(1)(C), p. 52). The Secretary has the authority to request additional information to carry out the law (1860D-11(b)(2)(F), p. 30).¹⁹ These data collection limitations protect drug industry price data and put Medicare at disadvantage in overseeing what it pays for prescription drugs.

Audits: In addition to limited reporting requirements, the audit requirement is weaker than that of the Medicare Advantage (MA) program. The Secretary "may" conduct periodic audits (1860D-2(d)(3), p 17). It cross-references only the part of current law that describes the nature of the audits – not the requirement that the Secretary conduct audits annually. This is despite the fact that gross Medicare spending on Part D is projected to be over 60 percent higher than that of Part C (MA) from 2005 through 2014.²⁰

Regulatory fixes: Require, as part of a plan's bid submission, data on a structured set of drug prices net of all price concessions that permits comparison across plans and identification of excessively high prices; assert that the Secretary shall conduct annual audits.

Legislative fixes: Require full drug price data disclosure for review for possible discrepancies; require the Secretary, in collaboration with the Attorney General, to develop and implement a plan to prevent and reduce fraud and provide funding to do so; create additional enforcement tools in the law such as large penalties to discourage fraud.

DRUG BENEFIT ELIGIBILITY AND ENROLLMENT

11. Entitles beneficiaries to access to a drug plan – not a drug benefit. The entitlement is structured so that individuals eligible for either Part A or Part B of Medicare are entitled to coverage through a qualified prescription drug coverage (1860D-1(a)(3)(A), p. 8). They are not entitled to enroll in a Part D benefit program; Part D is not a program but instead a set of rules governing private plans and access to them. As such, it is more similar to the structure of Medigap than Part B. This means that individuals lose the protections afforded by Part D if they do not remain continuously enrolled in a prescription drug plan or similar ("creditable") coverage (see #12 below).

Regulatory fixes: Provide notices to beneficiaries explaining the different structure of the benefit and the potential consequences of not enrolling when eligible, disenrolling, and having gaps in coverage.

Legislative fixes: Make the legal framework of Part D like that of Part B which improves the beneficiary protections and lessens the extent to which beneficiaries “fall through the cracks.”

- 12. Limits enrollment opportunities.** Individuals are allowed to enroll without a penalty at initial eligibility or during a special enrollment period which occurs when individuals involuntarily lose creditable coverage; their coverage falls below the actuarial value of the standard benefit; they are subject to errors in enrollment or special circumstances; or they become Medicaid eligible (1860D-1(b)(3); p. 10). Other individuals can enroll in a plan only during the annual open enrollment period and may have to pay a late enrollment penalty (1860D-13(b), p. 41) (see #19). Individuals who do not immediately sign up for drug coverage or who sign up for a plan and drop out during the year due financial hardship, for example, cannot sign up for a plan again until the annual open enrollment period.

“Snowbirds” and part-year residents: Some seniors live in different parts of the country during the year. The law treats these individuals similarly to how they are treated under the Medicare Advantage program (1860D-1(b)(1)(B); p. 8-9). However, Medicare Advantage program has yet to have an annual lock-in on enrollment, and its plans typically have consistent cost sharing throughout the year, unlike the drug benefit. For example, an individual may live in Florida from January through May and enroll in a plan generous plan there, move to Maine from June through October where there are only drug benefits with large gaps, and move back to Florida in November. Benefit portability may be a challenge for such an individual.

Regulatory fixes: For the first several years of the program, use the Secretary’s exceptions authority (1860D-1(b)(3)(C); p. 10) to provide all beneficiaries with a special enrollment period since individuals may not immediately sign up for a benefit – these individuals should be allowed to enroll at the time that they make that decision; create an explicit exemption for individuals who miss one premium payment so that they can reenroll in their plan; create an explicit exemption for people who want to reenroll who have low income; for part-year residents, require plans to have policies regarding coverage outside of the region (e.g., special arrangements to reduce out-of-network pharmacies).

Legislative fixes: Model Part D on Part B which would allow individuals to sign up for the Medicare drug benefit at any point (not just during initial and special enrollment periods).

13. **Guarantees minimal information prior to plan choice.** The law requires the Secretary to conduct activities to broadly disseminate information about the program prior to the open enrollment period. Information that must be provided in a standard format at least 30 days before annual enrollment begins includes only five basic elements: “benefits provided”; premiums; quality and performance, consumer satisfaction surveys; and “cost sharing required of part D eligible individuals under the plan” (1860D-1(c)(3); p. 11). These terms are not clearly defined. For example, the cost sharing information could be provided either in aggregate (e.g., an average) or on a drug-by-drug basis. What drugs are covered on the formulary (i.e., list of covered drugs) and how much is charged for each drug does not appear to be included.²¹ Note that in responding to questions, Administrator McClellan suggested that information on specific drugs (e.g., Lipitor) will be readily available and reasonably clear to beneficiaries.²² However, this is not required by the statute. There is a tension between full information and plan interest in participation in the program. The Administrator stated: “However, we also want to be sure that we do not place undue burdens on the drug plans or provide beneficiaries with too much information to the point where it becomes confusing.”²³

Information to enrollees: “At time of enrollment,” a PDP sponsor shall disclose to an enrollee, at a minimum, information on access to specific drugs, how the formulary is structured, general cost sharing requirements, and how to find out more information. General information on coverage and grievance policies are only available upon request (1860D-4(a)(1)(A), p. 18). Even though this information could be essential to making a decision about joining a specific plan, it is not clear that it must be available prior to making that decision.

Cost sharing information: At enrollment, a plan must disclose “beneficiary cost sharing requirements and how a part D eligible individual may obtain information on such requirements, including tiered or other copayment level applicable to each drug (or class of drugs), consistent with paragraph (3)” (1860D-4(a)(1)(B)(iii), p. 19). This suggests that only general information on cost sharing is available unless an enrollee calls the toll-free number or has access to the internet (what is referenced in paragraph 3).

Regulatory fixes: Use the Secretary’s authority regarding comparative information (1860D-1(c)(1), p. 11) to provide potential enrollees with: a subset of price data, compared to a benchmark to show percent savings; cost sharing information both for a specific drug and using summary measures; and formulary information so that an individual may compare plans and know whether a specific drug is on a plan’s formulary, and what cost sharing and other restrictions apply, prior to enrolling in it.

Legislative fixes: Require that essential information on drug prices, cost sharing and accessibility (i.e., formulary information) is available prior to enrollment in a plan; create and disseminate a ranking system that summarizes complex information for those interested in this sort of information rather than specific drug or cost sharing data; fund organizations like State Health Insurance

Assistance Programs to help beneficiaries navigate information prior to making plan decisions.

14. **Provides plans with personal information to use in marketing.** The Secretary may provide “identifying information” to private drug plans and Medicare Advantage plans to facilitate “efficient marketing” of plans (1860D-1(b)(4), p. 10). If “identifying” information is broadly interpreted, this could include information on age, health, or certain health conditions, for example. This would allow plans to selectively market to certain age groups, in wealthy neighborhoods, or to individuals with certain types of conditions.

Marketing rules for plans: The law states that the market rules applying to drug plans should be similar to those in the Medicare Advantage program (not identical to them) (1860D-1(b)(1)(B)(v); p. 9). Studies have found weak marketing standards may lead to problems such as lack of advertising in Spanish or other languages and placing important information in fine print that is difficult for most beneficiaries to read.²⁴ The potential for selective marketing is greater for prescription drug coverage than all Medicare benefits since it is easier to predict who might have high costs for this single benefit.

Regulatory fixes: Limit the definition of “identifying” information to names and addresses (not age, race, any health information); create through regulation a set of marketing standards to protect beneficiaries from specific types of marketing such as drug discount card providers using drug use data to market; prohibit drug discount card sponsors and their subcontractors from using or disclosing identifiable information obtained via the drug discount program for the design or marketing of a PDP; prohibit pharmacies from getting fees for marketing specific prescription drug plans; create a consumer panel to oversee marketing guidelines to prevent abuses.

Legislative fixes: Eliminate the provision of personal data to drug plans for marketing; create standards and enforcement tools in law to prevent selective marketing efforts; strengthen privacy protections by preventing any health information to be disclosed for the purpose of marketing to Medicare beneficiaries.

15. **Provides false sense of choice of drug plans.** Beneficiaries are guaranteed access to two drug plans, but this condition is met if one of those plans is a Medicare Advantage plan (i.e., there may be only one drug plan option for an individual wishing to stay in traditional Medicare) (1860D-3(a)(1), p. 18). The “choice” provision says nothing about the nature of the choices guaranteed, so that both plans might have high premiums or restrictive formulas relative to what is offered to similar beneficiaries in different areas of the country.

Less choice for low-income beneficiaries: Although the law guarantees that certain low-income individuals do not have to pay premiums for drug coverage

(1860D-14(a)(1)(A); p. 44), this premium protection is only for plans whose premiums are below a “low-income benchmark premium amount” or the region’s weighted average premium for the standard benefit or its equivalent (1860D-14(b); p. 49-50). This means that if there are only two plan options in an area, the low-income beneficiary must enroll in the lower-premium plan in order to receive the full subsidy – irrespective of whether that plan meets the beneficiary’s needs.

Enrollment for dual eligibles: Full-benefit dual eligible individuals (defined in Sec. 103(b) / 1935(c)(6), p. 96) who do not voluntarily choose a prescription drug plan or MA-PD will be default-enrolled in a plan (1860D-1(b)(2)(C); p. 9). They will only be enrolled in a plan whose premium is below the low-income benchmark (see previous point). They can switch plans or opt out of any prescription drug plan altogether. However, they cannot keep their current Medicaid drug benefit since Federal matching payments for prescription drug coverage for such individuals will end on January 1, 2006 (see Sec. 103(c), p. 96). This default enrollment, while designed to minimize gaps in coverage, could result in assignment of beneficiaries to plans ill-designed to meet their needs.

Regulatory fixes: Use some of the \$1 billion discretionary funds for implementation of the law (Sec. 1015, p. 389) to fund states to have case managers work with dual eligible individuals to ensure that they are enrolled in a Part D plan by January 1, 2006 when their Medicaid coverage ends and to educate them about their initial choices and option to switch out of a default plan if it does not meet their needs.

Legislative fixes: Ensure that all beneficiaries in traditional Medicare have two drug plan options; ensure that low-income beneficiaries in traditional Medicare have two drug plan options at no cost if they qualify for the full premium subsidy; default enroll dual-eligible individuals only into plans that meet a formulary test to ensure that they have access to needed medications; suspend the elimination of Medicaid funding for drug coverage for dual eligibles for those individuals who are not yet enrolled in a Part D plan, to ensure that there are not gaps in coverage.

