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42 CFR Parts 417, 422 and 423
Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422 and 423

[CMS 4138–IFC]

RIN 0938–AP52

Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (IFC) revises the regulations governing the Medicare Advantage (MA) program (Part C), prescription drug benefit program (Part D) and section 1876 cost plans. This IFC makes conforming changes to the MA regulations to reflect new statutory requirements regarding special needs plans (SNP), private-fee-for-service plans (PFFS), regional preferred provider organizations (RPPO) plans, Medicare medical savings accounts (MSA) plans, and new statutory provisions governing cost-sharing for dual-eligible enrollees in the MA program prescription drug pricing, coverage, and payment processes in the Part D program. In addition, this IFC sets forth new requirements governing the marketing of Part C and Part D plans which by statute must be in place at a date specified by the Secretary, but no later than November 15, 2008. Both the conforming changes to the regulations to reflect new statutory provisions and the new marketing requirements are based on provisions in the Medicare Improvements for Patients and Providers Act (MIPPA), which became law on July 15, 2008.

DATES: *Effective Date:* September 18, 2008.

Comment Date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 17, 2008.

ADDRESSES: In commenting, please refer to file code CMS–4138–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' and enter the filecode to find the document accepting comments.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4138–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4138–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201;

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Private-Fee-For-Service Plans—Sabrina Ahmed, 410–786–7499.

Special Needs Plans—LaVern Baty, 410–786–5480.

Cost Plans—Chris McClintick, 410–786–4682.

Medicare Medical Savings Account Plans—Anne Manley, 410–786–1096.

Enrollment—Lynn Orlosky, 410–786–9064.

Payment—Frank Szeflinski, 303–844–7119.

Marketing—Camille Brown, 410–786–0274, or Chevell Thomas, 410–786–1387.

Contract provision relating to Part D drug benefit—Vanessa Duran, 410–786–8697, or Deborah Larwood, 410–786–9500.

Low-income subsidy and late enrollment penalties—Deondra Moseley, (410) 786–4577 or Meghan Elrington, (410) 786–8675.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://regulations.gov. Follow the search instructions* on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted on December 8, 2003. The MMA established the Medicare prescription drug benefit program (Part D) and made revisions to the provisions in Medicare Part C, governing what is now called the Medicare Advantage (MA) program (formerly Medicare+Choice). The MMA directed that important aspects of the new Medicare prescription drug benefit program under Part D be similar to and coordinated with regulations for the MA program.

The MMA also directed implementation of the prescription drug benefit and revised MA program provisions by January 1, 2006. The final rules for the MA and Part D prescription drug programs appeared in the **Federal Register** on January 28, 2005 (70 FR 4588 and 70 FR 4194, respectively). Many of the provisions relating to applications, marketing, contracts, and the new bidding process, for the MA program, became effective on March 22, 2005, 60 days after publication of the rule, so that the requirements for both programs could be implemented by January 1, 2006. All of the provisions regarding the new Part D prescription drug program became effective on March 22, 2005.

As we gained more experience with the MA program and the prescription drug benefit program, we proposed to revise areas of both programs and issued a proposed rule on May 16, 2008 (73 FR 28556) that would have clarified existing policies or codified current guidance for both programs. Several of these proposed regulatory revisions have been overtaken by statutory provisions enacted in the Medicare Improvements for Patients and Providers Act (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008. These MIPPA provisions directly address in statute several issues we proposed to address through rulemaking, and thus supersedes our rulemaking in these areas. Comments on our proposals in these areas thus are no longer relevant, as we have no authority to depart from the statutory requirements Congress has enacted (these requirements largely track the regulatory proposals in the May 16 proposed rule). Because the law has changed in these areas, however, conforming changes must be made to the relevant sections of the Code of Federal Regulations in order for the regulations to accurately reflect the new state of the law under MIPPA. This interim final rule with comment period (IFC) makes these changes.

MIPPA also called upon the Secretary to revise the marketing requirements for Part C and Part D plans in several areas specified in MIPPA. With the exceptions noted in this interim final rule, these new rules are to take effect at a date specified by the Secretary, but no later than November 15, 2008. This IFC contains provisions that implement these latter MIPPA requirements. Some provisions in our May 16 proposed rule addressed issues in areas in which MIPAA required that we establish marketing limits no later than November 15th. As a result, to the extent our policies were informed by these comments, we will address them in our discussion of the marketing provisions we have developed in implementing these provisions of MIPPA. In addition we will publish in the near future, a separate final rule responding to public comments on those provisions of the May 16, 2008 proposed rule that were not addressed in MIPPA. Because MIPPA and the May 16, 2008 proposed rule often specified requirements in the same general areas, we are publishing separate regulations in order to clearly distinguish between provisions which are statutory and those provisions which we proposed to promulgate through rulemaking and will be finalizing based on public notice and comment.

B. Relevant Legislative History and Overview

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established a new ''Part C'' in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)) which provided for a Medicare+Choice (M+C) program. Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Medicare Part B, except for most individuals with end-stage renal disease (ESRD), could elect to receive benefits either through the original Medicare program or an M+C plan, if one was offered where he or she lived.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), Public Law 106–111, amended the M+C provisions of the BBA. Further amendments were made to the M+C program by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), enacted December 21, 2000.

As noted above, the MMA was enacted on December 8, 2003. Title I of the MMA added a new ''Part D'' to the Medicare statute (sections 1860D–1 through 1860D–42) creating the Medicare Prescription Drug Benefit Program, the most significant change to the Medicare program since its inception in 1965.

Sections 201 through 241 of title II of the MMA made significant changes to the Part C program. Title II of the MMA renamed the M+C program the MA program and included new payment and bidding provisions, new regional MA plans and special needs plans, reestablished authority for medical savings account (MSA) plans that had been provided in the BBA on a temporary basis, and made other changes. Title I of the MMA created prescription drug benefits under Medicare Part D, and a new retiree drug subsidy program.

Both the MA and prescription drug benefit regulations were published separately, as proposed and final rules, though their development and publication were closely coordinated. On August 3, 2004, we published in the **Federal Register** proposed rules for the MA program (69 FR 46866) and the prescription drug benefit program (69 FR 46632). In response to public comments on the proposed rules, we made several revisions to the proposed policies for both programs. For further discussion of these revisions, see the respective final rules (70 FR 4588) and (70 FR 4194).

On July 15, 2008, the Medicare Improvements for Patients and Providers Act became law, leading to the revisions to the MA and Part D prescription drug benefit programs discussed in Section II, Provisions of the Interim Final Rule.

II. Provisions of the Interim Final Rule

In the sections that follow, we discuss the revisions made in this IFC to final provisions to the regulations in 42 CFR 417, 422 and 423 governing, respectively, section 1876 cost plans, and the MA and prescription drug benefit programs. Several of the final provisions affect both the MA and Part D programs. In our discussion, we note when a provision affects both the MA and prescription drug benefit and include in section II C, a table comparing the proposed Part C and Part D program changes by specifying each issue and the sections of the Code of Federal Regulations that we are revising for both programs.

A. Changes to the Regulations in Part 422—Medicare Advantage Program

1. Special Needs Plans

The Congress first authorized special needs plans (SNP) to exclusively or disproportionately serve individuals with special needs. The three types of special needs individuals eligible for enrollment identified by the Congress include (1) institutionalized individuals (defined in § 422.2 as an individual residing or expecting to reside for 90 days or longer in a long term care facility), (2) individuals entitled to medical assistance under a State plan under title XIX, and (3) other individuals with severe or disabling chronic conditions that would benefit from enrollment in a SNP.

The number of SNPs approved as of January 2008, is 787. This figure includes 442 dual-eligible SNPs, 256

chronic care SNPs, and 89 institutional SNPs.

a. Model of Care (§ 422.101(f))

Section 164 of MIPPA adds care management requirements for all SNPs effective January 1, 2010, as set forth in section 1859(f)(5) of the Act (42 U.S.C. 1395w–28(f)). The new mandate requires dual-eligible, institutional, and chronic condition SNPs to implement care management requirements having two explicit components. While our revisions specifically reflect the MIPPA provisions, it should be noted that in our May 16, 2008 proposed rule, we proposed other, related provisions which we will finalize, based on public notice and comments, in a final rule to be published soon after this IFC.

The first component is an evidence-based model of care with an appropriate network of providers and specialists to meet the specialized needs of the SNP target population. We do not endorse any particular set of evidence-based guidelines or protocols but expect that SNPs will develop such guidelines and protocols through sources such as the Agency for Healthcare Research and Quality (*http://www.ahrq.gov/*). The AHRQ does not endorse any particular set of evidence-based guidelines or protocols but its Web site includes access to nationally-recognized evidence-based practices. The second component is a battery of care management services that includes (1) a comprehensive initial assessment and annual reassessments of the individual's physical, psychosocial, and functional needs, (2) an individualized plan of care having goals and measurable outcomes, including specific services and benefits to be provided, and (3) an interdisciplinary team to manage care. In addition, MIPPA mandates the periodic audit of SNPs to ensure that plans meet the model of care requirements.

