

M E D I C A R E

The Obama Administration's 2010 Call Letter for Medicare Advantage and Prescription Drug Plans: Implications for Beneficiaries

Prepared By:

The Center for Medicare Advocacy

For:

The Henry J. Kaiser Family Foundation

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Executive Summary

Each year, the Centers for Medicare and Medicaid Services (CMS) issues a "Call Letter" that functions as a request for proposals to private health insurers and organizations that want to sponsor Medicare Advantage (MA) Plans or Medicare Prescription Drug Plans (PDPs). The Call Letter provides potential plan sponsors with information to assist them in submitting their bids for the following year. It also discusses CMS policy for implementing related legislative and regulatory changes, including relevant provisions in the Medicare Improvements for Patients and Providers Act (MIPPA). CMS uses the Call Letter to highlight problem areas from the previous year, express expectations for the coming year, and describe its priorities for the coming year.

This policy brief examines key provisions and changes in plan requirements, as described by the new Administration in its first Call Letter issued on March 30, 2009.

As in previous years, the Call Letter discusses rules that plan sponsors need to know in order to operate in the Medicare program. The 2010 Call Letter indicates an intention to focus on new issues of importance to consumers with an eye toward greater enforcement of existing and new rules.

These changes announced by CMS focus on accountability, informed choice among beneficiaries and other beneficiary protections, and include the following:

Accountability

- Sponsors that file incomplete and inaccurate plan applications, bids, and formularies could be subject to a range of corrective actions.
- Plans that fail to meet standards for timely resolution of complaints recorded through the Health Plan Management System Complaints Tracking Module will be considered to be out of compliance with regulatory and contractual requirements.
- Plans will be subject to targeted, data-driven and risk-based audits focused on enrollment processes, appeals and utilization management criteria in formularies.
- Sponsors will be subject to stricter rules for marketing their plans.

Promoting Informed Health Plan Choices For Beneficiaries.

- Medicare Advantage (MA) sponsors are encouraged to eliminate plans with low enrollment or duplicative benefit structures, and limit their offerings to no more than three MA plans by plan type in a region, in an effort to ease beneficiary confusion.
- Plans are required to use standardized descriptions of the extent of drug coverage in the coverage gap or doughnut hole to facilitate comparisons across plans.
- Plans are required to publish drug formulary utilization management requirements and use standard plan types in plan names to inform beneficiaries and promote transparency

Increasing Beneficiary Protections

- Plans with high cost-sharing requirements for services associated with chronic and acute conditions will be reviewed by CMS and will not automatically be accepted for 2010, including cost-sharing, even if they were approved for 2009.
- Plans with out-of-pocket expenses capped at more than \$3,400, or with cost-sharing for certain services higher than Medicare cost-sharing, would be subject to greater scrutiny for discriminatory practices.
- Chronic condition special needs plans will have stricter enrollment eligibility criteria and be subject to new standards for their benefit packages.
- Private fee-for-service plans will be required to make their cost-sharing requirements more transparent, particularly in situations when beneficiaries fail to notify a plan prior to receiving treatment; failure by plans to comply could result in sanctions or civil monetary penalties.
- Medication Therapy Management programs will have more detailed requirements that address enrollment, targeting, intervention and outcomes-reporting and are based on what CMS identified as best practices in these areas.
- Plans will no longer be permitted to use reference-based pricing in their formularies, whereby plans add a surcharge to cost-sharing of certain prescription drugs.

The 2010 Call Letter emphasizes compliance with rules, regulations, and guidance. CMS states that some problem areas, such as reporting of medical-loss ratios and reassignment of low-income subsidy individuals, warrant additional consideration, and seeks input on how to make the program work more efficiently for beneficiaries, plan sponsors, and health care providers. CMS indicates it will continue its oversight of marketing and other areas such as enrollment and appeals to ensure that beneficiaries receive necessary health services.

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Introduction

Organizations that want to sponsor Medicare Advantage (MA) plans under Medicare Part C and/or Prescription Drug Plans (PDP) under Medicare Part D must enter into a new contract with the Centers for Medicare & Medicaid Services (CMS) each year.¹ The contracting process is complex. Plans must submit their applications, which include their pricing bids and their plan benefit packages (PBPs), within strict time frames. CMS must review the information, send comments to the sponsors, approve the applications, establish premium amounts, and review marketing materials within an equally tight time frame. The goal is to have the entire process completed by the end of September so that Medicare beneficiaries have the information they need to make health care choices at the start of the Parts C and D annual enrollment period on November 15 of the same year.² New contract years, referred to as plan years, begin on January 1.

The contracting process commences early in the new plan year with the issuance by CMS of the Call Letter. The Call Letter functions as a request for proposals to act as Medicare Advantage plans and PDPs for the following year. Hence, the Call Letter issued in 2009 is called the 2010 Call Letter. It provides current and potential plan sponsors with information to assist them in submitting their bids. The Call Letter discusses legislative and regulatory changes that have recently gone into effect or will go into effect for the next plan year as well as CMS policies to help implement statutory and regulatory requirements. CMS uses the Call Letter to highlight problem areas from the previous year, to express its expectation of plan sponsors for the upcoming year, and, in effect, to describe its priorities for monitoring plan compliance with statutory, regulatory, and contractual obligations.

CMS initially releases the Call Letter in draft form, providing interested parties the opportunity to comment on the Call Letter, its requirements for plans, and the agenda CMS sets out for itself in terms of oversight and enforcement. Parties are given a limited time frame in which to submit comments. The initial Call Letter, released January 8, 2009, was rescinded by the new administration on January 22 and reissued on February 23, with comments due to CMS on March 6. The final 2010 Call Letter was issued on March 30, 2010.³ CMS indicates that it received approximately 190 comments on the draft document from a wide range of interested parties, including health plans, consumer groups, states, pharmacists, health care providers, and members of Congress.

The 2010 Call Letter follows the format of previous Call Letters.

- **Section A** of the call letter focuses on issues related to Medicare Advantage, including the bidding process, audits, the number of plans per sponsor, and benefit design.
- **Section B** of the call letter focuses on Medicare Prescription Drug Plans, including the bidding process and formularies.
- **Section C** examines issues related to plan marketing and beneficiary communications.

The Call Letter discusses new rules that became effective in 2009 or that will become effective in 2010 as a result of passage of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2009⁴ and of CMS directives. It includes comments on good and poor plan practices and highlights areas for oversight and enforcement.

The focus of the Call Letter is on the new guidance plan sponsors will need to prepare their contract submissions. Three areas in which CMS will continue to evaluate its policies based on response to its request for comments in the draft Call Letter are the following: methodologies for calculation and dissemination of information about plans' medical loss ratios⁵; improvements to the reassignment process of low-income subsidy eligible individuals whose Part D plan no longer qualifies for the low-income subsidy; and appropriate methods, for plans that are losing members due to reassignment, for discussing with members how they may remain in their current plan and their premium obligations if they choose to do so. This brief examines the 2010 Call Letter. Rather than a section-by-section analysis, the brief examines themes and trends to determine what some of the policy changes may indicate for beneficiaries.

SECTION A – MA, MA-PD, AND COST PLANS

Section A of the draft Call Letter contains provisions relevant to Medicare Advantage plans (MA) and other managed care plans. CMS solicited comments on a number of issues relevant to MA plans in the draft version, particularly in regard to improving the Part C program for Medicare beneficiaries. The Call Letter also discusses MIPPA changes that go into effect in 2010.

INCREASED ACCOUNTABILITY

Plan Bidding Process and Audits

Plan Bids and Plan Corrections: Both the 2009 and 2010 Call Letters state that plan bids must be submitted by the deadline stated in the Call Letter, and that late bids will not be accepted. Both also indicated that plan sponsors will not be able to request plan corrections for the following year after the October 1

deadline. The goal is to have plan benefit packages in sufficient time for CMS to include correct and accurate plan information on its web site for the start of the annual enrollment period in November.