16. Locks beneficiaries into drug plans which could change during the year.

The coverage period in prescription drug plans (PDPs) or Medicare Advantage plans (MA-PDs) is the same for the drug benefit as for the Medicare Advantage program (will be 180 days in 2006, 1 year in 2007) (1860D-1(b)(1)(B); p. 9). However, while beneficiaries will be locked into a plan for a year, there is no prohibition on plans changing their formularies, cost sharing, or pharmacy networks during the year. The only requirement is that they provide notice through the internet or a toll-free number (1860D-4(a)(3), p. 19; see also (1860D-4(b)(3)(E), p. 22). The law prohibits the Secretary from implementing regulations that impose new significant requirements on PDP sponsors or plans except for at the beginning of the year (1860D-12(f)(2), p. 39).

Regulatory fixes: -- [see #24 for ideas on limiting formulary changes during the year]

Legislative fixes: Allow beneficiaries to switch plans during the year if cost sharing increases significantly (see also #24).

DRUG BENEFIT PREMIUMS

17. Lets private plans, not Medicare, set annual premiums. The Medicare drug benefit does not have a single, set premium. The \$35 monthly premium which is often quoted is the Congressional Budget Office's estimate of what average premiums might be in 2006. Instead, private plans set their own premiums for enrollees in a given plan and region, taking into account the government subsidies. The government will provide each plan with a per-capita payment (plus risk corridor and reinsurance payments (see Appendix)). The per-capita payments are adjusted only for price variation, not utilization variation, even though utilization variation is probably greater²⁵ (1860D-15(c)(2), p. 53). This adjustment for prices cannot increase Federal costs (i.e., must be budget neutral). These payments are also adjusted for the risk of the enrollee in an effort to discourage "cream skimming" of low-cost enrollees. Risk adjustment must also be budget neutral. To implement it, the Secretary shall require PDP plans to submit drug claims that can be matched with data from Parts A and B of the Medicare program (1860D-15(c)(1)(C), p. 52). This premium structure means that the amount a beneficiary pays for drug coverage will vary geographically and by plan choice, and will increase at different rates depending on these factors, among others.

Regulatory fixes: Aggressively implement risk adjustment in an attempt to keep premiums low in plans with disproportionate enrollment of high-cost beneficiaries.

Legislative fixes: Ensure that all beneficiaries have access to an affordable premium by: disapproving plans with premiums above a certain level, expanding geographic adjustment of government payment to lessen variation, and/or limiting the annual increase that beneficiaries pay to overall program growth. Alternatively, move to a premium system similar to that in Part B of the program, where the premium is the same nationwide and where plans compete on drug prices and quality, not premiums.

18. Does not protect Social Security benefit increases from drug premiums. The Part D premium will be collected in the same manner as MA premiums (1860D-13(c)(1), p. 43). This means that beneficiaries will have the option of premiums being collected by (a) withholding from Social Security checks; (b) electronic funds transfer; (c) other manner specified by the Secretary (see Sec. 222(c), p. 139). The current provision, 1839(f), that prevents Medicare's

premiums from resulting in lower Social Security checks, does not appear to apply. This means that a person enrolling in a plan with a high premium could have her entire cost of living adjustment erased and her next year's benefit reduced due to Medicare premiums.²⁶

Regulatory fixes: As part of the Secretary's authority to disseminate information prior to enrollment, require that plans with high premiums (e.g., 20 percent or more above the base beneficiary premium) alert potential enrollees about the possibility that enrollment could reduce Social Security benefit checks.

Legislative fixes: Apply section 1839(f) to the Part D premiums.

19. Increases premiums for those who do not enroll when they should.

Although "voluntary," the drug benefit under the new law creates a late enrollment penalty to encourage immediate and continuous enrollment. Individuals who, after their initial enrollment period, lack continuous creditable drug coverage for more than 63 days must pay this penalty if they enroll in a plan. The penalty amount is added to the individual's monthly premium for the rest of their lives. The amount is the greater of an amount that is actuarially sound for the uncovered months or 1 percent of the base premium (national average drug premium in the current year) for each uncovered month (1860D-13(b)(3), p. 41-42). It is possible that the "actuarially sound" penalty is determined on the basis of health status and could have a similar effect to medical underwriting. While a late enrollment penalty is used in Part B, the Part D penalty is based on months rather than an annual amount to prevent people from joining a plan, dropping it when they hit the coverage gap, joining again in January, and avoiding a penalty. An individual who loses creditable coverage (including Part D coverage) midway through the year and does not qualify for the special enrollment period would have to pay a late enrollment premium for the months that they wait until the annual enrollment period. If the 1 percent penalty applies, the amount that an individual will pay will increase each year as the base premium on which the penalty is calculated increases. A recent focus group study found that seniors view this penalty negatively since it lessens the extent to which this law is viewed as "voluntary."²⁷

Medigap not creditable coverage: A person with "creditable" coverage may avoid the late enrollment penalty. This coverage must be actuarially equivalent (i.e., have about the same value) compared to the standard benefit. Medigap H, I, and possibly J plans' drug coverage does not meet this standard. This means that individuals keeping their Medigap drug coverage will have to pay the late enrollment fee if they later decide to enroll in a prescription drug plan (1860D-13(b)(5), p. 42).

Regulatory fixes: Provide grace periods and other protections for seniors and persons with disabilities who have difficulty understanding their options or paying their premiums; use the Secretary's authority to create exceptions to

waive late enrollment penalties for the first several years of the program when there is likely to be significant beneficiary confusion and plan instability.

Legislative fixes: Reduce the penalty (e.g., link it to that of Part B) to make the decision to opt out of the drug benefit more voluntary and reversible; cap the penalty so it never results in premium increases of more than 50 or 75 percent; make it a fixed dollar amount rather than an amount that increases in each year for the remainder of one's life; eliminate the individually-determined late enrollment penalty based on the actuarial value of uncovered months since it effectively allows Medicare to "medically underwrite;" extend the initial enrollment period for 2 years, for example, to give beneficiaries more time to understand their options and reverse their decision without permanent financial consequences.²⁸

20. Does not ensure that low-income enrollees pay low or no premium. As described earlier (see #15), the law provides full premium subsidies for a large fraction of low-income beneficiaries, but that subsidy only extends to plans with premiums below the "low-income benchmark" (1860D-14(b); p. 49-50). This could mean low-income beneficiaries could have no choice of drug plans if they want to stay in traditional Medicare and receive the full premium subsidy. Since these low-income beneficiaries also qualify for reduced cost sharing for on-formulary drugs, this single plan choice could provide affordable access even if it has drugs in classes with high cost sharing for other enrollees. However, if the plan has a restricted formulary, aggressive cost management tools like "fail first" procedures, or a limited pharmacy network, then the low-income individual may have to pay a premium to join a different plan to access needed drugs.

Regulatory fixes: --

Legislative fixes: Ensure that low-income beneficiaries who want to stay in traditional Medicare have a choice of two drug plans; ensure that low-income beneficiaries who qualify for a full premium subsidy get it regardless of plan choice.

21. Charges late enrollment fee to low-income beneficiaries. Low-income individuals who otherwise qualify for a full premium subsidy will have to pay part of a late enrollment penalty. Specifically, those with income that qualifies them for a full premium subsidy, including Medicare-Medicaid dual eligibles, will pay 20 percent of any penalty for up to 60 months (five years) (1860D-14(a)(1)(A)(ii), p. 44). Those with income between 135 and 150 percent of poverty pay it on a sliding scale (1860D-14(a)(2)(A), p. 45). This could have serious implications for some, including nursing home residents. Take the case of an individual who is in a nursing home as a private pay patient. She does not sign up for the drug benefit immediately because most of her drugs are provided through Medicare Part A. However, her health worsens over time, she depletes her savings, and ends up on Medicaid. Because of her income, she qualifies for

a full premium subsidy and pays \$1 to \$3 per prescription. However, she still must pay part of a late enrollment fee. This could consume a large fraction of her monthly personal needs allowance.

Regulatory fixes: --

Legislative fixes: Eliminate the late enrollment penalty for the lowest-income beneficiaries (e.g., dual eligibles) or all individuals qualifying for a full premium subsidy; protect personal needs allowance for nursing home residents from Part D premium penalties.

DRUG BENEFIT COST SHARING AND COVERAGE

22. Lets plans define what classes of drugs are covered. While the law permits a large set of prescription drugs to qualify for coverage (called “covered Part D drugs” (1860D-2(e), p. 17)), plans may use formularies, or drug lists, to restrict coverage to a subset of drugs. Drugs not on the formulary will not qualify for any Medicare or plan payment (unless subject to a successful appeal; see #29). Plans may define the drug classes that they will cover and determine which two drugs (the statutory minimum; see (1860D-4(b)(3)(C)(i), p. 21) will be covered in each class.²⁹ Plans may, but do not have to, use therapeutic categories and classes defined by U.S Pharmacopeia; plans can set their own therapeutic class (1860D-4(b)(3)(C)(ii), p. 22). The only limitation on plans developing broad classes, that could allow them to cover few drugs and reduce costs, is an ability of the Secretary to disapprove the plan. Plans may only be approved if, “The Secretary does not find that the design of its plan and benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals” (1860D-11(e)(2)(D), p. 32). The standards for what qualifies as “substantial” discouragement or “certain” part D eligible individuals are undefined. To the extent that a plan uses broad classes of drugs, it can cover fewer drugs which could pose access problems.³⁰

Regulatory fixes: Create strict standards for review of plans that deviate from the U.S. Pharmacopeia classes of drugs.

Legislative fixes: Require plans to use the set of classes developed by the Secretary, in consultation with the U.S. Pharmacopeia and others.

23. Permits formulary to be developed by people with financial conflicts. Pharmacy and Therapeutic (P&T) Committees will develop plans’ formularies. Each Committee’s majority must include practicing physicians or pharmacists. However, the Committee has to include only one physician and one pharmacist who are “independent and free of conflict” (1860D-4(b)(3)(A)(ii)(I), p. 21). As such, the voting majority of the Committee may have a financial stake in the outcomes of their decisions.

Standards for deciding which drugs to cover at what level of cost sharing: The law requires P&T Committees to take into account evidence and standards of practice when making clinical decisions, and to take into account safety and efficacy when making formulary decisions (1860D-4(b)(3)(B), p. 21).

Regulatory fixes: Define “take into account evidence” as “make decisions primarily based on evidence” to lessen the role of plan savings in formulary decisions.