In this IFC, we are revising § 422.101(f), effective January 1, 2010, to reflect the new MIPPA provisions requiring a SNP model of care. Specifically, we are revising the regulation to reflect the statutory components described in the preceding paragraph. We also issued guidance on the SNP model of care in our 2008 and 2009 Call Letters. Care coordination and a provider network comprised of clinical experts pertinent to the target population have been the cornerstones of the SNP model of care.

We expect that MA organizations having the commitment and resources to serve vulnerable special needs beneficiaries through SNPs will perpetually evaluate their own model of care by collecting and analyzing performance data to continually improve their model of care. Through the analysis of SNP performance data and monitoring visits, the review of scientific research on the efficacy of other care models, and feedback from beneficiaries, advocacy groups, and healthcare professionals, we will continue to evaluate models of care. As we look longitudinally at evidence-based advancements in care coordination, we will also issue guidance through our Call Letters and informational memoranda to share innovations and facilitate improvement in the SNP model of care framework.

b. Dual-Eligible SNPs and Contracts With States (§ 422.107)

In the May 16, 2008 proposed rule, we proposed in new section § 422.107 to require, effective January 1, 2010, that MA organizations offering a dual-eligible SNP have a documented relationship with the State Medicaid agency, and that the arrangements, at a minimum, include a means to (1) verify enrollees' eligibility for both Medicare and Medicaid, (2) identify and share information on Medicaid provider participation, and (3) identify Medicaid benefits which are not covered by Medicare.

CMS' proposed § 422.107, which sought to require a documented relationship between MA organizations and State Medicaid agencies for dual-eligible SNPs, has been superseded by Section 164 of MIPPA. Section 164 of MIPPA adds new requirements to section 1859(f) of the Act for dual-eligible SNPs. Beginning on January 1, 2010, MA organizations offering new dual-eligible SNPs must have a contract with the State Medicaid agency to provide benefits, or arrange for benefits to be provided, for individuals entitled to receive medical assistance under title XIX. In order to implement the MIPPA requirement for a contract, we are specifying in this IFC that the contract with the state Medicaid agency include the category(ies) of eligibility covered under the SNP, the service area covered under the SNP, and the contract period for the SNP. We also specify that MA organizations with existing dual-eligible SNPs may continue to operate through 2010 without a State contract provided they meet all other statutory requirements, that is, care management and quality improvement program requirements. It should also be noted that under MIPPA, States are not required to enter into written contracts with plans, and plans that do not establish contracts with States in 2010 cannot expand their service areas.

We are incorporating the above MIPPA requirements in a revised version of our proposed § 422.107, with an effective date of January 1, 2010.

c. SNPs and Quality Improvement Program (§ 422.152)

Section 164 of MIPPA adds a new clause (ii) to section 1852(e)(3)(A) of the Act and a new paragraph (6) to section 1857(d) of the Act. Section 1852(e)(3)(A)(ii) of the Act now mandates that, beginning on a date specified by the Secretary (but in no case later than January 1, 2010), data collected, analyzed, and reported as part of the plan's quality improvement program must measure health outcomes and other indices of quality at the plan level with respect to the model of care as required in section 1859(f)(2–5). As a Medicare Advantage plan, each SNP must implement a documented quality improvement program for which all information is available for submission to CMS or for review during monitoring visits. The focus of the SNP quality improvement program should be the monitoring and evaluation of the performance of its model of care (see § 422.101(f)). The program should be executed as a three-tier system of performance improvement. The first tier consists of data on quality and outcomes that is collected and analyzed to enable beneficiaries to compare and select from among health coverage options. In calendar year (CY) 2008, CMS required the submission of thirteen HEDIS measures and three structure and process measures to pilot the development of comparative measures to facilitate beneficiary choice. We continue to work on this initiative and will issue guidance to SNPs on collecting comparative measures for submission using CMS required tools in CY 2009.

The second tier of the quality improvement program for SNPs, effective January 1, 2010 replaces the requirements in § 422.152(b) with requirements in a new § 422.152(g) that reflects the new statutory requirement that SNPs collect, analyze, and report data that measures the performance of their plan-specific model of care (section 1852(e)(3)(A)(ii) of the Act). This new rule establishes CMS requirements for measuring essential components of the model of care using a variety of plan-determined methodologies such as claims data, record reviews, administrative data, clinical outcomes, and other existing valid and reliable measures (ACOVE, MDS, HEDIS, CAHPS, HOS, OASIS, etc.) at the plan level to evaluate the effectiveness of the process of care and

clinical outcomes. Specifically, each SNP should collect, analyze, and be prepared to report data for its performance on: Access to care; improvement in beneficiary health status; care management through its staffing structure and processes; assessment and stratification of health risk; care management through an individualized plan of care; provision of specialized clinical expertise targeting its special needs population; the coordination and delivery of services and benefits through transitions across settings and providers; the coordination and delivery of extra services and benefits that meet the needs of the most vulnerable beneficiaries; the use of evidence-based practices and/or nationally recognized clinical protocols; and the application of integrated systems of communication. Each SNP must coordinate the systematic collection of data using indicators that are objective, clearly defined, and based on measures having established validity and reliability. Indicators should be selected from a variety of quality and outcome measurement domains such as functional status, care transitioning, disease management, behavioral health, medication management, personal and environmental safety, beneficiary involvement and satisfaction, and family and caregiver support. SNPs must document all aspects of the quality improvement program including data collection and analysis, actions taken to improve the performance of the model of care, and the participation of the interdisciplinary team members and network providers in quality improvement activities.

We are developing the third tier of the quality improvement program which is the required reporting of monitoring data. The monitoring data will consist of a prescribed sample of data that SNPs will already be collecting in tier two to measure the performance of their model of care. We will draw from a pool of measures across several service delivery domains, and, whenever possible, use valid measures that SNPs have reported they currently collect. We are also soliciting comments from the public regarding the types of monitoring data that we should require SNPs to submit. We will issue guidance on the requirement to report monitoring data and the collection methodology after reviewing the public comments and completing development of the initiative for implementation in calendar year 2010.

Section 1857(d)(6) stipulates that CMS will conduct reviews of the SNP model of care in conjunction with the periodic audits of the MA organizations. As of January 1, 2010, these reviews will focus on how the SNPs have operationalized their models of care and how their quality improvement programs have affected their care management as structured by the model of care.

d. Special Needs Plans and Other MA Plans With Dual-Eligibles: Responsibility for Cost-Sharing (§ 422.504(g)(1))

Section 165 of MIPPA, which revised section 1852(a) of the Act, provides that for those persons who are full benefit dual-eligible individuals or a qualified Medicare beneficiary enrolled in a dual-eligible special needs plan, as described in section 1859(b)(6)(B)(ii) of the Act, the plan may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted if the individual were under title XIX and were not enrolled in a special needs plan. The effective date of this provision is January 1, 2010. In order to reflect this provision, we are updating our regulations by updating part 42 by adding new paragraph (g)(1)(iii) to § 422.504(g).

Additionally, section 164 of MIPPA requires that the plan provide each prospective enrollee, prior to enrollment, a comprehensive written statement, describing the benefits and cost-sharing protections for which the individual would be entitled under title XIX as well as the MA plan.

We are reflecting these statutory requirements in the regulations at § 422.504(g)(1), effective January 1, 2010.

While our revisions specifically reflect the MIPPA provisions, it should be noted that in our May 16, 2008 proposed rule, we proposed other, related provisions which we will finalize, based on public notice and comments, in a final rule to be published soon after this IFC.

2. Revisions to Requirements for MA PFFS Plans (§ 422.114)

Section 162 of MIPPA revised the requirements for PFFS plans in a number of significant ways that will affect how employer and non-employer PFFS plans can meet access requirements. Below we describe each of the changes to PFFS plans as a result of MIPPA.

Note: See also section A.3., Revision to Quality Improvement Programs, for discussion of new requirements related to PFFS plans and quality improvement features.

a. Changes in Access Requirements for PFFS Plans

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 ''network'' MA plan must satisfy when selecting providers to furnish benefits covered under the plan.

We are revising § 422.114(a)(2)(ii) to reflect this new statutory requirement.

b. Requirement for Certain Non-Employer PFFS Plans To Use Contract Providers

Prior to MIPPA, section 1852(d)(4) of the Act and § 422.114(a) described how an MA organization that offers an MA PFFS plan must demonstrate to CMS that it can provide sufficient access to services covered under the plan. An MA organization was permitted to meet access requirements if, with respect to a particular category of providers, the plan has met one of the conditions in § 422.114(a)(2). That is, the plan has—

- Payment rates that are not less than the rates that apply under Original Medicare for the provider in question;
- Contracts or agreements with a sufficient number and range of providers to furnish the services covered under the MA private fee-for-service plan; or
- A combination of the above.

Section 1852(j)(6) of the Act and § 422.216(f) provide that if a provider who does not have a contract or agreement with a PFFS plan furnishes services to an enrollee of that plan that are not considered emergency services, the provider is deemed to have a contract with the PFFS plan if the following conditions are met:

(1) The provider is aware, in advance of furnishing health care services, that the patient is enrolled in a PFFS plan.

(2) The provider has reasonable access to the plan's terms and conditions of payment.

(3) The provider furnishes services that are covered by the plan.

