

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

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CENTER FOR DRUG and HEALTH PLAN CHOICE

DATE: September 15, 2008

TO: Medicare Advantage Organizations
Medicare Advantage-Prescription Drug Organizations
Cost-Based Contractors
Prescription Drug Plan Sponsors
Employer/Union-Sponsored Group Health Plans

FROM: Abby L. Block, Director, Center for Drug and Health Plan Choice (CPC)

RE: Guidance for regulations in CMS 4131-F and CMS 4138-IFC

I am pleased to provide this guidance as an update/supplement to the Medicare Marketing Guidelines to help you implement the recently released regulations, CMS 4131-F and CMS 4138-IFC, which include changes to the Medicare Advantage and Medicare Prescription Drug Programs. Because the CMS Marketing Guidelines apply to the Cost plans as well as MA and PDP plans, some of this guidance that applies to MA and PDP plans also has applicability to cost-based contractors. This document also provides guidance on a provision of the Medicare Improvements for Patients and Providers Act (MIPPA) (Pub. L. 110-275) that affects only cost plans. This memo focuses on information designed to help you fulfill the requirements for the 2009 marketing and contract year. Guidance for provisions that are effective at later dates may be included in separate guidance documents, such as the 2010 Call Letter. As you prepare for CY2009, it is essential that you also review all program requirements, the Managed Care and Prescription Drug Benefit Manuals, Health Plan Management System (HPMS), and other CMS guidance for comprehensive information on both programs.

CMS will be engaging in a wide-variety of oversight and surveillance activities beginning with this fall's 2009 plan year marketing season. We are confident that the release of this information will help you implement CMS policies and procedures and comply with critical program requirements.

Guidance for regulations in CMS 4131-F and CMS 4138-IFC

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I. 1876 Cost Plan Guidance

A. Extending Effective Date of Cost Plan Competition Provisions

No regulatory reference

Effective immediately

Section 167 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) revised section 1876(h)(5)(C) of the Act to provide that, beginning January 1, 2010, Cost plans may not renew a contract in a service area, or portion of a service area, if during the previous year, two or more organizations offering a local Medicare Advantage (MA) plan meet a minimum enrollment test, or two or more organizations offering a regional MA plan meet the same test. Cost plans not having competitors meeting these requirements in an area may expand their service areas to that area as long as they meet all other regulatory requirements. As has been the case since 1997, CMS cannot approve new Cost contracts.

As a result of the new date established by MIPPA, a Cost plan in markets that do not meet the enrollment test will receive a non-renewal notice in 2010, based on enrollment data from the previous year, and would be unable to offer a plan beginning in 2011 - the first year a plan could be prohibited based on the MIPPA requirement. (See additional clarifications related to this provision below.)

B. Clarifying the Conditions under which 1876 Cost Plans or Portions of their Service Areas May Be Prohibited

42 CFR 417.402(c)(1)-(3) -- CMS 4138-IFC

Effective date: September 18, 2008

Section 167 of MIPPA revised section 1876(h)(5)(C) of the Act to clarify the rules prohibiting the renewal of a cost plan, or a portion of a cost plan's service area in an area where, during the previous year, two or more organizations offering a local MA plan meet a minimum enrollment test, or two or more organizations offering a regional MA plan meet the same test. The test is that the local or regional plan must have at least 5000 enrollees in any portion of its service area that includes a Metropolitan Statistical Area (MSA) with a population over 250,000 (enrollment in counties contiguous to the MSA count toward the 5000) and enrollment of at least 1,500 in the other portion of its service area. MIPPA clarified that--

- The two plans triggering the prohibition may not be offered by the same MA organization.
- If a cost plan's service area falls within more than one MSA with a population over 250,000 and the local or regional plans have a minimum of 5000 enrollees, the determination to prohibit a plan will be made with respect to each MSA and counties contiguous to each MSA. In other words, if a cost plan's service area or portion of a service area lies within two MSAs, then two local or regional plans meeting the minimum enrollment requirements in one MSA would prohibit the offering of the cost plan in the one MSA and allow the cost plan to continue to operate in the other.

- If a cost plan's service area or portion of a service area falls in one MSA only, the determination to prohibit a plan will be based on the competing local or regional plans' enrollments in that MSA only.
- Cost plans are only required to vacate the service area or portion of service area where the actual competition exists.

II. SNP Guidance

A. Model of Care

42 CFR 422.101(f) - CMS 4138-IFC

Effective date: January 1, 2010

In the 2009 Call Letter, CMS discussed its requirement that Special Needs Plans (SNP) have a model of care (MOC), namely, a structure and process by which they delivered healthcare services and benefits to the special needs individuals they elected to target. We emphasized that, as MA plans, we expected all SNPs to offer coordinated care delivered by a network of providers who had the clinical expertise to meet the target population's specialized needs, and who did not discriminate against its most vulnerable beneficiaries. The Call Letter guidance substantively fleshed out the SNP MOC architecture by describing eight components designed to support service delivery for special needs individuals. These components included:

- 1) Goals and objectives pertinent to the plan's targeted special needs beneficiaries
- 2) Comprehensive risk assessment using a risk assessment tool
- 3) Specialized provider network
- 4) Care coordination
- 5) Service delivery system including protocols and out-of-network specialists
- 6) Communication and accountability system
- 7) SNP training for network providers
- 8) Performance measurement and improvement activities

The Call Letter also indicated that we would review the SNP MOC during regularly scheduled MA organization audits.

MIPPA added new specific statutory requirements pertaining to a SNP MOC. Beginning January 1, 2010, all SNPs must not only have an evidence-based care model with specialized providers, but must also have care management services that add the following components:

1. A comprehensive initial health risk assessment and annual reassessment of the physical, psychosocial, and functional needs of the special needs individual;
2. A care plan for each beneficiary that addresses goals and objectives, services and benefits provided, and measurable outcomes; and
3. An interdisciplinary team used in the care management of each beneficiary.

In the preamble of CMS 4138-IFC, we briefly discussed these new MIPPA requirements and are expanding our guidance in this compendium. First, SNPs are responsible for implementing an evidence-based MOC, a requirement which can be accomplished in several ways. Many existing SNPs have either a Medical Director or medical advisory committee who can monitor peer-reviewed medical journals and infuse research-supported systems and practices into its care management model. SNPs can contract with providers who use nationally-recognized clinical protocols developed by professional medical specialty societies or federally financed research scientists (see National Guideline Clearinghouse, Agency for Healthcare Research and Quality, at <http://www.guideline.gov/>). SNPs can also contract with providers who are accredited by nationally recognized quality and healthcare safety accreditation organizations whose standards assure evidence-based practice. Regardless of what approach is taken, SNP management must be able to articulate how this requirement is met and measure the extent to which evidence-based care management is ongoing.