Legislative fixes: Increase the number of P&T Committee members who are free from financial conflict to ensure that a majority of the Committee is independent; require Committees to comply with Federally-promulgated and other commonly-accepted standards of clinical practice.³¹

24. Allows plans to change formularies during the year. Prescription drug plans and Medicare Advantage drug plans may remove a drug or change its preferred or tiered status at any time so long as appropriate notice is given (1860D-4(b)(3)(E), p. 22). At a minimum, the law suggests that this notice be through a specific request on a toll-free number, a request for information in writing, or through an internet posting (see also (1860D-4(a)(3), p. 19)). Thus, a beneficiary may enroll in a plan because her specific set of drugs are on its preferred list (assuming that this information is available prior to enrollment; see #13). However, she may then lose access to those drugs at the preferred cost sharing rate during the year if the plan changes its formulary. The beneficiary may appeal for access to the drug at the preferred cost sharing level (see #29) but cannot change plans.

Regulatory fixes: Create a lower appeal standard and simplified process for drugs whose cost sharing increases or that are removed from the formulary after the enrollee enrolls in the plan; strengthen the notice requirement for when a drug cost sharing increases or it is removed from the formulary (e.g., require that plans notify users of a specific drug whose cost sharing is changing to be notified at least 30 days before the change).

Legislative fixes: Prohibit mid-year changes that increase enrollee cost sharing; grandfather access to preferred or lower cost sharing for those who use the drug during the year prior to the change.

25. Allows plans to alter standard cost sharing. With Secretarial approval and within certain limits, a plan may offer different cost sharing than the standard coverage (i.e., \$250 deductible, 25 percent coinsurance through \$2,250 in total spending, \$3,600 limit in out-of-pocket spending, with all values indexed to drug cost growth per capita) (1860D-2(a)(1)(B), p. 12). For example, the cost sharing below the initial coverage limit could be actuarially equivalent “to an average expected payment of 25 percent of such costs” (1860D-2(b)(2)(A)(ii),

p. 13). This means that spending from \$250-1,000 could have lower coinsurance than spending from \$1,000-2,200 if the resulting payment equals 25 percent of costs on average. Plans may also use “tiered” cost sharing, meaning that one of the drugs in a class is considered “preferred” with lower cost sharing and the other (or others) are “non-preferred” with higher and possibly varied cost sharing. There is nothing in the law about how tiers are structured; a plan could put a drug on the top tier with cost sharing that approaches – or even exceeds – the retail price for that drug.

Actuarial equivalence and determination: Plans can lower the deductible, change the initial coverage limit, and apply different coinsurance up to initial coverage limit so long as the plans’ assessment of the “actuarial value” of the plan remains equal to that of the standard benefit (1860D-2(c), p. 15-16). Plans cannot raise the deductible or change the out-of-pocket threshold.³² The actuarial equivalence test has three parts: compared to standard coverage, the alternative coverage must have the same overall value, value of coverage in the initial coverage limit, and value of unsubsidized coverage. Although the Secretary develops processes and methods (1860D-11(c)(1), p. 30-31), plans determine their own actuarial value (1860D-11(c)(3), p. 31). Plans may but do not have to use independent, qualified actuaries to certify that their plans are actuarially equivalent to the standard plan.

Regulatory fixes: Include in the definition of design features that “discourage enrollment of certain individuals” (1860D-11(e)(2)(D), p. 32) cost sharing patterns (e.g., plans that have low cost sharing for the first \$1,000 but higher cost sharing afterwards to discourage enrollment of high-cost beneficiaries); create rigorous standards for actuarial equivalence; require that plans submit standardized, detail actuarial equivalence reports.

Legislative fixes: Limit the types of changes in cost sharing to those that have less potential for encouraging risk selection (e.g., uniform changes in the coinsurance rate); create limits on tiering to ensure that there truly is access to at least two drugs per class and that the highest tier cost sharing is not excessive.

26. Allows preferred drug cost sharing to differ across classes of drugs. The law does not prohibit a plan from having different preferred cost sharing across different classes of drugs (e.g., a cancer drug class has a preferred coinsurance of 50 percent while a hypertension drug class has a coinsurance of 15 percent). Such changes must meet the actuarial equivalence test as well as the test in the plan approval process, that the cost sharing and formulary design do not substantially discourage enrollment of certain beneficiaries. However, should such cost sharing designs pass these test, they could dramatically affect access to certain types of drugs.

Regulatory fixes: Assume that any difference in preferred cost sharing across classes will discourage enrollment of certain individuals and limit it.

Legislative fixes: Accomplish the same change through law.

27. Allows drug cost sharing to be higher at out-of-network pharmacies.

The law allows plans to create pharmacy networks that provide discounts relative to other pharmacies which must also meet its terms and conditions (1860D-4(b)(1)(B), p. 20). These discounts must be done so that they do not increase Federal costs. This suggests that in the actuarial value determination, there will have to be some calculation of estimated in- and out-of-network pharmacy use, to calibrate coinsurance that makes the use of networks budget neutral. The pharmacy network must meet Secretarially-defined standards to assure access. The law appears to allow plans to change their pharmacy network during the year.

Nursing home, Indian Health Service pharmacies: The Secretary may but does not have to include standards with respect to access to pharmacy services for enrollees who are in nursing homes or on reservations (1860D-4(b)(1)(C)(iv), p. 20).

MA pharmacy access: Part D rules are waived if Secretary determines that the network is “sufficient to provide comparable access” (1860D-21(c)(3), p. 61).

Regulatory fixes: Create a special appeals process for rural beneficiaries, Native Americans, and others who may face difficulties in accessing pharmacies in the network; require that plans have in place access provisions for nursing home residents.

Legislative fixes: Prohibit mid-year changes in the pharmacy network since some enrollees, especially in rural areas, may choose a plan because the local pharmacy is included; require plans to take into account special access needs of vulnerable populations, as designated by the Secretary.

28. Places no explicit limits on cost management tools. The law explicitly allows plans to use cost management tools such as formularies, but does not restrict some practices that could cause access problems. For example, a plan may be able to limit the number of prescriptions filled per month, limit prescriptions to a 30-day supply, or allow for interchange without permission (i.e., providing an enrollee with a different drug than what was prescribed if that substitute is considered equivalent). A plan might also be able to restrict prescribing for off-label use (i.e., for an indication not approved by the Food and Drug Administration (FDA)). This could have a disproportionate impact on people with rare conditions, for example, for whom conducting the required studies to get FDA approval would be difficult.³³ The CMS administrator has said that practices such as “limits on the number of prescriptions, limiting the maximum daily dosage, limiting the frequency of dispensing a drug, limiting the number of

refills" will not be permitted, suggesting that the Administration may use its regulatory authority to constrain their use.³⁴

Regulatory fixes: Include in the definition of design features that "discourage enrollment of certain individuals" (1860D-11(e)(2)(D), p. 32) cost management tools that could impede access to prescribed drugs, allowing the Secretary to disapprove plans that employ such practices.

Legislative fixes: Require the Medicare Payment Assessment Commission, in its annual report to Congress, to identify practices that potentially discourage access rather than over-utilization; prohibit such practices by law.

29. Includes a vague appeals process. The new drug benefit differs from other benefits in that it allows plans to restrict access to drugs that Medicare will cover. As such, having a process to appeal the plans' formulary decisions is particularly important, especially for those with disabilities and low income who would have difficulty affording to pay for off-formulary drugs without coverage.³⁵ The law creates a process for enrollees to appeal to access both off formulary drugs and preferred status for non-preferred drugs on the formulary. General information on how to appeal to access off-formulary drugs only available on request (is not required to be included in enrollment material) (1860D-4(a)(2), p. 19).

Determinations and reconsiderations: Plans must have in place processes for determinations, reconsiderations and expedited considerations in the same manner as MA for "covered benefits under the prescription drug plan it offers."¹ (Note that the term "covered benefits" is ambiguous and could refer only to on-formulary drugs.) The law explicitly sets the standard for accessing preferred cost sharing for an on-formulary but non-preferred drug by creating an "exceptions" process. Specifically, an enrollee would have access to an exceptions process if the prescribing physician determines that the preferred drug would not be as effective or would have adverse health effects for the individual. Such determinations must be "consistent with guidelines from the Secretary" (1860D-4(g), p. 27-28).

Appeals: Prescription drug appeals process is linked to that of the Medicare Advantage program (1860D-4(h)(1), p. 28). This process allows for appeals only in a case involving \$100 or more (may aggregate claims over a 60 day period).² Unlike Medicare Advantage, "only the part D eligible individual shall be

¹ 1852(g)(1)(2)(3). Expedited determinations are allowed if the normal time frame for making a determination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function; this happens in less than 72 hours; allows physician to appeal.

² 1852(g)(5) APPEALS.--An enrollee with a Medicare+Choice plan of a Medicare+Choice organization under this part who is dissatisfied by reason of the enrollee's failure to receive any health service to which the enrollee believes the enrollee is entitled and at no greater charge than the enrollee believes the enrollee is required to pay is entitled, if the amount in controversy is \$100 or more, to a hearing before the Secretary to the same extent as is provided in section [205\(b\)](#), and in any such hearing the

entitled to bring such an appeal". This prevents enrollees from having physicians or others conduct the process on their behalf – which could be problematic for people with severe cognitive or physical disabilities or nursing home residents. It also limits the extent to which a class of individuals can appeal for a plan's change in coverage policy.

Special rule for off-formulary drugs: To appeal an off formulary drug, the physician would have to determine that all covered part D drugs on any tier of the formulary for treatment of the condition would not be as effective for the individual or would have adverse effects for the individual (1860D-4(h)(2), p. 28). By addressing access to off-formulary drugs only in the appeals section, there is an implication that an individual may not be able to use the internal process for coverage determination and redeterminations for off-formulary drugs.

Regulatory fixes: Clarify that the coverage redeterminations process includes off-formulary drugs and provides for expedited appeals when deemed necessary by the prescribing physician; include in the guidelines for the redeterminations process that an individual must be notified of their appeal rights in the event of denial; create special process for low-income enrollees including provisions used in Medicaid (e.g., consideration of prior authorization decisions within 24 hours; require provision of an emergency supply of the prescribed drug pending the outcome of the appeal); for those in the low-income drug benefit, lower the threshold for accessing the appeals process; allow an individual to designate a surrogate for themselves if they are incapable of conducting the appeals process themselves.

Legislative fixes: Explicitly authorize special appeals process for low-income beneficiaries and others who may be vulnerable (e.g., a senior whose specific drug's cost sharing rises during the year when she is locked into a plan).