Section 162(a)(1) of MIPPA added a new paragraph (5) to section 1852(d) of the Act. The new paragraph creates a 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 (employer/union sponsored PFFS plans are addressed in a separate provision of MIPPA) 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). As noted above, in order to meet the access standards in section 1852(d)(4), PFFS plans must have contracts with a sufficient number and range of providers to meet the access and availability standards described in section 1852(d)(1) of the Act. These PFFS plans may no longer meet the 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 MIPPA is reflected in regulations at 42 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 with respect to portions of their service area in which access standards are met 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 continue 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.

For purposes of making the judgment of provider network adequacy for PFFS plans that will be required to operate using a network of contracted providers in plan year 2011 and afterwards, we will apply the same standards for PFFS plans that we apply to coordinated care plans. To determine where a PFFS plan's proposed network meets access and availability standards, we will follow the procedure described in the section above on ''changes in access requirements for PFFS plans.''

We are revising § 422.114(a)(3) to reflect the requirements in section 162(a)(1) of MIPPA.

c. Requirement for All Employer/Union Sponsored PFFS Plans To Use Contracts With Providers

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.

We are revising § 422.114(a) to reflect this statutory change. Specifically, § 422.114(a) now sets forth how an MA organization that offers a PFFS plan must demonstrate to CMS that it can provide sufficient access to services covered under the plan. 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 requirements 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 or 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.

We are adding paragraph (a)(4) to § 422.114 in order to reflect this new statutory requirement for employer/union sponsored PFFS plans.

d. Variation in Payment Rates to Providers

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 for a provider based on increased utilization of specified preventive or screening services. Section 162(b) of MIPPA is effective at the time of publication of this rule.

We are revising paragraph (a)(3)(ii) of § 422.4 and paragraph (a) of § 422.216 to add the clarifications in Section 162(b) of MIPPA.

3. Revisions to Quality Improvement Programs § 422.152

a. Requirement for MA PFFS and MSA Plans To Have a Quality Improvement Program

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 quality improvement programs meeting specified statutory requirements. Beginning plan year 2010, each MA PFFS and MSA plan must have an ongoing quality improvement program that meets the requirements under § 422.152(a).

We are revising § 422.152(a) to delete language exempting PFFS and MSA plans from having quality improvement programs.

b. Data Collection Requirements for MA PFFS and MSA Plans

Section 1852(e)(3)(A)(i) of the Act amended by Section 163(b)(1) of MIPPA by adding that MA PFFS and MSA plans must provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality, but these requirements for PFFS and MSA plans can not exceed the requirements established for MA local plans that are PPO plans beginning in plan year 2011 and are subject to an exception for plan year 2010 (as discussed below). We interpret this to mean that for plan year 2011 and subsequent plan years, similar to MA local plans that are PPO plans, PFFS, and MSA plans are required to collect, analyze, and report health outcomes and quality data only to the extent that data are furnished by providers who have a contract with the PFFS or MSA plan. For plan year 2011 and subsequent plan years, we are requiring that the data collection requirements for MA PFFS and MSA plans are not subject to requirements that exceed the requirements specified in § 422.152(e) for MA local plans that are PPO plans.

The statute provides for a special rule that applies for plan year 2010, when MA PFFS and MSA plan quality requirements are not restricted to the data collection requirements established for MA local plans that are PPO plans under § 422.152(e). Instead, they must, for 2010 only, meet the data collection requirements with respect to administrative claims data, as specified in CMS guidance. We interpret this exception to mean that for plan year 2010, MA PFFS and MSA plans are required to report quality data based on administrative claims data from all providers that include contract, deemed (applicable to PFFS plans only), and non-contract providers.

c. Data Collection Requirements for MA Regional Plans

Section 163(b)(2) deleted clause (ii) of Section 1852(e)(3)(A) of the Act. Section 1852(e)(3)(A)(ii) had provided for CMS to establish separate regulatory requirements for MA regional plans relating to the collection, analysis, and reporting of data that permit the measurement of health outcomes and other indices of quality and also provided that these requirements for MA regional plans could not exceed the requirements established for MA local plans that are PPO plans. Furthermore, section 163(b)(3) amended Section 1852(e)(3)(iii) of the Act by adding that MA regional plans are subject to the data collection requirements under Section 1852(e)(3)(A)(i) of the Act only to the extent that data are furnished by providers who have a contract with the MA regional plan. This provision is effective for plan years beginning on or after 2010 and allows for consistent data collection requirements between MA local plans that are PPO plans and MA regional plans.

No change to regulatory text is needed since existing language in § 422.152(e) describes the requirements for MA local plans that are PPO plans as well as MA regional plans.

4. Phase-Out of Indirect Medical Education Component of MA Capitation Rate (422.306)

Section 161 of MIPPA adds a new paragraph (4) to § 1853(k) of the Act. The new paragraph directs the Secretary to phase-out indirect medical education (IME) amounts from MA capitation rates. The maximum adjustment percentage per year is .60. Implementation of the IME payment phase-out begins in plan year 2010. Each year after 2010 the maximum adjustment percentage will increase up to an additional .60 percent until the entire IME portion of the MA capitation rate in an area is reduced to zero. PACE programs are excluded from the IME payment phase-out. Payment to teaching facilities for indirect medical education expenses for MA plan enrollees will continue to be made under § 1886(d)(11) of the Act by original Medicare.

We are adding a new paragraph (c) to § 422.306 to reflect this statutory IME phase-out.

B. Changes to the Part D Prescription Drug Benefit Program

1. Use of Prescription Drug Event Data for Purposes of Section 1848(m) (423.322(b))

Section 132 of MIPPA revises section 1848(m) of the Act, as added and amended by section 131 of MIPPA, to provide incentive payments to eligible professionals for successful electronic prescribing. A successful electronic prescriber for a reporting period is one who meets the requirements for submitting data on electronic prescribing quality measures or, if the Secretary determines appropriate, submitted a sufficient number (as determined by the Secretary) of prescriptions under Part D during the reporting period. Congress added paragraph (3)(iv) to section 1848(m) to permit the Secretary to use the data regarding drug claims (prescription drug event data) submitted for payment purposes under the authority of section 1860D–15 of the Act as necessary for purposes of carrying out section 1848(m), notwithstanding the limitations set forth under section 1860D–15(d)(2)(B) and (f)(2) of the Act.

Consistent with the authority granted to the Secretary regarding the use of the prescription drug event data for purposes of section 1848(m), we have revised § 423.322(b) to remove the restriction placed on officers, employees and contractors of the Department of Health Human Services when using these data in accordance with section 1848(m).

2. Elimination of Medicare Part D Late Enrollment Penalties Paid by Subsidy Eligible Individuals (§§ 423.46 and 423.780)

Each year since the beginning of the Medicare prescription drug program, 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 with no penalty. The demonstration has tested the number and characteristics of the beneficiaries that benefited from the waiver of the LEP, and the cost of the waiver to Medicare. Originally, this payment demonstration, as announced on June 14, 2006, allowed certain Medicare beneficiaries to enroll in a Medicare prescription drug plan through December 31, 2006 with no late enrollment penalty. Specifically, CMS did not collect the late enrollment penalty from beneficiaries who enrolled in Medicare Part D in 2006 and were either eligible for the low-income subsidy or lived in an area affected by Hurricane Katrina. This payment demonstration was amended to include beneficiaries who were eligible for the low-income subsidy and enrolled in Medicare Part D in 2007 and 2008.

Section 114 of MIPPA revises the statute to incorporate the terms of the demonstration into the Part D program. We accordingly are revising section 423.780(e) in order to reflect this MIPPA change. Under the revised regulation, CMS will not charge subsidy eligible individuals (defined in 423.773) a late enrollment penalty. This provision will become effective January 1, 2009 when the current demonstration that is supplanted by section 114 of MIPPA ends. We also are making a conforming change to § 423.46(a) to reflect the fact that subsidy eligible individuals may enroll in Medicare prescription drug plan with no penalty.

3. Prompt Payment of Clean Claims (§ 423.505 and § 423.520)

Section 171 of MIPPA amended sections 1860–12(b) and 1857(f) of the Act by adding provisions with regard to prompt payment by prescription drug plans (PDPs) and Medicare Advantage prescription drug (MA–PD) plans, both of which are Part D sponsors as defined in § 423.4. We have codified these new requirements in § 423.505 and § 423.520 of this IFC.

In accordance with the new sections 1860D–12(b)(4) and 1857(f)(3)(A) of the Act, and as codified in § 423.520 of this IFC, effective January 1, 2010, CMS' contract with Part D sponsors must include a provision requiring sponsors to issue, mail, or otherwise transmit payment for all clean claims submitted by network pharmacies—except for mail-order and long-term care pharmacies—within specified timeframes for electronic and all other (non-electronically submitted) claims.

Consistent with section 1860D–12(b)(4)(A)(ii) of the Act, a clean claim is defined in § 423.520(b) of this IFC as a claim that has no defect or impropriety—including any lack of any required substantiating documentation—or particular circumstance requiring special treatment that prevents timely payment of the claim from being made under the requirements of § 423.520 of this IFC. We note that this definition is consistent with the clean claim definitions under Parts A, B, and C of Medicare, as required under sections 1816(c)(2)(B), 1842(c)(2)(B), and 1857(f)(1) of the Act, respectively.

