



Medicare Rights Center

**IMPROVING THE MEDICARE
PROGRAM FOR BENEFICIARIES:**

**ADMINISTRATIVE RECOMMENDATIONS FOR
THE INCOMING ADMINISTRATION**

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Executive Summary

Executive Summary

The Medicare Rights Center (MRC) is the nation's largest independent source of Medicare information and assistance for people with Medicare. Founded in 1989, MRC helps older adults and people with disabilities to receive high quality, affordable health care. MRC's extensive experience counseling Medicare beneficiaries and advocating on their behalf uniquely positions MRC to identify how Medicare can be improved for those it was designed to serve. To that end, this memorandum highlights what MRC believes to be the most meaningful administrative actions that should be taken on behalf of Medicare beneficiaries. These recommendations focus on the Medicare Advantage (MA) program and the Part D drug benefit and are designed to improve accountability under both these programs and to provide vital beneficiary protections. Many of these recommendations overlap with those identified by the Government Accountability Office as important transition issues for the Department of Health and Human Services.¹

We offer the following recommendations to improve the Medicare program:

- 1. Prohibit excessive and discriminatory out-of-pocket spending in Medicare Advantage plans and standardize available plan options.** The MA and Part D marketplaces are characterized by an overwhelming number of offerings with widely varying benefit designs. Particularly in Medicare Advantage, loopholes have left many beneficiaries, and especially sicker beneficiaries, vulnerable to significant out-of-pocket (OOP) spending. We urge CMS to use the 2010 Call Letter, to be issued in late January 2009, to implement strict requirements that all plans: (1) limit cost-sharing for each identified service to no more than the cost-sharing permitted under Original Medicare, and (2) incorporate a comprehensive OOP limit set at the average premium for comprehensive supplemental Medigap coverage (\$2,330). In addition, CMS should facilitate consumer choice by limiting the Part D and Medicare Advantage offering from each sponsor. **Requirements should be proposed in Draft 2010 Call Letter issued in mid-January 2009 and finalized in final Call Letter issued in mid-March 2009.**
- 2. Provide LIS beneficiaries with timely retroactive reimbursement of premiums and cost sharing amounts.** Part D beneficiaries who qualify for the LIS generally have one to four months of retroactive LIS coverage and are entitled to receive automatic refunds for payments made for excessive drug premiums and cost sharing. Part D plans routinely fail to make these retroactive reimbursements automatically and make it burdensome for beneficiaries to request reimbursement. We urge CMS to amend its regulations to expressly and clearly require plans to automatically reimburse Part D beneficiaries who newly qualify for LIS. We also urge CMS to change the way that Part D plans are reimbursed, so that Part D plans receive payment only upon proof that they have made the proper payments to beneficiaries. **Reforms should be implemented by finalizing regulations amended in the May 16, 2008 proposed rule.**
- 3. Finalize regulations ensuring Part D prices are not inflated to include the "spread" retained by pharmacy benefit managers (PBMs).** CMS has yet to implement a May 16, 2008 proposed rule defining "negotiated prices" under Part D that ensures that drug plan prices do not exceed the reimbursement rate, plus any dispensing fee, received by pharmacies. This will

¹ See http://www.gao.gov/transition_2009/agency/hhs/improving-medicare-management.php.

prohibit PBMs from collecting a “spread” between the rate negotiated with network pharmacies and the price charged to beneficiaries, Part D plans and taxpayers. These inflated prices result in higher cost sharing for beneficiaries and higher government payments for reinsurance and low income subsidies. **Reforms should be implemented by finalizing regulations amended in the May 16, 2008 proposed rule.**

- 4. Protect beneficiaries from unfair and misleading marketing by authorizing states to regulate the marketing practices of Medicare private plans.** Since passage of the Medicare Modernization Act, Medicare beneficiaries have been subject to abusive marketing practices by Medicare Advantage (MA) plans. While plans’ use of improper marketing tactics has received widespread attention, CMS has been unable to exercise effective oversight because of its limited resources for monitoring and enforcement. We urge CMS to re-interpret its current regulations to enlist state insurance departments in policing plan marketing conduct. Specifically, CMS should clarify that states are not preempted from requiring Medicare private plans to comply with federal and state laws as they relate to insurance marketing practices. **Reforms should be proposed in time for final rulemaking before October 1, 2009, the start of the 2010 marketing season.**
- 5. Improve coordination of care for vulnerable beneficiaries enrolled in Special Needs Plans.** CMS should strengthen current regulations to improve the coordination and management of care for individuals enrolled in MA Special Needs Plans (SNPs). We also urge CMS to restrict the special enrollment period for newly-eligible individuals to join chronic care SNPs as set out in sub-regulatory guidance. This permanent open enrollment period subjects the most vulnerable Medicare beneficiaries to year-round, aggressive SNP marketing from plans with no proven record of improving care for beneficiaries with chronic conditions. **Reforms can be implemented through revisions of the September 15, 2008 interim final rule and in the Draft 2010 Call Letter issued mid-January 2009 and finalized in final Call Letter issued in mid-March 2009.**
- 6. Enable beneficiaries to receive medically necessary off-label prescription drugs.** Current CMS regulations restrict coverage of medications to those indications that are consistent with FDA approved marketing labels or supported by one or more compendia identified by statute. As a result, beneficiaries are denied coverage of medically necessary medicines prescribed for off-label indications even when they have demonstrated efficacy in peer-reviewed medical literature. CMS should revise its regulations to permit coverage of drugs prescribed for off-label indications where the prescribed drug is supported either by the specified compendia or by clinical evidence published in peer-reviewed medical literature. This is the coverage standard that applies for Part B drugs. **Reforms should be implemented in final rulemaking prior to the mid-April submission of Part D formularies for 2010.**
- 7. Strengthen Part D appeals procedures.** The appeals process is a critical tool for guaranteeing beneficiary access to medically necessary drugs that initially are denied by a Part D plan. The appeals processes can be improved by enforcement of existing rules and requirements, and by additional regulations that allow beneficiaries to initiate actions for timely review of their appeals. In addition, CMS should improve the fairness of administrative law judge (ALJ)

hearings by making the regulations governing Part D cases consistent with the rest of Medicare. **Reforms should be implemented through regulations in early 2009.**

- 8. Utilize data from Part D plans to identify and address disruptions in drug coverage for high-risk beneficiaries.** Although Part D plans must have in place transition and appeal policies to minimize interruptions in drug regimens caused by plan formulary restrictions, CMS lacks sufficient information to assess the effectiveness of these policies in ensuring access to medically necessary drugs. We urge CMS to use its broad data collection authority to require Part D plans to collect and report information about rejected claims and to use this data to develop measures for evaluating the effectiveness of plan policies to affect uninterrupted drug access for beneficiaries with chronic conditions. **Requirements should be proposed in the Draft 2010 Call Letter issued mid-January 2009 and finalized in final Call Letter issued in mid-March 2009.**
- 9. Enhance stability of drug coverage for low income beneficiaries by reforming the calculation of the Low Income Subsidy (LIS) benchmark.** The value of the regional LIS benchmark, which determines the maximum premium subsidy for low income beneficiaries, is undermined by Medicare Advantage plans that use excess payments to buy down the Part D premium. As a result, particularly in states with high Medicare Advantage payments, the benchmark no longer reflects the average cost of Part D coverage and low income beneficiaries have a dwindling number of plans with premiums that qualify for a full subsidy. CMS should amend its regulations to eliminate MA rebates from its benchmark calculation. To further restore the benchmark, CMS also should re-weight its benchmark formula to include average plan premiums for all Part D enrollees and not just LIS beneficiaries thereby ensuring that the formula reflects the true average cost of Part D coverage. **Reforms should be implemented through rulemaking in advance of CMS' calculation of LIS benchmarks in August 2009.**
- 10. Target reassignment of LIS beneficiaries to Part D plans that meet their individual needs.** The instability of the LIS benchmark results in large scale reassignments of beneficiaries to below-benchmark plans, with over one million low income beneficiaries reassigned in both 2007 and 2008. CMS reassigns these beneficiaries randomly to below-benchmark plans, with no regard to whether the assigned plan covers the beneficiary's drugs. This policy results in major disruptions in drug coverage and pharmacy access for the most vulnerable Medicare beneficiaries. CMS should revise its reassignment methodology to ensure that beneficiaries are assigned to plans that maximize coverage of their current medications and offer access to beneficiaries' preferred pharmacies. **Reforms should be implemented through rulemaking in advance of the reassignment process in October 2009.**

The Medicare Rights Center looks forward to working with the Obama Administration on these and other important improvements to the Medicare program. Should you have any questions or require additional information please contact Paul Precht, Director for Policy and Communications, at 202-544-5561 or pprecht@medicarerights.org, or Michealle Carpenter, Deputy Policy Director and Counsel, at 202-544-5581 or mcarpenter@medicarerights.org.

Section 1

CMS SHOULD BEGIN STANDARDIZING AND SIMPLIFYING MEDICARE ADVANTAGE AND PART D PLANS

CMS SHOULD BEGIN STANDARDIZING AND SIMPLIFYING MEDICARE ADVANTAGE AND PART D PLANS

The Centers for Medicare and Medicaid Services (CMS) should take steps toward standardization of Medicare Advantage (MA) and Part D plans. These programs were designed to provide flexibility to plan sponsors in order to increase competition and develop products that best serve beneficiaries in the most cost-efficient manner. The current marketplace for MA plans, however, is characterized by an overwhelming number of offerings with widely varying benefit designs and loopholes that have left many beneficiaries vulnerable to significant out-of-pocket (OOP) costs. Similarly, the flexibility currently afforded to Part D plan sponsors has led to an overwhelming number of choices for beneficiaries and caused many to enroll in plans ill-suited to their individual needs. The Medicare Rights Center's ultimate goal is full standardization of MA and Part D plans, but at a minimum, CMS must quickly address discriminatory plan design by requiring limits on cost-sharing and a comprehensive OOP spending cap.

The MA program gives plan sponsors flexibility in designing benefit packages so long as they provide all Medicare-covered services, adhere to cost-sharing requirements that are the same as or actuarially equivalent to those under traditional fee-for-service Medicare, and do not discriminate on the basis of enrollee health status. The number and variety of benefits and benefit structures offered within this framework has led to beneficiary confusion. For example, one report noted that in 2007, "the State of Florida reported that thirty-seven insurance carriers marketed and sold over 300 different [MA plans]. All of these plans had different coverage levels, cost-share amounts and premium rates."ⁱ What is of more concern is that this proliferation of varying plans masks significant deficiencies in some benefit packages that are extremely difficult for consumers to discover, even with the use of CMS' decision-making tools. These deficiencies include:

- Consumers suffering from chronic illnesses incur widely varying levels of cost-sharing under different plans;
- Many plans do not provide a limit on enrollees' annual OOP spending for medical services or exempt certain services, such as chemotherapy, from such limits; and,
- Many plans charge more than Original Medicare for specific services, such as inpatient hospital care, nursing home stays, or home health care.

Indicative of the significant variation in cost-sharing for beneficiaries, annual out-of-pocket costs for plan members in 2005 ranged from under \$100 for beneficiaries in good health to over \$6,000 for those in poor health.ⁱⁱ

Similarly, Part D sponsors have broad discretion to offer an array of plan types, including the benefit structure defined in statute, alternative plans with actuarial equivalence, and enhanced plans that offer greater benefits in exchange for higher premiums. This flexibility extends to cost-sharing, formulary design (within CMS guidelines), and limitations on coverage (such as prior authorization). Although this flexibility was intended to increase competition and innovation, the proliferation of plans and the inconsistent and even misleading ways in which plans are described have made informed comparison and meaningful choice nearly impossible. The state of Florida, for example, reported that there were 57 stand-alone Part D plans in 2007, with many sponsors offering multiple plans.ⁱⁱⁱ

While laudable, CMS efforts to provide more information about plan benefits are not sufficient. Studies have shown that too many choices discourage informed participation.^{iv} AARP reported, for example, that beneficiaries with more knowledge of the benefit were just as likely to feel confused about Part D as those with less knowledge of the benefit.^v The MA and Part D markets “may have reached a point similar to that of the Medigap market prior to [legislative and regulatory reforms to that program in] the 1990s, where the confusion caused by differing benefit packages outweighed any advantages associated with these differences.”^{vi}

Medicare beneficiaries would be better able to make informed decisions about their coverage options and be better protected against the deficiencies noted above if MA and Part D sponsors were allowed to offer only a finite number of standardized benefit packages. The Medicare Rights Center recognizes that full standardization would represent a significant shift from the original design of the programs, and our recommendations include incremental steps to improve protection of beneficiaries in the short term while the elements of full standardization are being designed and negotiated.