30. Does not count payments for off-formulary drugs toward catastrophic benefit. Only out-of-pocket payments for on-formulary drugs counts toward the threshold (1860D-2(b)(4)(C)(i), p. 14). If a person does not go through an appeals process to access an off-formulary drug, payment for that drug does not count. As such, the individual not only pays the drug's full price, with no negotiated discount, but could end up paying more than the out-of-pocket threshold for drugs in a year since the off-formulary drug payments do not count toward the benefit's limit. Note: retiree plans or supplemental plans offered by PDPs or MA-PDs could offer coverage for off-formulary drugs without

Secretary shall make the organization a party. If the amount in controversy is \$1,000 or more, the individual or organization shall, upon notifying the other party, be entitled to judicial review of the Secretary's final decision as provided in section [205\(g\)](#), and both the individual and the organization shall be entitled to be parties to that judicial review. In applying subsections (b) and (g) of section [205](#) as provided in this paragraph, and in applying section [205\(l\)](#) thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

these payments counting toward the out-of-pocket threshold, but doing so would be administratively difficult.

Regulatory fixes: Ensure a simple appeals process for off-formulary drugs, since individuals discouraged from appealing access to a specific drug may not only have to pay for it out-of-pocket but would not be allowed to count that payment toward the annual out-of-pocket threshold.

Legislative fixes: Provide true out-of-pocket protection by counting beneficiary spending on all drugs that are permitted to be covered by Medicare.

31. **Allows drug cost sharing to increase faster than income.** The standard benefit defined in the law for the year 2006 includes a \$250 deductible, initial coverage limit of \$2,250, and annual out-of-pocket threshold of \$3,600. These values will be increased in subsequent years by a measure of drug cost growth per person. Specifically the index is the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs for eligible individuals for the year ending in July of the previous year (1860D-2(b)(6), p. 15). Because drug cost growth is projected to be higher than that of Medicare generally, these values will grow rapidly. For example, the Congressional Budget Office projects that the deductible will be \$445 and the out-of-pocket threshold \$6,400 by 2014.³⁶ As a result, drug cost sharing will consume an increasing share of seniors' income which is growing at a much lower rate.

Regulatory fixes: --

Legislative fixes: Index drug benefit parameters, including those for the low-income drug benefit, to the projected growth in seniors' income; at a minimum, index the out-of-pocket threshold to this index to protect those with the highest drug cost from the rapid increase in drug cost sharing.

BENEFIT GAP AND SUPPLEMENTAL INSURANCE

32. **Does not require clear notice as to when the "gap" will begin.** For beneficiaries enrolled in plans with standard coverage, their coverage has a "gap" in which they pay 100 percent of drug costs, between \$2,250 and \$5,100 in 2006. While plans must provide notices about the initial coverage limit and out-of-pocket threshold, such notices "need not be provided more often than as specified by the Secretary" (1860D-4(a)(4)(B), p. 19). If notice is not provided frequently, an enrollee could find out at the pharmacy that her initial coverage limit has been hit and she has to pay 100 percent of the cost of the prescription out-of-pocket.

Regulatory fixes: Require plans to provide monthly notices in writing plus instant access to information on one's proximity to the gap and out-of-pocket threshold via a toll-free number and through pharmacists.

Legislative fixes: Accomplish the same change through law.

33. Defines “out-of-pocket” spending to discourage supplemental coverage.

The new law includes a catastrophic benefit that ensures that no enrollee pays more than \$3,600 out-of-pocket in 2006 (that amount indexed by per capita drug cost growth in subsequent years). “Out of pocket” is defined as payment by individuals or “another person such as a family member, on behalf of the individual” or a State Pharmaceutical Assistance Program. The law explicitly prevents payments from retiree health plans and other insurers from counting toward the limit. Since such payments lower what counts as out-of-pocket payments for the purposes of the catastrophic benefit, it increases the total amount of drug spending that needs to be incurred before triggering this benefit (which provides both low coinsurance and Medicare payments to the plan). The law also appears to not count as out-of-pocket payments those from the Veterans Administration (VA), state AIDS Drug Assistance Programs (ADAPs), church groups, etc. The law also appears to prevent territories’ Medicaid low-income protections from counting toward threshold (1860D-2(b)(4)(C)(ii), p. 14).

Regulatory fixes: Extend the provision in the Medicare replacement drug demonstration that allows contributions from charitable organizations to count as out-of-pocket payments for the purpose of triggering the Medicare catastrophic benefit.³⁷

Legislative fixes: Count some or all types of insurance payments toward the out-of-pocket threshold to ensure that all beneficiaries with the same level of total spending get the same Medicare catastrophic benefit; allow VA, ADAP and other government program payments to count toward the out-of-pocket threshold; allow only a certain amount of insurance payments to count (e.g., \$2,000 or half of the insurer’s payment or some other amount that could count toward the out-of-pocket threshold).

34. Prohibits Medicaid from covering drugs for Medicare beneficiaries. The law prohibits Federal Medicaid matching payments for Part D covered drugs for full-benefit dual eligibles (i.e., those Medicare beneficiaries who qualify for full Medicaid benefits) (Sec. 103(c) / 1935(d)(1), p. 96). This means that states cannot access Federal matching payments to pay for Medicare cost sharing for non-preferred drugs or for nonformulary drugs (including nonformulary drugs for nursing home residents). This is a departure from how the two programs inter-relate on other benefits, where Medicaid “wraps around” Medicare and pays for any cost sharing for those who qualify for the programs. If plans have restrictive formularies, states could be under pressure to pay for off-formulary drugs since access to these drugs could lessen nursing home and other Medicaid service use for which states must pay.

Regulatory fixes: --

Legislative fixes: Eliminate the Medicaid prohibition so that Medicaid will wrap around the drug benefit as it does other Medicare benefits.

35. Prohibits sale of Medigap coverage for drugs. The law prohibits current Medigap drug coverage options for individuals enrolled in a PDP or MA-PD. Medigap H, I, J (the Medigap options that offer drug coverage) and grandfathered plans cannot be sold, issued or renewed to those in a Medicare drug plan. Individuals who do not enroll in a PDP or MA-PD may continue to renew their Medigap drug coverage (Sec. 104(a)(1), Sec. 1882(v)(1), p. 99). However, such policies do not count as creditable coverage which means that these individuals will be charged a late enrollment fee and will not qualify for special enrollment periods if they eventually decide to join a plan (see 1860D-13(b)(5), p. 42).

Allows for Medigap plans with drug coverage to drop it: Issuers of H, I and J plans may modify those plans to eliminate drug plans and continue to issue or renew such options (Sec. 104(a)(1), Sec. 1882(v)(2)(C), p. 100).

Allows guarantee issue into other Medigap plans, but not with rating protections: Individuals who have an H, I or J policy have the one-time option of accessing an A, B, C or F plan offered by the same issuer. The premium may not vary due to health or experience but may be age rated (Sec. 104(a)(1), Sec. 1882(v)(3), p. 101).

Regulatory fixes: --

Legislative fixes: Create an integrated Medigap option (or options) that can supplement the drug benefit with its payments counting toward the out-of-pocket threshold; create Medigap-like standards for the supplemental coverage offered by PDPs and MA-PDs to reduce confusion and promote premium competition.

36. Creates incentives that could lower retiree drug coverage. Over 11 million Medicare beneficiaries have prescription drug coverage through their former employers' retiree health plan. This coverage generally pays for a much larger fraction of prescription drug costs than does the new Medicare benefit. Under the law, employers that offer qualified coverage get a Medicare subsidy of 28 percent of costs from \$250 to \$5,000 in total covered Part D drug expenditures per enrollee (1860D-22(a)(3), p. 63-64). To qualify for this coverage, the sponsor of the plan must annually attest that the value of the coverage is actuarially equivalent to that of the standard benefit. This test is less restrictive than that for alternative coverage offered by prescription drug plans (e.g., employer plans do not have to have a \$3,600 out-of-pocket threshold). There is also a question of whether employers have to maintain

their contribution to drug coverage to qualify for the subsidy.³⁸ Although the law does not specify that the employer contribution must be maintained, the CMS Administrator stated, “the intent of Congress is perfectly clear: to use federal dollars to leverage private dollars and keep employers offering prescription drug coverage to their retirees.”³⁹ Employers may drop their primary coverage and supplement coverage offered by a prescription drug plan in Part D, but their payments would not count toward the out-of-pocket limit, effectively reducing the Medicare subsidy available to their retirees. Because of this unequal subsidy structure, an estimated 3 million seniors with retiree coverage now could lose it under the law, according to the Congressional Budget Office.

Regulatory fixes: To prevent employers from receiving the subsidy and further eroding their own contribution, define actuarial equivalence to be based only on the value of the employer contribution (i.e., they cannot reduce their contribution to coverage below the Medicare benefit’s actuarial value); alternatively, limit the reduction in the employer contribution (e.g., an employer cannot reduce its contribution per person in each class of retirees by more than the per capita amount of the subsidy).

Legislative fixes: Allow employers to supplement the Medicare drug benefit without the effective reduction in the Medicare subsidy above the out-of-pocket threshold; provide employers whose coverage meets certain standards with a subsidy that is the same size as what their retirees would receive were they enrolled Medicare Part D; eliminate the imbalance in subsidy between employers who maintain coverage and drop coverage and “wrap around” the Medicare drug benefit.

37. Allows drug plans to sell unregulated supplemental coverage.

Prescription drug plans can offer coverage that supplements the basic prescription drug coverage so long as they offer the basic coverage (a standard or actuarially equivalent plan) in an area (1860D-2(a)(2), p. 12). Unlike Medigap supplemental coverage, there are no guidelines for the benefit design, marketing, enrollment or disenrollment in such supplemental coverage. Payments by this supplemental coverage do not count as out-of-pocket spending, so such coverage delays the start of the catastrophic benefit as well as the Federal reinsurance for plans that comes with it (1860D-2(a)(5), p. 13 and 1860D-2 (b)(4)(C), p. 14).

MA-PDs supplemental coverage: Medicare Advantage plans are allowed to offer supplemental coverage without a basic coverage option if such plans have no additional premium. Plans may be able to reduce the premium for the extra coverage through the MA rebate system (1860D-21(a)(2), p. 59-60). Under this system, MA plans have the option of returning some of the Federal overpayments (relative to traditional Medicare) through reduced Part B or Part D premiums. While this type of supplementation could attract high-cost individuals, MA-PDs could use other benefit design options to discourage adverse selection (e.g., higher hospital or home health copayments, exclusion of

specialists). If MA-PDs attract healthier beneficiaries, they are less likely to be affected by the delayed government reinsurance for spending above the out-of-pocket threshold. PDPs, on the other hand, have very little incentive to offer supplemental coverage since they are more prone to adverse selection, have fewer tools to offset it, and are more likely to be affected by the loss of the reinsurance.