As provided in section 1860D–12(b)(4)(B) of the Act and codified in §§ 423.520(a)(1)(i) and (ii) of this IFC, Part D sponsors must make payment for clean claims within 14 days of the date on which an electronic claim is received and within 30 days of the date on which non-electronically submitted claims are received. Consistent with MIPPA, sections 423.520(a)(2)(i) and (ii) of this IFC define receipt of an electronic claim as the date on which the claim is transferred, and receipt of a non-electronically submitted claim as the 5th day after the postmark day of the claim or the date specified in the time stamp of the transmission, whichever is sooner.

Additionally, as provided in section 1860D–12(b)(4)(D)(i) of the Act and as codified in § 423.520(c)(1) of this IFC, a claim will be deemed to be a clean claim to the extent that the Part D sponsor that receives the claim does not issue notice to the submitting network pharmacy of any deficiency in the claim within 10 days after an electronic claim is received and within 15 days after a non-electronically submitted claim is received. A claim deemed to be a clean claim must be paid by the sponsor within 14 days (for an electronic claim) or 30 days (for a non-electronic claim) of the date on which the claim is received, as provided in §§ 423.520(a)(1)(i) and (ii) of this IFC.

Under section 1860D–12(b)(4)(D)(ii) of the Act and in § 423.520(c)(2) of this IFC, if the Part D sponsor determines that a submitted claim is not a clean claim, it is required to notify the submitting pharmacy that the claim has been determined not to be clean, specify all the defects or improprieties rendering the claim not a clean claim, and list all additional information necessary for the sponsor to properly process and pay the claim. This notification must be provided within 10 days after an electronic claim is received for an electronic claim, and within 15 days after a non-electronically submitted claim is received.

Once the submitting pharmacy resubmits the original claim with the additional information specified by the Part D sponsor as necessary for properly processing and paying the claim, the sponsor has 10 days, consistent with section 1860D–12(b)(4)(D)(iii) of the Act, and, as specified in § 423.520(c)(3) of this IFC to provide notice to the submitting pharmacy of any defect or impropriety in the resubmitted claim. If the sponsor does not provide notice to the submitting pharmacy of any defect

or impropriety in the resubmitted claim within 10 days of the sponsor's receipt of such claim, the resubmitted claim is deemed to be a clean claim and must be paid consistent with the timeframes specified in § 423.520(a)(1) of this IFC (within 14 days of the date on which a resubmitted electronic claim is received and within 30 days of the date on which a non-electronically resubmitted claim is received).

To clarify these requirements, we provide the following example. Assume a Part D sponsor receives an electronic claim on January 1, 2010. If the sponsor were to find a defect or impropriety in that claim, it would be required to communicate that defect or impropriety to the submitting pharmacy no later than January 11, 2010 (within the 10-day window established in § 423.520(c)(1)(i) of this IFC). If the sponsor received a resubmitted claim on January 12, 2010, it would then be required to either deem the claim to be clean or else provide notice to the submitting pharmacy of any defect or impropriety with the resubmitted claim no later than January 22, 2010 (within the 10-day window established in § 423.520(c)(2)(ii) of this IFC). Assuming the resubmitted claim contains all additional information necessary for the sponsor to properly process and pay the claim, the sponsor would be required to pay the resubmitted claim within 14 days of receiving it—in this case, not later than February 5, 2010.

In accordance with section 1860D–12(b)(4)(D)(iv) of the Act, § 423.520(d) this IFC specifies that payment for a clean claim is considered to have been made on the date payment for an electronic claim is transferred and on the date a non-electronic claim is submitted to the United States Postal Service or common carrier, respectively. To the extent that a Part D sponsor does not issue, mail, or otherwise transmit payment for a clean claim within 14 days of the date on which an electronic claim is received and within 30 days of the date on which a non-electronically submitted claim is received, as specified in § 423.520(a)(1) of this IFC, section 1860D–12(b)(4)(C) of the Act requires that the sponsor pay interest to the submitting pharmacy. As required under section 1860D–12(b)(4)(C)(i) of the Act, and as codified in § 423.520(e)(1) of this IFC, the Part D sponsor must pay such interest at a rate equal to the weighted average of interest on 3-month marketable Treasury securities determined for such period, increased by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which the payment is made under § 423.520(d) of this IFC. For purposes of CMS payments to Part D sponsors for qualified prescription drug coverage, any interest amounts paid under § 423.520(e)(1) of this IFC do not count against the Part D sponsor's administrative costs, nor are they treated as allowable risk corridor costs, under § 423.308. In other words, the Part D sponsor is fully liable for any interest payments for claims not paid timely, consistent with § 423.520(d) of this IFC. In accordance with section 1860D–12(b)(4)(C)(ii) of the Act and as codified in § 423.520(e)(2) of this IFC, CMS may determine that a Part D sponsor will not be charged interest under § 423.520(e)(1) as appropriate, including in exigent circumstances such as natural disasters and other similar unique and unexpected events that prevent timely claims processing. CMS will make such determinations on a case-by-case basis at the sponsor's request.

Section 1860D–12(b)(4)(E) of the Act and § 423.520(f) of this IFC require that a Part D sponsor pay all electronically submitted clean claims by electronic funds transfer (EFT) if the submitting network pharmacy requests payment via EFT or has previously requested payment via EFT. For ease of sponsor execution, the requirement that payment be provided via EFT if a sponsor has previously requested EFT payment means that any such previous request must have occurred during the current contract year. This requirement also means that all Part D sponsors must have the capacity to pay via EFT so that they may pay via EFT any of their network pharmacies requesting payment for submitted claims in this manner. In addition, under § 423.520(f), for any payment made via EFT, the Part D sponsor may also make remittance electronically.

In accordance with section 1860D–12(b)(4)(F)(i) of the Act and as codified in § 423.520(g)(1) of this IFC, the requirements in § 423.520 do not in any way prohibit or limit a claim or action that any individual or organization may have against a pharmacy, provider, or Part D sponsor that is unrelated to the new requirements in § 423.520. Further, as provided under section 1860D–12(b)(4)(F)(ii) of the Act and § 423.520(g)(2) of this IFC, consistent with any applicable Federal or State law, a Part D sponsor may not retaliate against an individual, provider, or pharmacy for any such claim or action. Finally, as provided under section 1860d–12(b)(4)(G) of the Act and codified in § 423.520(h), any determination that a claim submitted by a network pharmacy is a clean claim as defined in § 423.520(b) of this IFC shall not be construed as a positive determination regarding the claim's eligibility for payment under Title XVIII of the Act. In addition, any determination that a claim is a clean claim as defined in § 423.520(b) of the Act is not an indication that the government approves, or acquiesces regarding the submitted claim and does not relieve any party of civil or criminal liability, nor offer defense to any administrative, civil, or criminal action, with respect to the submitted claim.

In addition to adding a new § 423.520 to reflect the prompt payment requirements of section 1860D–12(b)(4) of the Act, we are amending § 423.505(b) to include the prompt payment provisions as one of the required elements of the contract between CMS and the Part D sponsor. Therefore, § 423.505(b)(19) of this IFC requires that, effective contract year 2010, the contract between CMS and the Part D sponsor must include the prompt payment provisions at § 423.520 of this IFC.

We are also amending § 423.505(i)(3) with respect to contracts or written arrangements between Part D sponsors and pharmacies or other providers, first tier, downstream and related entities to ensure that Part D sponsors' contracts with these entities include prompt payment provisions consistent with § 423.520. Section 423.505(i)(3)(vi) thus requires that sponsors' pharmacy contracts include the prompt payment provisions of § 423.520. We intend to review pharmacy contract templates (except for mail-order and LTC pharmacy templates) for new applicants to ensure the addition of these prompt payment provisions.

We are aware that some pharmacies, particularly independent pharmacies, work with agents for purposes of negotiating and/or signing contracts with Part D sponsor, and that these agents may receive claim payments from Part D sponsors on their participating pharmacies' behalf. To the extent that such agents are authorized to receive payment on behalf of a participating pharmacy for claims submitted to a Part D sponsor, there is no distinction between a pharmacy and its agent for purposes of the prompt payment provisions at § 423.520. Thus, the prompt payment provisions at § 423.520 extend to an agent authorized to receive payment for claims submitted to a Part D sponsor, as long as it is in compliance with all Federal and State laws.

The revisions to the regulations reflecting the above-described MIPPA prompt payment provisions are all effective on January 1, 2010.

4. Submission of Claims by LTC Pharmacies (§ 423.505)

Section 172 of MIPPA amended sections 1860D–12(b) and 1857(f)(3) of the Act to add a provision on the submission of claims by pharmacies located in or having a contract with a long-term care facility. Effective January 1, 2010, new sections 1860D–12(b)(5) and 1867(f)(3)(B) of the Act direct us to incorporate into each contract CMS enters into with a Part D sponsor a provision addressing the submission of claims by long-term care pharmacies. Specifically, CMS contracts with Part D sponsors must provide that long-term care pharmacies must have not less than 30 days, nor more than 90 days, to submit claims to the sponsor for reimbursement under the plan. We are codifying this new statutory contract requirement at § 423.505(b)(20). Effective January 1, 2010, this provision will apply to any claim submitted by a long-term care pharmacy, as defined in § 423.100.