If a plan correction is requested, CMS will consider the bid to be incomplete or inaccurate, will question the validity of the certification and verification, and will question the ability of the sponsor to submit correct bids. Most important, CMS advises sponsors for the first time⁶ that request of a plan correction will result in issuance of a corrective action warning letter. Corrective action files are posted on the CMS website.⁷

Audit Approach: The Call Letter states that in 2010 CMS will conduct targeted, data-driven and risk-based audits of plans, rather than the routine audits the agency previous had conducted. The focus will include areas such as enrollment processes and appeals, which have the greatest potential harm for plan enrollees. CMS will target poor performing organizations, and will assess the effectiveness of internal monitoring, auditing and other plan compliance programs.

CMS states that, in 2010, MA and PDP plan sponsors, as well as cost plans, should audit the Part C and Part D data they report to CMS for plan monitoring and performance measurement. CMS notes that it has not be able to respond to Congressional and other inquiries about costs, availability of services, use of services, safety and grievance rates either because of an absence of data or because the data submitted by Part D plan sponsors have been of questionable validity. To address the issue, CMS will develop data validation specifications to ensure reliability, completeness and comparability. The specifications will be phased in, starting with areas of most concern to beneficiaries.⁸

Sponsors must report the results of their audits, including measures for which they do not pass. CMS indicates that “not pass” on an audit measure will be treated as a failure to submit the data. They may be considered as non-compliance, and plans may be requested to develop corrective action plans. Again, CMS makes information about corrective action plans available on its web site.

Although CMS imposes strict standards for audits, the Call Letter does not discuss the statutory requirement that at least one-third of MA plans be audited annually.⁹ The Call Letter does not adopt recommendations made by the Government Accountability Office (GAO) that would allow CMS to meet the one-third audit requirement and that would make other improvements such as including terms in its contracts for pursuing financial recoveries against plan sponsors that have been overpaid.¹⁰

Quality and Performance Measures

MIPPA Requirements: MIPPA extended to private fee-for-service (PFFS) and Medical Savings Accounts (MSAs) the quality improvement measures applicable to other MA plans. The Call Letter describes the new rules and their applicability to PFFS and MSA plans. The Call Letter is silent, however, concerning the reporting of information for could have required all Part C plans to report on and disclose information on disparities in the use of health services by plan enrollees, and on plan policy, practices and procedures to assist beneficiaries with limited English proficiency.

Response to Complaint Tracking Module: The Call Letter establishes for 2010 standards for resolution by Part C and Part D plans of complaints recorded through the Health Plan Management System Complaints Tracking Module. Plans must comply with strict time frames in at least ninety-five percent (95%) of the cases. Time frames vary with the designation of the complaint - immediate need, urgent need, unclassified – with CMS reserving the right to reclassify any complaint that does not fit the definitions of immediate need and urgent need specified in the Call Letter. CMS will consider plans that fail to meet the threshold as out of compliance with a number of requirements, including those related to enrollment, coverage and organization determinations, appeals, and claims processing. This provision is significant for beneficiaries. It establishes set time frames by which problems must be resolved, helping to ensure that beneficiaries have access to medically necessary services. It also points out the high regard CMS places on timely complaint resolution, since plans that do not meet the thresholds will be considered out of compliance.

Grievance, Organization and Coverage Determinations, and Appeals: Previous Call Letters have addressed a number of beneficiary concerns about Part C and Part D plan failure to implement and comply with regulations concerning grievances, determinations and appeals. The 2010 Call Letter spends little time on these issues. The draft Call Letter required all plans to send the relevant Evidence of Coverage and formulary on a CD with every file appealed to the independent review entity (IRE). The idea was to expedite decisions at both the IRE and administrative law judge (ALJ) levels of review by ensuring that complete and accurate information is available to the reviewers. CMS eased the requirement in the final version, however, and simply extended through 2010 the previous recommendation that plans send the complete COS and formulary, if applicable.

CMS could have included in the Call Letter a reminder that plans must comply with the regulatory time frames, and that the time frames represent hours and calendar days, not business hours and business days. Although CMS indicates in the section on responses to the complaint tracking module that plans that fail to comply may be found out of compliance with appeals provisions, CMS could also have included that reminder in this section. As it did in other sections of the

Call Letter, CMS could have requested information about the need to issue proposed regulations to make the process work more efficiently for beneficiaries, particularly with regard to the notice of appeal rights.

PROMOTING INFORMED CHOICE AND EASE IN ENROLLMENT

Both Part C and Part D are premised on beneficiaries having a choice of options in order to enroll in the plan that best meets their needs. Yet beneficiaries have difficulty differentiating among the multiple plan offerings by the same sponsor, generally because the differences in benefit packages are subtle, and the plans have the same or very similar names. Additionally, when people are presented with too many choices they may end up making an inappropriate choice or no choice at all. A number of new recommendations in the 2010 Call Letter are designed to improve the choice and enrollment processes.

Multiple and Low Enrollment Plan Offerings: CMS recommends in the Call Letter that plan sponsors limit plan offerings in several ways. First, CMS states that plan sponsors should eliminate for 2010 plan offerings that have low enrollments. CMS notes that these plans may not have the financial stability to provide the quality health care to which beneficiaries are entitled. According to CMS, there are “currently large numbers of plan offerings with fewer than 10 enrollees.”¹¹

CMS regulations require a minimum of 5,000 beneficiaries enrolled in each organization after three years, and 1,500 enrollees in rural areas.¹² CMS could go further than just strongly encouraging plan sponsors not to submit bids for such plans in 2010. CMS has the statutory authority to deny renewal of contracts for plans that do not meet the statutory standards, and CMS could exercise its authority not to renew.

Second, CMS also states that sponsors should eliminate plans that are duplicative of other plans they offer, and should ensure that the differences in plan offerings are transparent to plan enrollees. The Call Letter cites as examples plans with or without drug benefits or specific supplemental benefit options as well as different plan benefit types. Again, CMS can take action in this regard, by not renewing or approving multiple plan offerings from the same sponsor where the benefit structures do not vary significantly, and by developing standardized marketing materials that make differences in costs and benefits clear.

In the draft Call Letter, CMS solicited comments on whether it should issue rules that would limit plan sponsors to no more than a specified number of benefit designs in a given service area. The final Call Letter includes the “expectation” that plan sponsors offer no more than three MA plans of each plan type in each market, and that the plans offered can be easily distinguished based on plan type, benefit package, and access. Additionally, CMS says that, based on the

comments received, the agency is considering issuing proposed rules concerning the number of benefit designs and consolidation of low enrollment plans.

Providing Information About Plan Changes: Plans send their current enrollees two important information tools that describe in detail the benefits they cover. The Annual Notice of Change (ANOC), sent in the fall before the annual enrollment period begins, explains plan changes in benefit structure, premiums, cost-sharing and formulary for the upcoming plan year. The ANOC is designed to be used by enrollees to help decide whether to remain in their current plan. It is often a dense document, and may be too dense for some beneficiaries to use effectively. The second informational tool, the Evidence of Coverage (EOC), is the formal, detailed plan document that serves as the explanation of plan benefits and costs, plan procedures, and beneficiary rights and protections. It, too, is a lengthy document with complex information.

When CMS first announced the use of a combined ANOC/EOC, beneficiary organizations filed objections in their comments to previous Call Letters that the combined document would be too long and that information about plan changes would get lost. Beneficiary advocates believe that CMS could have helped to highlight benefit cost-sharing and structural changes, and therefore eased some of the complexities of choosing a health plan, by requiring that the ANOC and EOC be sent separately. Despite continued objections by beneficiary organizations, CMS is requiring plans to submit and use the combined ANOC/EOC again for 2010.