Regulatory fixes: Create and require plans to use and publish a standardized reporting form for supplemental coverage under the Secretary's authority to define comparative information before enrollment (1860D-1(c)(3); p. 11); prohibit Medicare Advantage plans from lowering coverage for any Medicare benefit (e.g., raising coinsurance on radiation services) that would allow plans to reduce premiums for supplemental coverage while discouraging sicker people from applying.

Legislative fixes: Give authority to an independent group of experts (e.g., Medicare Payment Assessment Commission or the National Association of Insurance Commissioners) to create and periodically update defined standard supplemental benefit packages as is done in Medigap; allow payments from such plans to apply toward triggering the out-of-pocket threshold, since the beneficiary is paying for the premiums out-of-pocket; allow Medicare to offer a supplemental benefit package, modeled on the drug benefit of most Members of Congress, that would wrap around private benefits.

- 38. Could limit options for state programs to fill in the gap.** State Pharmaceutical Assistance Programs (SPAPs) are explicitly allowed to supplement the drug benefit with their payments counting as out-of-pocket spending for the purpose of the catastrophic benefit (1860D-2(b)(4)(C)(ii), p. 14). Such programs are defined as state programs providing financial assistance for prescription drug costs. They must meet the coordination requirements under the law (1860D-23(a-c), p. 66-67). They also must supplement any plan in which the individual is enrolled (i.e., cannot coordinate with only one PDP). Given that they are the only programs that could fill in the gap without penalty, states will be under enormous pressure to create and expand them by those beneficiaries who do not qualify for the low-income drug benefit (described below).

Issues for State Pharmaceutical Assistance Programs: The law permits PDPs to charge other plans fees for coordination of benefits (1860D-11(j), p. 36). This means that a State program might have to pay a fee to a private plan in order to supplement it. Plans may also set limits on how much SPAPs can supplement. Specifically, they "shall not impair or prevent a PDP sponsor or MA organization from applying cost management tools (including differential payments)..." (1860D-24(c), p.68). However, PDP sponsors (not MA-PDs) must permit supplementation by State Pharmaceutical Assistance Programs and Rx Plans (see 1860D-11(j), p. 36).

Medicaid Rx Plans: Even though the law prohibits Federal Medicaid matching funds for full-dual eligible individuals (see above), the law suggests that states could use waiver programs to fill in the cost sharing for low-income beneficiaries who are not full-benefit dual eligibles, so long as they follow the coordination of coverage rules outlined in this section (1860D-24(b)(1), p. 68).

Regulatory fixes: Explicitly allow state programs like the AIDS Drug Assistance Programs to qualify as SPAPs; allow states to create SPAP buy-in programs for middle-income beneficiaries; clarify the autonomy of SPAPs in defining their benefits so that the PDPs' authority to implement its cost management tools does not supercede it; ensure that the coordination rules are not too onerous for states.

Legislative fixes: Eliminate the provision that allows PDPs cost management tools to limit how SPAPs supplement the drug benefit; allow states to create Medicaid Rx Plans that include all low-income beneficiaries, including dual eligibles.

LOW-INCOME DRUG BENEFIT AND STATE ISSUES

39. Includes somewhat arbitrary limits on eligibility for low-income assistance. The law provides four levels of assistance beyond the standard drug benefit for certain low-income beneficiaries (see Appendix for a description of low-income benefits). This assistance is generous compared to the standard benefit but includes somewhat arbitrary eligibility limits.

Use of assets test: The new law applies an assets test for each eligibility category. The vast majority of beneficiaries with low income also have low assets, making the test redundant for most. Moreover, assets tests have proven a barrier to enrollment because verification is time consuming and many beneficiaries mistakenly believe that houses count as assets and would have to be given up if they enroll. About one-third of those who would be income-eligible for the new assistance are disqualified due to assets such as cars whose value exceeds \$4,500.⁴⁰

Only dual eligibles with income below 100 percent of poverty: The law guarantees lower cost sharing for on-formulary drugs for people who qualify for both Medicaid and Medicare, but limits that assistance to those individuals whose incomes are below the poverty level (1860D-14(a)(1)(D)(ii), p. 45). This means that individuals who are "spending down" to Medicaid and by definition have high health care needs may have to pay more than other dual eligibles.

Only dual eligibles who are covered by Federal law automatically qualify for additional assistance: The law requires the Secretary to provide the most generous low-income assistance to those are full-benefit dual eligibles or who qualify for Supplemental Security Income (SSI). The Secretary has option to deem other dual eligibles (e.g., those covered through home and community-

based care waiver programs and other state options) as eligible for this assistance (1860D-14(a)(3)(B)(v), p. 47). This decision could have significant effects: a narrow interpretation could mean that few of the optional dual eligibles get the most generous low-income assistance; a broad interpretation could put millions more low-income beneficiaries into the most generous category.

Excludes individuals in territories from low-income assistance: Medicare does not provide low-income assistance for Medicare beneficiaries residing in the territories. They may get it through Medicaid (1860D-14(a)(3)(F), p. 49; see also Sec. 103(d) / 1935(e), p. 97). There are no prohibitions on Medicaid matching payments for Part D drugs in the territories, so that people not enrolled in Part D could get Medicaid drug coverage from the territories' capped allotments which are increased under the law. However, unlike Medicare low-income assistance, these payments are not counted towards the out-of-pocket threshold (see 1860D-2(b)(4)(C)(ii), p. 14 which counts Medicare low-income assistance towards the threshold, but not the Medicaid funding spent by territories).

Regulatory fixes: Revisit rules about what counts as assets; use the Secretarial authority to ensure that all poor individuals who qualify for Medicaid receive the most generous assistance; in creating the new eligibility determination systems, require states and the Social Security Administration to use a uniform, simple methodology for counting assets and require self-declaration of assets.

Legislative fixes: Remove the income limitation and allow all dual eligibles to qualify for the most generous assistance; eliminate or simplify the assets test so it does not prevent low-income beneficiaries who need assistance from getting it; apply the same eligibility and enrollment processes established for the Transitional Assistance program to the Part D low-income program; clarify the treatment of the territories to ensure that its low-income beneficiaries get equal access to the new Medicare subsidies.

40. **Creates difficult and complicated enrollment process.** The law adopts a simplified application and enrollment process for the Transitional Assistance program prior to 2006, but does not do so for the low-income benefit in 2006. It requires both the Social Security Administration (SSA) and states through Medicaid to conduct eligibility determinations.

Eligibility process for low-income assistance: Although the Secretary shall develop a model simple application for the assets test, state are not required to use it (1860D-14(a)(3)(E)(ii), p. 48). States do not have an incentive to aggressively enroll beneficiaries since those that they find who are also eligible for full Medicaid coverage would result in new state costs. In addition, the state "clawback" payment to offset the Medicare drug benefit are based on the number of dual eligible enrollees in a month (see Sec. 103(b) / 1935(c)(6), p.96). It also appears that the current Medicaid rules regarding retroactive

eligibility for the low-income benefit generally do not apply. This means that an individual cannot get assistance for drug costs that were incurred while they were waiting for their application to be processed.

Duration of the low-income assistance: The legislation is silent about the length of eligibility for the assistance, making it no longer than 1 year, but leaving open the possibility that beneficiaries would have to come in to Medicaid eligibility offices on a quarterly or every six months to check income and assets to determine eligibility (1860D-14(a)(3)(B)(ii), p. 46).

Different rules for eligibility determinations by states and SSA: While including SSA broadens the opportunities for applying for assistance, it presents challenges as well. The law describes processes that SSA must use for eligibility redeterminations and appeals (1860D-14(a)(3)(B)(i), p. 46). But, it provides no guidance on processes for initial eligibility determination. In addition, the law requires that states inform the Secretary of determinations for eligibility under 1860D-14 (Sec. 103(a), p. 92). There is no apparent similar requirement for SSA when it conducts its required eligibility determinations. SSA also does not have to screen for Medicaid eligibility (see below).

Screen and “enroll”: Individuals applying for the low-income drug benefit are not only potentially eligible for one of four levels of drug assistance, but could be eligible for full or partial Medicaid coverage. Unlike a similar requirement in the State Children’s Health Insurance program, the law’s “screen and enroll” provision requires states only to screen for eligibility for Medicare cost sharing assistance programs (not full dual eligibility) and to only offer eligibility (rather than enrollment) to individuals passing the test (Sec. 103(a)(2) / 1935(a)(3), p. 93). SSA has no authority to determine Medicaid eligibility and no apparent responsibility to refer potentially eligible individuals to states for such determinations. As such, it is not clear if individuals applying for assistance will be screened and processed for the more generous assistance provided to certain Medicaid beneficiaries.

Regulatory fixes: Issue regulations that ensure that states and SSA follow the same eligibility processes.

Legislative fixes: Require states and SSA to use the same, simple application form that has individuals self-declare their income and assets; allow for mail-in applications; limit eligibility redeterminations to no more than once a year; require retroactive eligibility; delink the “clawback” payments from actual enrollment of dual eligibles since this further discourages states from aggressive outreach; allow prescription drug plans to make beneficiaries presumptively eligible to ensure that they have access to plans and affordable drugs.

- 41. Provides important but still potentially insufficient assistance.** Although the cost sharing for low-income individuals is significantly lower than that of the standard benefit, it still could be high and pose access barriers for some.

Although the copayments for the dual eligible beneficiaries are indexed to general inflation, cost sharing for other groups of low-income beneficiaries is indexed to drug cost growth per capita. By 2014, copayments for poor beneficiaries who do not qualify for Medicaid could rise from \$5 to \$9 per brand name drug.⁴¹ Those who qualify for the 15 percent coinsurance may pay more if plans are allowed to vary that coinsurance. It is also not clear whether all on-formulary drugs or just the preferred drugs would qualify for the 15 percent coinsurance (1860D-14(a)(2)(C), p. 46). In addition, the law is silent about whether a low-income beneficiary can be charged higher coinsurance for using out-of-network pharmacies.

Regulatory fixes: Clarify that the cost sharing amounts specified by the law are ceilings (i.e., a beneficiary who qualifies for 15 percent coinsurance shall not pay more than that for any drug on the formulary; pharmacies cannot charge more than these amounts, even if they are out-of-network).

Legislative fixes: Index the cost sharing for low-income beneficiaries to general inflation.