It is important to note that this new requirement does not eliminate the requirement, specified in a CMS policy memorandum dated May 25, 2007 (available at *insert URL*) for Part D sponsors to provide a new timely claims filing period for claims incurred by dual-eligible beneficiaries during a period of retroactive Part D enrollment. The CMS memorandum, entitled ''Special Transition Period for Retroactive Enrollment,'' requires that in retroactive enrollment situations Part D sponsors must use the date of Medicaid notification to establish a new timely claims filing period to ensure that dual-eligible beneficiaries and other parties, including pharmacies, have the opportunity to request reimbursement for claims incurred during the retroactive period. Therefore, consistent with this policy, sponsors must provide a new period, as specified in § 423.505(b)(20), for long-term care pharmacies to submit claims for reimbursement.

Effective contract year 2010, new sections 1860D–12(b)(5) and 1867(f)(3)(B) of the Act require that CMS contracts with Part D sponsors include a provision requiring sponsors to provide long-term care pharmacies (as defined in § 423.100) not less than 30 days, nor more than 90 days, to submit claims for reimbursement under the plan. In addition to adding this requirement to the contract provisions specified in § 423.505(b), we are amending § 423.505(i) to specify that timeframes for submission of claims by long-term care pharmacies must be contained in Part D sponsor contracts with the long-term care pharmacies. As provided in § 423.505(i)(3)(vii), all sponsor contracts with long-term care pharmacies must contain a provision that establishes timeframes, consistent with § 423.505(b)(20), for the submission to the sponsor of claims for reimbursement.

5. Regular Update of Prescription Drug Pricing Standard (§ 423.505)

Section 173 of MIPPA amended sections 1860D–12(b) and 1857(f)(3) of the Act, effective January 1, 2009, to add a provision on the regular updating of prescription drug pricing standards. In accordance with new sections 1860D–12(b)(6) and 1857(f)(3)(C) of the Act, which we are codifying in § 423.505(b)(21) of this IFC effective January 1, 2009, 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). As codified in §§ 423.505(b)(21)(i) and (ii), these updates, if applicable, must occur on January 1 of each contract year and not less frequently than every 7 days thereafter.

We are also amending § 423.505(i)(3) with respect to contracts or written arrangements between Part D sponsors and pharmacies or other providers, first tier, downstream and related entities to ensure that Part D sponsors' contracts with these entities include provisions for regularly updating any prescription drug pricing standard used by sponsors to reimburse their network pharmacies, as provided in § 423.505(b)(21) of this IFC. Specifically, section 423.505(i)(3)(vi)(A) of this IFC requires that sponsors' pharmacy contracts include the pricing standard update requirements at § 423.505(b)(21) of this IFC, if applicable.

Implicit in the statutory requirement that pricing standards be updated is the fact that such standards are being used. This information is also necessary in order to monitor for compliance with MIPPA updating requirement. Accordingly, § 423.505(i)(3)(viii)(B) of this IFC specifies that a Part D sponsor's pharmacy contract must indicate the source used by the Part D sponsor for making such pricing updates.

Given the applicability of the pricing standard update provisions beginning in contract year 2009, Part D sponsors must ensure that they amend their current pharmacy contracts consistent with § 423.505(i)(3)(viii) of this IFC. 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.

We are aware that some pharmacies, particularly independent pharmacies, work with agents for purposes of negotiating and/or signing contracts with Part D sponsors, and that these agents may receive claim payments from Part D sponsors on their participating pharmacies' behalf. To the extent that such agents are authorized to receive payment on behalf of a participating pharmacy for claims submitted to a Part D sponsor, there is no distinction between a pharmacy and its agent for purposes of the drug pricing standard update requirements at § 423.505(b)(21) of this IFC. Thus, the drug pricing standard update requirements at § 423.505(b)(21) of this IFC extend to an agent authorized to receive payment for claims submitted to a Part D sponsor, as long as it is in compliance with all Federal and State laws.

6. Use of Part D Data (§ 423.505(m))

On May 28, 2008, prior to the passage of MIPPA, CMS published a final regulation (73 FR 30664) regarding the collection and use of Part D claims data. This regulation resolved the statutory ambiguity between section 1860D–12(b)(3)(D) and section 1860D–15 of the Act. One of the incorporated provisions at section 1860D–12(b)(3)(D) of the Act, is section 1857(e)(1) of the Act, which provides broad authority for the Secretary to add terms to the contracts with Part D sponsors, including terms that require the sponsor to provide the Secretary, ''with such information as the Secretary may find necessary and appropriate.'' As we stated in our final rule on Part D claims data, we believe that the broad authority of section 1860D–12(b)(3)(D) of the Act authorizes CMS to collect the same prescription drug event data we currently collect to properly pay sponsors under the statute for other purposes unrelated to payment. However, we acknowledged that section 1860D–15 of the Act contains provisions that might be viewed as limiting such collection, thus compelling CMS to clarify the Secretary's broad authority under section 1860D–12(b)(3)(D) in our final regulation. Accordingly, in the final Part D data rule, we implemented the broad authority of section 1860D–12(b)(3)(D) of the Act to permit the Secretary to collect claims data that are collected for Part D payment purposes for other research, analysis, reporting, and public health functions. For a complete

discussion of this regulation, please see the final Part D data rule at 73 FR 30664.

Section 181 of MIPPA amends section 1860D–12(b)(3)(D) to make clear that, notwithstanding any other provision of law, information provided to the Secretary under the application of section 1857(e)(1) may be used for purposes of carrying out Part D, and may be used to improve public health through research on the utilization, safety, effectiveness, quality, and efficiency of healthcare services. Thus, MIPPA further strengthens CMS' final rule on Part D claims data and confirms our authority to use claims data collected under 1860D–12 of the Act for purposes of reporting to the Congress and the public, conducting evaluations of the overall Medicare program, making legislative proposals to Congress, and conducting demonstration projects.

While MIPPA does not alter our ability to collect and use data for purposes outlined in our final rule on Part D claims data, section 181 of MIPPA adds a provision with respect to the disclosure of claims data to Congressional support agencies. Specifically, section 181 of MIPPA adds clause (ii) to section 1860D–12(b)(3)(D), which requires the Secretary to make data collected under section 1860D–12(b)(3)(D) available to Congressional support agencies, in accordance with their obligations to support Congress as set out in their authorizing statutes, for the purposes of conducting Congressional oversight, monitoring, making recommendations, and analysis of the Part D program. In our previously issued final rule on Part D claims, we specified that we would only release the minimum data necessary to Congressional oversight agencies in accordance with our data sharing policies. Section 1860D–12(b)(3)(D), as amended, removes the minimum necessary data restriction when data are requested by a Congressional support agency that is requesting the data in accordance with its obligation to support Congress as set out in its authorizing statute.

Section 423.505(f)(3) of the regulation establishes that Part D plan sponsors must submit the 37 original data elements included as part of their drug claims ''for all purposes deemed necessary and appropriate by the Secretary, including, but not limited to,'' reporting to Congress and the public on the operation of the Part D program, conducting evaluations of the overall Medicare program, making legislative proposals, conducting demonstrations and pilot projects, supporting care coordination and disease management programs, supporting quality improvement and performance measurement activities, and populating personal health care records. Section 423.505(m)(1) of the regulations currently provides that with respect to data collected under section 423.505(f)(3), ''CMS may release the minimum data necessary for a given purpose to Federal executive branch agencies, congressional oversight agencies, States, and external entities in accordance with the applicable Federal laws, CMS data sharing procedures, and subject, in certain cases to encryption and or aggregation of certain sensitive information. MIPPA revised 1860D–12(b)(3)(D) of the Act to provide specifically that information collected pursuant to this section be made available to Congressional support agencies, in accordance with their obligations to support Congress as set out in their authorizing statutes, for the purposes of conducting Congressional oversight, monitoring, making recommendations, and analysis of the Medicare Part D program. Consistent with this new statutory provision, we have revised § 423.505(m)(1) of our regulations, to omit any reference to ''Congressional oversight agencies.'' We are also adding a new paragraph § 423.505(m)(3) specifying that the Secretary will make the information collected under § 423.505(f)(3) available to Congressional support agencies in accordance with their obligations to support Congress as set out in their authorizing statutes.

We are using the same definition for Congressional support agencies in § 423.505(m)(3) that we previously used for Congressional oversight agencies in the regulation at § 423.505(m)(1)(iv). As with the definition of Congressional oversight agencies at 423.505(m)(1)(iv), we are not including Congressional Research Service (CRS) as a Congressional support agency unless it is requesting the data on behalf of a Congressional committee consistent with 2 U.S.C. 166(d)(1). As previously explained in the preamble to CMS–4119–F, when CRS is not acting as the agent of a Congressional committee, it does not have the same authority to request data from departments or agencies of the United States, and would be restricted in the same manner as external entities when requesting prescription drug event data.