Secondly, MIPPA is requiring that SNPs not only conduct an initial comprehensive health risk assessment, but also a comprehensive annual reassessment. The health risk assessment includes a medical, psychosocial, cognitive, and functional assessment that guides care management and accounts for health status changes. We expect the initial risk assessment to be conducted within ninety (90) days of enrollment and the annual risk assessment to be done within 12 months of the last risk assessment. Special needs individuals are likely to have labile health status and need more frequent assessments; consequently, annual reassessment should be adjusted to coincide with health status changes, not a fixed schedule tied to the initial assessment date.

Finally, MIPPA mandated an individualized care plan and an interdisciplinary care team for the care management of each beneficiary. The care plan must include essential care management elements such as goals and objectives, standard and specialized services and benefits that meet the specialized needs identified in the initial and subsequent risk assessments, and measurable outcomes that enable the SNP to determine the effectiveness of the care management plan. The care plan should reflect a stratification of needs matched to services and benefits in which the most vulnerable and sickest beneficiaries receive care proportionate to their increased needs. SNPs have latitude in determining the composition of the interdisciplinary care team for each beneficiary. They may adopt a standard team construct or consider each beneficiary's risk assessment results to develop a unique team. For example, a chronic condition SNP may adopt a standard interdisciplinary care team modeled on a disease management paradigm and composed of a primary care provider, clinical pharmacist, nurse educator, and disease-specific medical specialists. An institutional SNP having institutional equivalent beneficiaries living in the community may have an interdisciplinary team comprised of a geriatrician, clinical pharmacist, discharge-planning nurse, restorative therapist, and geriatric psychiatrist. SNPs may also consider having other interdisciplinary team members be social workers, pastoral counselors, or caregiver/family members. Regardless of how the care team is developed, the SNP must design its teams to meet this MIPPA requirement, and must measure the effectiveness and extent to which each beneficiary's care is managed by an interdisciplinary care team.

B. Quality Improvement Program

42 CFR 422.152 – CMS 4138-IFC

Effective date: January 1, 2010

As a Medicare Advantage organization (MAO), all SNPs are required to have a quality improvement program. Existing CMS regulations stipulate that the MAO quality improvement program must include a chronic care improvement program and quality improvement projects that measure and demonstrate improvement in health outcomes and beneficiary satisfaction. MIPPA has further focused quality improvement requirements by directing SNPs to examine, measure, and improve care management for special needs individuals. Beginning on a date to be determined by CMS, but no later than January 1, 2010, SNPs must collect, analyze, and report data that measures health outcomes and quality indices of care management.

In the preamble of CMS 4138-IFC, we described the SNP quality improvement program as a three-tiered program. The first tier consists of the mandatory collection and reporting of data using thirteen HEDIS measures and three structure and process measures. CMS requires all Plans to participate in this assessment activity to meet its strategic goal of achieving confident, informed consumers through transparent public reporting on health plan performance. CMS is collaborating with the National Committee on Quality Assurance (NCQA) on a three-year initiative to refine SNP reporting measures and make them relevant to special needs individuals.

The second tier reflects the quality improvement requirements established in the January 28, 2005 final rule implementing changes to Part C made in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). SNPs, as an MA coordinated care plan, must have a chronic care improvement program and quality improvement projects to favorably impact health outcomes and beneficiary satisfaction. MIPPA elaborated on the quality improvement program required under MMA by directing SNPs to collect, analyze, and report data measuring health outcomes and quality indices pertaining to special needs individuals at the plan level as well as measuring the effectiveness of care management and their model of care. SNPs can meet both directives by making the collection and analysis of health outcomes and quality indices pertaining to special needs individuals the focus of their quality improvement projects and chronic care improvement program. For example, existing SNPs have indicated that they collect and analyze data from a variety of sources (claims, medical record reviews, pharmacy records, surveys, etc.) to measure service utilization rates (preventive care visits, hospitalizations, emergency room visits, etc.), functional status changes, complaints and grievances, disease management outcomes, and beneficiary satisfaction in an effort to improve service delivery and health status among their enrollees. SNPs should use existing validated measures that could include, but are not limited to, MDS¹, HEDIS, ACOVE², and OASIS³ measures pertinent to their special needs individuals to assess quality and health outcomes within the context of their chronic care improvement program and quality improvement projects. SNPs should also draw their measures from a variety of healthcare domains. Suggested healthcare domains include end-of-life care, functional status, care coordination, care transitions, behavioral health, patient safety, medication management, clinical outcomes, and family/caregiver support. The following examples illustrate the collection of data using validated measures from different health care domains.

- Clinical outcome: If a vulnerable elder has diabetes, then his or her glycated hemoglobin level should be measured at least every 12 months (see ACOVE measures referenced in footnote below).
- Behavioral health: Prevalence of symptoms of depression in nursing home residents without antidepressant therapy (see MDS 3.0 measures referenced in footnote below).

- Medication management: Percentage of beneficiaries receiving home health services who have been assessed to determine their ability to independently take the correct oral medication(s) and proper dosage(s) at the correct times.

CMS is developing the third tier of the quality improvement program. This tier involves CMS monitoring of care management implementation through the collection, analysis, and reporting to CMS of selected data that measure the effectiveness of SNP models of care. We will identify measures (including the consideration of the validated measures currently used by SNPs) to monitor implementation of the model of care. We intend to use these data to track the performance of SNP models of care in meeting a second CMS strategic goal, the achievement of high-value health care for high risk populations. Additional guidance regarding the development of monitoring measures will be forthcoming.

C. Comprehensive Written Statement for Prospective Enrollees

42 CFR 422.111(b)(2)(iii) - CMS 4138-IFC

Effective Date: January 1, 2010

MIPPA outlined new provisions for dual Special Needs Plans (SNPs). Section 164(c)(3)(C) requires dual SNPs to provide each *prospective* enrollee, *prior* to enrollment, with a comprehensive written statement (using standardized content and format established by the Secretary) that describes the benefits and cost-sharing protections that the individual is entitled to under title XIX. Additionally, the comprehensive written statement must describe which of those benefits and cost-sharing protections are covered under the specific special needs plan for dual individuals. It is intended that providing prospective enrollees with this information prior to enrollment will give individuals enough information to compare the benefit packages of dual SNPs and to make an informed choice.