42. **Does not ensure that nursing home residents have affordable access to drugs.** The law provides special protections to institutionalized beneficiaries who are also full-benefit dual eligibles (1860D-14(a)(1)(D)(i), p. 45). It exempts such individuals from any cost sharing for on-formulary drugs, and these individuals qualify for a full premium if subsidy is they choose a low-cost plan (see #20). However, these individuals must go through the same appeals process to access off-formulary drugs and, like other beneficiaries, must conduct the appeal themselves. Although the law gives the Secretary authority to create different standards for pharmacy access for nursing home residents (1860D-4(b)(1)(C)(iv), p. 20), the Secretary does not have to do so. And, as described earlier (see #21), nursing home residents are not exempt from paying a late enrollment penalty, which could erode their personal needs allowance which is only \$30 per month in most states.

Regulatory fixes: Create a special, simplified appeals process for nursing home residents; require that every prescription drug plan have a provision to ensure access to pharmacies in nursing homes, since, without this provision, plans have an incentive to avoid providing access in nursing homes since their residents are likely to be high-cost enrollees.

Legislative fixes: Exempt nursing home residents from all premiums and cost sharing; ensure access to drugs in nursing homes.

43. **Creates “clawback” that could cause state budget problems.** The law creates, for the first time, a maintenance of effort on state spending for a Medicaid service assumed by Medicare. The so-called “clawback” is a monthly payment from states to the Federal Medicare program that represents a

discounted amount that states would have spent had they continued to share the cost of prescription drugs for Medicare-Medicaid dual eligibles (Sec. 103(b), 1935(c), p. 93-96; see Appendix for the formula). Because of state variation in base-year spending, enrollment of dual eligibles, and drug cost growth, clawback spending may exceed savings from the law in some states. In addition, because the actual number of full-benefit dual eligibles is included in the clawback calculation, there is a disincentive for states to aggressively enroll such individuals. Payments from the Medicaid clawback are transferred to Medicare (1860D-16(c)(1), p. 58) and considered dedicated revenue for purpose of assessing the Medicare trust fund. This means that if Congress reduces the state clawback, it not only increases Medicare costs but worsens Medicare's trust fund status according to the new rules (see #49). In addition, the clawback payments will grow at a rate likely to exceed that of state general revenue growth, limiting some states' ability to fund Medicaid and other priorities.⁴²

Regulatory fixes: --

Legislative fixes: Establish a lower or ceiling growth rate for the clawback so that states can accommodate other state spending priorities; phase out the clawback over time by reducing the clawback percentages in each year; remove the classification of the clawback as dedicated revenue for the purpose of the new Medicare trust fund warning since this otherwise creates an incentive for the Federal government to increase state payments to ameliorate a Medicare trust fund crisis.

44. **Shifts costs to states through administrative costs and Medicare cost sharing.** While states no longer will manage the drug benefit for Medicare-Medicaid dual eligible beneficiaries, they gain a new set of responsibilities. States, along with the Social Security Administration, are responsible for eligibility determinations for the new Medicare low-income drug benefit. Given that there are about 6 million current dual eligibles, and about 14 million beneficiaries eligible for the new program, this could double the number of determinations that they are required to conduct. It is not clear how much funding the Social Security Administration will receive for its new responsibilities. States will be required to pay for half of these administrative costs. In addition, they will pay for the "woodwork" effect, or increase in enrollment in existing programs due to the creation of the new one. Many Medicare beneficiaries eligible for various levels of Medicaid assistance are not enrolled in these programs but could learn of them as they sign up for the low-income drug benefit. The Congressional Budget Office estimates that this could increase state costs by \$5.8 billion over 10 years.⁴³ In addition, the law increases the Part B deductible which states help to offset through Medicaid's Medicare Savings Programs for poor beneficiaries. States are estimated to achieve savings, on net, over the budget period (they also benefit from other policies such as an increase in Medicaid disproportionate share hospital (DSH) payments). However, these policies are estimated to create short-term

aggregate costs; will likely result in some states paying more or receive less savings than others; and create incentives that could harm beneficiaries.

Regulatory fixes: --

Legislative fixes: Increase to 100 percent the Federal matching payments for administrative costs associated with the Medicare drug benefit; simplify the application system (e.g., self-attestation on assets) to reduce the workload associated with eligibility determinations.

BEYOND THE DRUG BENEFIT

45. Saves more through cost shifting than cost containment. The law contains numerous changes to Medicare provider payment rates, as well as changes to beneficiary cost sharing for existing benefits. Putting the drug benefit aside, gross Medicare spending, not including the drug benefit, will increase by \$5 billion over the next decade, worsening its financial outlook. This cost is offset by savings from an increase in the Part B deductible and a new income-related Part B premium. Thus, rather than true cost containment, the law raises costs and hides this through a cost shift.

Regulatory fixes: --

Legislative fixes: Adopt Medicare Payment Assessment Commission recommendations on ways to make Medicare more efficient without cost shifting to beneficiaries.

46. Overpays Medicare Advantage plans. The Medicare law increases payment rates in Medicare Advantage (formerly Medicare+Choice, the program in which private HMOs and other managed care organizations get paid a fixed amount per person to deliver Medicare benefits). Specifically, beginning in 2004, it pays private plans the highest of current rates, the previous year's rate increased by the national average growth rate in traditional Medicare, or 100 percent of the average local costs in the traditional program on a per-capita basis. One study estimates that these changes will contribute to the payments for managed care plans being 8.4 percent higher than those of the traditional program – over \$550 per enroll in managed care.⁴⁴ This overpayment could exacerbate the current system's problems: HMOs and PPOs cost more, selectively serve profitable parts of the country, and use premium and benefit changes to attract healthy and avoid sick beneficiaries.⁴⁵

Regulatory fixes: More aggressively implement risk adjustment (e.g., make it budget neutral across the whole program, not just the managed care program); minimize risk selection by prohibiting plans from increasing cost sharing over levels allowed in the traditional program.

Legislative fixes: Eliminate the overpayment to managed care plans.

47. Creates “slush fund” to attract regional preferred provider organizations.

The law creates new payment systems to encourage participation in Medicare by regional and nationwide private plans like preferred provider organizations (PPOs), effective in 2006 (sec. 221, p. 119-132). Payment rates for the regions, which will be set up by the Secretary (1858(a)(2), p. 120), will be a blend of the county rates in the region (Sec. 221(b)(4), p. 128). In addition, risk corridors will have Medicare increase what it pays if costs exceed plan bids by at least 3 percent; if costs exceed the target amount by 8 percent, then plans receive both 80 percent of the amount of the excess above that threshold and an overall amount equal to 2.5 percent of the target. This means a plan can bid low, charge low premiums to attract beneficiaries, and receive an end-of-the-year extra government subsidy to cover costs above their bids.

Stabilization fund: The law also creates a “stabilization fund” or “slush fund” that the Secretary may use to encourage entry and retain plan participation in all regions (1858(e), p. 123-128). From 2007 through 2013, the Secretary can spend up to \$10 billion from this fund plus an amount equal to 25 percent of savings that Medicare might gain from participation of low-cost MA regional plans. The law suggests that the stabilization fund be used, in part, for bonus payment of 3 percent of benchmark rates for plans that offer in all regions, if none do so. The Secretary may also provide payment increases in selected regions, so long as all plans in the region receive some amount of extra funding. The program funding is subject to a global cap, meaning that the sum of both amounts spent from the fund and new Medicare costs incurred as beneficiaries change plans cannot exceed the fund amount. Since these regional plans are likely to have higher payment rates than traditional Medicare and some local HMOs, enrollment in them will probably increase Medicare costs and decrease the amount that the Secretary can spend from the fund. To maintain spending within this global cap, the Secretary may impose enrollment caps (rather than payment rate reductions).

The rationale for the regional plan system is that these higher payments and larger regions will bring loosely-organized managed care to rural areas, and create national plans similar to the Federal Employees’ Blue Cross Blue Shield plan. However, this outcome comes at a large cost to Medicare, beneficiaries (through higher Part B premiums) and taxpayers since rates could be significantly above those of the traditional program.

Regulatory fixes: Set out clear, objective criteria for use of the stabilization fund to avoid its use for other purposes.

Legislative fixes: Eliminate overpayments to PPOs; eliminate the stabilization fund that not only provides the Secretary with discretion over billions of dollars

with little Congressional oversight but sets a precedent for creating a Medicare “budget” that is met through enrollment caps.

48. **Launches premium support demo that has troubling implications.** The law includes a “premium support” demonstration called the “comparative cost adjustment program” (Sec. 241, p. 154-161). Beginning in 2010 and lasting through 2015, this program changes the way that premiums are set for the traditional program in selected areas. Phased in over a four-year period, the program would base premiums for traditional Medicare on the difference between average traditional Medicare costs and a benchmark based on a weighted average of MA and traditional Medicare costs. This amount is constrained to be no more than 5 percent. The change is restricted to six metropolitan statistical areas (MSAs) selected by the Secretary in which at least 25 percent of eligible beneficiaries are enrolled in local MA plans and there are at least 2 local MA plans at the time that the selection is made. The idea behind the demonstration is to set the premiums for traditional Medicare based on its cost relative to MA cost. However, in so doing, it effectively creates a defined contribution for traditional Medicare. This could raise the premiums for the traditional program if healthier people join the MA program.⁴⁶ In addition, the program is not small; millions of beneficiaries could live in areas where the calculation of their Part B premium changes.

Regulatory fixes: In selecting areas for this program, the Secretary should ascertain local beneficiaries’ interest in participating since, once selected, all beneficiaries in the area would be required to participate and potentially pay higher premiums for the same Medicare.

Legislative fixes: Eliminate the program.

49. **Creates new trust fund accounting that could result in radical legislation.** The law creates a new concept of a Medicare trust fund and its solvency (Sec. 801, p. 298-305). Under a section entitled, “cost containment,” it defines a “Medicare funding warning.” This warning is issued in the second consecutive year in which there is “excess general revenue Medicare funding” in the current fiscal year or in the subsequent six fiscal years. Excess general revenue Medicare financing occurs when general revenue funding as a percentage of total Medicare outlays exceeds 45 percent. “General revenue funding” equals total Medicare outlays (expenditures under Parts A, B, C and D; Medicaid administrative payment; reductions for fraud collections) minus dedicated financing sources (hospital insurance tax; certain Social Security taxes; state transfers from the clawback; premium payments; gifts). This new measure is arbitrary, since the 45 percent level has no justification, nor does the 7-year projection window. It ignores interest earnings on the trust fund surpluses. Moreover, the new measure ignores the fact that Medicare is supposed to be financed in part by general revenues, not dedicated revenues.⁴⁷ In their 2004 report, the Medicare trustees projected that there would be

“excess general revenue Medicare funding” in 2012;⁴⁸ should expenditures continue to rise at rapid levels, there could be an “excess” within the 7-year window, possibly leading to a warning in 2006.