7. Exemptions From Income and Resources for Determination of Eligibility for Low-Income Subsidy (§ 423.772)

Section 1860 D–14 of the Social Security Act describes the rules for determining financial eligibility for the Medicare Part D Low-Income Subsidy (LIS). These rules closely conform to the Supplemental Security Income (SSI) methodology for determining financial eligibility. Section 116 of MIPPA amended the types of income and resources to be taken into consideration for determining financial eligibility for LIS to deviate from the SSI methodology in two areas. Specifically, section 116 of MIPPA amended 1860D–14(a)(3) by exempting from the determination of LIS the following:

- Support and maintenance furnished in kind from income; and
- Value of any life insurance policy from resources.

Support and maintenance furnished in kind is any food or shelter that is given to the applicant/spouse or received because someone else pays for it. This includes room, rent, mortgage payments, real property taxes, heating fuel, gas, electricity, water, sewage, and garbage collection services.

Life insurance policy includes whole life, term, and products that combine features of whole life and term policies.

In general, it is the responsibility of the Social Security Administration to determine eligibility for LIS. However, the Centers for Medicare & Medicaid Services (CMS) maintain in regulation broad parameters for income and resources for the Medicare Part D Low-Income Subsidy. These regulations also govern how State Medicaid Agencies process LIS applications when individuals apply there. In order for CMS regulations to conform to the new law, CMS is updating its regulations to reflect the new exclusions from income and resources.

In order to reflect these changes, we are revising the definitions of ''income'' and ''resources'' in § 423.772.

The amendments made by this provision are effective with respect to LIS applications filed on or after January 1, 2010.

C. Changes to the MA and Prescription Drug Benefit Programs

In order to assist readers in understanding how the final provisions we discuss in this section apply to both programs, we are including Table 1, which highlights the provisions affecting both programs and the pertinent Part 422 and Part 423 CFR sections.

TABLE 1—PROVISIONS AFFECTING BOTH THE PART C AND PART D PROGRAMS

Provision	Part 422–subpart	Part 422 CFR section	Part 423—subpart	Part 423 CFR section
Disclosure of plan information	Subpart C	422.111	Subpart C	423.128
Marketing: Standards for MA/Part D marketing: • Nominal gifts • Scope of marketing • Co-branding • Including plan type in plan name	Subpart V	422.2268		423.2268
Marketing: Reporting terminations	Subpart V	422.2272		423.2272
Marketing: • Broker and agent compensation • Training and testing	Subpart V	422.2274		423.2274

1. Disclosure of Plan Information (§§ 422.111)

Section 164 of the Medicare Patients and Providers Improvement Act revised section 1859(f) of the Act to require, effective January 1, 2010, disclosure of SNP plan information to beneficiaries. In order to reflect the MIPPA changes, we are adding new paragraph (b)(iii) to § 422.111. The addition requires to require dual-eligible SNPs to provide the information specified in §§ 422.111(b) and 423.128(b) of the MA and Part D program regulations, both prior to enrollment to each prospective enrollee and at least annually thereafter, 15 days before the annual coordinated election period. CMS plans to develop a model comprehensive statement for beneficiaries that could be included with any description of benefits offered by the SNP plan. Note that in a related final rule to be published on or about the date of publication of this IFC, we will be finalizing provisions from the May 16, 2008 proposed rule related to disclosure of plan information for MA organizations.

2. Medicare Advantage and Prescription Drug Program Marketing Requirements (New Subparts V)

a. General

In a separate final rule (that appears in this issue of the **Federal Register**) finalizing several of the marketing provisions proposed in our May 16, 2008 proposed rule we established a new marketing subpart V for Parts 422 and 423. In this IFC, we refer to the codification of marketing requirements that reflects those changes (revised Code of Federal Regulations sections established in the final rule). With the exception of the provisions relating to including plan type in the name of the plan, and the reporting by plans of agent and broker terminations to States, all of the Part C and Part D marketing requirements discussed below are effective upon publication of this interim final rule.

b. Standards for MA and PDP Marketing (§§ 422.2268, 423.2268)

In the May 16, 2008 proposed rule, we proposed several regulatory requirements in §§ 422.2268 and 423.2268, providing additional protections to ensure that beneficiaries are not the victims of inappropriate marketing techniques. Several areas we addressed in these proposed regulatory marketing requirements were addressed by Congress in MIPPA, which required in section 103(b)(1)(B) that the Secretary ''establish limitations with respect to'' five areas specified in statute. With the exceptions noted above, these MIPPA-mandated marketing limitations are required to be in effect ''on a date specified by the Secretary, but in no case later than November 15, 2008.'' Because this deadline is less than 150 days after the enactment of MIPPA, under section 1871(b)(2)(B) of the Act, we may publish rules implementing these MIPPA provisions without prior notice and comment. Some provisions in the May 16, 2008 proposed rule were similar to those in MIPPA. As a result, to the extent that our policies were informed by comments we received on the proposed rule, we will discuss the public comments in connection with the marketing provisions we have developed in implementing the MIPPA provisions.

(i) Nominal Gifts

In our May 16, 2008 NPRM, we proposed a new regulatory requirement in §§ 422.2268(b) and 423.2268(b) under which organizations would be required to limit the offering of gifts and other promotional items offered to potential enrollees at promotional events to gifts of ''nominal value'' that are offered to all potential enrollees. This proposed paragraph also contained a prohibition against offering meals that we are addressing in a separate rule.

In section 103(b)(1)(B) of MIPPA, the Secretary was charged with ''establish[ing] limitations with respect to * * * the offering of gifts and other promotional items other than those of nominal value (as determined by the Secretary) to prospective enrollees at promotional activities.'' Section 103(b)(2) of the MIPPA revises the Act to apply these same guidelines to PDP sponsors.

We are implementing this MIPAA requirement in a revised version of the nominal value gift portion of our proposed §§ 422.2268(b) and 423.2268(b). Commenters on our May 16, 2008 proposed version asked if the requirement that promotional items be available to all eligible individuals meant that the promotional items had to be offered to current members. Other commenters recommended that a dollar limit approach be adopted to ensure that the permitted promotional items were truly of nominal value.

Our revised version of the nominal gift portion of our proposed §§ 422.2268(b) and 423.2268(b) clarifies that the promotional items must be available to all potential enrollees at promotional events without regard for whether or not the beneficiary enrolls. With respect to the dollar amount issue, the Marketing Guidelines and guidance currently specify a dollar limit of $15 to ensure that promotional items are of nominal value. CMS will update this number as necessary to account for inflation and other relevant factors. Examples of nominal gifts include pens, pencils, and calendars.

(ii) Limiting the Scope of Health Care Products To Be Discussed

In §§ 422.2268(g) and 423.2268(g) of the May 16, 2008, rule, we proposed to limit any appointment with a beneficiary involving marketing of health care related products (for example, whether Medicare supplement, Medicare Advantage, stand-alone PDP will be discussed) to the scope agreed upon by the beneficiary. We further proposed to require, that, in advance of any marketing appointment, the beneficiary

must have the opportunity to agree to the range of choices that will be discussed, and that agreement would have to be documented by the plan. Under proposed §§ 422.2268(h) and 423.2268(h), additional lines of plan business (for example, MA, MA–PD, PDP or Medigap) not identified prior to the in-home appointment would require a separate appointment that could not be re-scheduled until 48 hours after the initial appointment.

In section 103(b)(1)(B) of MIPPA, the Secretary was charged with ''establish[ing] limitations with respect to * * * the scope of any appointment with respect to the marketing of a Medicare Advantage plan.'' Section 103(b)(2) of MIPPA revises the Act to apply these same guidelines to PDP sponsors. The statute further provides that ''[s]uch limitation shall require advance agreement with a prospective enrollee on the scope of the marketing appointment and documentation of such agreement by the Medicare Advantage organization. In the case where the marketing appointment is in person, such documentation shall be in writing.''

We are here adopting our proposed version of §§ 422.2268(g) and (h) and 423.2268(g) and (h) to implement these MIPPA provisions, and in light of a comment on the proposed rule expressing confusion about what a line of business is, we clarify here that ''lines of business'' are considered Prescription Drug Plans, Medicare Advantage Prescription Drugs Plans or Medicare Advantage only and Medigap.

(iii) Use of Names and Logos, Co-Branding

As an additional beneficiary protection, in §§ 422.2268(n) and 423.2268(n) of the May 16 proposed rule, we proposed to limit the use of names and/or logos of co-branded network providers on member information and marketing materials including plan membership identification cards. We also proposed to codify existing policies that MA organizations may include on plan membership cards, provider names/logos that are specific to the members selection of providers or provider organizations. In addition, all member information and marketing materials except for plan identification cards should indicate that other providers are available in the network. We believed that this requirement would reduce the tendency of members to mistakenly believe they must use the co-branded network provider in order to obtain plan benefits.

In section 103(b)(1)(B) of MIPPA, the Secretary was charged with ''establish[ing] limitations with respect to * * * ''[t]he use of the name or logo of a co-branded provider on Medicare Advantage plan membership and marketing materials.'' Section 103(b)(2) of MIPPA revises the Act to apply these same guidelines to PDP sponsors.