Mandatory Use of the Online Enrollment Center: The 2010 Call Letter requires for the first time that almost all Part C and Part D plans accept enrollments made through the Medicare Plan Finder that is available on the CMS website for Medicare beneficiaries. Plan sponsors are required to download pending enrollments at least once a day. Some beneficiaries have reported in the past that when the beneficiary calls the plan to enroll, some plans enroll them in different plans than what the beneficiary selected. The new policy is designed to protect against such situations and to help the enrollment process move smoothly.

The draft Call Letter required all plans to accept on-line enrollment through the CMS website. The final Call Letter made such use optional for plans that require additional eligibility information, such as special needs plans and religious fraternal benefit plans. The final Call Letter also indicates that MA plans that are available only to employer groups cannot use on-line enrollment to prevent confusion for other beneficiaries who are not eligible to enroll in such plans. Medicare Cost plans and Medical Savings Account plans also cannot participate in on-line enrollment because they use a different enrollment format and require additional information.¹³

Enrollment Choices When a Plan Exits the Market: If MA plan sponsors eliminate a low-enrollment or duplicative plan bid, or if CMS terminates a contract with a plan, enrollees in the terminated plan must make a choice about how to receive their health care. The issue also arises in the context of Part D if a PDP sponsor decides not to renew a plan's contract for the following year or if the contract is terminated by CMS.

CMS initially used "passive enrollment," that is, enrollment by CMS, in 2005 to place beneficiaries, who did not voluntarily elect an MA plan, into a Medicare special needs plan; this resulted in litigation.¹⁴ Medicare beneficiary advocates commented on the draft 2010 Call Letter, on previous Call Letters, and on proposed regulations that CMS lacks the authority to place individuals in an MA plan that they did not choose for themselves. The Medicare statute makes enrollment in an MA plan voluntary; an individual who does not make an election is deemed to elect to remain in traditional Medicare. The statute also says that once someone elects an MA plan, that election will continue until the individual changes the election or the plan no longer serves the area in which the individual resides. CMS guidance creates a special enrollment period (SEP) for enrollees whose health plan is terminated or is non-renewing. The guidance states that plan enrollees who do not elect a new plan before the end of the plan's contract are to be defaulted into traditional Medicare.¹⁵

The Call Letter states that, where appropriate, CMS will authorize the transition of exiting plan enrollees to another plan offered by the same sponsor. The Letter acknowledges that affected beneficiaries have a SEP to change plans under the existing CMS policy on plan non-renewals. The Call Letter also states that where a plan sponsor does not offer another, similar plan, enrollees will be returned to traditional Medicare unless they elect a different plan.

BENEFICIARY PROTECTIONS

Several provisions in the Call Letter implement and expand upon new and existing protections for beneficiaries with regard to cost-sharing, benefit design, and transparency of information.

Cost-sharing for Dual Eligibles: Section 165 of MIPPA prohibits special needs plans (SNPs) for dual eligible individuals from imposing cost-sharing requirements on dual eligibles or Qualified Medicare Beneficiaries that would exceed the amounts permitted under the State Medicaid plan if the individual were not enrolled in the Dual-SNP. The MIPPA provision is effective January 1, 2010. Provisions of both Medicare and Medicaid that existed before MIPPA as well as extensive CMS guidance are much broader. They include cost-sharing limitations for all dual eligibles, whether in traditional Medicare or any kind of Medicare Advantage plan (regardless of whether it is a SNP). The amount and nature of the cost-sharing protections vary based on a variety of complicated factors, and were set forth in CMS Guidance issued in May 2008.¹⁶

The Call Letter section on cost-sharing protections for dual eligible enrollees, citing two interim final regulations issued by CMS in September 2008,¹⁷ applies the limitation on cost-sharing to all MA plans, not merely to Special Needs Plans for dual-eligibles, as included in MIPPA. The Call Letter aims to reduce billing problems encountered by dual eligibles by requiring a provider contract provision that enrollees not be held liable for cost-sharing that should be paid by Medicaid programs. Plans must inform providers of Medicare and Medicaid benefits and eligibility rules on a frequent basis since many are not aware of how the rules work.

Some other provisions could strengthen this section. The Call Letter could refer to the regulatory language that all contracts must state that the providers will "(A) Accept the MA plan payment as payment in full, or (B) Bill the appropriate State source."¹⁸ It could also require all plans serving dual eligibles to work with the Medicaid agency in the state in which they operate to assure that their statement of Medicaid benefits provided to providers is accurate.

Limit on Out-of-pocket Costs: The section on cost-sharing guidance continues efforts by CMS to improve transparency so that beneficiaries may predict more easily their out-of-pocket (OOP) costs if they were to enroll in a particular plan. There are two separate issues in determining OOP costs. As the GAO found, some MA plans charge cost-sharing that is greater than what beneficiaries would pay under the traditional Medicare program. And, while some plans have caps on OOP costs, they may also exclude some services from the caps, so that beneficiary costs continue to accrue even after the cap is reached.¹⁹

The 2009 Call Letter stated that plan sponsors may not design benefit packages to discourage enrollment by people with severe or chronic conditions, and that cost sharing or deductibles determined to be discriminatory would not be approved. The 2010 Call Letter indicates that it will continue to review cost sharing for services associated with chronic and acute conditions, and those that are high utilization and high cost. Additionally, benefit designs, including cost-sharing, approved for 2009 will not automatically be accepted for 2010. In addition, the Call Letter says that it will "likely" not consider a co-insurance amount to be discriminatory if the plan has an overall OOP maximum of \$3,400, the co-insurance for certain services (renal dialysis, Part B drugs, psychiatric hospitalization, and skilled nursing facility services) does not exceed the co-insurance under traditional Medicare, and the plan does not carve out any services covered under Part A and Part B from its OOP maximum. \$3,400 represents the 85th percentile of projected beneficiary spending in 2010.

As with several other issues, CMS indicates that it is considering amending regulations that would impose a requirement for an out-of-pocket amount. The regulations could reduce the OOP maximum from its current level. The \$3,400 OOP maximum represents approximately 16 percent of income for the 46 percent of Medicare beneficiaries with incomes below 200 percent of the federal

poverty level (\$21,660/individual in 2009).²⁰ Proposed regulations could strengthen out-of-pocket protections by stating clearly the services for which plans may not charge more than traditional Medicare. For example, the regulation could include the services CMS said it would review as services associated with chronic and acute conditions.

Benefit Design: The Call Letter addresses several issues involving the design of a MA plan's benefit package. These include incentives to encourage the use of preventive benefits, supplemental over-the-counter benefit packages, supplemental home infusion drug packages, and the use of rebate dollars to enhance the traditional Part A and Part B benefit package.

In keeping with efforts by CMS over the past several years to promote the use of Medicare preventive benefits, the Call Letter contains directions about the use of incentives by MA plan sponsors to encourage plan enrollees to use Medicare-covered preventive benefits. CMS reminds plans that the emphasis of their benefit package should be the provision of Part A and B covered benefits at a lower cost. The use of incentives should be directed at enrollees, not potential enrollees, and should be directed towards using the services and not an outcome. Incentives are not to be advertised as a plan benefit or included in the bid as a benefit, but costs related to incentives are to be included with other non-covered benefit costs.

CMS also updates the guidance provided in the 2009 Call Letter on supplemental over-the-counter (OTC) benefit packages. The updated guidance helps clarify when a plan may provide a supplemental OTC benefit and how the benefit should be provided. CMS indicates that it will no longer use lists of categories of OTC items from other sources, and includes a listing of categories in Appendix I to the draft Call Letter. This change aims to standardize the items that may be offered and may help in the beneficiary comparison process. The Call Letter also precludes the offering of a debit card for OTC benefits that is usable in only one pharmacy chain; the stated intent of this prohibition is to preclude the steering of beneficiaries to that pharmacy chain.