CMS disseminated a memo dated August 15, 2008, with the subject “CY 2009 Summary of Benefits Global Hard Copy Changes, Model Transition Letter, and Required Changes to the Standardized EOC Due to the Medicare Improvements for Patients and Providers Act of 2008,” which detailed information on Global Hard Copy changes permitted in the Summary of Benefits (SB) without prior approval from CMS Central Office. It included the permissible hard copy changes in SB for SNPs. It stated that “plans may include a Section 4 to the SB to list additional Medicaid benefits not covered by Medicare.” Plans should include the required comprehensive written statement in Section 4 of the SB.

D. SNP Cost-Sharing

42 CFR 422.504(g)(1)(iii) - CMS 4138-IFC

Effective Date: January 1, 2010

MIPPA outlined several new provisions for Special Needs Plans (SNPs). One such provision put a limitation on out-of-pocket costs for full-benefit dual eligibles or qualified Medicare

beneficiaries. MIPPA states that for individuals who are full-benefit dual eligibles (as defined in section 1935(c)(6) of the Act) or those who are qualified Medicare beneficiaries (as defined in section 1905(p)(1) of the Act) and who are enrolled in a MA plan for special needs individuals described in section 1859(b)(6)(B)(ii), that the plan may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under title XIX if the individual were not enrolled in such plan.

In our May 18, 2008 proposed rule, we proposed to require that such protection be provided by all MA plans to dual eligible enrollees, not just those enrolled in SNPs. In a future final rule, we will decide, based on comments received, whether to finalize this proposal, which would go beyond what Congress required in MIPPA.

Footnotes:

¹ Minimum Data Set 3.0 (MDS) measures can be found at <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf>

² Assessing Care of Vulnerable Elders (ACOVE) measures can be found at <http://www.rand.org/health/projects/acove/acove3/>

³ OASIS outcome measures can be found at http://www.cms.hhs.gov/HomeHealthQualityInits/10_HHQIQualityMeasures.asp#TopOfPage

III. PFFS Plan Guidance

A. Variation in Payment Rates to Providers

42 CFR 422.4(a)(3)(ii) and 42 CFR 422.216(a) – CMS 4138-IFC

Effective date: September 18, 2008

Section 162(b) of MIPPA added a clarification to the definition of an MA PFFS plan found at section 1859(b)(2) of the Act. Prior to MIPPA, the statute defined an MA PFFS plan as an MA plan that pays providers at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk; does not vary the rates for a provider based on the utilization of that provider's services; and does not restrict enrollees' choice among providers who are lawfully authorized to provide covered services and agree to accept the plan's terms and conditions of payment. Section 162(b) of MIPPA added that although payment rates cannot vary based solely on utilization of services by a provider, an MA PFFS plan is permitted to vary the payment rates for a provider based on the specialty of the provider, the location of the provider, or other factors related to the provider that are not related to utilization. Furthermore, this section of MIPPA also allows MA PFFS plans to increase payment rates to a provider based on increased utilization of specified preventive or screening services. We added these clarifications to 42 CFR §422.4(a)(3)(ii).

The MIPPA provision permitting payments to vary based on provider specialty or location, or "other factors" not related to utilization constitutes a limited exception to the uniform payment requirement for PFFS in 42 CFR §422.216(a)(1)(i). Previously, under the uniform payment requirement, a PFFS plan was required to establish uniform payment rates in its terms and conditions of payment for items and services that applied to all contracting providers, regardless

of whether the provider had a direct contract or was deemed to have a contract with the plan, and was required to pay all providers (whether deemed or direct contracting) at the applicable payment rates set forth in its terms and conditions of payment.

PFFS plans are still required to establish uniform payment rates for providers in their terms and conditions of payment at levels that meet Medicare access requirements under 42 CFR §422.114(a). However, plans will now have the flexibility to establish through agreement with specific providers payment rates that are above the rates listed in the terms and conditions that would otherwise apply as long as the variations in payment rates are not based on utilization (as described above). Except for payment rates, PFFS plans may not vary other provisions of the terms and conditions for deemed providers.

PFFS plans may utilize the flexibility to establish provider-specific payment rates to encourage participation by providers who otherwise would not have agreed to accept the payment rates listed in the terms and conditions of payment. For example, a PFFS plan that lists a payment rate of 100% of Original Medicare for cardiology services in the terms and conditions of payment that apply to deemed providers can establish a higher provider-specific payment rate (e.g., 110% of Original Medicare) to encourage a provider in a rural area to provide these services.

A PFFS plan that intends to increase payment rates to a provider based on increased utilization of specified preventive or screening services may indicate this information in its contracts with providers and/or terms and conditions of payment if the plan intends for this policy to apply to all providers. However, the plan may also choose to apply this policy on a provider-by-provider basis.

MIPPA allows PFFS plans to vary payment rates among contract providers as long as the different rates are not based on utilization, with the payment rates being effective according to the terms of the contract between the plan and the provider. As described above, MIPPA also allows PFFS plans to vary payment rates among deemed providers; however, it should be noted that all deemed providers have the right to decide, on a patient-by-patient and visit-by-visit basis, whether to treat plan members unless the provider enters into a specific agreement or contract with the plan to see patients over an certain period of time.

PFFS plans must maintain a record of all provider-specific payment rates that they negotiate with providers along with the final rates paid. PFFS plans must also have the capacity to report this information to CMS or to an independent entity contracted by CMS upon request.

B. Requirement for Certain Non-Employer PFFS Plans to Use Contract Providers

42 CFR 422.114(a)(3) – CMS 4138-IFC

Effective date: January 1, 2011

Section 162(a)(1) of MIPPA amended section 1852(d) of the Act by creating a new requirement for certain non-employer MA PFFS plans to establish contracts with providers. Specifically, for plan year 2011 and subsequent plan years, MIPPA requires that non-employer/union MA PFFS plans that are operating in a network area (as defined in section 1852(d)(5)(B) of the Act) must meet the access standards described in section 1852(d)(4)(B) of the Act through contracts with providers. As discussed in C. below, section 1852(d)(4)(B) of the Act, as amended by MIPPA, now requires that these PFFS plans must have contracts with a sufficient number and range of providers to meet the accessibility and availability access standards described in section 1852(d)(1) of the Act. These PFFS plans may no longer meet access standards by paying not less than the Original Medicare payment rate and having providers deemed to be contracted as provided under §422.216(f). Section 162(a)(1) of MIPAA is reflected in regulations at 422 CFR §422.114(a)(3).

“Network area” is defined in section 1852(d)(5)(B) of the Act, for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as having at least two network-based plans (as defined in section 1852(d)(5)(C) of the Act) with enrollment as of the first day of the year in which the announcement is made. For plan year 2011, we will inform PFFS plans of their network areas in the announcement of CY 2010 MA capitation rates, which will be published on the first Monday of April 2009. We will use enrollment data for January 1, 2009 to identify the location of “network areas.”