BACKGROUND

With the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), Congress granted CMS broad authority to review and approve plan bids and to prohibit discrimination based on beneficiary health status. CMS can use its power to simplify plan choice and establish minimum benefit standards for Medicare Advantage and Part D plans. The Medicare statute and implementing regulations make clear that the Secretary cannot approve any MA or Part D plan that is designed to discriminate against eligible beneficiaries based on health status.^{vii} CMS has already stated its willingness to use this authority to more strictly review MA plans as potentially discriminatory when they apply cost-sharing that is higher than that of Original Medicare for individual items and services that typically are used by sicker Medicare beneficiaries.^{viii}

In addition, CMS has broad authority to shape the design of most plans offered to beneficiaries within the MA and Part D statutory frameworks.^{ix} The Medicare statute sets forth specific information that CMS must request from plan sponsors and which it must review and approve as part of the bidding process. This includes information regarding the bid amounts, the benefits provided, the service area, the actuarial value of the coverage, and the level of risk assumed.^x In implementing the Medicare Advantage program, the statute authorizes CMS to review “deductibles, coinsurance, and co-payments applicable under the plan, and the actuarial value of such deductibles, coinsurance, and copayments”^{xi} and further to “negotiate regarding monthly bid amounts.”^{xii} In implementing the Part D program, the statute gives CMS authority to “negotiate the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan” and to “approve or disapprove the prescription drug plan.”^{xiii} In both programs, CMS is granted authority “similar to” that of the administrator of the Federal Employees Health Benefits Program, which includes “prescrib[ing] reasonable minimum standards for health benefits plans.”^{xiv}

Pursuant to this authority, CMS currently issues new requirements for participating MA and Part D plans through the Call Letter process. Components of the short-term recommendations below build on or modify requirements that CMS has already made through Call Letters, and we expect that these proposals can also be implemented through the plan year 2010 Call Letter process.

SHORT-TERM RECOMMENDATIONS

The following steps should be taken immediately through the plan year 2010 Call Letter.

1. Prevent Excessive and Discriminatory Out-of-Pocket Spending

The most critical short-term goal must be to protect MA enrollees from excessive OOP spending. To do so effectively, given the challenge of understanding plan coverage with the current variation and proliferation of plans, CMS should use its authority to implement strict requirements that all plans (1) limit cost-sharing for the services identified below to no more than that under Original Medicare, and (2) incorporate a comprehensive OOP limit that does not exclude any Part A or Part B covered services.

a) Limit cost-sharing for individual Part A and Part B services

Under the Medicare statute, CMS has the authority to prohibit discriminatory cost-sharing structures. At a minimum, therefore, CMS should prohibit plans from charging enrollees more than Original Medicare cost-sharing amounts for those items and services that are typically used by sicker Medicare beneficiaries. Allowing plans to charge more than Original Medicare cost-sharing for these services is discriminatory and will drive these beneficiaries from the plan or leave them with significant OOP liability. CMS' current approach of strictly scrutinizing plans with high cost-sharing for these services does not adequately protect beneficiaries, as plans are permitted to maintain these higher cost-sharing requirements. CMS has identified the following services for which higher cost-sharing may be discriminatory:

- Dialysis;
- Chemotherapy drugs;
- Inpatient acute and psychiatric hospital services;
- Skilled nursing facility stays;
- Home health services; and
- Durable medical equipment and supplies.^{xv}

In addition, through our experience advising beneficiaries, we have identified the following services for which cost-sharing amounts should be limited to avoid discriminatory impact on sicker beneficiaries:

- All inpatient hospital services;
- Some Part B drugs, including immunosuppressants, injectable biologics and drugs for the treatment of chronic obstructive pulmonary disease;

CMS could permit flexible plan design while still adhering to the requirement that cost-sharing not exceed that under Original Medicare. For example, CMS could permit plans to adopt copayments instead of coinsurance or deductibles. However, CMS should not allow copayment structures, such as per day charges for inpatient hospital stays,^{xvi} if such copayments would be less expensive for the

average beneficiary but would cost more than Original Medicare for those in poor health, who are likely to incur longer stays.

b) Require all Medicare Advantage plans to set an annual out-of-pocket maximum for all Medicare-covered Part A and Part B services

CMS should require all Medicare Advantage plans to set a comprehensive OOP spending cap for Medicare Part A and Part B services at a level determined by CMS. This recommendation builds on and strengthens the voluntary cap currently included in CMS' 2009 Call Letter.^{xvii} In setting a mandatory cap, CMS can rely on both its broad statutory authority to negotiate and approve plan cost-sharing and its authority to prohibit discriminatory cost-sharing structures.

CMS has interpreted its authority to prohibit discriminatory cost-sharing as prohibiting benefit designs that discourage enrollment of severely or chronically ill beneficiaries.^{xviii} This broad prohibition is not disease or service specific; it encompasses any cost-sharing structure likely to discourage enrollment of beneficiaries with the potential to incur high medical costs because of a history of chronic and severe illness. Given the variety of services that trigger high OOP spending—Part B drugs, inpatient or SNF stays—and the lack of standardization in cost-sharing for these services, the only reasonable method for beneficiaries to estimate potential OOP spending before enrollment is by comparing OOP limits across plans. The *absence* of a comprehensive OOP limit, by its nature, discourages enrollment of beneficiaries likely to incur high spending for the treatment of chronic illness, particularly when comparison is made to MA plans with such a limit or to Medigap supplemental plans, all of which limit OOP spending for A and B services.

Like the authority of the FEHBP on which it is patterned, CMS' broad authority to review and approve plan bids, including cost-sharing structures, encompasses the authority to set "reasonable minimum standards for health benefits plans." This bid review authority, however, specifically excludes PFFS plans.

Mandatory OOP limits should cover all Medicare-covered services. Plans that currently incorporate OOP limits have selectively used service carve-outs to exclude some of the non-discretionary services identified above, such as chemotherapy or Part B drugs, effectively permitting the imposition of discriminatory levels of cost-sharing, and either driving these beneficiaries from the plan or leaving them with significant OOP liability. This is certainly contrary to the Secretary's statutory obligation to prohibit discrimination. CMS should adopt a standard method for determining when the OOP cap has been reached that is comprehensive and covers all Original Medicare benefits.

CMS sets the current voluntary cap at the 75th percentile of Original Medicare beneficiary OOP spending (\$3,350 for 2009).^{xix} A mandatory cap set at the average annual premium for Medigap plan F, which covers all cost-sharing under A and B, would ensure that the cost-sharing obligations under MA plans do not discourage enrollment by people with disabilities and older, less healthy beneficiaries who tend to pay more than the average cost of Medigap premiums. The average annual plan F premium, projected to reach \$2,329 in 2011,^{xx} is also comparable to the average OOP cap found in employer-sponsored health plans.^{xxi}

2. *Simplify the decision-making process for beneficiaries by limiting the number of Part D plans and MA plans a sponsor can offer.*

Until effective steps are taken toward standardization, simply reducing the sheer number of available plans will decrease beneficiary confusion. CMS should limit Part D sponsors to two offerings: one with a basic benefit and one with an expanded benefit that includes gap coverage. CMS should limit MA sponsors to two benefit packages per type (HMO, PPO, PFFS) per county. If CMS determines that beneficiary coverage will be significantly disrupted by the removal of plans from the market, the agency could consider a one-year transition. Each plan to be eliminated could be maintained through that year, but would not enroll new beneficiaries. CMS has already has previously applied limits on the number of plan types per sponsor through the Call Letter process.^{xxii}

LONG-TERM RECOMMENDATIONS

To pursue full standardization in the longer term, we recommend that CMS convene a panel of experts, including CMS staff, independent experts, consumer representatives, state representatives, and plan representatives, to:

- Establish new standard Medicare Advantage cost-sharing structures;
- Standardize the definition of PPO and HMO under Medicare Advantage;
- Standardize tiers for Part D plans;
- Standardize copayment options for each tier for Part D plans
- Standardize requirements for Part D gap coverage.

CMS should implement these standards under its bid review authority and through regulation as necessary. Steps taken to standardize Part D plans should also be applied to prescription drug coverage in MA plans to support consistency across these programs.

ⁱ National Association of Insurance Commissioners, *Draft White Paper on the Regulation of Medicare Private Plans*, July 25, 2008, available at http://www.naic.org/documents/committees_b_senior_issues_080805_medicare_whitepaper.pdf.

ⁱⁱ Brian Biles et al., *Medicare Beneficiary Out-of-Pocket Costs: Are Medicare Advantage Plans a Better Deal?*, Commonwealth Fund (May 2006), at 1.

ⁱⁱⁱ National Association of Insurance Commissioners, *Draft White Paper on the Regulation of Medicare Private Plans*, July 25, 2008.

^{iv} See, e.g. See, e.g. Judith Hibbard, Dr.P.H. et al., *An Assessment of Beneficiary Knowledge of Medicare Coverage Options and the Prescription Drug Benefit*, AARP, May 2006, at 31(citing Tversky, Sattah, & Slovic, 1988) (older adults faced with too much information are likely to make no decision and stay with the status quo); Jim Hahn, *Standardized Choices: Medigap Lessons for Medicare Part D*, CRS, March 2006, at 6.

^v *Id.*

^{vi} Paul Precht et al., *Informed Choice: The Case for Standardizing and Simplifying Medicare Private Health Plans*, Medicare Rights Center (Sep. 2007) available at <http://www.medicarerights.org>

^{vii} For Medicare Advantage non-discrimination provisions, See 42 U.S.C. § 1395w-22(b); 42 C.F.R. § 422.100(f)(2); See also 42 C.F.R. § 422.110. For Part D provisions, See 42 U.S.C. § 1395w-111(e); 42 C.F.R. § 423.272(a)(2)(i).

^{viii} Medicare Managed Care Manual, Ch. 4, Section 20.13, available at <http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf>

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- ix We note that CMS' bid review authority does not extend to private fee-for-service (PFFS) plans. *See e.g.* 42 U.S.C. §§ 1395w-24(a)(5)(B), (a)(6)(B)(iv); 42 C.F.R. § 422.256(d). Congressional action may be necessary for more complete standardization of these plans. CMS does have authority to prohibit PFFS plans from engaging in discriminatory activities.
- x For Medicare Advantage, *see* 42 U.S.C. § 1395w-24(a) *et seq.*; *See also, e.g.*, 42 C.F.R. §§ 422.254(b), 256. For Part D, *See* 42 U.S.C. § 1395w-111; *See also* 42 C.F.R. § 423.272.
- xi 42 U.S.C. § 1395w-24(a)(6)(A)(iv).
- xii *Id.* at § 1395w-24(a)(6)(B); 42 U.S.C. § 1395w-111(d)(2)(A).
- xiii *Id.* at §§ 1395w-111(d)(2)(A), (e).
- xiv 5 U.S.C. § 8902(e), as referenced in the Medicare Advantage laws at 42 U.S.C. § 1395w-24(a)(6)(B), and in the Part D laws at 42 U.S.C. § 1395w-111(d)(2)(A).
- xv Medicare Managed Care Manual, Ch. 4, Section 20.13, available at <http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf>
- xvi According to a recent Commonwealth Fund report, "Some plans, for example, have a copayment of \$200 or \$300 per hospital day. For individuals in poor health requiring three hospital stays a year, each an average of four days, the out-of-pocket costs can total up to \$3,600." Brian Biles et al., *Medicare Beneficiary Out-of-Pocket Costs: Are Medicare Advantage Plans a Better Deal?*, Commonwealth Fund (May 2006).
- xvii *See* CMS FY2009 Call Letter, at 10.
- xviii Medicare Managed Care Manual *See* <http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf>
- xix *See* CMS FY2009 Call Letter, at 10.
- xx Eliot Fishman et al., *Medicare Out-of-Pocket Costs: Can Private Savings Incentives Solve the Problem?*, The Commonwealth Fund, March 2008, at 5, available at http://www.commonwealthfund.org/usr_doc/Fishman_Medicareout-of-pocketcosts_1113.pdf?section=4039
- xxi Dale Yamamoto et al., *How Does the Benefit Value of Medicare Compare to the Benefit Value of Typical Large Employer Plans?*, Kaiser Family Foundation, September 2008, available at <http://www.kff.org/medicare/upload/7768.pdf>
- xxii *See* CMS FY2008 Call Letter, at 64-65.