The Call Letter also addresses the confusion surrounding payment for home infusion drugs. In traditional Medicare, if the drugs are covered under the Part B durable medical equipment (DME) benefit, then Medicare pays for both the home infusion drugs and the durable medical equipment through which they are delivered. If the home infusion drugs are covered under Part D, however, the Part D plan pays only for the drugs, and the beneficiary is responsible for obtaining and paying for the delivery mechanism. Despite the fact that MA-PDs are supposed to provide all Parts A, B and D-covered services, some plans reject payment for home infusion drugs as not covered under Part D when the drugs may be coverable under Part B, or they will cover the drug under Part D but not the related supplies.²¹ The Call Letter requires plans with a Part C mandatory supplemental benefit that bundles home infusion drugs to pay for the home

infusion drugs under Part C, rather than under Part D as would happen if the drugs and supplies were not bundled. The bundled package must include the drugs and the supplies needed to provide the drugs. CMS waives the definition of a Part D drug with regard to home infusion drugs covered under a bundled package, provided that the plan applies no cost-sharing for the bundled services. Plans must ensure that even enrollees who are long-term care facility residents are eligible for the bundled services. CMS stated that policy is being adopted to make it easier for beneficiaries to calculate whether they would be better off with the supplemental Part C benefit or having the drugs covered under Part D. This policy could help beneficiaries in nursing facilities since that Medicare Part B does not cover DME, and the drugs supplied through DME, for such beneficiaries.²²

Another benefit design issue concerns the reallocation of rebate dollars towards benefits after CMS determines the MA plan bid amount. The Call Letter reminds plans that they cannot use the rebate re-allocation process to change their basic Medicare benefit package and premium. CMS reiterates its admonition from previous years against reallocating rebate reductions by increasing cost sharing for more limited-use services such as inpatient, skilled nursing facility (SNF), and home health care unless reductions in non-Medicare covered benefits or increases in cost-sharing for widely used services have been made first. As in the past, CMS says that the first priority of rebate reductions should be to reduce the Part D premium to the lower amount targeted by the plan sponsor. While reduction of Part D premiums may appear to be a beneficiary-friendly priority, the policy is not without problems. Plans that have to increase their cost sharing for more costly services in order to keep a \$0 or reduced Part D premium may be discriminating against sicker beneficiaries who utilize these services.

CHANGES MADE BY MIPPA

CMS devotes a portion of the Call Letter to explain the new plan requirements contained in the MIPPA, in interim final rules issued by CMS on September 18, 2008 and in final rules published January 12, 2009.²³ Some of the MIPPA provisions concerning reporting of quality measures were discussed in an earlier section of the paper. This portion of the paper focuses on implementation of MIPPA and regulatory changes for Special Needs Plans (SNPs) and Private Fee-for-Service (PFFS) plans. It includes suggestions on how CMS could strengthen the MIPPA protections in future years.

Special Needs Plans: It is interesting to note that the section of the Call Letter discussing SNPs includes many references to new plans for the 2010 plan year. MIPPA section 164(b), however, precludes the designation of new plans in the 2010 plan year, continuing the moratorium first put in place in the Medicare, Medicaid and SCHIP Extension Act of 2007 governing the time period January 1, 2008 - December 31, 2009. It is unclear why CMS ignores the moratorium. CMS could have eliminated all references in the SNP section to new plans.

Models of Care: One of the new requirements for SNPs is that they have an evidence-based model of care (MOC) that is appropriate to each SNP. The Call Letter indicates that the requirement applies to new and existing SNPs.

CMS in future years could strengthen the Call Letter language about MOC requirements in a number of ways. First, the language concerning the development of the care plan could be stronger than requiring consultation with the individual “as feasible.” The plans could be required to consult with the individual unless such consultation is impossible and with anyone the individual chooses to have involved in the care planning, including a delegated surrogate. Second, assessment and annual reassessment is required by MIPPA; CMS could add language that requires reassessment as needed when the beneficiary's circumstances change. Given that SNPs serve the most vulnerable populations, more than an annual reassessment may be needed to ensure that the plan is providing all necessary services. Third, plans could be required to demonstrate how they will serve people with limited English proficiency who are disproportionately represented in the dual eligible population. Fourth, since models of care are what distinguish SNPs from other MA plans or delivery models, CMS could require plans to describe their MOCs in all plan marketing materials and make them publicly available. CMS could have included more detail in the Call Letter concerning the review and subsequent audit of MOCs to ensure that SNPs are providing the special services for which they were intended.

Institutional SNP – Level of Care Assessment Tool: MIPPA requires all institutional SNPs (I-SNPs) to conduct an assessment to determine the eligibility for beneficiaries who live in the community but need a skilled level of care. The statute also requires the I-SNP sponsor to use the state assessment tool for the state in which the plan operates. The Call Letter states that CMS will monitor to make sure the plans use the appropriate assessment, with plan sponsors bearing the burden of demonstrating that they follow the practice of the state. Furthermore, I-SNPs cannot provide bonuses or payment differentials to independent assessment entities for qualifying members for the I-SNP, and must use credentialed agents for conducting the assessment.

SNP Quality Improvement and Chronic Care Improvement Programs: The Call Letter discusses the MIPPA and CMS regulatory requirements concerning quality improvement programs (QIP) and care management, and indicates that it may focus increased oversight and audit activities on monitoring of these programs.

The Call Letter provides examples of QIPs for the three kinds of SNPs. The examples provided in the Call Letter would not necessarily assess the uniqueness of the SNP to address the needs of the appropriate population. The first example of a QIP for dual eligible SNPs suggests an evaluation of the effect of add-on-transportation services on utilization rates of primary care and

preventive health services. Since many state Medicaid programs already pay for transportation services, in those states, the add-on transportation services from the SNP may not provide any additional benefit than already exists, for full dual eligibles.

The examples of QIPs for institutional SNPs also may not accurately assess whether the I-SNP is providing something of extra value to its enrollees. One example suggests evaluating the effect of an annual health risk assessment. However, provisions in the Nursing Home Reform Law concerning the frequency and timing of assessments by the SNFs suggest that an annual health risk assessment by the SNP for non-institutional beneficiaries may not be sufficient to identify problems before adverse outcomes occur. The second example provided in the Call Letter, whether the SNP “sent timely reports on beneficiary health status to the interdisciplinary care team resulting in a continuous update of the individualized care plan,” duplicates the requirement imposed on SNFs by the Nursing Home Reform Act to assess residents and update their care plans, annually, quarterly, and on significant change in a resident’s condition.²⁴

Chronic Condition SNPs (C-SNPs): The Call Letter advises C-SNPs that they must demonstrate their special attributes in order to be of value to their enrollees and to get the special marketing and enrollment accommodations that are accorded to them. The Call Letter further advises that their benefit packages must include more than just Part A and Part B services, and must be more extensive than the care coordination required of all MA coordinated care plans.

The C-SNPs that are offered in 2010 will have to be structured around 15 severe or disabling conditions that were identified by CMS as meeting the statutory definition of severe or disabling chronic condition. Pursuant to a requirement in MIPPA, CMS convened a panel to identify the conditions. Advocacy organizations have concerns that, without additional clarifications, C-SNPs can design plans around the 15 severe or disabling chronic conditions that are not distinguishable from other MA plans. CMS places additional limitations on the populations that C-SNPs may enroll to discourage C-SNPs that are “a general market product rather than a product tailored for a particular population.”

Acknowledging the continuing concern regarding C-SNP enrollment of beneficiaries who do not have the chronic condition to be served by the C-SNP, CMS states that it will conduct focused audits to determine that plans are verifying that enrollees have the conditions the C-SNP has been approved to serve.