“Network-based plan” is defined in section 1852(d)(5)(C) of the Act as (1) an MA plan that is a coordinated care plan as described in section 1851(a)(2)(A)(i) of the Act, excluding non-network regional PPOs; (2) a network-based MSA plan; or (3) a section 1876 cost plan. Types of coordinated care plans that meet the definition of a “network-based plan” are HMOs, PSOs, local PPOs, as well as regional PPOs for the PPO’s service areas substantially meeting access requirements through establishing written contracts or agreements with providers. MIPPA specifies that the term “network-based plan” excludes a regional PPO that meets access requirements in its service area substantially through the authority of §422.112(a)(1)(ii), rather than through written contracts. Section 422.112(a)(1)(ii) permits regional PPOs to meet access requirements using methods other than written agreements with providers (that is, allowing members to see non-contract providers at in-network cost sharing in areas where the plan does not have established a network of contracted providers).

For purposes of determining the network area of a PFFS plan, we will determine whether any network-based plans with enrollment exist in each of the counties located within the PFFS plan’s service area. Beginning in plan year 2011, in counties where there is availability of two or more network-based plans (such as an HMO plan, a PSO plan, a local PPO plan, a network regional PPO plan, a network-based MSA plan, or a section 1876 cost plan), a PFFS plan operating in these counties must establish a network of contracted providers to furnish services in these counties in accordance with the amended section 1852(d)(4)(B) of the Act. In such counties, a PFFS plan would no longer be able to meet access requirements through providers deemed to have a contract with the plan at the point of service in these counties. In counties where there are no network-based plan options, or only one other network-based plan, the statute allows PFFS

plans to meet access requirements in accordance with section 1852(d)(4) of the Act and §422.114(a)(2). Regardless of whether a PFFS plan meets access requirements through deeming or is subject to the requirement that it establish a network of providers with signed contracts, providers who do not have a contract with the PFFS plan may continue to be deemed to have a contract with the plan if the deeming conditions described in §422.216(f) are met.

An existing PFFS plan may have some counties in its current service area that meet the definition of a network area and other counties that do not. In order to operationalize section 162(a)(1) of MIPPA, CMS will not permit a PFFS plan to operate a mixed model where some counties in the plan's service area are considered network areas and other counties that are non-network areas. Beginning in plan year 2011, an MA organization offering a PFFS plan will be required to create separate plans within its existing service areas where it is offering PFFS plans based on whether the counties located in those service areas are considered network areas or not. For example, if an existing PFFS plan has some counties in its current service area that are network areas and other counties that are non-network areas, then in order to operate in this service area in plan year 2011 and subsequent plan years, the MA organization must establish a unique plan with service area consisting of the counties that are network areas and another plan with service area consisting of the counties that are non-network areas. Consequently, the PFFS plan operating in the counties that are network areas must establish a network of contracted providers in these counties in accordance with section 1852(d)(4)(B) of the Act in order to meet access requirements. The PFFS plan operating in the counties that are not network areas can continue to meet access requirements under §422.114(a)(2) by paying rates at least as high as rates under Medicare Part A or Part B to providers deemed to have a contract with the plan if the conditions described in §422.216(f) are met. The MA organization must file separate plan benefit packages for the PFFS plan that will operate in network areas and the plan that will operate in non-network areas. We recognize that the creation of unique plans based on network and non-network areas will potentially create an artificial increase in the total number of PFFS plans offered in plan year 2011 and subsequent plan years; this would not reflect an actual increase in PFFS plan offerings, but rather a change in how these PFFS offerings are structured and identified. To determine whether a PFFS plan's proposed network meets access and availability standards, we will follow the procedure described in the section below on "Changes in access requirements for PFFS plans."

We will provide additional guidance on the implementation of these provisions in the 2010 Call Letter. In our guidance, we will address topics such as the impact of these provisions on application and contracting requirements, CMS review of network adequacy, potential impact on State licensure, transition period, and time frames.

C. Changes in Access Requirements for PFFS Plans

42 CFR 422.114(a)(2)(ii) – CMS 4138-IFC

Effective date: January 1, 2010

As noted above, section 162(a)(3) of MIPPA amended section 1852(d)(4)(B) of the Act to require, effective January 1, 2010, that PFFS plans meeting access standards based on signed

contracts meet access standards with respect to a particular category of provider by establishing contracts or agreements with a sufficient number and range of providers to meet the access and availability standards described in section 1852(d)(1) of the Act. Section 1852(d)(1) of the Act describes the requirements that MA organizations offering a MA plan must meet when selecting providers to furnish benefits covered under the plan when the MA organization offers a “network” plan. Federal regulations at 42 CFR §422.114(a)(2)(ii) reflect this statutory requirement.

Currently, even though the statutory language governing contract-based access standards for PFFS plans differs from that which applies to coordinated care plans, CMS has required PFFS plans with a partial or complete network of contracted providers to meet the same network adequacy requirements as are coordinated care plans. These requirements will continue to apply to PFFS plans in plan year 2010 and beyond. CMS reviewers follow the same procedure when reviewing the Health Service Delivery Tables for initial and service area expansion applications for coordinated care, PFFS, and network MSA plans in order to determine whether the applicant’s proposed network meets access and availability standards. PFFS plans must submit information about their proposed provider networks. We review that information as part of the application approval process to ensure that timely, accessible, and appropriate care is provided. The access and availability rules for coordinated care plans are described in 42 CFR §422.112(a) and section 120.2 of Chapter 4 of the Medicare Managed Care Manual. As mentioned above, the same standards currently apply to PFFS plans seeking to meet access standards through signed contracts, so the MIPAA change effective in 2010 should not affect CMS’s operational procedures.

Section 1852(k)(1) of the Act describes requirements that an MA organization offering a “network” plan must meet when making payment for covered services furnished by non-contracting providers. These requirements will also apply to PFFS plans with a partial or complete network of contracted providers when making payments on a non-contract basis. The rules for services furnished by non-contracting providers and suppliers are described in 42 CFR §422.214, and section 10.2 of Chapter 4 of the Medicare Managed Care Manual.