Section 2

**CMS SHOULD ADDRESS THE
ONGOING FAILURE OF MEDICARE
PART D PLANS TO PROVIDE
RETROACTIVE REIMBURSEMENT
FOR LOW-INCOME SUBSIDY
ENROLLEES**

CMS SHOULD ADDRESS THE ONGOING FAILURE OF MEDICARE PART D PLANS TO PROVIDE RETROACTIVE REIMBURSEMENT FOR LOW-INCOME SUBSIDY ENROLLEES

People who are enrolled in Part D plans and then qualify for LIS, either by applying directly to the Social Security Administration (SSA) or by being deemed eligible through Medicaid or a Medicare Savings Program (MSP), are entitled to receive automatic refunds for the excess drug premiums and cost-sharing that they have paid. Private plans are paid by Medicare to make these retroactive reimbursements. Individuals who are deemed eligible for LIS through Medicaid or a MSP often have a retroactive coverage period, the period between the LIS effective date and the date that the Part D plan recognizes a member's LIS status, of five or six months, during which the beneficiary pays cost-sharing above the LIS levels. Overpayments by low-income individuals with Medicare can amount to hundreds or even thousands of dollars.

Part D enrollees who apply for LIS directly through the SSA also end up with significant premium and cost-sharing overpayments. For these individuals, the effective date of LIS coverage is the first day of the month in which a LIS application is submitted.ⁱ In the Medicare Rights Center's experience, it usually takes one month from the date of application for a beneficiary to receive a LIS award letter from the SSA, and at least another two weeks for the beneficiary's Part D plan to receive notification of LIS status. Accordingly, overpayments by these individuals extend over at least six weeks.

Research by the Government Accountability Office, as well as the Medicare Rights Center's experience advocating for refunds on behalf of its low-income clients, demonstrates that plans regularly fail to automatically reimburse beneficiaries for excess copayments and premiums paid.ⁱⁱ Not only do plans fail to reimburse beneficiaries, plans also fail to clearly communicate to enrollees how they can receive such reimbursement. While the letter from CMS and the model plan letter used by plans indicate that beneficiaries may be entitled to this reimbursement, neither letter sets out a clear process that beneficiaries should follow to seek reimbursement from plans.

Further complications arise when the beneficiary actively seeks reimbursement, but the plan fails to abide by requirements that plans treat requests for reimbursements as coverage determinations, which are subject to regulatory timeframes.ⁱⁱⁱ Beneficiaries can spend months awaiting reimbursement of overpaid cost-sharing, even though plans are required to authorize reimbursement within seven calendar days and make payment within 30 calendar days.^{iv} Recognizing the scope of this problem, the Government Accountability Office recommended that CMS evaluate its retroactive reimbursement policies as a transition issue.^v

The Medicare Rights Center urges CMS to promulgate and enforce regulations and sub-regulatory guidance that will ensure low income beneficiaries receive prompt reimbursement for excess premiums and copayments paid during periods of retroactive LIS eligibility

BACKGROUND

Federal regulations provide that a person receiving the LIS is entitled to reimbursement from his or her Part D plan of any non-LIS amounts paid during the period between the first day of the month that the beneficiary applies for the benefit—or the start of his or her retroactive eligibility for

Medicaid or a MSP, through which he or she is deemed eligible for LIS—and the date that the plan recognizes the enrollee’s LIS status. This includes reimbursement of any premiums (or, for recipients of partial LIS, any portions of premiums above their LIS portions) and any co-payment amounts that would have been covered by LIS.^{vi}

Medicare guidance states that failure by a Part D plan to reimburse an enrollee for these amounts is considered “fraud, waste, and abuse.”^{vii} Guidance indicates that plans should automatically reimburse members for excess premiums and cost-sharing paid after the LIS effective date.^{viii} In addition, CMS’ 2009 Standardized Model Combined Annual Notice of Change/Evidence of Coverage says that individuals who have qualified for LIS should be reimbursed for excess co-payments and suggests that the process will be automatic.^{ix} Additionally, the 2009 Evidence of Coverage LIS Rider states, in referring to LIS beneficiaries whose cost-sharing level will decrease, “If we owe you money, *we will let you know how much.*”^x (Emphasis added). This language implies that plans have the capacity to determine the amount beneficiaries are owed and will refund that amount automatically.

RECOMMENDATIONS

To ensure that low-income people with Medicare receive the payments to which they are entitled, the Medicare Rights Center urges CMS to implement the following changes:

1. CMS should amend 42 C.F.R. § 423.800(c) to reflect plans’ affirmative obligation to automatically reimburse excess premiums and cost-sharing paid by Part D beneficiaries who newly qualify for LIS, as follows:

(c) Reimbursement for cost-sharing paid before notification of eligibility for low-income subsidy. Within 30 days of notification that an individual is eligible for the low-income subsidy, whether or not a reimbursement request has been received from the individual, the Part D sponsor offering the Part D plan must review the individual’s records of premiums paid and covered prescriptions purchased during the time between the individual’s effective date of eligibility for the subsidy and the date the Part D sponsor’s records correctly reflect the individual’s subsidy and, based on the plan’s records or other proof provided by the individual or organizations paying cost-sharing on behalf of the individual, reimburse the subsidy-eligible individual or organizations any excess premiums and cost-sharing paid by such individual or organization after the effective date of the individual’s eligibility for a subsidy under this subpart.

2. CMS should issue new guidance expressly mandating plans to automatically reimburse beneficiaries. In addition, CMS should amend the model plan letter regarding LIS eligibility to include an explanation to beneficiaries about their entitlement to reimbursement for cost-sharing during the retroactive period, and to clearly and accurately explain the process that the beneficiary should follow to request such reimbursement.
3. When beneficiaries receive reimbursement, Part D plans often send a check without any accompanying explanation. Part D plans should be required to provide an accounting to the beneficiary of reimbursements provided. The accounting should include a detailed explanation of

what premiums and cost-sharing are included in the reimbursement check, as well as an explanation of the procedures the beneficiary should follow if she or he disputes the reimbursed amount.

4. CMS should change the way Part D plans are reimbursed for this period of retroactive coverage. Currently, Medicare pays Part D plans a monthly payment for each LIS recipient enrolled in the plan. The monthly payment consists of three components: a direct “risk adjustment” subsidy payment to the plan for the additional cost of providing standard drug coverage to the LIS recipient, a payment to cover the plan premium, and a payment to cover cost-sharing based on an estimate of beneficiaries’ monthly cost-sharing.^{xi} As a result of this payment method, plans are paid in advance of reimbursing beneficiaries for premiums and cost-sharing paid above the LIS levels in the retroactive coverage period. Yet CMS has previously said that it will not pay plans for these costs until beneficiaries are reimbursed. In particular, CMS stated, in response to comments expressing concern that plans would violate the requirement to reimburse members for cost-sharing incurred during the period of retroactive coverage, “plans [are] to directly reimburse the beneficiary, according to the data it has kept on the beneficiary’s incurred and paid expenses. *We will then reimburse the plan for these expenses.*”^{xii} (Emphasis added). Reimbursing plans upon proof that they have made the proper payments to the beneficiary is the better approach. This ensures that beneficiaries receive the reimbursement they are entitled to and that plans are reimbursed for only the expenses that they incur. The Secretary of Health and Human Services has the authority to reimburse plans using this process under 42 U.S.C. § 1395w-115.

5. CMS should actively track the money paid to plans for LIS recipients and monitor the reimbursement process to ensure that plans are properly reimbursing beneficiaries for the expenses they incurred during the period of retroactive coverage.

ⁱ 42 C.F.R. § 423.774(b).

ⁱⁱ These problems have been verified independently. In June 2007, the Government Accountability Office (GAO) issued a report on Medicare Part D prescription drug coverage for people who receive both Medicare and Medicaid (so-called “dual-eligible” beneficiaries). GAO found that in 2006 and 2007, CMS failed to notify new dual-eligible beneficiaries of their right to be reimbursed for drug costs incurred between the effective and actual date of their Part D coverage enrollment. Additionally, CMS also failed to monitor Part D plans’ reimbursements to these individuals, even as it paid Part D plans approximately \$100 million for retroactive coverage. As detailed by the GAO, these reimbursement problems were not limited to dual-eligible beneficiaries. *See generally* Government Accountability Office, *Medicare Part D: Challenges in Enrolling New Dual-Eligible Beneficiaries*, GAO-07-272, at 28 (May 2007).

ⁱⁱⁱ 42 CFR 423.566(b), 42 CFR 423.568, Prescription Drug Benefit Manual, Chapter 18, Section 30.

^{iv} 42 CFR 423.568(b), Prescription Drug Benefit Manual, Chapter 18, Section 130.1.

^v *See* http://www.gao.gov/transition_2009/agency/hhs/improving-medicare-management.php.

^{vi} *See* 42 C.F.R. § 423.800(c).

^{vii} CMS Prescription Drug Benefit Manual, Chapter 9, Section 70.1.1.

^{viii} *See* Centers for Medicare & Medicaid Services, *LIS Incorrect Cost-Sharing – Making the Beneficiary Whole*, CMS, available at http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/QALISMakingBeneWhole_07.06.06.pdf

^{ix} *See* CMS 2009 Combined Call Letter, at 166 (“When we receive the evidence showing your co-payment level, we will update our system or implement other procedures so that you can pay the correct co-payment when you get your next prescription at the pharmacy. Please be assured that if you overpay your co-payment, we will reimburse you. Either we will forward a check to you in the amount of your overpayment or we will offset future co-payments.”)

^x 2009 Evidence of Coverage LIS Rider, at 3.

^{xi} *See* GAO-07-272, at 28.

^{xii} 70 Fed. Reg. 4391 (Jan. 28, 2005).

Section 3

**CMS SHOULD IMPLEMENT ITS
PROPOSAL TO REDEFINE PART D
NEGOTIATED PRICES**

CMS SHOULD IMPLEMENT ITS PROPOSAL TO REDEFINE PART D NEGOTIATED PRICES

CMS has yet to finalize regulations initially proposed on May 16, 2008 that ensure drug prices under the Part D benefit are based on pharmacy reimbursement rates and are not inflated by Pharmacy Benefit Managers (PBMs) under the so-called “lock-in” pricing model. Lock-in pricing is a pricing model used by some PBMs that subcontract drug benefit administration for Part D plans and Medicare Advantage plans. PBMs that use the lock-in pricing model establish drug prices for the plan sponsor that are often substantially greater than the reimbursement rate the PBM negotiates with network pharmacies, particularly for certain generics. The differential, or “spread,” between the pharmacy reimbursement rate and the price set for the plan and its enrollees accrues to the PBM. These higher prices translate into higher copayments, quicker attainment of deductibles, and more rapid acceleration toward the coverage gap for beneficiaries, and higher reinsurance and low-income subsidies for the government.

Consistent with the revised definition of negotiated prices in the May 2008 proposed rule, CMS should implement a definition of negotiated prices for Part D drugs so that the spread amounts captured by PBMs are not included in negotiated prices. With this change, the price used to calculate spending under the drug benefit by plans, beneficiaries, and the government would not be higher than the reimbursement rate, including dispensing fees, negotiated between the pharmacy and the Part D plan (or PBM).

BACKGROUND

Under Part D, total spending, including both beneficiary cost sharing and plan payment, is used to calculate progress toward the initial coverage limit, which marks the beginning of the coverage gap, or “doughnut hole,” when beneficiaries must pay the full cost of their drugs. Because prices under the lock-in model are higher than the prices negotiated with pharmacies, beneficiaries in Part D plans employing this model are more likely to enter the coverage gap and are more likely to enter the coverage gap earlier in the year.