Requirement for Dual-Eligible SNPs (D-SNPs) to Contract with State Medicaid Agencies: MIPPA adds new requirements for 2010 that define the relationship between D-SNPs and state Medicaid agencies. CMS states in the Call Letter that D-SNPs best serve their population when they have strong connections to the Medicaid program in the state in which they operate. MIPPA requires that

plans tell prospective enrollees the benefits and cost sharing protections under their Medicaid program and which of those are offered under the SNP. However, as CMS has noted elsewhere, SNPs must provide the same cost-sharing protections as are available to duals under Medicaid and under CMS regulations. The Call Letter language as to the nature of the state-SNP collaboration/cooperation could be stronger. Plans are required by regulation to have eligibility verification arrangements with states and to identify and share information about Medicaid provider participation. The latter requirement should prevent plans from being approved as D-SNPs if they have no Medicaid providers in their networks. The statutory requirement for a contract with the state is waived for plans that do not expand their service area. CMS could still require all plans to coordinate with the state in the above mentioned areas, even if it is through a less formal arrangement than a contract. Any MA plan serving dual eligibles, but most especially D-SNPs, should have the capacity to help duals navigate both Medicare and Medicaid benefits successfully to get the services they need.

CMS also indicates in the Call Letter that it will create a resource contact, through the contracting process, to work with states to develop model and best practices for state-SNP relationships. This action is to implement a MIPPA requirement to provide resources to states.

Enrollment requirements for 2010: The Call Letter sets forth general guidance for transitioning of SNP enrollees from 2009 to 2010 and indicates that more detailed guidance will be issued later in the year. The general guidance is designed to ensure that SNP enrollees in 2010 are members of the group that the SNP is authorized to serve; that the transition for individuals who no longer meet the eligibility criteria is seamless; and that affected plan enrollees receive clear and timely information about their options. While CMS discusses the general guidance in terms of individuals who no longer meet the conditions targeted by a C-SNP, the guidance can also apply to individuals who no longer are eligible for a D-SNP or an I-SNP.

Under the general rules, individuals who continue to meet the eligibility criteria, either because the SNP remains the same or because the targeted condition is subsumed into a broader SNP, would remain in the SNP unless they elect another option. If a C-SNP that targeted multiple conditions breaks up into separate plans, 2009 plan enrollees would be passively enrolled to the new plan that targets their condition, unless they elect a different option. Enrollees in the 2009 plan who do not meet the new categories would be ineligible to enroll in any of the 2010 SNPs.

Beneficiary organizations in their comments on the draft 2010 Call Letter raised concerns about the automatic assignment into different MA plans of 2009 plan enrollees who no longer meet the eligibility criteria of the new SNP, or whose plan sponsor terminated all SNP offerings. CMS indicated that it will consider

proposals for passive enrollment into a different plan in 2010 if the sponsoring organization can establish to the satisfaction of CMS that the plan into which they will be enrolled has similar benefits, formularies, premiums, and network rules. CMS also states that affected beneficiaries have a special election period (SEP) whenever they transition to a different SNP or MA plan, or return to traditional Medicare.

CMS, in its future guidance, can address concerns about the existing SEP for C-SNPs, which allows enrollment at any time into a C-SNP, but which does not provide for disenrollment at times outside the general enrollment period. Individuals who enroll mid-year in a C-SNP that is not appropriate for them must remain in that plan until the annual enrollment period. If the SEP is retained, CMS could add a SEP for disenrollment at any time. The current SEP has led to year-round marketing of C-SNPs, sometimes inappropriately, and resulted in concerns that plans are being marketed to people who may not be eligible to enroll in them.²⁵ D-SNPs and I-SNPs may enroll year round because the populations they target, duals and individuals in institutions, are entitled to the SEP. Unlike the SEP for C-SNPs, the SEP for D-SNPs and I-SNPs is not specific to any particular type of plan and allows the dual or institutionalized individual to enroll in or disenroll from all MA plans, except MSAs, at any time. The SEP for C-SNPs is problematic because it allows only for enrollment and not for disenrollment. Individuals who enroll mid-year in a C-SNP that is not appropriate for them must remain in that plan until the annual enrollment period.

Private Fee-for-Service (PFFS) Plans: MIPPA made a number of significant changes to PFFS plans. Effective January 1, 2011, most PFFS plans must establish contracts with providers. The Call Letter discusses the changes and how CMS intends to implement them. The Call Letter discusses two problem areas related to PFFS plans: provider payment and prior notification.

Provider Payment: CMS acknowledges receipt of numerous complaints that PFFS plans are not paying non-contract providers the traditional Medicare rate as required by statute. The Call Letter reminds plan sponsors that failure to pay the appropriate rates is a compliance matter, and that the agency previously issued a program memorandum concerning the process for resolving provider payment disputes. The Call Letter reiterates the expectation that plan sponsors will cooperate fully with the contractor that serves as the independent review entity for reimbursement adjudications.

Prior Notification: The Call Letter provides clarification concerning the difference between prior authorization/referral and prior notification, and reminds PFFS plans that they are prohibited from requiring prior authorization or referral. Under prior notification practices, plans charge increased cost-sharing for certain high-cost items and services if beneficiaries do not notify the plan in advance of obtaining those items and services. CMS reminds plans that they must cover a

service if they did not receive prior notification; the only difference is in the cost-sharing they may charge.

The prior notification process may be burdensome for some beneficiaries experiencing a health care crisis. Prior notification requirements and cost-sharing variations may not be transparent to enrollees, and the process for providing prior notification may not be explained adequately. Providers may be unaware of prior notification requirements when they prescribe or order an item or service for the beneficiary. CMS says it expects that PFFS will include in their marketing materials the cost sharing amount if prior notification procedures are not followed. Plans that do not clearly list prior notification policies or that treat the policies as prior authorization requirements will be subject to sanctions or civil money penalties.

CMS indicates that it is considering whether to issue proposed rules to prohibit the use of prior notification. If prior notification is not prohibited, CMS could include in future guidance increased transparency requirements, such as clearer notices in marketing materials, and caps on the amount plans may charge if prior notice is not received.²⁶

SECTION B – 2010 PRESCRIPTION DRUG PLANS

Section B of the Call Letter contains the provisions that are relevant to Part D prescription drug plans (PDPs). With the exception of the sections on plan bids and formulary submissions discussed earlier, this section contains few new policies for PDP sponsors. Some of the additional beneficiary protections, such as those involving utilization management criteria, are extensions of protections included in previous Call Letters.

INCREASED ACCOUNTABILITY

Plan Bidding Process and Audits: The 2009 Call Letter provided little guidance about the bidding process. CMS reminded plan sponsors of the need to comply with the instructions for submitting contracts and of the need to submit accurate, timely materials. Plan sponsors were warned that if they did not include all of the required information they might not get included in the *Medicare & You Handbook*, which is sent to every Medicare beneficiary in advance of the annual enrollment period in the fall.

The 2009 Call Letter addressed timely formulary submissions separately. Sponsors whose formulary submissions were untimely were informed that they “may face a CMS determination” that their bids could not be approved, resulting in the termination of their contract at the end of the plan year. CMS “would decline” to enter into contracts with new applicants that did not meet formulary submission deadlines.

The 2010 Call Letter, on the other hand, outlines substantial problems with application submissions by Part D sponsors. It indicates that, since implementation of Part D began in 2005, some plan sponsors submitted required documents that were so incomplete or inaccurate that they failed to constitute a valid, timely submission. CMS states that some sponsors might have knowingly submitted incomplete or inaccurate information to meet timelines and avoid non-renewal of the contract. For 2010, CMS will consider the completeness and accuracy of the application, formulary, and bid in determining whether a deadline has been met. The Call Letter includes examples of invalid submissions. Applications that include blank documents or blank spreadsheets will be denied as not meeting the definition of a completed application.²⁷

The 2010 Call Letter is more definitive in regard to formulary submissions and goes beyond the timeliness of the submission. CMS will not consider formulary submissions that do not show a good faith effort to provide a formulary that meets the requirements set out in the Part D Manual. Examples of inadequate formularies are those that include only one Part D drug in the majority of the formulary categories and classes or that include significantly fewer drugs than other Part D formularies. If a formulary submission is inadequate, CMS will either not renew the sponsor's existing contract or not enter into a new contract for failure to submit a timely formulary. CMS further advises that such a decision is not appealable.²⁸ Additionally, all contracts must be linked to the appropriate formulary. CMS will not check on contracts without formulary links, and those without timely links will be denied.