Action occurring when the warning is issued: When a Medicare funding warning is issued, several things must and may happen (Sec. 802-43, p. 301-305). The President must submit, within 15 days of the subsequent budget, legislation to address the warning. The House Majority and Minority Leaders must introduce the President’s legislation within 3 days of receiving it. In a year in which this occurs, the appropriate House committees of jurisdiction must report Medicare legislation by June 30 that is either the bill proposed by the President or any bill which is titled “a bill to respond to a Medicare funding warning.” If this legislation is certified by the House Budget Committee as eliminating the “excess general revenue Medicare funding” in the 7-year reporting period and gets a vote on final passage, nothing further happens. However, if neither of these happens in the given or previous year, then a minority (one-fifth) of the House may bring to a floor vote, with limited debate, legislation that accomplishes the goals. The Senate has similar expedited rules for consideration if legislation to address the Medicare funding crisis is not considered. These rules allow for potentially radical legislation to be considered without either appropriate committee action or majority support.

Regulatory fixes: --

Legislative fixes: Require the Medicare Payment Assessment Commission or another body to develop a new Medicare trust fund measure that recognizes legitimate sources of revenue and triggers a warning without an arbitrary cap; eliminate the provision.

50. Creates Health Savings Accounts that could undermine group insurance.

The MMA included a provision completely unrelated to Medicare that created Health Savings Accounts (HSAs). Any individual who enrolls in a high-deductible health insurance plan with a deductible of at least \$1,000 for individuals and \$2,000 for family coverage may establish one of these tax-favored savings account. Certain preventive services such as annual physicals and routine screenings may be exempted from the health insurance deductible. Both employers and employees may make deductible contributions to HSAs up to 100 percent of the health insurance deductible so long as the contributions do not exceed an annual limit, which is set at \$2,600 for individuals and \$5,150 for family coverage in 2004. Funds held in these accounts may be invested, with earnings accruing on a tax-free basis. Withdrawals from the account also are exempt from tax if they are used to pay for out-of-pocket medical costs such as deductibles, co-payments, and other uncovered medical expenses. Withdrawals for non-medical purposes are subject to income tax and a financial penalty of 10 percent, but no penalty applies to non-medical withdrawals made after reaching age 65.

This provision, unrelated to Medicare, has the potential to weaken employer-based health insurance which insures the vast majority of Americans. Because HSAs will be most attractive to healthy and more affluent workers, HSAs are likely over time to result in “adverse selection” – a siphoning off of healthy and wealthier workers into different insurance arrangements. This leaves sicker workers in existing more comprehensive insurance, raising its costs and making it more difficult to access for those with few to no alternatives or resources. In addition, HSAs breach the long-standing rule of the tax code that savings accounts may not feature *both* tax-deductible contributions *and* tax-free withdrawals. It also does not include income limits as do traditional individual retirement accounts. Thus, they provide lucrative tax shelters for higher-income individuals.⁴⁹

Regulatory fixes: --

Legislative fixes: Eliminate the provision; make HSAs tax treatment the same as retirement savings accounts.

APPENDIX

Premiums and Payments for Prescription Drugs Under The MMA

PREMIUMS

Generally, each PDP or MA-PD's premium is set by increasing or decreasing a plan-specific premium by the difference between the plan's bid and a price-adjusted, national average bid. Specifically, the monthly beneficiary premium is the "base beneficiary premium" adjusted for the difference between the each plan's "standardized bid amount" and "adjusted national monthly average bid amount". This amount would be increased if there is a late enrollment fee or supplemental benefit premium that the enrollee decides to purchase, and decreased for certain low-income beneficiaries.

Base Beneficiary Premium is the "beneficiary premium percentage" multiplied by the "national average monthly bid amount".

$$\text{Beneficiary Premium Percentage} = \frac{.255}{1.00 - \left(\frac{\text{Total Reinsurance Payments} + \text{Total Premium Payments} + \text{Medicare Payments for Bids}}{\text{Total Reinsurance Payments} + \text{Total Premium Payments} + \text{Medicare Payments for Bids}} \right)}$$

National Average Monthly Bid Amount: Equals the average of standardized bid amounts for PDPs and MA-PDs, weighted by enrollment.

Standardized Bid Amount: Each plan's approved bid for basic prescription drug coverage.

Adjusted National Monthly Average Bid Amount: Equals the average of standardized bid amounts, weighted by enrollment and adjusted (in a budget-neutral way) to reflect region differences in prices.

PLAN PAYMENTS

The overall subsidy level in the bill is to be consistent with 74.5 percent for basic prescription drug coverage.

Direct Subsidy: Equals each plan's standardized bid amount, adjusted by a budget-neutral risk adjuster, minus the beneficiary's premium for the base prescription drug benefit.

Reinsurance: 80 percent of "allowable reinsurance costs" attributable to gross covered prescription drug costs incurred after the individual has exceeded the annual out-of-pocket threshold.

Allowable Reinsurance Costs: Part of gross covered prescription drug costs (costs incurred net of administrative costs) actually paid (net of discounts, etc) by the plan for basic prescription drug coverage.

Risk Corridors: End-of-the-Year Payment Adjustments

Prescription drug plans will be paid through direct subsidies, reinsurance and end-of-the-year “risk corridor” payments. These risk corridor payments would be based on the difference between total payments (Medicare plus beneficiary premiums minus administrative costs) and actual costs, called adjusted allowable risk corridor costs. If costs were above payments by a certain amount, then Medicare will send to the plan additional payments. If costs were below payments by a similar amount, then plans repay Medicare part of the amount of overpayments.

Risk Corridor	2006	2007	2008 & Subsequent Years**
Costs <u>Above</u> Second Threshold	+5%+ of Payments Medicare pays amount below plus 80% of difference between costs and second threshold	+5%+ of Payments Medicare pays amount below plus 80% of difference between costs and second threshold	+10%+ of Payments Medicare pays amount below plus 80% of difference between costs and second threshold
Costs <u>Above</u> First Threshold, Below Second Threshold	+2.5-5% of Payments Medicare pays plan 75%* of difference between costs and first threshold	+2.5-5% of Payments Medicare pays plan 75%* of difference between costs and first threshold	+5-10% of Payments Medicare pays plan 50% of difference between costs and first threshold
Payments Near Costs	No payment adjustment	No payment adjustment	No payment adjustment
Costs <u>Below</u> First Threshold, Below Second Threshold	-2.5-5% of Payments Plans pay Medicare 75% of difference between costs and first threshold	-2.5-5% of Payments Plans pay Medicare 75% of difference between costs and first threshold	-5-10% of Payments Plans pay Medicare 50% of difference between costs and first threshold
Costs <u>Below</u> Second Threshold	-5%+ of Payments Plans pay Medicare amount above plus 80% of difference between costs and second threshold	-5%+ of Payments Plans pay Medicare amount above plus 80% of difference between costs and second threshold	-10%+ of Payments Plans pay Medicare amount above plus 80% of difference between costs and second threshold

The term “costs” in this table is referred to as “adjusted allowable risk corridor costs”. The term “payments” in this table is referred to as the “target” in the bill.

* If, in 2006 and 2007, at least 60 percent of prescription drug plans and MA-PD plans representing 60 percent of part D enrollees have costs exceeding the first threshold, then Medicare would pay for 90 percent of the costs between the first and second threshold.

** In 2012 and beyond, the Secretary can raise the levels of the risk corridor thresholds.

Adjusted Allowable Risk Corridor Costs: Allowable costs reduced by reinsurance payments and low-income subsidy payments. Allowable costs equal costs not including administrative costs actually paid (net of discounts, etc) for basic prescription drug coverage net of any utilization effect of supplemental coverage under the plan.

Target Amount: For each plan, the target amount is the total amount of payments paid to it by Medicare and enrollees for basic drug coverage, adjusted for risk and reduced by administrative costs.

State "Clawback" or Phased-Down State Contribution

States and the District of Columbia shall pay a monthly amount to the Prescription Drug Account in the SMI Trust Fund beginning in January 2006 to offset the cost of Part D. This amount for each state for each month is equal to:

Amount = (Per capita amount) x (Number of full-benefit dual eligibles) x (Factor)

Per capita amount: The Secretary shall compute for each state a base year state Medicaid per capita expenditures for covered Part D drugs for full-benefit dual eligible individuals. This is calculated by estimating the enrollment-weighted average of:

- Gross per capita Medicaid expenditures for prescription drugs for CY 2003, including dispensing fees, per full-benefit dual eligible, with downward adjustments for:
 - o Expenditures attributable to drugs not covered by Part D
 - o Aggregate rebates
- Estimated actuarial value of prescription drug benefit provided under a capitated managed care plan per full-benefit dual eligibles

This per capita amount is multiplied by: 1/12th (to get a monthly amount) and 100 percent minus the state's Federal Medical Assistance Percentage (FMAP) matching rate (to get the state share of the total per capita expenditures).

This base year state Medicaid per capita expenditures for covered Part D drugs for full-benefit dual eligible individuals is multiplied by an applicable growth factor for each year between the base year (2003) and the present year. For 2004 through 2006, this growth factor is equal to the average annual percentage change in the national health expenditures' drug cost growth per capita. In subsequent years, the growth factor is the annual growth in part D expenditures per enrollee (same index for standard benefit values).

Number of full-benefit dual eligibles: This is the monthly number of individuals both enrolled in a PDP or MA-PD and who are determined eligible by the state for medical assistance for full benefits.

Factor: The product of the per capita amount and number of full-benefit dual eligibles would be multiplied by a factor to reduce it. This factor is:

<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>2015 and beyond</u>
90%	88.3%	86.6%	85%	83.3%	81.6%	80%	78.3%	76.6%	75%

Note that both the per capita amount and the number of full-benefit dual eligibles are calculated to reflect present values.