The higher “lock-in” prices are also used to calculate coinsurance rates as well as “actuarially equivalent” copayment rates. As a result, plans that use these inflated prices provide a diluted benefit, since average beneficiary cost-sharing between the deductible and the initial coverage limit is no longer equivalent to 25 percent of the cost of drugs. By inflating the drug price to include the “spread” retained by the PBM, consumers effectively on average pay more 25 percent of the actual cost of the drug at the pharmacy counter.

The lock-in pricing model tends to raise prices for commonly prescribed generics. Consumers generally switch to a generic because of coverage restrictions imposed on brand-name drugs in the same therapeutic class, to reduce out-of-pocket spending, and to avoid falling in the Part D coverage gap. It is unfair that these consumers, after taking action they thought would lower their costs, should be subject to a pricing model that not only fails to deliver the full savings benefit of generic substitution but could also push them into the coverage gap earlier in the year.

The “lock-in” pricing model also results in higher prices for consumers when they are in the deductible or coverage gap phases of the benefit, when beneficiaries pay the full cost of drugs but are required by statute to have access to “negotiated prices.” Congress’s intent in guaranteeing

access to negotiated prices in all phases of the benefit was surely intended to ensure access to prices that are lower than those charged to cash customers. It defies belief to argue that a Part D plan can meet this requirement by providing access to prices that are higher than the price paid by cash customers because of the spread retained by the PBM.

The higher prices and coinsurance rates under the lock-in pricing model also raise the cost to taxpayers of the low-income subsidy, which picks up most of the cost sharing otherwise borne by consumers. Medicare costs are also raised by using higher, lock-in prices in calculating reinsurance subsidies that plans receive for providing coverage during the catastrophic phase of the benefit.

RECOMMENDATION

Under existing regulations, “negotiated prices” are defined as “prices for covered Part D drugs that (1) Are available to beneficiaries at the point of sale at network pharmacies; (2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and (3) Includes any dispensing fees.”ⁱ

In May 2008, CMS proposed to revise 42 C.F.R. § 423.100 so that “the first part of the definition of ‘negotiated prices’ would state that negotiated prices are prices that the Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount the network dispensing pharmacy or other network dispensing provider will receive, in total, for a particular drug.”ⁱⁱ

The Medicare Rights Center strongly supports CMS’ proposed revisions described above. Finalizing the proposal would go far in limiting beneficiaries’ financial burdens that result from the lock-in pricing practice.

ⁱ 42 C.F.R. § 423.100.

ⁱⁱ 73 Fed. Reg. 28556, 28564 (May 16, 2008). Negotiated prices would be defined as “prices for covered Part D drugs that— (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug; (2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and (3) Includes any dispensing fees.”

Section 4

CMS SHOULD ALLOW STATES TO ENFORCE STATE LAWS GOVERNING THE MARKETING PRACTICES OF MEDICARE PRIVATE PLANS

CMS SHOULD ALLOW STATES TO ENFORCE STATE LAWS GOVERNING THE MARKETING PRACTICES OF MEDICARE PRIVATE PLANS

The role of private insurers in the Medicare marketplace has grown significantly over the past five years, and CMS and the states have recognized a corresponding need to protect beneficiaries from deceptive and abusive marketing practices. Recent history indicates that both federal and state efforts are needed to properly protect Medicare beneficiaries. Unfortunately, CMS has interpreted the Medicare statute as preempting state laws governing the marketing of Medicare Advantage and Part D prescription drug plans. The Medicare Rights Center urges CMS to revisit its interpretation of the scope of federal preemption and to recognize the strong legal and policy bases for allowing states to enforce these important beneficiary protections as they relate to plan marketing practices.

The Medicare Modernization Act (MMA) offered numerous incentives to private insurers to participate in the Medicare program. As new insurers flooded the Medicare Advantage and Part D prescription drug markets, seniors suddenly were subject to aggressive and deceptive marketing practices. These abuses are well documented and have been discussed at numerous congressional hearings. As recently as October 2008, the ranking member of the Senate Special Committee on Aging sent a letter to CMS (and other federal agencies) with concerns about unsolicited telemarketing to potential MA enrollees. Yet the explosive growth in the number of participating plans, along with differing and state-specific insurance marketplaces, have made it difficult for CMS to develop an effective national framework for protecting Medicare beneficiaries.ⁱ The intermediate sanctions, such as corrective action plans and fines, have proven inadequate. Joint federal-state initiatives, although well intentioned, have not resulted in extensive information sharing.ⁱⁱ Further, we recognize that CMS has only a limited amount of resources, which are needed not only to regulate marketing practices, but also to vet marketing materials and oversee all other aspects of the Medicare Advantage and Part D programs. We expect the Medicare Improvements for Patients and Providers Act (MIPPA) and the recently issued implementing regulations to further restrict improper marketing tactics. Yet we remain concerned that, given CMS' fiscal constraints, these new requirements cannot lead to adequate federal protection of Medicare beneficiaries.

States have significant experience protecting their citizens and historically have regulated marketing of insurance by incorporating unfair trade practice or similar consumer protection laws into their licensure scheme. These laws regulate the conduct of insurance companies, not the content of insurance policies. Insurers already comply with these laws when marketing non-Medicare products. Medicare beneficiaries should not be deprived of important protections simply because they enroll in Medicare private plans. They would be best protected if CMS utilized states' expertise by clarifying that these important consumer protections are not preempted to the extent that they relate to marketing practices and do not directly conflict with Medicare rules.

BACKGROUND

Prior to passage of the MMA, the Medicare statute generally preempted states' laws that were inconsistent with Medicare + Choice rules. In addition, the statute specifically preempted state laws relating to: (1) benefit requirements; (2) requirements relating to the inclusion or treatment of providers; (3) coverage determination and appeals; and (4) marketing materials.ⁱⁱⁱ

Federal courts reached different conclusions about the types of state laws preempted under this earlier language,^{iv} and Congress sought to clarify federal preemption in the MMA. The new language, which applies to both Medicare Advantage and Part D prescription drug plans, preempts all state law “with respect” to these plans, with the exceptions of “state licensing laws” and “state laws relating to plan solvency.”^v

Each of the key terms is not further defined. Specifically, the statutory language does not explain what it means for a state law to be “with respect” to Medicare Advantage or the Part D program. Nor does it specify what type of state law qualifies as a “state licensing law.” The legislative history provides little additional guidance. The Conference Report only states, “[t]his clarifies that the MA program is a federal program operated under Federal rules. State laws, do not, and should not apply, with the exception of state licensing laws or state laws related to plan solvency. There has been some confusion in recent court cases.”^{vi}

CMS understood the statutory change as broadening the scope of federal preemption.^{vii} In addition, CMS took a narrow view of the licensing exception. The agency explained that it intended to prohibit states from using the exception as an indirect means of regulating health plans. Specifically, CMS explained that the exception “must be limited to State requirements for becoming State licensed, and would not extend to any requirement that the State might impose on licensed health plans that, absent Federal preemption, must be met as a condition for keeping a State license.”^{viii} Responding to concerns that federal preemption would eliminate basic state protections, CMS explained that it was “aware of the need for strong consistent oversight of MA plans” and promised to “ensure appropriate oversight of MA plans.”^{ix}

CMS also recognized the limits to federal preemption. Specifically, the agency noted that “State health and safety standards, or generally applicable standards, that do not involve regulation of a MA plan are not preempted.”^x Other examples of laws not preempted include environmental law, tort law, labor law, and civil rights law.^{xi}

RECOMMENDATION

Allow States to Enforce State Laws Governing the Marketing Practices of Medicare Private Plans

We urge CMS to reexamine states’ authority to regulate the marketing of Medicare private plans. CMS should amend its current regulation by either (1) expanding its interpretation of the statutory licensing exception; or (2) specifying that consumer protection laws relating to marketing practices that are of general applicability – laws that govern the marketing practices of all insurance products within a state – may be enforced with respect to Medicare private plans. While CMS has acknowledged that strong plan oversight is critical, the level of abuse requires empowering states to join the federal government in protecting their citizens.

The current licensing exception is of limited value to states in their efforts to protect citizens from marketing abuse. The major beneficiary protections appear to be preempted and state power extends little beyond requiring insurers to file articles of incorporation with the appropriate state agency. Neither the legislative history nor any other contemporaneous materials indicate that Congress

intended such a narrow interpretation of the exception. Nor did Congress indicate that laws “relating to” Medicare private plans extend beyond those state laws that specifically conflict with federal regulations (such as state laws that govern marketing materials). Finally, the applicability of unfair trade practice laws was not an issue in the conflicting decisions that led to the MMA clarification.

Licensing insurers has long been an essential function of each state, and unfair trade practice or similar consumer protection laws have developed into a critical component of state licensing schemes. The Medicare statute does not define licensure, leaving discretion in the hands of individual states. In New Jersey, the insurance commissioner may reject an insurer’s request to issue a health insurance policy if “the policy is sold in such a manner as to mislead the insured.”^{xii} In Massachusetts, the insurance commissioner may suspend or revoke the license of an insurer that violates the state’s marketing regulations.^{xiii} These laws govern the fitness of insurers to sell insurance products within the state and do not impinge on areas under federal jurisdiction, such as the type of benefits offered. CMS is well within its statutory authority to find that states may enforce unfair trade practice or other consumer protection laws as they relate to plan marketing practices if these laws are integral to the licensing of insurers.

Alternatively, CMS should amend the current regulation so that state laws of general applicability that relate to marketing practices are not preempted by the Medicare statute. A recent decision of the Eleventh Circuit supports this interpretation. Medicare beneficiaries brought a tort action against a Medicare private plan based on marketing abuse. The district court found that the case could be removed to federal court and that the causes of action were preempted by the Medicare Act.^{xiv} The Eleventh Circuit reversed and remanded the case to state court, accepting the possibility that state-based claims may be brought against Medicare private plans for improper marketing tactics.^{xv}

While there may be concerns that this recommendation would subject Medicare plans to many state laws, as opposed to a single federal standard, we do not believe that this would be overly burdensome on plans since most, if not all, insurers offering Medicare plans must already comply with states’ requirements in the non-Medicare insurance market. They, therefore, have significant experience complying with these state laws. In addition, CMS could work with the states to develop a more uniform enforcement framework. For example, the National Association of Insurance Commissioners could develop model unfair trade practice laws that then could be incorporated into state licensure schemes or be applied as laws of general applicability. These laws would not be subject to federal preemption and would be similar across states.

ⁱ See California Health Advocates and the Medicare Rights Center, *The Reluctant Regulator: Centers for Medicare and Medicaid Services’ Response to Marketing Misconduct by Medicare Advantage Plans*, July 2007, available at <http://www.medicarerights.org>; California Health Advocates and the Medicare Rights Center, *After the Goldrush: The Marketing of Medicare Advantage and Part D Plans*, Jan. 2007, available at <http://www.medicarerights.org>.

ⁱⁱ National Association of Insurance Commissioners, *Draft White Paper on the Regulation of Medicare Private Plans*, July 25, 2008, available at http://www.naic.org/documents/committees_b_senior_issues_080805_medicare_whitepaper.pdf

ⁱⁱⁱ 42 U.S.C. § 1395w-26(b)(3).

^{iv} See e.g., *Massachusetts Ass’n of Health Maint. Org. v. Ruthardt*, 194 F.3d 176 (1st Cir. 1999) (interpreting the scope of the preemption clauses and congressional intent).

^v 42 U.S.C. §§ 1395w-26(b)(3), 112(g).

^{vi} H. R. Rep. No. 108-391, at 556-57 (2003).

^{vii} 70 Fed. Reg. 4588, 4663 (Jan. 28, 2005).

^{viii} *Id.* at 4663-64.

ix	<i>Id.</i> at 4664-65.
x	<i>Id.</i> at 4665.
xi	69 Fed. Reg. 46632, 46696 (Aug. 3, 2004).
xii	N.J. Stat. Ann. § 17B:26-1.
xiii	Mass. Gen. Laws Ch. 175, § 110E.
xiv	<i>Dial v. Healthspring of Alabama, Inc.</i> , 501 F. Supp. 2d 1348 (S.D. Ala. 2007).
xv	<i>Dial v. Healthspring of Alabama, Inc.</i> , No. 07-00412 (11th Cir. Aug. 26, 2008).