If, as the 2010 Call Letter indicates, problems have been apparent in the submission of bids since the inception of Part D, then CMS did not previously enforce the legal requirements for applying to offer a Part D plan. The 2010 Call Letter states clearly that the practices of some plan sponsors will no longer be tolerated.

Processing of Payment Requests: The Call Letter addresses two issues involving payment of claims. The first involves payment of pharmacy claims. Plan sponsors are reminded of the MIPPA requirement that, effective January 1, 2010, they must make prompt payments for retail pharmacy claims. MIPPA also requires that, effective on January 1, 2010, long-term care pharmacies are accorded between 30 and 90 days to submit claims for reimbursement.

The second issue involves processing of out-of-network reimbursement requests made by plan enrollees. CMS discusses plan compliance problems related to the time frames for reimbursement for out-of-network claims, and extends the time frames beyond those required by the regulations. The intent of CMS is to ensure that beneficiaries receive their reimbursements without having to go through the full appeals process. However, this contract provision modifies existing rules that went through the notice and comment rulemaking process. Federal law generally requires that existing regulations be modified through the issuance of a

notice of proposed rulemaking, which gives the public an opportunity to comment on the proposed change.

Quality and Performance Measures: The Call Letter indicates that CMS will be implementing new reporting requirements for 2010 based on proposed requirements published in the Federal Register for comment in January 2009. Additionally, CMS adds new expectations for quality assurance requirements involving concurrent drug utilization review, retrospective drug utilization review, and medication error identification and reduction.

The response times for complaints filed under the complaint tracking module, discussed under the section on Medicare Advantage plans, are the same for Part D plans.

Prohibition of Mid-Year Enrollment by State Pharmaceutical Assistance Programs (SPAPs): The Call Letter states that, as a result of complaints from Part D sponsors about SPAPs performing large numbers of mid-year plan enrollment changes, CMS is discouraging SPAPs with authority to make plan enrollments from making such mid-year changes. Additionally, CMS warns SPAPs that if they continue to make substantial mid-year changes, CMS may determine that the SPAPs fail to meet the definition of an SPAP. If that happens, payments made by these programs will not count towards the catastrophic coverage limit for SPAP enrollees.

SPAPs may change Part D enrollment for their SPAP enrollees during the plan year for a number of reasons, including if the plan did not cover the drugs needed by the individuals. However, such action may result in confusion on the part of plans. CMS could have announced it would investigate the reasons for such action as part of its increased oversight and accountability efforts.

PROMOTING INFORMED CHOICE AND EASE IN ENROLLMENT

Beneficiary Understanding of Benefits: The 2010 Call Letter places some focus on making sure that Medicare beneficiaries understand the information they need to choose and access drug coverage. In a new Call Letter section on beneficiary understanding of Part D benefits and the labeling of benefit designs, CMS discusses the four benefit types set out in its regulation. CMS further acknowledges that these distinctions do not provide all of the information beneficiaries use to choose a plan. For example, they do not indicate which drugs are on the plan's formulary or which pharmacies are in the plan's network.

The Call Letter includes a chart used in 2009 to describe levels of coverage in the coverage gap (i.e., "doughnut hole"). While the chart for 2009 is a good first step, the chart itself could be clarified. CMS says that it will continue to review comments regarding the calculation of gap coverage levels.

CMS also says that it is interested in receiving comments on the post-enrollment provision of benefits information to plan enrollees. They are particularly interested in how the Explanation of Benefits can be used to convey information.

BENEFICIARY PROTECTIONS

The 2010 Call Letter includes provisions designed to provide additional protections for beneficiaries. A number of those concern formulary issues and access to prescribed medications.

Access to Covered Part D Drugs: In 2006 CMS designated six classes of drugs as six classes of clinical concern. Drug plan sponsors are required to include all or substantially all drugs within those six classes on their formularies. MIPPA codified this requirement but was interpreted by some as possibly including more classes in the coverage requirement than just the six previously designated by CMS. The 2010 Call Letter states that for 2010 there will be no change in the six classes from those identified in the CMS guidance manual.

CMS proposes, starting in January 2010, to reject claims for national drug codes for which the Food and Drug Administration (FDA) is unable to provide regulatory status determinations through their regular processes. CMS states that plan sponsors should consider proper FDA listings concerning national drug codes when making a coverage determination. The Call Letter cautions current plan sponsors that any changes would apply to 2010, not 2009, and advises them to provide notice and information to pharmacy benefit managers and network pharmacies concerning national drug codes the sponsors decide not to cover under Part D.

CMS also advises of revisions to the formulary reference file to eliminate duplicate codes for the same drugs or to remove inactive or obsolete codes.

Transitions: The Call Letter continues efforts to ensure access to prescriptions when a beneficiary is faced with formulary changes. Starting for the 2010 contract year, plan sponsors will have the option to send required transition fill notices to network long-term care (LTC) pharmacies. This process may allow pharmacies to act more quickly to seek an exception or to have the medication filled. Notice to the pharmacy will be sent in addition to the model transition notice that is mailed to long-term care facility residents within three business days after a transition fill has occurred. Plan sponsors that choose to provide notice to the LTC pharmacy as well as to the enrollee will have to document the pharmacies' willingness to receive the notices, maintain electronic communications with the pharmacy once the transition fill has occurred, and be able to demonstrate that notice has been provided to the beneficiary.

Plan sponsors that change formularies for a subsequent plan year have transition requirements with regard to their current enrollees. The 2010 Call Letter clarifies

that the transition requirements also apply to prior authorization and step therapy restrictions that are added to drugs on the existing formulary. CMS could apply the transition requirements to new quantity limits as well, or require plans to advise the beneficiary of coverage changes in the specific drugs they take.

Specialty Tier Threshold: When drug plan sponsors utilize a specialty tier for high-cost drugs, plan enrollees who rely on these drugs pay high cost-sharing for the drugs, ranging from 25% to 33% of the cost of the drug. In addition, current CMS regulations preclude beneficiaries from seeking a tiering exception for these drugs as a way to reduce the cost-sharing amount. The Medicare Payment Advisory Commission (MedPAC) issued a recent report that found that four classes of drugs (antineoplastics, immunologics, antivirals, and antibacterials) account for two-thirds of specialty tier drugs. They also found that specialty tier drugs vary greatly from plan to plan, with 40% of such drugs being listed on a specialty tier in fewer than half of all plans. Additionally, specialty tier drugs are subject to utilization management much more frequently than other drugs.²⁹

The Call Letter states that CMS will continue to analyze and evaluate the specialty tier for high cost and unique drugs, and it will maintain the \$600 threshold for drugs to be placed on a specialty tier. However, as part of its formulary review, CMS will evaluate formularies to ensure that they do not discourage certain classes of beneficiaries from enrolling. CMS encourages continuing discussion of its specialty tier policy and the need for rulemaking.³⁰

Reference-Based Pricing: CMS eliminates the practice of reference based pricing for 2010. Under this practice, plan sponsors require beneficiaries to pay a cost-sharing amount in addition to the tiered-cost sharing for designated brand name drugs. The practice generated confusion among beneficiaries during the fall 2008 annual enrollment period due to the lack of transparency of the actual price of their drugs.

Utilization Management: The Call Letter includes plan submission requirements to make it easier for CMS to review new 2010 or modified 2009 utilization management criteria. It also includes additional directions, based on common errors in previous submissions that sponsors must follow in order to be compliant with CMS guidance.