D. Requirement for All Employer/Union Sponsored PFFS Plans to Use Contracts with Providers

42 CFR 422.114(a)(4) -- CMS 4138-IFC

Effective date: January 1, 2011

Section 162(a)(2) of MIPPA amended section 1852(d) of the Act by adding a new requirement for employer/union sponsored PFFS plans. For plan year 2011 and subsequent plan years, MIPPA requires that all employer/union sponsored PFFS plans under section 1857(i) of the Act meet the access standards described in section 1852(d)(4) of the Act only through entering into written contracts or agreements in accordance with section 1852(d)(4)(B) of the Act, and not, in whole or in part, through establishing payment rates meeting the requirements under section 1852(d)(4)(A) of the Act. Federal regulations at 42 CFR §422.114(a)(4) reflect this statutory change.

In order to meet the access requirements beginning plan year 2011, an employer/union sponsored

PFFS plan must establish written contracts or agreements with a sufficient number and range of health care providers in its service area for all categories of services in accordance with the access and availability standards described in section 1852(d)(1) of the Act. An employer/union sponsored PFFS plan will not be allowed to meet access requirements by establishing payment rates for a particular category of provider that are at least as high as rates under Medicare Part A and Part B. While an employer/union sponsored PFFS plan must meet access standards through signed contracts with providers, providers that have not signed contracts can still be deemed to be contractors under the deeming procedures in section 1852(j)(6) that currently apply.

Sections 162(a)(2) of MIPPA is effective for plan year 2011 and subsequent plan years. We will provide guidance on the implementation of these provisions in the 2010 Call Letter. In our guidance, we will address topics such as the impact of these provisions on application and contracting requirements, potential impact on State licensure, transition period, and time frames.

IV. Quality Improvement Program Requirements

A. Requirement for MA PFFS and MSA Plans to have a Quality Improvement Program

42 CFR 422.152(a) – CMS 4138-IFC

Effective date: January 1, 2010

Section 163(a) of MIPPA repeals, effective January 1, 2010, the current statutory exemption found at section 1852(e)(1) of the Act for MA PFFS plans and MSA plans from the requirement that MA plans have ongoing quality improvement programs. Beginning plan year 2010, each MA PFFS and MSA plan is required by CMS regulations at 42 CFR §422.152(a)(1), (2) and (3) to implement quality improvement projects on an annual basis, implement chronic care improvement programs, and encourage its providers to participate in CMS and HHS quality improvement initiatives. CMS requires all Plans to participate in this assessment activity to meet its strategic goal of achieving confident, informed consumers through transparent public reporting on health plan performance. In order to implement the CMS' quality improvement requirements, these organizations should follow Chapter 5 of the Medicare Managed Care Manual and seek assistance from State Quality Improvement Organizations as well as CMS.

V. Part D Guidance

A. Elimination of the Late Enrollment Penalty (LEP) for LIS Individuals

42 CFR 423.46(a) and 423.780(e) – CMS 4138-IFC

Effective date: January 1, 2009

From 2006 – 2008, CMS has conducted a Medicare payment demonstration entitled “Elimination of the 2006 Late Enrollment Penalty”, such that Medicare beneficiaries who qualify for the low-income subsidy for Medicare prescription drug coverage were able to enroll in a Medicare prescription drug plan with no late enrollment penalty.

Section 114 of MIPPA, which became law on July 15, 2008, has permanently eliminated the late enrollment penalty for low income subsidy eligible beneficiaries. Under this new statute, CMS will not charge low income subsidy eligible individuals (defined in 42 CFR 423.773) a late enrollment penalty. This provision will become effective January 1, 2009, when the previously mentioned demonstration ends. To implement this new statute, we are changing the regulation at 423.46(a) and 423.780(e) to eliminate the late enrollment penalty for low income subsidy eligible beneficiaries.

The implementation of the MIPPA LEP provision does not require any change in the reporting of uncovered months for low-income subsidy eligible beneficiaries. Part D sponsors should continue to follow the guidance provided in the April 11, 2008, HPMS memorandum entitled “Updated Guidance on Creditable Coverage Period Determinations and the Late Enrollment Penalty” and Chapter 4 of the Prescription Drug Benefit Manual. Specifically, Part D sponsors should continue to report 0 uncovered months for any new enrollee who is LIS eligible at the time s/he makes the enrollment request or at the time that the enrollment becomes effective.

B. Regular Update of Prescription Drug Pricing Standard

42 CFR 423.505(b)(21) -- CMS 4138-IFC

Effective: January 1, 2009

Effective January 1, 2009, and as provided in 42 CFR 423.505(b)(21), CMS’ contracts with Part D sponsors must include a provision requiring sponsors to regularly update any prescription drug pricing standard they use to reimburse network pharmacies based on the cost of the drug (for example, average wholesale price, wholesale average cost, average manufacturer price average sales price). These updates must occur on January 1 of each contract year and not less frequently than every 7 days thereafter.

In addition, as provided in 42 CFR 423.505(i)(3)(vi), Part D sponsors must ensure that any contracts or written arrangements between Part D sponsors and pharmacies or other providers, first tier, downstream and related entities include provisions for regularly updating any prescription drug pricing standard used by sponsors to reimburse their network pharmacies, if applicable. The Part D sponsor’s contract must also indicate the source used by the Part D sponsor for making such pricing updates, as this information is necessary in order to monitor for compliance with this requirement.

Part D sponsors must amend their current PBM and pharmacy contracts consistent with this new requirement to the extent that their contracts currently address regular pricing updates. CMS will review pharmacy contract templates (except for mail-order and LTC pharmacy templates) for new applicants beginning for contract year 2010 to ensure the addition of this provision, if applicable. Most importantly, however, sponsors must ensure that they design their internal

processes to ensure that fee schedules tied to any drug pricing standard are updated within these prescribed timeframes, and that all claims are adjudicated in accordance with appropriately updated fee schedules.

VI. Marketing

A. Disclose Plan Info to Beneficiaries Upon Enrollment and at Least Annually Thereafter 15 days prior to AEP

422.111(a)(3) and 423.111(a)(3) -- CMS 4131-F

Effective date: September 18, 2008

To ensure that beneficiaries receive comprehensive plan information regarding their healthcare options, CMS regulations now provide that MA and PDP organizations must disclose certain plan information both at the time of enrollment and at least annually, 15 days prior to the Annual Election Period. This requirement includes the annual dissemination of the standardized Annual Notice of Change and Evidence of Coverage that must be received by members no later than October 31 each year.

B. Elimination of File & Use Eligibility

42 CFR 422.2262 and 423.2262 -- CMS 4131-F

Effective date: September 18, 2008

Effective for materials submitted on or after October 1, 2008, Medicare Advantage Plans, Medicare Prescription Drug Plans, and Medicare Cost plans may no longer submit any materials through the File and Use Eligibility process. All organizations may submit qualified materials through the File & Use Certification process.