We are implementing this requirement through a modified version of our proposed §§ 422.2268(n) and 423.2268(n). Specifically, as a result of comments on the May 16, 2008 proposed rule, we are revising the proposed version of these rules to clarify that MA organizations may include provider names/logos on the member identification card related to the member selection of specific providers or provider organizations. We further clarify here that ''other marketing materials'' requiring the statement that other providers are available in the network, are marketing materials as defined in §§ 422.2260 and 423.2260.

(iv) Inclusion of Plan Type in Plan Name

Section 103(c)(1) of MIPPA requires that MA organizations and PDP sponsors include the plan type within the name of each plan being offered for plan years beginning on or after January 1, 2010. We are adding new paragraph (q) in §§ 422.2268 and 423.2268 to reflect this requirement. For consistency across plans, it will be required that the plan type is included at the end of the plan name. For example, a plan previously submitted as ''Medicare ABCXYZ Gold'' could be submitted as ''Medicare ABCXYZ Gold HMO'' or ''Medicare ABCWYZ Gold HMO Plan.''

c. Reporting Agent and Broker Terminations (§§ 422.2272 and 423.2272)

Section 103 of the Medicare Improvements for Patients and Providers Act (MIPPA), requires us to expand our proposed requirements on plans that use licensed agents and brokers. In accordance with MIPPA, §§ 422.2272(d) and 423.2272(d) implement the requirement, effective January 1, 2009, that MA organizations and Part D sponsors are required to report to the State in which the MAO or Part D sponsor appoints an agent or broker, the termination of any such agent or broker, including the reasons for the termination if State law requires that the reasons for the termination be reported.

d. Broker and Agent Compensation (§§ 422.2274, 423.2274)

Section 103(b)(1)(B) of MIPPA revises the Act to charge the Secretary with establishing guidelines to ''ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the Medicare Advantage plan that is intended to best meet their health care needs.'' Section 103(b)(2) of MIPPA revises the Act to apply these same guidelines to PDP sponsors.

This is another area that we addressed in proposals set forth in the May 16 proposed rule. Our proposed rules were based on our program experience showing that the current compensation structure permitted under the Marketing Guidelines had the potential to create a financial incentive for agents to only market and enroll beneficiaries in some plan products and not others. This compensation structure has led some agents to encourage beneficiaries to enroll in products that may not meet the beneficiaries' health needs but pays the agents the highest commission. In addition, there is a potential financial incentive for agents to encourage beneficiaries to change plans each year. Therefore, in order to prevent agents from unnecessarily moving beneficiaries from plan to plan and to ensure that beneficiaries are receiving the information and counseling necessary to select the best plan based on their health care needs, CMS proposed in the May 16 proposed rule to add new rules regarding compensation at §§ 422.2274(a)(1) and (a)(2) and 423.2274(a)(1) and (a)(2).

In developing our policy for implementing the MIPPA changes to the Act regarding agent and broker compensation, we benefited from public comments we received on our proposal in our May 16 proposed rule.

For example, several commenters on that proposal wanted clarification on the definition of ''independent broker or agent,'' and whether the changes apply to both independent agents selling Medicare products and plan employees or to the employer retiree group market. There was a strong feeling among the commenters on the May 16 proposed rule that the nature of compensation for employees was very different than that of independent agents, and that it would be difficult to develop a level compensation structure for both groups.

Several commenters wanted clarification on the distinction between compensation and commission. Also, commenters had questions specifically about bonuses. Some recommended that prizes, awards, trips, and similar

bonuses and incentives be excluded from the proposed provisions. Some commenters felt that these incentives should be prohibited. Others felt there should be exceptions made for convention credits, exceptions for incentives that reward high member retention, or one-time bonuses for administrative efficiency (for example, encourage electronic submission of applications).

Several commenters recommended a new provision that level commissions be advanced to agents, but have to be earned at a level rate (for example, one-twelfth of the annual amount per month as long as the member is active with the plan sponsor). Along with the new provision, the commenters requested that CMS continue to require plans to charge back all commissions for applications that result in rapid disenrollments within 60 days. One of the commenters asked that the period for charge back be expanded to 6 months. There was one commenter who wanted to know how the proposed structure would work with mid-year plan changes or renewals (for example, with full duals).

The comments we received through the public notice and comment process helped us implement the MIPPA changes to the Act regarding agent and broker compensation. As a result, the structure we are implementing in this IFC, while directed to Medicare Advantage organizations and Part D sponsors that market ''through independent brokers or agents,'' includes compensation paid to employees that is based on volume of sales. By ''independent brokers or agents'' we mean contracted brokers or agents, whether they sell for one plan, multiple plans, or work through a Field Marketing Organization (FMO), general agent (GA), or other similar subcontracted marketing organizations.

The proposal in the May 16 proposed rule defined commission to include other compensation. Based on the comments received on that proposed rule, our definition of compensation under our rule implementing MIPPA 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, certification, and testing costs; and reimbursement for mileage to and from appointments with beneficiaries and reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials are also not considered compensation. We have clarified our proposal by revising paragraph (a)(1) of §§ 422.2274 and 423.2274 to clarify what is considered compensation.

We also include in this IFC a provision that compensation for a sale 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 prorated basis only for the months in which the enrollee was actually a member of the plan.

We also received comments on our proposal in the proposed rule that the commission an agent received in the first year after an enrollment could not exceed the commission the agent receives in all subsequent years. Many commenters recommended that CMS follow the industry standard practice for Medicare supplements or modify the provision to allow for a higher commission in the first year because there is a significantly greater amount of work done in the initial year than in subsequent ones. They requested that the subsequent years be limited to five years. They also wanted clarification on what was meant by ''all subsequent years.''

Based in part on these comments, in developing our policy implementing MIPPA's changes to the Act regarding agent and broker compensation, this IFC provides that 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 5 renewal years. This creates a 6-year compensation 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 5 renewal years (6-year total compensation cycle). The agent will receive renewal compensation for the 5-year renewal period (years 2 through 6) based on this compensation structure as long as the member remains active in a like-plan type (for example, PDP, MA plan, or cost plan). We believe that this provision places limits on compensation paid to agents. It also encourages agents to establish longer term relationships with their clients, rather than short term relationships. This provision eliminates the incentive for agents to move their clients from plan to plan since the compensation that agents receive for a replacement plan will be nearly the same as if the client had stayed in the original plan. Additionally, since most plan changes occur in the first three months of the plan year and agents typically are paid for the entire year in the first three months, we are requiring that agents and brokers earn compensation for months four through twelve and that they be paid by a given plan only for months in which the beneficiary is enrolled in that plan. This means that plans may pay agents and brokers up-front or prorate compensation payments over 12 months or over months 4 through 12, but when a beneficiary disenrolls from the plan, the plan must recover all compensation paid-for months in which the beneficiary is not enrolled, and during months 1 through 3 if the beneficiary disenrolls during the first 3 months and compensation was paid in advance.

Several commenters on the proposal in the May 16 proposed rule expressed concern about our proposal in 422.2274(a)(2) and 423.2274(a)(2) that commissions must be the same for all plan and plan product types offered by plan's parent organization. These commenters wanted ''parent organization'' defined. They were also concerned about how this would apply to field marketing organizations (FMOs) and general agents (GA), organizations composed of various levels of agents and that provide additional services beyond selling insurance products (for example, training, document management and storage, office space, supplies, and equipment). The questions about FMOs centered around whether the commission was paid at the ''street level'', meaning directly to the agent, or at the FMO level, where the FMO would then be responsible for paying the agent. One commenter suggested that plans could include a term in their contracts with FMOs stating that the FMO would receive a fee from the plan and out of that fee, the agent would be paid the specified amount in accordance with CMS' rules. The statement could be detailed enough to address the prohibition against prizes, awards, trips and other types of incentives. One commenter suggested that CMS should consider evaluating fees paid to FMOs for future regulation.

There were many comments about variable commissions. Several addressed the problems that a national plan would face in developing a commission that would apply across the country because the average may be too high for some areas and too low for others. They recommended that commissions should be based on local

geographic areas. One commenter stated that basic drug plans should have reduced commissions or not have commissions at all because leveling them with commissions for enhanced plans would create additional costs that would make it difficult for them to meet the regional low-income benchmarks. Several commenters felt that there should be a different commission for MA plans and PDPs. Some suggested that there should be different commissions for all MA types. One commenter asked whether the level commission applied to other products (for example, Medicare supplements, dental, vision, auto, etc).

Several commenters suggested ways to design a variable commission including—commissions based on percent of premium amount; tiered commission structure based on volume of sales; commissions based on amount of work required to sell product; commissions based on education, experience, tenure, or services provided; commissions based on performance; establishing a cap on commissions, separate commissions for agents that only provide leads; or special commissions for SNPs.