CMS will return formulary submissions with utilization management criteria that are inconsistent with widely used treatment guidelines or which have significant quality control issues. Such submissions may be subject to a focused audit to determine whether the plan's Pharmacy and Therapeutic Committee reviewed the criteria before submission. Plans that continue the practice, as identified for plan year 2009, of attempting to use prior authorization criteria to limit access to only some of the FDA-approved labeled indications will have their criteria returned. The criteria will be rejected if the plan sponsor does not submit reasonable justifications. Plans will not be allowed to require enrollees to try an

off-label indication first unless the off-label use is supported by guidelines that represent best practices. Plans are warned against criteria such as requiring an enrollee to try and fail more than two formulary alternatives to the prescribed medicine.

CMS warns sponsors that it will return formulary submissions without review if there are many errors or if the sponsor fails to follow CMS guidance, with the result that their formularies may not be filed in time. CMS also reminds sponsors that it will continue to evaluate utilization management criteria against exceptions and appeal statistics and beneficiary complaints to determine whether they meet current medical practice and allow access to covered drugs.

To promote additional transparency of utilization management criteria, CMS is also requiring plan sponsors to post submitted step therapy requirements on their web sites. In 2009, CMS required the posting of prior authorization criteria.

The Call Letter language concerning utilization management criteria addresses some but not all of the problems beneficiaries encounter. CMS in the future could preclude sponsors from applying such criteria to all of the drugs in a particular category or class. CMS also could clarify problems with the plan sponsors' application of the exception and appeals process to utilization management criteria. For example, some plans that impose multiple criteria on one drug will require a beneficiary who seeks an exception for one criterion, for example prior authorization, to then seek a second exception for the second criterion in order to get access to the drugs. Additionally, CMS could clarify the relationship between prior authorization, on the one hand, and step therapy and quantity limits on the other.

Medication Therapy Management (MTM): For the first time, the Call Letter provides detailed requirements for MTM programs. The requirements address enrollment, targeting, intervention and outcomes-reporting and are based on what CMS identified as best practices in these areas. CMS states that all Part D sponsors, with the exception of PFFS plans, must follow the requirements in establishing their program. CMS reminds PFFS plans that they have an equal responsibility to provide a quality drug benefit and, using language common to previous Call Letters, encourages PFFS organizations to establish their own MTM programs.

Starting in 2010, plans must enroll beneficiaries in an MTM program with an opt-out process. The plans must target beneficiaries for enrollment at least quarterly, and the plans cannot require targets of the MTM program to have more than three chronic diseases. The Call Letter includes a list of seven core chronic diseases to target. Sponsors will be expected to have procedures to increase participation and to reach targeted enrollees through various approaches. CMS reduces from \$4,000 to \$3,000 the minimum annual cost threshold that targeted individuals are likely to incur.

The Call Letter includes minimum services to be included as part of the MTM program. It also includes requirements as to the services to be measured and reported to CMS. CMS expects sponsors to analyze and evaluate their programs and make continuous improvements.

The standards included in the Call Letter result from reviews conducted by CMS of current MTM programs. The fact that CMS mandates requirements and standards is a departure from previous policies towards the design of the Part D benefit.

LOW-INCOME SUBSIDY (LIS) POLICY

The 2010 Call Letter contains only a limited discussion of LIS policy issues. For example, it does not describe new requirements for plans concerning the best available evidence (BAE) process for beneficiaries to establish that they are eligible for the low-income subsidy. The provisions in this section provide no indication of potential policy shifts for LIS-eligible beneficiaries.

Reassignment of LIS-eligible Individuals: Re-assignment of LIS-eligible individuals when their PDP fails to qualify as an LIS plan for the following plan year remains a problem. The Call Letter states that CMS expects to reassign LIS-eligible individuals again in the fall of 2009. It also states that CMS will work with plans to reach out to their enrollees who are being reassigned to explain how to remain in the plan and their potential premium liability.

CMS says it is continuing to study the problem of reassignment. The agency encourages suggestions to improve the process that are consistent with its existing statute.

Retroactive Auto-Enrollment of Full Benefit Dual Eligible Individuals: The Call Letter describes the intention of CMS to implement in 2010 a demonstration contract to assign new full benefit dual eligible beneficiaries with retroactive coverage to a single contractor for the retroactive periods. The demonstration does not address reimbursement issues for all LIS-eligible individuals who paid premiums and cost-sharing out-of-pocket while their Medicaid or LIS applications were pending.

SECTION C – MARKETING/BENEFICIARY COMMUNICATIONS

Reports of unscrupulous marketing practices by some MA plans and PDPs, their brokers, and agents have generated publicity since the Part D program began in 2006. MIPPA included provisions addressing some of the problems. CMS has issued memoranda and other marketing guidance, as well as rules to implement the MIPPA changes. The agency has taken corrective action measures against plans that violate marketing rules. CMS has also used the Call Letter as a

vehicle to provide updates and clarifications about permissible and non-permissible marketing practices.

The 2010 Call Letter, as in past Call Letters, addresses marketing problems. It includes a list of some of the surveillance activities the agency has under taken and will continue in order to monitor marketing activities. The Marketing section begins with the following:

“CMS will not accept any continued attempts by some in the industry to avoid complying with our marketing requirements and guidance. CMS will take very strong action against any entity attempting to circumvent our rules.”

It concludes with the reminder:

“...[R]epeated violations that demonstrate a pattern of misconduct will be considered more substantial violations than those that merited initial noncompliance notices and warning letters this past [Annual Enrollment Period.]”

The Marketing section of the 2010 Call Letter contains strong language to encourage plan sponsors to comply with marketing requirements.

Payment of Agents: Before the 2008 Annual Enrollment Period, agents received substantially higher commissions and other remuneration for enrolling beneficiaries in MA plans than in PDPs. This disparity in compensation rates was considered one of the factors that induced agents to engage in marketing abuses.³¹ As a result, CMS, as required by MIPPA, published rules in September 2008 and additional guidance throughout the fall enrollment period concerning agent compensation.

The 2010 Call Letter provides two clarifications to plan sponsors about one of the provisions of the new rules concerning the amount that can be paid to agents and brokers. One clarification allows plan sponsors to pay agents their base fee for 2009 before CMS issues reports identifying new enrollees to PDPs or MA plans, with adjustments made after the reports are released. The other is a direction to cease immediately attempts to circumvent the new agent compensation limits by paying exorbitant referral fees to agents. CMS emphasizes that the practice is out of compliance with its new regulations and guidance and cites its new regulatory provision.

Marketing Materials: CMS reminds plan sponsors that all marketing materials must be reviewed and approved by CMS before they are used, including third party marketing materials developed by agents and others. The Call Letter creates an exception for generic materials that do not discuss plan specific information. CMS could do limited spot checking of such materials to ensure that plans and agents do not take advantage of this exception.

CMS announces in the Call letter that it will make minor changes to some Part D marketing materials for 2010 and will release the updated materials at a later date. Some of the proposed changes are designed to provide beneficiaries with more information. They include an indication in the evidence of coverage of the formulary cost-sharing tiers to which drugs that were approved as part of the exception process will be assigned, and a new model notice to be used when plans transfer prescriptions from network retail pharmacies to network mail-order pharmacies without enrollee consent.

Standardization of Plan Name Type: For plan years that begin on January 1, 2010, MIPPA requires all MA plans and PDPs to include the plan type as part of their name. As required by MIPPA, CMS developed standard terminology to be used as part of the name, and included the list in the Call Letter. There are 18 different plan types listed. The list does not account for the benefit package variations within each of these types of plans. Not all beneficiaries are eligible to enroll in all plan types, and not all plan types will be available in every part of the country. CMS could use the list as a starting point for discussions on the advisability of limiting the number of plans each sponsor may offer and developing standardized benefit packages.