All plans qualify to use File & Use Certification. PDPs qualify automatically, and may begin submitting eligible documents through that process immediately. MAs, MA-PDs, and Cost organizations that have not already received File & Use Certification must submit a one-time certification form. While this File & Use certification form has previously been accepted during the application or the yearly renewal process, we are waiving that limitation and organizations not already approved for File & Use Certification should submit the certification form, found on page 102 of the Medicare Marketing Guidelines, as soon as possible. To facilitate the process, a .pdf file of the signed form should be submitted to the organization's Regional Office account manager as an attachment to an email. Once the File & Use Certification form is received and the system is updated, it is effective until further notice from CMS.

Organizations are required to submit at least 90% of materials that qualify for File & Use Certification under this process. A list of materials qualified for File & Use Certification can be found in HPMS under the Marketing Code Lookup. (Note that the standardized 2009 ANOC/EOC should be submitted through File & Use.) If model documents are available they must be used without modification in order to be submitted through File & Use Certification.

Plans that modify model documents will need to submit those documents for the standard review.

Organizations using the File & Use Certification process must submit File & Use Certification marketing materials to CMS five calendar days prior to distribution and certify that the materials comply with the Marketing Guidelines.

For further guidance on the File & Use Certification Process, see Page 99 of the Medicare Marketing Guidelines.

C. Nominal Gifts

42 CFR 422.2268(b) and 423.2268(b) -- CMS 4138-IFC

Effective date: September 18, 2008

Organizations can offer gifts to potential enrollees as long as such gifts are of nominal value, not readily convertible to cash and are provided whether or not the individual enrolls in the plan. Nominal value currently is defined as an item worth \$15 or less, based on the retail purchase price of the item regardless of the actual cost. CMS will update the nominal value in guidance as necessary to account for inflation and other relevant factors.

D. Marketing through Unsolicited Contacts

42 CFR 422.2268(d) and 423.2268(d) -- CMS 4131-F

Effective date: September 18, 2008

Beginning September 18, 2008, the prohibition on door-to-door solicitation extends to other instances of unsolicited contact that may occur outside of advertised sales or educational events. Prohibited activities include, but are not limited to, the following:

- Outbound marketing calls, unless the beneficiary requested the call. This includes contacting existing members to market other Medicare products, except as permitted below.
- Calls to former members who have disenrolled, or to current members that are in the process of voluntarily disenrolling, to market plans or products, except as permitted below.
- Calls to beneficiaries to confirm receipt of mailed information, except as permitted below.
- Calls to beneficiaries to confirm acceptance of appointments made by third parties or independent agents.
- Approaching beneficiaries in common areas (i.e. parking lots, hallways, lobbies, etc.)
- Calls or visits to beneficiaries who attended a sales event, unless the beneficiary gave express permission at the event for a follow-up call or visit.

Organizations may do the following:

- Conduct outbound calls to existing members to conduct normal business related to enrollment in the plan, including calls to members who have been involuntarily disenrolled to resolve eligibility issues.
- Call former members after the disenrollment effective date to conduct disenrollment survey for quality improvement purposes. Disenrollment surveys may be done by phone or sent by mail, but neither calls nor mailings may include sales or marketing information.
- Under limited circumstances and subject to advance approval from the appropriate CMS Regional Office, call LIS-eligible members that a plan is prospectively losing due to reassignment to encourage them to remain enrolled in their current plan.
- Agents/brokers who enrolled a beneficiary in a plan may call that beneficiary while they are a member of that organization.
- Call beneficiaries who have expressly given permission for a plan or sales agent to contact them, for example by filling out a business reply card or asking a Customer Service Representative (CSR) to have an agent contact them. This permission applies only to the entity from whom the beneficiary requested contact, for the duration of that transaction, or as indicated by the beneficiary.

All outbound scripts must be submitted for review and approval prior to use in the marketplace. When conducting outbound calls:

- Scripts must include a privacy statement clarifying that the beneficiary is not required to provide any information to the plan representative and that the information provided will in no way affect the beneficiary's membership in the plan.
- Plans are prohibited from requesting beneficiary identification numbers (e.g., Social Security Numbers, bank account numbers, credit card numbers, HICN).
- Plans are allowed to say they are contracted with Medicare to provide prescription drug benefits or that they are Medicare-approved MA-PD/PDP.
- Plans cannot use language in outbound scripts that imply that they are endorsed by Medicare, calling on behalf of Medicare, or Medicare asked them to call the member.

E. Cross-selling

42 CFR 422.2268 (f) and 423.2268(f) -- CMS 4131-F

Effective date: September 18, 2008

Effective September 18, 2008, marketing non-health care related products (such as annuities and life insurance) to prospective enrollees during any MA or Part D sales activity or presentation is considered cross-selling and is a prohibited activity. Beneficiaries already face difficult decisions regarding Medicare coverage options and should be able to focus on Medicare options without confusion or implication that the health and the non-health products are a package. Plans may sell non-health related products on inbound calls when a beneficiary requests information on other non-health related products. Marketing to current plan members of non-MA plan covered health care products, and/or non-health care products, is subject to Health Insurance Portability and Accountability Act (HIPAA) rules.

CMS is concerned about the marketing of non-health related products during hold-time messages and on interactive voice response (IVR) systems that plans may use to automate their inbound calling interface. We are considering providing guidance on prohibiting or limiting cross-selling during these types of messages, and are interested in receiving industry feedback during User Group Calls.

F. Scope of Appointments

42 CFR 422.2268(g) and (h); 423.2268(g) and (h) -- CMS 4138-IFC

Effective date: September 18, 2008

Under current Medicare Marketing Guidelines, marketing representatives are to clearly identify the types of products that will be discussed before marketing to a potential enrollee. To ensure beneficiaries have accurate information to make an informed choice about their Medicare benefits without being pressured, marketing representatives that initially meet with a beneficiary to discuss specific lines of plan business (Examples of separate lines of business include Medigap, MA, and PDP) must inform the beneficiary of all products that will be discussed prior to the in-home appointment.

Effective September 18, 2008, prior to any marketing appointment, the beneficiary must agree to the scope of the appointment and that agreement must be documented by the plan. This documentation may be in writing or recorded by phone. For example, if a beneficiary attends a sales presentation and schedules an appointment, the agent must obtain written documentation that is signed by the beneficiary agreeing to the products that will be discussed during the appointment. Appointments that are made over the phone must be recorded in order to provide documentation. Organizations should use their existing systems to monitor and track calls where there is beneficiary interaction. Organizations that contact a beneficiary in response to a reply card may only discuss the products that were included in the advertisement.