Section 5

CMS SHOULD IMPROVE THE COORDINATION OF CARE WITHIN SPECIAL NEEDS PLANS

CMS SHOULD IMPROVE THE COORDINATION OF CARE WITHIN SPECIAL NEEDS PLANS

The Medicare Improvements for Patients and Providers Act (MIPPA) and the recently published interim final rule affecting Medicare Advantage (MA) plans have changed the definition and scope of MA Special Needs Plans (SNPs).¹ Many of these changes should lead to improved care coordination for people enrolled in SNPs. However, the Medicare Rights Center believes that neither MIPPA nor the new regulations fully optimize the potential for such coordination. Specifically, the current SNP regulations do not go far enough in detailing the extent to which care coordination and case management are required.

Efficient coordination of care is an essential element of all SNPs, as it is this coordination that makes SNPs of particular value to their target populations. The Medicare Rights Center recommends that CMS adopt specific criteria for robust case management and coordination for SNPs. With regard to chronic care SNPs, we also recommend ending the current policy permitting open enrollment and instead adopting a more limited enrollment period.

RECOMMENDATIONS

1. Strengthening Models of Care

While MIPPA and the recently published interim final rule require an evidence-based model of care for SNPs, there are other important steps CMS should take to ensure that SNP enrollees receive the level of services that they need. Specifically, the new 42 C.F.R. § 422.101(f) does not include basic components that should be a part of any model of care submitted by SNPs. Setting out these components does not require CMS to endorse a particular model of care. However, these components will ensure the delivery of basic key elements of case management and care coordination to beneficiaries, while allowing plans the necessary flexibility to develop evidence-based models of care. CMS should amend its current regulations to improve the coordination and management of care for individuals enrolled in MA Special Needs Plans (SNPs).

CMS should require SNPs' models of care to include:

a) Care Coordination and Case Management:

Care coordination and case management must be available to all SNP enrollees automatically; they should not have to request such services, since SNP members are, by definition, people with chronic conditions and/or complex health needs. Care coordination plans should be provided to enrollees and retained by their primary care physicians. Care coordination plans should also be updated at least annually, and always after changes in the enrollee's physical, functional or psychosocial status. If an enrollee does not want such an assessment, the SNP must document the enrollee's refusal.

b) Care Transition/Continuity of Care:

SNPs should be required to provide transition coverage for enrollees for either (1) six months or (2) two visits to any given provider after the effective date of coverage, or after the completion of a necessary course of treatment. Transition coverage should include allowances for coverage of non-

network providers, services, and prescription drugs during the transition period. Existing enrollees also should be granted a transition period when a provider drops out of the network or when a previously covered service or prescription has been removed from the benefit package. A plan's transition coverage policies should be explained in its materials given to prospective enrollees and again after enrollment.

c) Network Structure and Requirements:

In its Call Letters, CMS has required SNPs to have an appropriate network of providers and specialists to meet the specialized needs of the SNP target population. However, CMS should go further in addressing the SNPs' network structure. SNPs must ensure that their provider networks meet the specific needs of their enrollees with respect not only to providers and specialists, but also to geographic spread, transportation needs, language and cultural access, and access for people with disabilities. SNPs must ensure that all network hospitals have at least one network doctor as well as a network provider affiliated with the hospital to provide diagnostic and other ancillary services. SNPs must also ensure that ancillary services are actually delivered to enrollees. Finally, SNPs must ensure that providers in the network understand and use the coordinated care model.

2. SNPs and Quality Improvement Program

As part of the SNP documented quality improvement program (§422.152), CMS should require plans to implement an effective complaint process for beneficiaries. Plans should be required to investigate all complaints and report how the problem(s) was resolved. Both complaints and documented steps taken to resolve the problem should be elements of data reported to CMS for monitoring and evaluating the performance of the SNPs' model of care. CMS should also clarify, in regulations, the notice and appeals process that applies to SNP enrollees.

3. Limiting the Enrollment Period for Chronic Care SNPs

With the exception of SNPs with a demonstrated record in improving health outcomes, CMS should abolish the special enrollment period allowing individuals to join chronic care SNPs outside the open enrollment period. Medicare guidance permits individuals with qualifying conditions to join chronic care SNPs at any time.ⁱⁱ There is no evidence that enrollees in chronic care SNPs have better health outcomes than beneficiaries with the same conditions in other MA plans or in Original Medicare. In addition, it is clear from the mushrooming of chronic care SNPs, as well as the increase in the marketing of chronic care SNPs for dubious conditions, such as high cholesterol, that insurers view these plans primarily as a vehicle for avoiding lock-in rather than as a means for improving quality of care. Moreover, patients eligible for chronic care SNPs often have complex health issues that leave them vulnerable to undue influence by aggressive marketing outside the Open Enrollment period, when SNPs are the primary MA plan for which agents earn commissions.ⁱⁱⁱ Putting chronic care SNPs on an equal enrollment footing with other MA plans will require insurers to focus on providing care coordination that provides a competitive advantage.

4. Protecting Consumer Choice for Dual Eligibles

Now that dual-eligible SNPs are required to contract with state Medicaid agencies, the Medicare Rights Center recognizes the potential for improved care coordination for dual-eligible beneficiaries through a single delivery system. However, we are very concerned about the potential for state Medicaid programs to automatically enroll dual-eligible individuals into these dual-eligible SNPs. The enrollment of dual-eligible individuals in Medicare SNPs must remain voluntary, consistent with Medicare law promoting freedom of choice of provider.^{iv} For several years, CMS' informal policy has been to deny waiver requests that would permit states to require dual-eligibles to receive Medicare-covered services through an MA plan.^v We urge CMS to restate this policy more formally, whether through new guidance, rule-making or bid review authority, as a means of protecting consumer choice and to balance the interests of traditional fee-for-service Medicare and managed care.

ⁱ See Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275 (July 15, 2008); Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs, Interim Final Rule CMS 4318-IFC, 73 Fed. Reg. 54225 (Sept. 18, 2008).

ⁱⁱ In contrast, disenrollment from chronic care SNPs is limited to the Medicare Annual Enrollment Period or an available Open Enrollment Period. See Medicare Managed Care Manual Guidance Update, Chapter 2, §§ 30 and 30.4.4.13, Medicare Advantage Enrollment and Disenrollment, (June 20, 2007), available at <http://www.cms.hhs.gov/MedicareMangCareEligEnrol/Downloads/MAEnrollmentGuidanceUpdate.pdf>.

ⁱⁱⁱ The Senate Special Committee on Aging has held field hearings on how the aggressive sales tactics of MA plans in Missouri led individuals to make poor plan selections. See generally *What Seniors Don't Know Before They Enroll—Aggressive Sales of MA Plans in Missouri*, Transcript of Field Hearing Before the Special Committee on Aging, 110th Cong. (June 30, 2008), available at http://aging.senate.gov/hearing_detail.cfm?id=300238&

^{iv} States wishing to mandate the enrollment of dual-eligible recipients into a Medicaid managed care product must receive a CMS waiver of the Medicaid "freedom of choice" requirements. Even then, these waivers only permit states to require dual-eligibles to receive Medicaid services through a managed care product. See, e.g., 42 U.S.C. 1315 (2006); Free Choice of Providers Rule, 43 C.F.R. § 431.51 (2002). See also generally Centers for Medicare & Medicaid Services, "At-A-Glance" Guide to Medicaid Authorities for Integrated Programs," available at http://www.cms.hhs.gov/IntegratedCareInt/02_Integrated%20Care%20Roadmap.asp (describing the range of Medicaid statutory waiver authorities available to states building models under CMS' Integrated Care Initiative).

^v CMS has had a "long-standing policy since the mid-1990s of not approving such waivers." Centers for Medicare & Medicaid Services, CMS Draft State Guide to Integrated Medicare & Medicaid Models (March 1, 2006), available at <http://www.cms.hhs.gov/DualEligible/Downloads/StateGuide.pdf>. The CMS website notes that a revised version of this document is currently under consideration.

Section 6

**PART D PLANS MUST COVER
MEDICALLY NECESSARY OFF-
LABEL USE OF PRESCRIPTION
DRUGS BASED ON EVIDENCE
PUBLISHED IN PEER-REVIEWED
MEDICAL LITERATURE**

PART D PLANS MUST COVER MEDICALLY NECESSARY OFF-LABEL USE OF PRESCRIPTION DRUGS BASED ON EVIDENCE PUBLISHED IN PEER-REVIEWED MEDICAL LITERATURE

Many patients are prescribed medications to treat conditions for which the medication is not FDA-approved. Current CMS regulations, however, prohibit Part D coverage for such off-label indications (indications other than those listed on the FDA label) if the indication is not listed in one of three commercially published reference compendia.ⁱ This prohibition bars coverage of medically necessary medicines, even when clinical evidence published in peer-reviewed medical literature supports the intended use. The Medicare Rights Center urges CMS to require coverage of off-label use of medications when such uses are medically necessary and supported by clinical evidence published in peer-reviewed medical literature.

The prohibition against the use of peer-reviewed literature to support coverage is a more restrictive standard than applies to Part B, for which CMS allows carriers to consider “the major drug compendia, authoritative medical literature and/or accepted standards of medical practice” in determining whether an off-label use is medically accepted.ⁱⁱ Commercial insurers also reference both compendia and peer-reviewed literature in determining coverage. Denial of Part D coverage of drugs for unapproved indications results in a lower standard of care for Medicare beneficiaries unable to pay full price for their medications. Such denials also may result in higher costs to the Medicare program, since those who cannot afford their medications simply go without, which can result in costly emergency hospitalizations.

BACKGROUND

The Medicare Part D statute refers to the Medicaid statute’s definition of “covered outpatient drug” to define in part the term “covered Part D drug.” In particular, section 1860D-2(e)(1)(A) of the Social Security Act (the “Act”) refers to those provisions of the Medicaid definition that require a drug to be approved by the FDA to be eligible for reimbursement.ⁱⁱⁱ Section 1860D-2(e)(1)(B) further provides that the definition of “covered Part D drug . . . *includes* . . . any use of a covered Part D drug for a medically accepted indication” as defined in the Medicaid statute.^{iv} (Emphasis added) The Medicaid statute and, in particular, section 1927(k)(6) of the Act, defines “medically accepted indication” as “any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act . . . or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.” The three compendia listed in the referenced subsection are: (1) the American Hospital Formulary Service Drug Information, (2) the United States Pharmacopeia-Drug Information (or its successor publications); and (3) the DRUGDEX Information System.^v

Further, section 1101(b) of the Social Security Act, which sets forth definitions for the entire Act, provides that the terms “includes” and “including,” when used in a definition contained in the Act, **shall not** be deemed to exclude other things otherwise within the meaning of the term defined.

Although the Medicare statute defines a “covered Part D drug” to *include*, but not to be limited to, a drug used for a “medically accepted indication” (such term including any indication listed in the specified compendia), CMS has interpreted the statute in an overly restrictive manner to prohibit coverage of all off-label uses not listed in one of the specified compendia. Specifically, CMS has

promulgated regulations that narrow the statutory definition of “covered Part D drug” to include only prescriptions for indications listed in one of the specified compendia, each of which summarizes drug uses mentioned in certain clinical studies and peer-reviewed medical literature.^{vi} As such, the regulatory definition bars Part D coverage of certain off-label prescriptions, unless the prescribed use is both medically necessary and supported in one of the three medical compendia. Consequently, even if research published in peer-reviewed medical journals shows that the drug is effective for the prescribed use, and even if the drug is medically necessary for the patient, the Part D program will not cover the drug.

RECOMMENDATION

The exclusion from Medicare Part D coverage of off-label uses that are not listed in the compendia hurts the most vulnerable beneficiaries, including those for whom alternative medications are neither safe nor effective. For the following reasons, CMS should require coverage of off-label use of medications based on supportive clinical evidence in peer-reviewed medical literature.