Premium and Cost Sharing Assistance for Low-Income Individuals

	Premium	Deductible	Copayments from Deductible to Out-of-Pocket Threshold*	Copayment Above Out-of-Pocket Threshold*
Level 1: Institutionalized dual eligible individuals	\$0 for low-cost plan (20% of late enrolment penalty for up to 60 months if applicable)	\$0	\$0	\$0
Level 2: Dual eligible individuals with income below 100% of poverty	\$0 for low-cost plan 20% of late enrolment penalty for up to 60 months	\$0	\$1 preferred \$3 non-preferred in 2006, indexed to general inflation	\$0
Level 3: a. Dual eligible individuals with income above 100% of poverty b. Non-dual eligible individuals with income below 135% of poverty and assets below \$6,000 for singles / \$9,000 for couples	\$0 for low-cost plan (20% of late enrolment penalty for up to 60 months if applicable)	\$0	\$2 preferred \$5 non-preferred in 2006, indexed to drug cost growth per capita	\$0
Level 4: a. Non-dual eligible individuals with income below 135% of poverty and assets between \$6,000-10,000 for singles / \$9,000-20,000 for couples b. Non-dual eligible individuals with income between 135-150% of poverty and assets below \$10,000 for singles / \$20,000 for couples	Sliding Scale from \$0 at 135% of poverty to full premium at 150% of poverty (includes late enrollment penalty if any)	\$50	15%	\$2 preferred \$5 non-preferred in 2006, indexed to drug cost growth per capita

* For prescription drugs on the insurer's formulary. Note: assets limits are for 2006; they are indexed to general inflation in subsequent years.

NOTES

- ¹ For an overview, see Moon M. (June 2004). *How Beneficiaries Fare Under the New Medicare Drug Bill*. New York: The Commonwealth Fund.
- ² For a fuller description of the consumer issues in the new law, see Dallek G. (July 2004). *Consumer Protection Issues Raised by The Medicare Prescription Drug, Modernization, and Improvement Act of 2004*. Menlo Park, CA: The Henry J. Kaiser Family Foundation.
- ³ U.S. House of Representatives, Committee on Ways and Means. (November 21, 2003). *Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Conference Report to Accompany H.R. 1*. Washington, D.C.: U.S. Government Printing Office.
- ⁴ Bush GW. (January 20, 2004). *The State of the Union Address*. Washington, DC: The White House.
- ⁵ Marre K. (June 2, 2004). "Administration: No technical Medicare bill is necessary," *The Hill*, p. 16.
- ⁶ Cubanski J; Frank RA, Epstein AM. (April 14, 2004). "Savings from Discount Cards: Relief for Medicare Beneficiaries?" *Health Affairs Web Exclusive*; Center for Medicare and Medicaid Services. (June 29, 2004). *Medicare-Approved Discount Cards Offer Substantial Savings to Beneficiaries With Common Health Conditions*. Washington, DC: U.S. Department of Health and Human Services, CMS; House Committee on Government Reforms, Minority Staff. (June 2, 2004). *Medicare Drug Card Prices Remain High*. Washington, DC: U.S. House of Representatives.
- ⁷ Centers for Medicare and Medicaid Services. (July 15, 2004). *Press Release: Enhanced Medicare Website and 800 Number Make It Faster to Start Saving with Medicare-Approved Drug Discount Cards*. Washington, DC: U.S. Department of Health and Human Services, CMS.
- ⁸ Bendetto R. (June 14, 2004). "President to Discuss Medicare Program during Missouri Trip," *USA Today*.
- ⁹ Medicare Rights Center. (May 24, 2004). *Medicare-Approved Drug Discount Cards: A Prescription for Improvement*. New York: The Medicare Rights Center.
- ¹⁰ See, for example, S. 2413, Medicare Assurance of Rx Transitional Assistance Act of 2004.
- ¹¹ M. McClellan, FDA Commissioner. (October 20, 2003). Fifth Annual David A. Winston Lecture, National Press Club.
- ¹² See, for example, S. 2328, Pharmaceutical Market Access and Drug Safety Act of 2004.
- ¹³ Shaw T. (January 7, 2004). *Prescription Drug Prices: Harnessing Medicare's Purchasing Power*. Washington, DC: The Center for American Progress.
- ¹⁴ See, for example, H.R. 3767, Medicare Prescription Drug Savings and Choice Act of 2004.
- ¹⁵ -- (May 20, 2004). "Medco Reaches \$29 million Settlement with States over Allegations of Unethical Drug Switching, Not Passing Along Savings," *Kaiser Daily Health Policy Report*.
- ¹⁶ This is similar to the "Cantwell Amendment" included in the Senate-passed legislation.
- ¹⁷ McGlynn EA et al. (June 26, 2003). "The Quality of Health Care Delivered to Adults in the United State," *N Engl J Med* 348: 2635-45..
- ¹⁸ Medicare Payment Assessment Commission. (June 2004). *New Approaches in Medicare*. Washington, DC: MedPAC.
- ¹⁹ It might be argued that detailed submission of price discounts, rebates etc. are barred by the non-interference clause (1860D-11(i), p. 35-36). This clause prohibits the secretary from interfering in the negotiations between a plan and a drug manufacturer.
- ²⁰ Congressional Budget Office. (March 2004). CBO March 2004: MEDICARE Fact Sheet. Washington, DC.
- ²¹ Medicare Payment Assessment Commission. (June 2004). *New Approaches in Medicare*. Washington, DC: MedPAC.
- ²² Answers for the Record to Questions Submitted by Senator Max Baucus from the Senate Finance Committee Hearing on the Nomination of Mark B. McClellan, to be Administrator of the Center for Medicare and Medicaid Services. March 8, 2004.
- ²³ Answers for the Record to Questions Submitted by Senator Max Baucus from the Senate Finance Committee Hearing on the Nomination of Mark B. McClellan, to be Administrator of the Center for Medicare and Medicaid Services. March 8, 2004.
- ²⁴ See, for example, Neuman P et al. (July/August 1998). "Marketing HMOs to Medicare Beneficiaries," *Health Affairs* 14(4): 132-139.
- ²⁵ See data at www.statehealthfactsonline.org.
- ²⁶ Joint Economic Committee. (July 2004). *Rising Medicare Premiums Undermine the Social Security COLA: New Medicare Law Could Cut Benefits for Some*. Washington, DC: U.S. House of Representatives, JEC Democrats.

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- ²⁷ McInturf B; Garin G. (June 2004). *Reactions to the New Medicare Law*. Menlo Park, CA: The Henry J. Kaiser Family Foundation.
- ²⁸ Lambrew J. (February 12, 2004). *The New Medicare Drug Benefit: Not So Voluntary*. Washington, DC: The Center for American Progress.
- ²⁹ Note: the law makes reference to both therapeutic "categories" and "classes". Since these words appear to be used interchangeably, the term "class" is used to mean "category" throughout this paper.
- ³⁰ Huskamp HA, Keating NL. (July 2004). *The New Medicare Drug Benefit: Potential Effects of Pharmacy Management Tools on Access to Medications*. Menlo Park, CA: The Henry J. Kaiser Family Foundation. Note: this study includes a broad description of the use of formularies and cost sharing and suggests ideas on improving the law so that these tools do not impede access.
- ³¹ Crowley JS. (July 21, 2004). *The New Medicare Prescription Drug Law: Formulary Policies Could Limit Access to Necessary Medicines*. Washington, DC: The Center for American Progress.
- ³² Note that the term "out-of-pocket threshold" is used throughout; there is no true out-of-pocket limit because an individual must continue to pay coinsurance (up to 5 percent) once that threshold is met.
- ³³ Kaiser Commission on Medicaid and the Uninsured. (June 2004). *The New Medicare Prescription Drug Law: Issues for Dual Eligibles with Disabilities and Serious Conditions*. Washington, DC.
- ³⁴ Answers for the Record to Questions Submitted by Senator Max Baucus from the Senate Finance Committee Hearing on the Nomination of Mark B. McClellan, to be Administrator of the Center for Medicare and Medicaid Services. March 8, 2004.
- ³⁵ Crowley JS. (July 21, 2004). *The New Medicare Prescription Drug Law: Formulary Policies Could Limit Access to Necessary Medicines*. Washington, DC: The Center for American Progress.
- ³⁶ Congressional Budget Office. (November 20, 2003). Table 1. CBO Estimate of the Effect on Federal Direct Spending and Revenues of Title I of the Conference Agreement for H.R. 1. Washington, DC.
- ³⁷ Department of Health and Human Services, Centers for Medicare and Medicaid Services. (June 24, 2004). "Medicare Drug Replacement Demonstration Notice," *Federal Register*.
- ³⁸ Schultz EE, Francis T. (March 16, 2004). "How Cuts in Retiree Benefits Fatten Companies' Bottom Lines," *The Wall Street Journal*.
- ³⁹ Answers for the Record to Questions Submitted by Senator Max Baucus from the Senate Finance Committee Hearing on the Nomination of Mark B. McClellan, to be Administrator of the Center for Medicare and Medicaid Services. March 8, 2004.
- ⁴⁰ Summer L, Thompson L. (May 2004). *How Asset Tests Block Low-Income Medicare Beneficiaries from Needed Benefits*. New York: The Commonwealth Fund.
- ⁴¹ Based on growth rates in Congressional Budget Office. (November 20, 2003). Table 1. CBO Estimate of the Effect on Federal Direct Spending and Revenues of Title I of the Conference Agreement for H.R. 1. Washington, DC: CBO.
- ⁴² Schneider A. (June 2004). *The "Clawback:" State Financing of Medicare Drug Coverage*. Washington, DC: The Kaiser Commission on Medicaid and the Uninsured.
- ⁴³ Congressional Budget Office. (November 20, 2003). *Table 3. Estimated Change in State Medicaid Outlays Under Title I of the Conference Agreement on H.R. 1*. Washington, DC: CBO.
- ⁴⁴ Biles B, Nicholas LH, Cooper BS. (May 2004). *The Cost of Privatization: Extra Payments to Medicare Advantage Plans*. New York: The Commonwealth Fund.
- ⁴⁵ Dallek G, Biles B, Nicholas LS. (June 2003). *Lessons from Medicare+Choice for Medicare Reform*. New York: The Commonwealth Fund.
- ⁴⁶ For a discussion of premium support and its implications, see Rice T, Desmond KA. (February 2002). *An Analysis of Reforming Medicare through a "Premium Support" Program*. Menlo Park, CA: The Henry J. Kaiser Family Foundation.
- ⁴⁷ Park E; Greenstein R; Kogan R. (April 20, 2004). *Overlooked Element of Medicare Trustees' Report Could Spell Trouble for Beneficiaries in Future Years*. Washington, DC: Center on Budget and Policy Priorities.
- ⁴⁸ Medicare Trustees. (March 2004). *2004 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*. Washington, DC: U.S. Department of Health and Human Services.
- ⁴⁹ Greenstein R, Park E. (December 1, 2003). *Health Savings Accounts in Final Medicare Conference Agreement Pose Threats Both to Long-Term Fiscal Policy and to the Employer-Based Health Insurance System*. Washington, DC: The Center on Budget and Policy Priorities.