Additional products may not be discussed unless the beneficiary requests the information. In addition, any additional lines of plan business that are not identified prior to the in-home appointment will require a separate appointment. Appointments may not be re-scheduled until 48 hours after the initial appointment. Marketing representatives may leave plan materials, not including enrollment applications, related to the other product lines during the initial appointment.

G. Sales/Marketing in Health Care Settings

42 CFR 422.2268 (k) and 423.2268(k) -- CMS 4131-F

Effective date: September 18, 2008

Organizations may not conduct sales activities in healthcare settings except in common areas. Common areas where marketing activities are allowed include areas such as hospital or nursing home cafeterias, community or recreational rooms, and conference rooms. If a pharmacy counter is located within a retail store, common areas would include the space outside of where patients wait for services or interact with pharmacy providers and obtain medications. Plans are prohibited from conducting sales presentations and distributing and/or accepting enrollment applications in areas where patients primarily intend to receive health care services. These restricted areas generally include, but are not limited to, waiting rooms, exam rooms, hospital patient rooms, dialysis centers, and pharmacy counter areas (where patients wait for services or interact with pharmacy providers and obtain medications). Only upon request by the beneficiary are plans permitted to schedule appointments with beneficiaries residing in long-term care facilities. Additionally, providers are permitted to make available and/or distribute plan marketing materials as long as the provider distributes or makes available plan marketing materials for all plans with which the provider participates. Providers are also permitted to display posters or other materials announcing all plan contractual relationships.

H. Sales/Marketing at Educational Events

42 CFR 422.2268 (l) and 423.2268(l) -- CMS 4131-F

Effective date: September 18, 2008

Beginning September 18, 2008, educational events may not include sales activities such as the distribution of marketing materials or the distribution or collection of plan applications. CMS has clarified that the purpose of educational events is to provide objective information about the Medicare program and/or health improvement and wellness. As such, educational events should not be used to steer or attempt to steer a beneficiary towards a specific or limited number of plans. Organizations that sponsor or participate in educational events must include a disclaimer on event advertising materials that the event is “educational only and information regarding the plan will not be available.” Educational events may be sponsored by the plan(s) or by outside entities, and are events that are promoted to be educational in nature and have multiple vendors, such as health information fairs, conference expositions, state- or community-sponsored events, etc. A sales event is an event that is sponsored by a plan or another entity with the purpose of marketing to potential members and steering, or attempting to steer, potential members towards a specific or limited number of plan.

I. Co-branding

42 CFR 422.2268(n) and 423.2268(n) -- CMS 4138-IFC

Effective date: September 18, 2008

CMS has prohibited the use of names and/or logos of co-branded network providers on membership plan identification cards. This prohibition extends to all entities, but especially those entities and/or co-branding partners with a substantially similar names and/or logos of a network provider or providers. In addition, organizations are required to include the following disclaimer

on all marketing materials that include the name and/or logo of a co-branded network partner: “Other [pharmacies/physician/providers] are available in our network.” CMS must ensure that beneficiaries understand the availability of multiple network providers and are not misled to believe that the co-branded network provider is the only provider available to them. (Plans that have a network exclusive to that co-branded provider do not have to include the disclaimer.)

MA organizations may include provider names, and/or logos on the member identification card related to member selection of specific providers or provider organizations (e.g., physicians, hospitals). For example, in some plan types MA enrollees may select a primary care provider or particular group of service delivery providers, such as a hospital network. Given that the beneficiary has made the selection to identify the provider, that provider’s name or logo may appear on the card.

J. Prohibition on the Provision of Meals

42 CFR 422.2268(p) and §423.2268(p) -- CMS 4131-F

Effective date: September 18, 2008

Medicare Advantage and Medicare Prescription Drug Plans may not allow prospective enrollees to be provided meals, or have meals subsidized, at any event or meeting at which plan benefits are being discussed and/or plan materials are being distributed.

Agents and/or Brokers are allowed to provide refreshments and light snacks to prospective enrollees. Plans must use their best judgment on the appropriateness of food products provided, and must ensure that items provided could not be reasonably considered a meal, and/or that multiple items are not being “bundled” and provided as if a meal.

While CMS does not intend to define the term “meal” or create a comprehensive list of food products that qualify as light snacks, items similar to the following could generally be considered acceptable:

- Fruit
- Raw vegetables
- Pastries
- Cookies or other small dessert items
- Crackers
- Muffins
- Cheese
- Chips
- Yogurt
- Nuts

As with all marketing regulation and guidance, it is the responsibility of MA and PDP organizations to monitor the actions of all agents selling their plan(s) and take proactive steps to enforce this prohibition. Oversight activities conducted by CMS will verify that Plans and agents are complying with this provision, and enforcement actions will be taken as necessary.

K. State Appointment of Agents/Brokers

42 CFR 422.2272(c) and 422.2272 (c) -- CMS 4131-F

Effective date: September 18, 2008

The final rule codifies existing guidance that MA organizations and Part D sponsors that conduct marketing through independent agents must use state-licensed, certified, or registered individuals. Both independent agents and internal sales staff that perform marketing must be licensed.

Effective September 18, 2008, organizations must comply with State appointment laws that require plans to give the state information about which agents are marketing the Part C and D plans. As provided under section 103(d)(1) of MIPPA, and the new section 1851(h)(7) of the Act, effective January 1, 2009, organizations must also pay any fees that would be charged in connection with State appointment laws.

In addition to the above requirements, the final rule clarifies that there are plan activities that do not require the use of State-licensed marketing representatives. Providing factual information, fulfilling a request for materials, and taking demographic information in order to complete an enrollment application at the initiative of the enrollee by a customer service representative are legitimate customer service activities that would not require using State-licensed marketing representatives. A State-licensed representative is required when there is a marketing activity involved, which is defined in the marketing guidelines as steering, or attempting to steer, a potential enrollee towards a plan, or limited number of plans, and for which the individual or entity performing marketing activities expects compensation directly or indirectly from the plan for such marketing activities. To further clarify, when employee customer service representatives, employed or contracted agents, and/or external agents and brokers perform customer service functions, such as answering questions and/or accepting enrollments on behalf of enrollees who have already decided to enroll in a particular plan offered by the organization, these functions are considered legitimate CSR activities and do not trigger the need to use a state-licensed marketing representative. All required CMS enrollment procedures and guidance apply.

L. Plan Reporting of Terminated Agents

42 CFR §422.2272(d) and §423.2272(d) -- CMS 4138-IFC

Effective date: January 1, 2009

MAOs or Part D sponsors must report the termination of any brokers or agents, and the reasons for the termination, to the State in which the broker or agent has been appointed in accordance with the State appointment law.