First, the statutory definition of a covered Part D drug neither prohibits coverage of off-label uses nor imposes a compendia requirement. To support a compendia requirement, CMS has interpreted the statute’s use of the term “includes” as implicitly excluding any drug uses that are not explicitly mentioned. However, section 1101(b) of the Act provides that the term “‘includes’ . . . when used in a definition contained in this Act shall not be deemed to exclude other things otherwise within the meaning of the term defined.”^{vii} As a result, the term “includes” cannot be read as a limiting term, but must be interpreted as an illustrative term. In other words, a compendia-listed drug use is merely illustrative of a kind of drug that is a “covered Part D drug,” but is not an essential prerequisite for covered drug status. Moreover, none of the exclusions enumerated within the definition of “covered Part D drug,” and none of the exclusions to which the definition explicitly refers, support the compendia requirement that the regulation adopts.^{viii}

Second, the intent of Congress is clearly expressed by the plain language of the statute; the Act’s legislative history also indicates that Congress intended the definition to be read expansively. The Conference Report accompanying the law provides that “[t]he definition would include any use of a covered outpatient drug for a medically accepted indication. . . . A plan could exclude from coverage, subject to reconsideration and appeals provisions, any drug which would not meet *Medicare’s definition of medically necessary* or was not prescribed in accordance with the plan or Part D.”^{ix} (Emphasis added) The broad definition of medical necessity in the Medicare statute includes no compendia or other similar requirement.^x

ⁱ The Medicare Rights Center is currently challenging this regulation in the Southern District of New York on the grounds that it is inconsistent with the Social Security Act. *Layzer et al. v. Leavitt* (No. 07-CV-11339 (GEL)).

ⁱⁱ Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual*, September, 2008. This standard for off-label coverage applies to all drugs except anticancer chemotherapy drugs. With the passage of the Medicare Improvements for Patients and Providers Act, the Part B and Part D standards for off-label coverage of anticancer chemotherapy drugs are aligned.

ⁱⁱⁱ 42 U.S.C. § 1395w-102(e) (*incorporating* § 1396r-8(k)(2)(A)(i)-(iii)). These provisions also permit coverage of drugs commercially used or sold in the United States before 1962 or a drug for which the Secretary has determined there is compelling justification for its medical need.

^{iv} 42 U.S.C. § 1396r-8(k)(6)

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- v 42 U.S.C. § 1396r-8(g)(1)(B)(i).
- vi 42 C.F.R. § 423.100.
- vii 42 U.S.C. § 1301(b).
- viii *See* 42 U.S.C. §§ 1396r-8(d)(2) and 1396r-8(d)(3).
- ix *See* H.R. Rep. No. 108-391, at 442 (2003) (Conference Report)
- x The Medicare statute requires coverage for services or treatments that are “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” 42 U.S.C. § 1395y(a)(1)(A).

Section 7

CMS SHOULD STRENGTHEN AND ENFORCE PART D APPEALS PROCEDURES

CMS SHOULD STRENGTHEN AND ENFORCE PART D APPEALS PROCEDURES

The appeals process used by Medicare prescription drug plans is an important consumer protection that allows people with Medicare to access the benefits to which they are entitled. However, plans regularly fail to abide by the requirements of the appeals process. Improving the appeals process for Part D beneficiaries was one of the transition issues recently highlighted by the Government Accountability Office.¹ To improve this process and ensure plan compliance, the Medicare Rights Center recommends CMS take the following steps: (1) promulgate regulations to enforce beneficiary access to timely appeals; (2) promulgate regulations to improve the fairness of Administrative Law Judge (ALJ) hearings; and (3)(1) strictly enforce existing regulations governing the appeals process.

RECOMMENDATIONS

1. CMS Should Develop Regulations That Will Enforce Access to Timely Appeals

When a plan denies Part D coverage of a prescription drug, beneficiaries are entitled to a plan redetermination. A redetermination denial may be appealed for reconsideration by the IRE. IRE reconsiderations may be appealed to an ALJ, then a Medicare Appeals Council (MAC), and finally to federal court. We suggest that CMS develop regulatory provisions that allow escalation of an appeal to the next level of review if a decision by the reviewing body is not made in a timely manner. For example, if the ALJ fails to make a timely review, the request should be automatically escalated to the MAC. The regulations governing Part A and Part B appeals already contain such an escalation requirement.ⁱⁱ

Similarly, if a Part D plan fails to review a coverage determination or a request for redetermination within the mandatory timeframe, that failure constitutes an adverse determination and the plan must escalate the appeal to the IRE within 24 hours.ⁱⁱⁱ However, many Part D plans fail to escalate these appeals, and the enrollee is without recourse – often left waiting for access to medically necessary medication. We recommend that CMS allow either a Part D plan or the enrollee to escalate an appeal when the plan fails to issue a timely decision.

2. CMS Should Improve the Fairness of ALJ Hearings

We urge CMS to revise its regulations governing ALJ hearings to better allow beneficiaries to present their cases. Current regulations permit ALJs to request plan participation in the hearings, but do not require that beneficiaries be given notice of a plan's participation. Moreover, plans often are represented at these hearings by medical professionals, whereas beneficiaries typically represent themselves and may be inadequately prepared to rebut the evidence put forth by the plans' representatives. To improve the fairness of these proceedings, CMS should provide beneficiaries with better opportunities to present counter-evidence. Specifically, beneficiaries must be given appropriate advance notice that the ALJ has requested a plan's participation. In addition, beneficiaries should be permitted to request ALJ subpoenas of their own medical professionals and medical records to ensure their availability for a hearing. The Part A and Part B appeals regulations permit ALJs to issue such subpoenas in hearings for Part A and Part B appeals.^{iv}

CMS should relax the timeframes within which unrepresented beneficiaries must present their evidence. CMS has proposed that beneficiary evidence be submitted within 10 calendar days of receiving the hearing notice (and within two days in the case of expedited hearings).^v We recommend that CMS revise the Part D appeal timeframes so that they mirror the Parts A and B appeal standards, which provide that timeframes for admission of evidence do not apply to evidence submitted by an unrepresented beneficiary.^{vi}

Additionally, CMS should allow ALJs to review evidence pertaining to changes in a beneficiary's health that occurred after a denial of coverage, without requiring time-consuming remand back to the plan. Beneficiaries whose health conditions have worsened and require immediate medical treatment should not be required to restart the appeals process. If remand is required, ALJs should be required to remand to the IRE rather than to the plan and the appeal should be decided within an expedited timeframe.

We agree with CMS' proposal to limit requests by the IRE for MAC review of ALJ decisions in order to make the appeals process more administratively efficient. We also urge greater transparency for such requests when they are made. IREs often cite MAC decisions that are not available to the public in their requests for MAC review. These cases should be provided to the appealing beneficiary in redacted form so that the beneficiary can evaluate the applicability of the decision to his or her case.

3. *CMS Should Improve Enforcement of Part D Appeals Requirements*

In our representation of Medicare beneficiaries who have appealed Part D claim denials, we see significant non-compliance with CMS regulations. For example, we have witnessed: plan denials that do not clearly describe appeals processes or provide detailed explanations of denials;^{vii} plan failure to provide beneficiaries with information about appeal status;^{viii} plan failure to provide written appeals decisions to beneficiaries;^{ix} and plan failure to refer those appeals for which a plan has failed to make a timely decision to the Independent Review Entity (IRE).^x We have extensive examples of these ongoing violations. We recommend that CMS strengthen enforcement of its existing Part D appeals regulations and improve the regulatory framework, including codifying in regulation the Manual requirement that IREs monitor plan compliance with ALJ determinations.^{xi}

Frequently, the appeals process stretches beyond mandated regulatory timelines. We recommend that CMS enforce these timelines and provide detailed oversight of plan compliance. Also, CMS should enforce the guidance that states that these timeframes are based on calendar, not business, days.

ⁱ See http://www.gao.gov/transition_2009/agency/hhs/improving-medicare-management.php.

ⁱⁱ 42 C.F.R. §§ 405.1104, 405.1132

ⁱⁱⁱ 42 C.F.R. § 423.568(e); 42 C.F.R. § 423.590.

^{iv} 42 C.F.R. § 405.1036(f).

^v Proposed 42 C.F.R. § 423.2018, at 73 Fed. Reg. at 14360.

^{vi} 42 C.F.R. § 405.1018.

^{vii} 42 C.F.R. § 423.128 requires plans to explain appeal rights. CMS instructions to plans are available at: <http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/Downloads/CoverageDenialInstructions.pdf>

viii	42 C.F.R. § 423.562 requires a process be established for beneficiaries to request appeals of denials.
ix	42 C.F.R. § 423.590 requires written notification of redeterminations.
x	42 C.F.R. § 423.568(e) mandates referral to the IRE when redeterminations are not issued by plans in a timely manner.
xi	This responsibility is currently set out in the CMS Prescription Drug Benefit Manual § 130.4.

Section 8

**CMS SHOULD REQUIRE MEDICARE
PART D PLANS TO TRACK AND
REPORT CLAIM REJECTIONS DATA**

CMS SHOULD REQUIRE MEDICARE PART D PLANS TO TRACK AND REPORT CLAIM REJECTIONS DATA

Medicare Part D prescription drug plans and Medicare Advantage plans offering prescription drug coverage impose a variety of limits on beneficiary access to prescription drugs. These restrictions include quantity limits, prior authorization, and step therapy requirements and exclusion of drugs from formularies. Plans must have in place transition and appeals policies that are designed to ensure beneficiary access to medically necessary drugs, with minimal or no disruption. However, in the Medicare Rights Center's experience, beneficiaries are often unaware of these transition policies and appeals procedures. Even when beneficiaries are aware of their options, they are not easily accessible. As a result, beneficiaries too often stop taking medicine or pay out-of-pocket after facing an initial rejection. This is particularly troubling for chronically ill beneficiaries who have conditions, such as diabetes and schizophrenia, which require uninterrupted drug therapy and intensive care management.

CMS currently lacks sufficient information about claims rejections and whether beneficiaries whose claims are initially rejected ultimately receive access to medically necessary drugs. Although CMS requires plans to collect and report a broad array of claims and other data to ensure compliance with various Part D requirements, the agency does not require plans to submit information that demonstrates whether transition policies and appeals procedures are generally effective in preventing harmful disruptions to drug regimens. As a result, CMS lacks sufficient information to successfully monitor the effectiveness of current transition and appeals policies, and to identify what happens after a beneficiary's initial claim is rejected at the pharmacy or after a mandatory transitional fill is provided. Consequently, CMS, policymakers, and consumers are unable to assess how plans compare in providing beneficiaries with uninterrupted coverage of medically necessary medications. The Government Accountability Office recently included data collection as one of the important transition issues for the Department of Health and Human Services, noting that CMS does not have sufficient information to assess beneficiaries' experiences with Part D.ⁱ

In its draft 2009 Call Letter, CMS recognized the importance of collecting this information. Unfortunately, the agency ultimately did not adopt its own proposal to collect rejection and related claims data. We urge CMS to reconsider its rejection of these new contract reporting requirements in developing its 2010 Call Letter, and to require the reporting of this information as prescription drug event ("PDE") data. CMS should collect this information to assist in its enforcement of transitions, exceptions, and appeals requirements. The agency can also use this data to develop best practices and quality measures for use in its plan contracting process, and Medicare beneficiaries may also refer to the data when selecting drug coverage.

BACKGROUND

CMS has broad authority to collect data from plans participating in the Medicare Part D program. The Social Security Act authorizes CMS, as part of the agency's annual Part D contract terms, to require plans to submit information that "the Secretary may find necessary and appropriate."ⁱⁱ The Act requires CMS to collect from PDP sponsors "data regarding drug claims that can be linked at the individual level to Part A and Part B data and such other information as the Secretary determines necessary"ⁱⁱⁱ and requires plans to submit information CMS determines necessary to process Part D

claims. In enacting the Medicare Modernization Act, Congress also directed CMS to “identify any new data needs and a methodology to address new data needs” to “provide better health care for chronically ill Medicare beneficiaries.”^{iv}

CMS’ two primary methods of PDP data collection are 1) the collection of certain data as a term of its annual contracts with plan sponsors and 2) the collection of certain data as a prerequisite to claims payment. The terms of annual contracts are governed by CMS’ Medicare Part D Reporting Requirements. For Contract Year 2008, plans were required to submit 15 types of data to CMS.^v According to CMS, the agency uses this data, which is reported in the aggregate, “to monitor the prescription drug benefit provided to Medicare beneficiaries.”^{vi} Included among the 15 types of data that plans must report is information regarding generic drug utilization, grievances, transition policies, and certain limited information about exceptions and appeals.