Other Marketing Activities: As part of its continued vigilance over marketing activities, CMS could take additional steps to improve the information provided to beneficiaries. These range from adopting the recommendations in the White Paper developed by the National Association of Insurance Commissioners (NAIC)³² to precluding marketing after the end of the statutory enrollment period. Many marketing violations may occur after that time period. For example, agents may target PDP members who are unhappy with their drug coverage to encourage them to enroll in an MA plan, or may target beneficiaries who are eligible for a special enrollment period.

CONCLUSION

The 2010 Call Letter provides insights into how the new administration may interact with Medicare Advantage and Part D prescription drug plans. It emphasizes compliance with rules, regulations, and guidance. CMS acknowledges that some problem areas warrant additional consideration, and seeks input on how to make the program work more efficiently for beneficiaries, plan sponsors, and health care providers. CMS confirms its commitment to continue and strengthen its oversight of marketing activities and other areas such as enrollment and appeals, to help beneficiaries understand health plan options available to them, and receive the benefits to which they are entitled as MA or PDP enrollees.

¹ See, generally, 42 C.F.R. 422 Subpart F, 423 Subpart, Subpart F, for the bid submission and plan approval processes. 42 C.F.R. Part 422 contains the rules pertaining to Part C, and 42 C.F.R. Part 423 contains the rules pertaining to Part D.

² 42 C.F.R. §§ 422.62 ; 423.38.

³ See 2010 Call Letter,

<http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/2010CallLetter.pdf>

⁴ Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Pub. L. 110-275 (July 15, 2008).

⁵ A medical loss ratio is the percentage of premium dollars spent by health plans on medical care rather than on administration, marketing, and profit. The GAO has determined that in 2007 MA plans had, on average, a medical loss ratio of 0.87, meaning that they allocated about eight-seven percent (87%) of their revenue towards medical expenses. They also found, however, that the medical loss ratio varied among plans. GAO, *Medicare Advantage Organizations: Actual Expenses and Profits Compared to Projections for 2006* (GAO-09-132R, Dec. 8, 2008); <http://www.gao.gov/new/items/d09132r.pdf>. The law currently does not define a minimum medical loss ratio for MA plans, although plans may be subject to minimum loss ratios required in some states for licensure. Nor does it require that the information be made available to beneficiaries. Because various stakeholders had requested that the information be made public, CMS solicited comments in the draft Call Letter on how the medical loss ratio should be calculated in order to assist in making a decision about publication of the information

⁶ Compare 2010 Call Letter, Section A. II. Benefit Design, Plan Corrections for 2010 (pg 14), available at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/2010CallLetter.pdf>; with 2009 Call Letter, Section A. I. Benefit Design, C. Plan Corrections for 2009, pg 11, available at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CallLetter.pdf>. Note also that the 2010 Call Letter add to this section the regulation that requires actuarial certification and bid attestation.

⁷ <http://www.cms.hhs.gov/MCRAAdvPartDENrolData/>

⁸ For 2010, the Part C measures are benefit utilization, grievances, organization determinations/reconsiderations, and agent compensation structure. The Part D measures are grievances, exceptions and appeals, and drug benefit analysis. Call Letter at pg 28.

⁹ 42 USC 1395w-227(d)(1).

¹⁰ GAO, *Medicare Advantage: Required Audits of Limited Value*, (GAO -07-945 July 2007), <http://www.gao.gov/new.items/d07945.pdf>.

¹¹ Call Letter at pg 12.

¹² 42 USC 1395w-27(b).

¹³ 42 C.F.R. § 417.430.

¹⁴ In 2005 CMS began “passively enrolling” Medicare beneficiaries into Medicare Advantage plans by enrolling 200,000 individuals dually eligible for Medicare and Medicaid (dual eligibles) into Medicare special needs plans (SNPs) rather than into PDPs for their prescription drug coverage. The case challenging the authority of CMS to enroll into MA plans Medicare beneficiaries who did not enroll voluntarily into those plans was settled. *Erb v. McClellan*, No. 2:05-cv-6201 (E.D.Pa, filed Nov. 30, 2005).

¹⁵ Medicare Managed Care Manual, Chapter 2 Medicare Advantage Enrollment and Disenrollment, § 30.4.3,

<http://www.cms.hhs.gov/MedicareMangCareEligEnrol/Downloads/2009MAenrollmentguidance.pdf>.

¹⁶ See, Center for Medicare Advocacy, *Medicare Cost-Sharing for Dual Eligibles: Who Pays What for Whom?* (April 24, 2008); http://www.medicareadvocacy.org/MedSavProgs_08_04.24.CostSharing.htm.

¹⁷ 73 Fed. Reg. 54226 (Sept. 18, 2008).

¹⁸ 42 C.F.R. 422.504(g)(iii).

¹⁹ GAO, *Medicare Advantage: Increased Spending Relative to Medicare Fee-for-Service May Not Always Reduce Beneficiary Out-of-Pocket Costs*, (GAO 08-359 Feb. 2008), <http://www.gao.gov/new.items/d08359.pdf>.

²⁰ Kaiser Family Foundation, *Medicare: A Primer (2009)*; <http://www.kff.org/medicare/upload/7615-02.pdf>.

²¹ See CMS Memorandum to All Part D Sponsors, Home Infusion Therapy (March 10, 2006), <http://www.cms.hhs.gov/States/Downloads/HomeInfusionLetter.pdf>.

²² Residents of long-term care facilities who require home infusion therapy services may have the home infusion drugs paid for under Part D, but must find other payment sources for the services and supplies needed to deliver the home infusion therapy drugs.

²³ 73 Fed. Reg. 54226 (Sept. 18, 2008); (74 Fed. Reg. 1494) (Jan 12, 2009).

²⁴ 42 USC 1395i-3(b)(3), 1396r(b)(3).

²⁵ “CMS understands that there is continued concern that some MA organizations offering C-SNPs may be enrolling beneficiaries who do not have the chronic condition(s) for which the C-SNP is structured.” Call Letter, supra, at Section IX. Special Needs Plans, Verifying Chronic Conditions for Enrollees in Chronic Condition Special Needs Plans, pg. 38.

²⁶ In its December 2008 report on PFFS plans, the GAO gave as the example of a PFFS plan that charged 30% co-insurance for durable medical equipment if the beneficiary or provider pre-notified the plan, and 70% co-insurance if no pre-notification was received. GAO, Medicare Advantage: Characteristics, Financial Risks, and Disenrollment Rates of Beneficiaries in Private Fee-for-Service Plans (GAO, 09-25 Dec. 2008), <http://www.gao.gov/new.items/d0925.pdf>. Note that the 30% co-insurance exceeds the 20% co-insurance required under traditional Medicare.

²⁷ The Call Letter cites 42 C.F.R. 423.502(b); 423.503(c).

²⁸ The Call Letter cites to 42 C.F.R. 423.272(b)(ii); 423.506(d).

²⁹ *Drugs on Specialty Tiers in Part D* (February 2009),

http://www.medpac.gov/documents/Feb09_DrugsonSpecialtyTiers_CONTRACTOR_RS.pdf.

³⁰ The statutory provision establishing the exception process contains no exemption to the right to request a tiering exception. 42 USC 1395w-104(g)(2).

³¹ See, e.g., California Health Advocates, Medicare Rights Center, *After the Goldrush: the Marketing of Medicare Advantage and Part D Plans* (2007),

http://www.cahealthadvocates.org/_pdf/advocacy/2007/AfterTheGoldrush.pdf.

³² NAIC, *White Paper on Regulation of Medicare Private Plans* (Sept. 2008),

http://www.naic.org/documents/committees_b_senior_issues_medpp_white_paper_final.pdf.



The Henry J. Kaiser Family Foundation

Headquarters

2400 Sand Hill Road
Menlo Park, CA 94025
phone: 650.854.9400
fax: 650.854.4800

**Washington Offices and
Barbara Jordan Convergence Center**

1330 G Street, NW
Washington, DC 20005
phone: 202.347.5270
fax: 202.347.5274

www.kff.org

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