M. Agent/Broker Compensation

42 CFR 422.2274(a) and 423.2274(a) -- CMS 4138-IFC

Effective date: September 18, 2008

MIPPA required that we establish limits on agent and broker compensation that ensure that agents and brokers enroll individuals in the Medicare Advantage plan or Medicare Prescription Drug plan that is intended to best meet their health care needs. The limits in 42 CFR 422.2274(a) and 423.2274(a) implement this requirement. These limits apply to Medicare Advantage organizations and Part D sponsors that market through brokers or agents, including agents and brokers employed by the MAO or sponsor. These compensation rules are designed to eliminate inappropriate moves of beneficiaries from plan-to-plan. CMS expects that plans will set compensation at levels that are reasonable, and reflect fair market value for services performed. CMS encourages plans to keep compensation as level as possible across plan types, and among agents providing similar services. All parties remain responsible, however, for compliance with fraud and abuse laws, including the anti-kickback statute. Depending on the circumstances, agent and broker relationships can be problematic under the anti-kickback statute if they involve, by way of example only, compensation in excess of fair market value, compensation structures tied to the health status of the beneficiary (for example, cherry-picking), or compensation that varies based on the attainment of certain enrollment targets. We note that the Office of the Inspector General (OIG) advisory opinion process is available to parties seeking OIG's opinion as to the legality of a particular arrangement. Information about this process is available on the OIG's web site at <http://oig.hhs.gov/fraud/advisoryopinions.html>.

Compensation Structure

Medicare plans are not required to compensate brokers or agents for selling Medicare products. However, if they do compensate their brokers and agents, under our regulations implementing MIPPA, they must pay compensation for the initial year and each of five subsequent renewal years (creating a six-year compensation cycle), provided the member remains enrolled with the MAO or PDP. The first year of this cycle, for purposes of determining the compensation paid to an agent, is 2009 - provided that the beneficiary makes an enrollment change effective in 2009. The next move of this beneficiary after 2009 would be paid as a renewal commission. For beneficiaries who do not make an enrollment change in 2009, the first year of the six-year compensation cycle would start the year the beneficiary makes his or her first enrollment change after 2009.

For any movement of a beneficiary in 2009, an agent would be paid an initial compensation amount. Prior to 2010, CMS will develop system capabilities as part of the enrollment transaction to track the cycle by beneficiary and direct plans as to whether a first year or renewal compensation should be paid. In addition, CMS will provide further guidance on how commissions will be paid for subsequent years.

The compensation structure requirements are:

- The definition of compensation includes pecuniary or non-pecuniary remuneration of any kind relating to the sale or renewal of the policy (for example, commissions, bonuses, gifts, prizes, awards, and finders' fees). Salary or other benefits related to employment

are excluded from this definition (except if related to volume of sales). The payment of fees to comply with State appointment laws, training and testing, certification, reimbursement for mileage to and from appointments with beneficiaries and reimbursement for actual costs associated with beneficiary sales appointments such as venue rent and snacks, are also not considered compensation.

- An agent's aggregate first year compensation can not exceed 200 percent of the aggregate compensation in each individual subsequent renewal year, of which there must be a total of five renewal years. (This creates a six-year cycle.) This means that in the first year, the compensation paid can be no more than 200 percent of the compensation paid in the second year or any individual subsequent renewal year up to a total of five renewal years (six year total compensation cycle). The agent will receive renewal compensation for the five year renewal period (years two through six) as long as the member remains enrolled in the plan or enrolled by the agent in a like replacement plan.
- Compensation is earned in months 4 through 12 of the enrollment year as long as the member is active with the plan. If an enrollee leaves the plan prior to month 4, no compensation is earned. If an enrollee leaves the plan after month 3, compensation is paid on a pro-rated basis for the months in which the enrollee actually was a member of the plan.
- After the 2009 baseline year, no entity may provide, and no agent or broker may receive, compensation greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan type during the first year and 5 renewal years. "Like plan type" refers to PDP, MA or MA-PD, or Cost plan. Examples of replacements with like plan type are—PDP replace with another PDP, MA or MA-PD replaced with another MA or MA-PD, and cost plan replaced with another cost plan. If a PDP is added to an MA-only plan, then a new commission is paid for enrollment in the PDP.
- Plans must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year. Plans may not alter the compensation structure during the given plan year. Compensation structures must be in place by the beginning of the plan year marketing period, October 1, and must be available upon CMS request including for audits, investigations, and to resolve complaints.

N. Broker/Agent Training and Testing

42 CFR 422.2274(b) and 423.2274(b) -- CMS 4138-IFC

Effective date: September 18, 2008

MAOs and Part D sponsors must ensure, starting with sales and marketing for plan year 2009, that annually brokers and agents selling Medicare products are trained on Medicare rules and regulations and on plan details specific to the plan products being sold by the brokers and agents. MAOs and Part D sponsors must also ensure that brokers and agents selling Medicare products are tested annually on their knowledge of Medicare rules and regulations, as well as, on the plan specific details of the plan products being sold. In order to sell Medicare products, a broker or agent should receive a passing score of at least 85% on the test. Tests may be in the form of a written test or computerized. Organizations and sponsors must ensure that their training and

testing programs are designed and implemented in a way that the integrity of the training and testing is maintained. In doing so, they must have a process for handling instances in which agents do not pass the test on the first try.

VII. Other provisions

No guidance is needed at this time for the following provisions:

- ***Quality Data Collection Requirements for MA Regional Plans***, 42 CFR 422.152(e)
- ***Payment (IME) Capitation Rates***, 42 CFR 422.306(c) - CMS 4138-IFC
- ***Part D Incentives for Electronic Prescribing***, 42 CFR 423.322(b) – CMS 4138-IFC
- ***Use of Part D Data***, 42 CFR 423.505(m)(1) and 423.505(m)(3) – CMS 4138-IFC
- ***Dual eligible SNPs and Contracts with States***, 42 CFR 422.107 – CMS 4138-IFC

Guidance will be provided in the 2010 Call Letter on the following provisions:

- ***Quality Data Collection and Reporting Requirements for MA PFFS and MSA Plans***, 42 CFR 422.152(h) – CMS 4138-IFC
- ***Part D Pharmacy Claims***, 42 CFR 423.505(b)(20) and 423.505(i)(3)(vii) – CMS 4138-IFC
- ***Part D Prompt Payment of Clean Claims***, 42 CFR 423.505(b)(19), 423.505(i)(e)(vi), and 423.520 -- CMS 4138-IFC
- ***Required Inclusion of Plan Type in Plan Name***, 42 CFR 422.2268(q) and 423.2268(q) -- CMS 4138-IFC