As part of its claims payment processing requirements, CMS collects 37 “prescription drug event,” or (“PDE”), data elements.^{vii} The types of data collected include beneficiary ID, pharmacy ID, date of service, drug information, plan-paid amounts, beneficiary cost sharing, and low-income subsidy amount. Unlike the data that CMS collects as part of its contracting requirements, which is reported in the aggregate, the 37 PDE data elements are linked to each other and to a particular beneficiary. As a result, this data provides CMS with a set of information about a particular claim and allows CMS to track a beneficiary’s claims experience. Pursuant to CMS’ final Medicare Part D Claims Data rule, CMS has authority to use PDE data to evaluate the effectiveness of the Part D program, report to Congress on the operation of the Part D program, and make legislative proposals to Congress.^{viii} In addition, the final rule also makes PDE data available to external entities to evaluate the quality of care Medicare beneficiaries receive under Part D and to “conduct studies related to improving quality and reducing costs of care for chronically ill Medicare beneficiaries.”^{ix}

RECOMMENDATION

CMS should use its broad data collection authority to obtain information that will enable the agency to monitor plans’ compliance with Part D transition, exceptions, and appeals requirements; ensure that plans have developed and implemented adequate policies to “improve medication use;” and ensure that chronically ill beneficiaries receive uninterrupted access to necessary prescription drugs.^x Specifically, CMS should amend both its contract reporting requirements and its PDE data elements to include the reporting of this information. In addition, CMS should use this information to develop quality measures to evaluate plan success at ensuring that beneficiaries receive uninterrupted access to medically necessary drugs. Information about plan performance should be available to Medicare beneficiaries so that they may refer to this information when selecting a plan.

CMS’ current contract terms require PDPs to report rejections in a limited number of cases, including the number of pharmacy transactions rejected due to failure to complete step therapy and the need for prior authorization. CMS should expand these terms to require plans to report all claim rejections. In addition, CMS’ 2010 Call Letter and 2010 Contract Reporting Requirements should require plans to track and report beneficiary claims data after an initial rejection to monitor whether beneficiaries are receiving access to medically necessary drugs. Such tracking data should include: the provision of transitional fills; the processing of a claim after successful negotiation of utilization management or exceptions processes; the filling of a claim for any therapeutic alternatives; and the

absence of any subsequent claim, which may indicate that the beneficiary has ceased treatment or is paying out-of-pocket. CMS may want to ease the reporting burden on plans by identifying specific therapeutic classes, such as antipsychotics, or diseases, such as diabetes, as priority areas for reporting.

The agency's draft 2009 Call Letter would have required plans to report the number of prescriptions that are immediately filled at the point of sale compared with the number of prescription fills delayed as a result of prior authorization, step therapy, and other utilization management rules.^{xi} The agency noted in the draft Call Letter, "This information will allow CMS to evaluate our transition policy with respect to new members . . . and to assess in general how many prescriptions are delayed as a result of formulary coverage issues and drug utilization management procedures." Unfortunately, the agency did not include this requirement in its final 2009 Call Letter. We are pleased that CMS has recognized the importance of collecting this data and we urge the agency to include this reporting requirement in its 2010 Call Letter.

CMS should similarly amend its PDE data elements to require Part D plans to submit complete PDE data for rejected claims. Unlike contract reporting data, which is reported in the aggregate and is not available to the public,^{xii} PDE data is linked to a particular beneficiary and will enable the agency, Congress, and outside researchers to assess the impact that claims rejections have on beneficiaries with chronic conditions that require uninterrupted drug therapy.

ⁱ See http://www.gao.gov/transition_2009/agency/hhs/improving-medicare-management.php.

ⁱⁱ 42 U.S.C. § 1860D-12(b)(3)(D).

ⁱⁱⁱ 42 U.S.C. § 1860D-15(c)(1)(C).

^{iv} Medicare Prescription Drug Improvement and Modernization Act of 2003 § 723, Pub. L. No. 108-173, 117 Stat. 2348 (2003) (codified at 42 U.S.C. § 1395b-8).

^v CMS collects this information pursuant to 42 C.F.R. § 423.514 of its Medicare Part D implementing regulations. CMS, Medicare Part D Reporting Requirements Contract Year 2008, at 3 (Dec. 2007). Section 423.514(a) requires PDPs to report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics indicating the following: (1) The cost of its operations. (2) The patterns of utilization of its services. (3) The availability, accessibility, and acceptability of its services. (4) Information demonstrating that the Part D plan sponsor has a fiscally sound operation. (5) Other matters that CMS may require.

^{vi} Medicare Part D Reporting Requirements Contract Year 2008, at 3 (Dec. 2007).

^{vii} Medicare Part D Prescription Drug Event (PDE) Data Elements (April 8, 2008), available at <http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PDEDataElements.pdf> (last visited Sept. 4, 2008).

^{viii} 73 Fed. Reg. 30664, at 30683 (May 28, 2008) (codified at 42 C.F.R. § 423.505(f)(3)). In its proposed Medicare Part D Claims Data rule, CMS specifically stated that one of its goals in accessing PDE data for research and monitoring purposes is "to report statistics on issues such as the experience of Medicaid beneficiaries as their pharmacy coverage changes from the Medicaid to the Medicare program. . . . We anticipate potentially using this information to report statistics to Congress or the public or both with respect to the drug utilization of this unique population and whether they continue to receive the same mix of prescriptions as previously." Medicare Program; Medicare Part D Data Proposed Rule, 71 Fed. Reg. 61445, at 61449 (Oct. 18, 2006).

^{ix} 73 Fed. Reg. at 30683 (codified at 42 C.F.R. § 423.505(m)). According to CMS, public access to this information will "contribute positively to the evaluation and functioning of the Medicare program, and to improve the clinical care of beneficiaries." *Id.* at 30673. In addition, Congress enacted legislation, the Medicare Improvements for Patients and Providers Act ("MIPPA"), which grants CMS clear statutory authority to use PDE information for these broader purposes. Medicare Improvements for Patients and Providers Act, Pub. L. No. 110-275, § 181 (2008).

^x Section 1395w-104(c)(1) of the Social Security Act requires plan sponsors to develop "[q]uality assurance measures and systems to reduce medication errors and adverse drug interactions *and improve medication use.*" Section 1395w-104(c)(2) further

requires plans to institute medication therapy management programs for certain “targeted beneficiaries” that are “designed to assure . . . that covered part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use. . . .”

^{xi} CMS, Draft 2009 Call Letter, at 73-74 (Jan. 16, 2008).

^{xii} We also urge CMS to make publicly available the information it collects from PDPs as part of its contracting requirements. The regulation under which CMS requires plans to report information as a contract term also requires that plans make this information available to the public. In particular, section 423.514(a) provides that “[e]ach Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, *and to the general public*” information regarding “[t]he availability, accessibility, and acceptability of its services.” 42 U.S.C. § 423.414(a), (a)(3). As a result, CMS should implement and enforce this existing regulation, which requires public access to contract reporting data.

Section 9

**CMS SHOULD CALCULATE THE
LIS BENCHMARK TO REFLECT
THE TRUE COST OF PRESCRIPTION
DRUG COVERAGE**

CMS SHOULD CALCULATE THE LIS BENCHMARK TO REFLECT THE TRUE COST OF PRESCRIPTION DRUG COVERAGE

Medicare Part D beneficiaries who have the full-premium low-income subsidy can join a Part D plan (PDP) and pay no monthly premium as long as the plan's premium is below an amount known as the regional benchmark. The regional benchmark is determined by calculating the average monthly premium for PDPs and Medicare Advantage Prescription Drug (MA-PD) plans.ⁱ Since plans' bids to provide Part D coverage vary from one year to the next, plan premiums and regional benchmark premiums also vary annually. As a result, a plan's premium may be below the benchmark one year, but not the next. When a plan's premium shifts above the benchmark, CMS notifies full-premium LIS beneficiaries who were automatically enrolled in that plan that, if they do not opt to stay in the current plan, CMS will automatically reassign them to a new plan whose premium is at or below the benchmark. If they choose to stay in the current plan, they would pay a premium, the amount equal to the difference between the benchmark and the plan's new premium.

Since implementation of the Medicare Part D program, annual shifts in plan premiums and regional benchmarks have resulted in year-to-year changes in which plans qualified for full premium subsidies and in a substantial reduction in the number of benchmark plans available. A total of 508 benchmark plans were offered in 2008. In 2009, a total of 308 benchmark plans will be available.ⁱⁱ This reduction in the number of benchmark plans has resulted in large-scale reassignments of LIS beneficiaries to new plans each year, a problem CMS itself has recognized.ⁱⁱⁱ In 2007, 2.5 million full-subsidy Part D beneficiaries were enrolled in plans whose premiums rose above benchmark in 2008. Of these beneficiaries, 1.1 million were randomly reassigned to different plans at or below benchmark, while another 960,000 were reassigned to lower cost plans offered by the same company. Over 440,000 low income beneficiaries who had affirmatively selected their Part D plan were not reassigned, and consequently faced new premium liability as required by current regulations.^{iv} For 2009, 1.1 million full-subsidy beneficiaries will be randomly reassigned, 450,000 will be moved to plans offered by the same company and 620,000 "choosers" will face new, often substantial, premium liabilities in 2009.^v

High enrollment in MA-PD plans primarily drives the erosion of LIS benchmark premiums in the regions that experienced the greatest reductions. Nevada, a state with high MA-PD penetration, will have only one benchmark plan in 2009. Arizona, which also has enrollment in MA-PD plans, will have two.

Premiums for MA-PD plans are artificially low, as these plans can buy down the beneficiary premium for Part D with CMS rebates for providing Parts A and B coverage for less than the benchmarks for those services. The benchmarks for Part A and Part B services are set well above the comparable costs of providing coverage under Original Medicare, which results in substantial overpayments to MA plans and enables MA-PD plans to offer low or zero premium prescription drug coverage. Despite the fact that these rebates mask the actual cost of providing drug coverage, CMS uses the post-rebate MA-PD premium to calculate the LIS benchmark.^{vi}

Plan reassignments necessitated by benchmark reductions can cause significant disruptions in coverage for LIS beneficiaries. Many beneficiaries are reassigned to plans that do not cover all of their medications or to plans with less comprehensive formularies and higher rates of utilization

management. In addition to these disruptions, the Medicare Rights Center is concerned that further erosion of the LIS benchmark will lead to a two-tiered Part D system - one tier of limited formulary, high utilization management benchmark plans whose membership is comprised overwhelmingly of LIS beneficiaries, and a second tier of comprehensive formulary, low utilization management plans that cater to non-LIS beneficiaries. Creating this type of two-tiered system will result in risk concentration that threatens the availability of coverage for the most vulnerable Part D beneficiaries.

Although CMS attempted to address the problem of LIS benchmark erosion in its April 2008 final rule revising the benchmark calculation, we are concerned that this rule will have the unintended consequence of further eroding the benchmark. To that end, we urge CMS to amend 42 C.F.R. § 423.780(b)(2), its regulation that sets forth the manner in which the LIS benchmark is calculated, in two ways. First, CMS should revise the LIS benchmark calculation to completely eliminate Medicare Advantage rebates from the calculation. Second, CMS should return to its pre-April 2008 calculation of the weighted premium average, which was based on total Part D enrollment and not just LIS enrollment.

RECOMMENDATIONS

1. CMS Should Eliminate MA Rebates from Its Benchmark Calculation

CMS should amend its regulations to require calculation of the regional LIS benchmark to be based on the actual cost of providing Part D coverage by both stand-alone PDPs and MA-PDs. The MA-PD premium used in the calculation should be the beneficiary premium from the MA plan's bid to provide Part D coverage, before the application of the rebate for Part A and Part B services.

This alternative way of calculating the benchmark is permissible under a reasonable reading of the statute. Section 1860D-14(b)(2) of the Social Security Act requires CMS to calculate the LIS benchmark premium amount based on the weighted average of premiums charged by PDP plans and MA-PD plans. However, the statute requires CMS to calculate the weighted average for MA-PD plans using only "the portion of the MA monthly prescription drug beneficiary premium that is attributable to basic prescription drug benefits. . . ." ^{vii} The three elements of the MA-PD monthly premium are: (1) the base beneficiary premium, (2) the adjustment formula set forth in section 1854D-13(a)(1)(B) to reflect the difference between the plan's bid and national average bid, and (3) the amount of the rebate. ^{viii}

The law requires only that the portion of the MA-PD monthly prescription drug premium attributable to basic prescription drug benefits be used in calculating the benchmark. CMS should calculate this portion, therefore, before applying the Part A and Part B rebate, which is unrelated to the cost of providing prescription drug coverage. In other words, CMS should use the first two elements of the MA-PD monthly premium calculation, and not the third, which reflects application of the rebate, to calculate the portion of the premium attributable to prescription drug coverage. We urge CMS to amend its regulations accordingly. Doing so would restore the LIS benchmark in regions with high MA-PD penetration, where a very high number of LIS beneficiaries are reassigned each year.

2. *CMS Should Reweight the Benchmark Formula to Include Total Part D Enrollment*

In its April 3, 2008 final rule revising the LIS benchmark calculation, CMS revised the manner in which it calculates the weighted portion of the LIS benchmark.^{ix} Previously, CMS calculated the weighted portion using a weighted average of the MA-PD and PDP premiums that is based on total Part D enrollment. Under the new rule, CMS calculates the weighted portion based on LIS Part D enrollment. CMS' goal in revising the weighted portion was to reduce the formula's reliance on MA-PD plan premiums, which CMS acknowledged as tending to reduce the LIS benchmark.^x Indeed, there are fewer LIS beneficiaries enrolled in MA-PD plans and, as a result, reweighting the formula in this manner eliminates some of the negative impact of the MA-PD rebates. However, because most LIS beneficiaries are enrolled in benchmark plans, the revised formula will include only the lowest cost plans, which have less comprehensive formularies and higher rates of utilization management, thereby further eroding the benchmark premium amount and reducing the quality of zero-premium plans available to LIS beneficiaries.

ⁱ 42 U.S.C. § 1395w-114(b)(2).

ⁱⁱ *Low-Income Medicare Beneficiaries to Have Fewer Rx Plan Choices in 2009, Study Finds*, 13 Health Care Daily (BNA) 196 (Oct. 9, 2008).

ⁱⁱⁱ 73 Fed. Reg. 18176, 18178 (Apr. 3, 2008). (“The lower benchmarks have contributed to large-scale reassignments of LIS beneficiaries in many of these regions. This is because the relatively lower benchmarks result in many PDPs having a basic Part D premium that is not fully covered by the Federal premium subsidy.”)

^{iv} Centers for Medicare & Medicaid Services, *Year 2007 Re-Assignment Data – Premium Increases*, Nov. 2007, available at www.cms.hhs.gov/limitedincomeandresources/; Centers for Medicare & Medicaid Services, *Year 2007 Chooser Data*, Nov. 2007, available at www.cms.hhs.gov/limitedincomeandresources/.

^v Centers for Medicare & Medicaid Services *Year 2008 Reassignment Data*, Nov. 2008, *Centers for Medicare & Medicaid Services, Year 2008 Chooser Data*, Nov. 2008, available at <http://www.cms.hhs.gov/limitedincomeandresources/>

^{vi} 42 C.F.R. § 423.780(b)(2)(ii)(C).

^{vii} 42 U.S.C. § 1395w-114(b)(2)(B)(iii).

^{viii} 42 U.S.C. §§ 1395w-24(b)(2)(B), 1395w-113(a)(1)(B).

^{ix} 73 Fed. Reg. 18176.

^x *Id.* at 18178. (“MA-PD sponsors can lower their Part D premiums through the application of Part C rebates. As a result, the Part D premiums for MA-PD plans tend to be lower than PDP premiums. In addition, the benchmark amounts tend to be significantly lower in regions with high MA-PD penetration than in other Part D regions.”)

Section 10

CMS SHOULD IMPLEMENT BENEFICIARY-CENTERED PART D PLAN REASSIGNMENT

CMS SHOULD IMPLEMENT BENEFICIARY-CENTERED PART D PLAN REASSIGNMENT

Individuals dually eligible for Medicaid and Medicare were required to enroll in the Medicare Part D program when it became effective on January 1, 2006. To ensure that all dual eligibles were enrolled in a Part D plan by that date, on which they would lose access to their Medicaid prescription drug benefits, Congress directed CMS to assign those dual eligibles who did not select their own Part D plan to a plan with a monthly premium not exceeding the benchmark premium for people who receive the low-income subsidy (known as “benchmark” plans).ⁱ CMS also automatically assigns Part D plans to those who are not dually eligible, but who qualify for the full low-income subsidy (“LIS”) and do not select a plan on their own (dual eligibles and others eligible for LIS are referred to collectively as “LIS beneficiaries”). In addition, CMS automatically assigns beneficiaries who become dually eligible at any given time and do not make a Part D plan selection.ⁱⁱ Further, during each enrollment season, CMS automatically reassigns LIS beneficiaries who were previously auto-assigned and whose existing Part D plans no longer meet the premium benchmark.ⁱⁱⁱ

CMS randomly assigns and reassigns each beneficiary to a Part D plan without regard to whether the plan covers the prescription drugs the beneficiary needs or provides access to the pharmacy the beneficiary frequents. As a result, reassigned beneficiaries not only face new utilization management rules, but also may be enrolled in plans that do not provide access to their medically necessary prescription drugs or to pharmacies in their neighborhoods. For both the 2009 and 2008 plan years, there were more than 1.1 million beneficiaries subject to random reassignment.^{iv}

The Medicare Rights Center makes separate recommendations to stabilize the benchmark premium, which would limit the number of plan reassignments each year. We now urge CMS to adopt auto-assignment policies that assign beneficiaries to plans that maximize coverage of their current medications and offer access to beneficiaries’ preferred pharmacies. In addition, we recommend that CMS require plans receiving beneficiary reassignments to recognize prior authorizations the beneficiary obtained, step therapy requirements the beneficiary completed, and other coverage prerequisites the beneficiary met while enrolled in the previous plan. Beneficiaries who have met these requirements in one plan should be recognized as having met the same requirements in the plan to which they have been reassigned.

RECOMMENDATIONS

1. CMS Should Adopt a Beneficiary-Centered Assignment Methodology

Section 1860D-1(b)(1)(C) of the Social Security Act (the “Act”) directs CMS to enroll dual eligibles “who [have] failed to enroll in a prescription drug plan or an MA-PD plan . . . in a prescription drug plan that has a monthly beneficiary premium that does not exceed the [benchmark amount].”^v The Act further provides that if there is more than one plan that meets this criterion, “the Secretary shall enroll such an individual on a random basis among all such plans in the PDP region.”^{vi} CMS has interpreted this “random” assignment requirement to prohibit beneficiary-centered policies that would reassign LIS beneficiaries whose current plans are no longer at or below benchmark to plans that cover the beneficiaries’ prescription drugs and provide access to the pharmacies used under their previous plans.^{vii}

We urge CMS to reconsider its conclusion that the Act prohibits such assignment policies. Although the Act directs CMS to assign beneficiaries on a random basis, this requirement does not prohibit CMS from developing assignment policies that randomly assign beneficiaries to a select group of plans that cover a beneficiary's required medications and provide access to beneficiaries' preferred pharmacies. In fact, CMS has recognized that the law's "random" assignment requirement does not prohibit the agency from imposing certain assignment criteria. For example, CMS' 2009 Call Letter proposes to establish "Auto-Enrollment Readiness Audits," which would audit the matching of plans to LIS beneficiaries, call center performance, beneficiary notifications, and transition policies, among other measures.^{viii} According to the Call Letter, CMS will exclude from the randomization process any plan that fails the audit.^{ix} We support CMS' proposed audit process and encourage the agency to take further steps, including the adoption of beneficiary-centered assignment policies, to ensure that low-income beneficiaries are enrolled into plans that meet their medical needs.

We specifically recommend that CMS use claims data to reassign affected beneficiaries to plans that cover their current medications, impose the fewest utilization management restrictions, and provide access to preferred pharmacies. State pharmaceutical assistance programs have adopted similar techniques for their members and have successfully minimized disruptions in drug coverage.^x If more than one plan covers the beneficiary's medications, CMS would enroll the beneficiary into the plan that best meets objective quality-of-care standards subject to the audit process proposed in the 2009 Call Letter. If all of these plans provide equal coverage and quality of care, reassignment would be random.

The beneficiary-centered reassignment policy we propose is consistent with Congress' intent that beneficiaries be randomly assigned to Part D plans. Our proposal simply would limit the set of plans from which a particular beneficiary's plan would be chosen, as the plan's formulary and pharmacy network would be required to match the individual's medication needs and pharmacy preferences. The non-LIS population selects a Part D plan based on an assessment of whether the plan's formulary meets their own prescription drug needs and provides access to preferred pharmacies. LIS beneficiaries, who are at the mercy of annual benchmark fluctuations, should be assigned to plans that similarly meet their needs.

2. CMS Should Require Plans to Which LIS Beneficiaries Are Assigned to Recognize Completion of Utilization Management Policies in Prior Plans

The Act permits Part D plans to develop their own utilization management policies, including the adoption of formularies and other utilization management rules.^{xi} Nevertheless, plans receiving beneficiaries reassigned from another plan in which the beneficiary previously met prior authorization, step therapy, or other utilization management requirements should be required to recognize completion of these requirements. Such a requirement would not prohibit a plan from imposing its own utilization management policies to the extent these policies differ from the beneficiary's prior plan. Rather, this proposal would prohibit plans from requiring LIS beneficiaries to complete the same prior authorization, step therapy, or other utilization management requirement the beneficiary previously completed successfully. Since all utilization management criteria are based on clinical evidence and subject to CMS review, the criteria are substantially similar among different plans.

To facilitate recognition by the reassigned plan that a beneficiary previously satisfied prior authorization, step therapy, or other utilization management criteria, CMS should require the beneficiary's original plan to provide records documenting these facts to CMS. CMS, in turn, should provide this information to the plan to which the beneficiary is reassigned. The Act permits CMS to provide beneficiary information to PDP sponsors "to facilitate the marketing of, and enrollment of Part D eligible individuals in, prescription drug plans and MA-PD plans."^{xii} CMS should use this authority to ensure that beneficiaries are not required to satisfy duplicative utilization management requirements. CMS' provision of this information to the plan to which a beneficiary has been reassigned will enable this plan to quickly recognize that the beneficiary already met utilization management criteria.

ⁱ 42 U.S.C. § 1395w-101(b)(1)(A) ("The Secretary shall establish a process for the enrollment, disenrollment, termination, and change of enrollment of part D eligible individuals in prescription drug plans consistent with this subsection.").

ⁱⁱ 42 C.F.R. § 423.34(d).

ⁱⁱⁱ 42 C.F.R. § 423.34(c).

^{iv} Centers for Medicare and Medicaid Services, Limited Income & Resources, Overview, available at <http://www.cms.hhs.gov/limitedincomeandresources>

^v 42 U.S.C. § 1395w-104(b).

^{vi} 42 C.F.R. § 423.34(c).

^{vii} 73 Fed. Reg. 18176, 18179 (Apr. 3, 2008) ("Congress has favored random assignment by specifying it in the case of initial assignment. We believe that it is appropriate to extend this to re-assignment.").

^{viii} *Auto-Enrollment Readiness Audits*, Section XI.F. 2009 Call Letter (March 17, 2008), available at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CallLetter.pdf>

^{ix} *Id.*

^x See, e.g., Hoadley et al., *The Role of Beneficiary-Centered Assignment for Medicare Part D*, MedPAC (June 2007).

^{xi} 42 U.S.C. § 1395w-102(e)(3)(B) provides that a drug prescribed for a Medicare Part D beneficiary shall not be considered a "covered part D drug" if it is not prescribed "in accordance with the plan."

^{xii} 42 U.S.C. § 1395w-101(b)(4)(B)(ii).