Based in part on the issues raised by the above comments received on the May 16 proposed rule, CMS is adopting a different approach to compensation structure that focuses on creating incentives for agents and brokers to enroll beneficiaries in MA and Part D plans that best meet beneficiaries' health care needs. This shifts the focus from specific dollar values, as proposed in the May 16 proposed rule, to guidelines specifying how compensation is disbursed, whether an agent receives a new or renewal compensation, and what qualifies as compensation. However, CMS still expects that plans will set compensation at levels that are reasonable and reflect fair market value for the services. Accordingly, under this IFC, compensation can vary (for example, by geographic area, plan type, agent experience), but is subject to the requirements that renewal compensation be paid for five renewal years (6-year total compensation cycle), that compensation for a change in plans during that five-year period be the same as the renewal compensation, and the initial compensation may not exceed 200 percent of the renewal compensation. CMS encourages plans to keep compensation as level as possible across plan types and among agents providing similar services. As discussed above, we define ''compensation'' as including 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, and reimbursement for mileage to and from appointments with beneficiaries and reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials are also not considered compensation. Specifically, under the rule set forth in this IFC implementing our charge under MIPPA, MA organizations and PDP sponsors must adopt a compensation structure according to the following:

- The aggregate first year compensation is no more than 200 percent of the aggregate compensation paid for selling or servicing the enrollee in each individual subsequent year, of which there must be five total renewal years creating a 6-year compensation cycle.
- If compensation is paid in the first year, renewal compensation must be paid for no fewer than 5 renewal years (6-year compensation cycle), provided that the enrollee remains enrolled in the plan.
- No entity may provide and no agent or broker may receive aggregate 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 (6-year compensation cycle). ''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 compensation is paid for enrollment in the PDP.
- Compensation (for both first-year and renewals) is to be earned for months 4 through 12 of the enrollment year. Plans may pay agents and brokers up-front or prorate compensation payments over 12 months or over months 4 through 12, but when a beneficiary disenrolls voluntarily or involuntarily from the plan, the plan must recover all compensation paid-for months in which the beneficiary is not enrolled, and for months 1 through 3 if the beneficiary disenrolls during the first 3 months and compensation was paid in advance.
- Organizations and sponsors must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year. Compensation structures must be in place by the beginning of the plan marketing period, October 1.
- Compensation structures must be available upon CMS request including for audits, investigations, and to resolve complaints.

The compensation structure is designed to help prevent inappropriate moves of beneficiaries from plan-to-plan. 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.*

e. Agent and Broker Training (§§ 422.2274 and 423.2274)

Section 103(b)(1)(B) of MIPPA revised the Act to charge the Secretary with establishing ''limitations with respect to the use by a Medicare Advantage organization of any individual as an agent, broker, or other third party representing the organization that has not completed an initial training and testing program and does not complete an annual retraining and testing program.'' Section 103(b)(2) of MIPPA revises the Act to apply these same limitations to PDP sponsors.

In our May 16 proposed rule, we proposed rules establishing a requirement for training of agents that we hereby adopt under this IFC to implement the above MIPPA language. These rules are set forth in this IFC at §§ 422.2274 and 423.2274.

In 422.2274(b) and 423.2274(b), MA organizations and PDP sponsors are required to train all agents selling Medicare products on Medicare rules, regulations and compliance-related information annually.

In 422.2274(c) and 423.2274(c), agents selling Medicare products are required annually to pass written or electronic tests on Medicare rules, regulations and information on the plan products they intend to sell.

In 422.2274(d) and 423.2274(d), MA organizations and PDP sponsors are

required to provide to CMS the information designated by CMS as necessary to conduct oversight of marketing activities.

In 422.2274(e) and 423.2274(e), MA organizations and PDP sponsors are required to comply with State requests for information about the performance of licensed agents or brokers as part of a State investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

D. Changes to Section 1876 Cost Plans

Clarifying the Conditions Under Which 1876 Cost Plans or Portions of Their Service Areas May Be Prohibited

Section 1876(h)(5)(C) of the Social Security Act (the Act) prohibits 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. Section 167 of MIPPA clarified the application of minimum enrollment requirements by revising paragraphs 1876(h)(5)(C) of the Act.

The MIPPA-based revisions include clarifying in 1876(h)(5)(C)(iii) that the two plans triggering the prohibition may not be offered by the same MA organization.

In addition, by revising 1876(h)(5)(C)(iii)(I) of the Act, MIPPA clarified that 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.

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.

In order to reflect these changes we are revising paragraphs (c)(1)–(3) of § 417.402 of Title 42 of the Code of Federal Regulations.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. Below, we discuss the provisions of the rule and our reasons for the waiver of notice-and-comment procedure and, as specified, waiver of effective dates. If we do not specify that the effective date for a provision be waived, the date noted in the section should be considered the effective date.

A. Waiver of Notice-and-Comment Procedure

1. Marketing Provisions (Several Sections, Subpart V)

All of the marketing sections included in this regulation and listed below with the exception of the requirement that plans must include the plan type in the plan's name, and that plans report the termination of agents or brokers to States, must be implemented, according to MIPPA, by a date specified by the Secretary, but no later than November 15, 2008. Under section 1871(b)(1)(B) of the Act, prior notice and comment is not required when ''a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained. The deadline for the marketing provisions that must be in effect by November 15th is less than 150 days after enactment of HIPAA, and these provisions thus may be published in final form without prior notice and comment.

2. Other Provisions

The remainder of the provisions in this IFC either update or revise existing regulations or add new regulations to conform to the statutory changes made by MIPAA. Since these provisions are set in law without regard to what public commenters might say, seeking public comment is unnecessary and contrary to the public interest.

B. Waiver of Delay of Effective Date

In addition, for those provisions discussed above which were required by statute to be in effect by a date specified by the Secretary, but in no case later than November 15, 2008, we find good cause to waive the 30-day delay in effective date that would otherwise apply under section 1871(e)(1)(B)(i) of the Act and section 553(d) of the Administrative Procedure Act (APA).

Section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act ordinarily require that a regulation be effective no earlier than 30 days after publication. Under section 553(d)(3) this requirement can be waived for good cause, and under section 1871(e)(1)(B)(ii) this requirement can be waived if necessary to comply with statutory requirements, or if a delay is contrary to the public interest.

As noted above, Congress enacted MIPPA on July 15, 2008 and directed that many of the marketing provisions in this rule be effective on a date specified by the Secretary, but in no event later than November 15, 2008, so that they could be implemented in time for this fall's marketing for the 2009 plan year. As a result, we find good cause to waive the APA delay of effective date, and find that a delay under section 1871 is contrary to the public interest.

In addition, 5 U.S.C. section 801 generally requires that agencies submit major rules to the Congress 60 days before the rules are scheduled to become effective. This delay does not apply, however, when there has been a finding of good cause for waiver of prior notice and comment as set forth above.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

Section 422.101 Requirements Relating to Basic Benefits

Section 422.101(f)(1) states that MA organizations offering special needs plans must implement a model of care with care management as a centerpiece designed to meet the specialized needs of the plan's targeted enrollees.

The burden associated with this requirement is the time and effort put forth by the special needs plan to establish a model that meets the requirements under Section 422.101(f). In the initial year of development, we estimate it would take one special needs plan 80 hours per year to meet this requirement. In subsequent years, we estimate that it would take 10 hours per year to revise the model of care based on performance data analysis through the plan's quality improvement program. Existing SNPs already have models of care and will need to revise, not develop, models of care. We estimate the 335 existing SNPs would have a cumulative annual burden of 3,350 hours to revise their model of care. In January 2010, we anticipate that CMS will approve 150 new SNPs. We estimate the 150 new SNPs would have a cumulative initial year burden of 12,000 hours to develop their model of care, and a cumulative annual burden of 1,500 hours to revise their model of care in subsequent years. In summary, we project the total annual burden in calendar year 2009 to be 3,350 hours. In calendar year 2010, we project the total annual burden to be 13,500 hours (12,000 hours for SNPs approved to begin operating January 1, 2010 and 1,500 hours for SNPs approved prior to January 1, 2010).

Section 422.107 Special Needs Plans and Dual-Eligibles: Arrangements With States

Section 422.107(a) requires that an MA organization seeking to offer a special needs plan serving beneficiaries eligible for both Medicare and Medicaid (dual-eligible SNPs) must have a contract with the State Medicaid agency. The MA organization retains responsibility under the contract for providing benefits, or arranging for benefits to be provided, for individuals entitled to receive medical assistance under Title XIX. Such benefits may include long-term care services consistent with State policy.

Section 422.107 also allows MA organizations with an existing dual-eligible SNP without a State Medicaid agency contract to continue to operate through 2010 provided they meet all other statutory requirements, that is, care management and quality improvement requirements, and do not expand their service areas.

The burden associated with this requirement is the time and effort put forth by each dual-eligible special needs plan to contract with the State Medicaid agency. We estimate it would take one special needs plan 18 hours for 6 months to comply with this requirement. We estimate 460 special needs plans would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 16,560 hours.

Section 422.111 Disclosure Requirements

Section 422.111(b)(2)(iii) states that each special needs plan must provide for prospective dual-eligible individuals, prior to enrollment, a comprehensive written statement describing cost-sharing protections and benefits that the individual is entitled to under title XVIII and the State Medicaid program under title XIX. This may be developed by the special needs plans and distributed by the agents selling Medicare products.

The burden associated with this requirement is the time and effort put forth by each SNP to develop and provide such written statement. We estimate that it would take one special needs plan 10 hours for 6 months to comply with this requirement. We estimate 460 special needs plans would be affected annually by this requirement; therefore the total annual burden associated with this requirement is 4,600 hours.

Section 422.114 Access to Services Under an MA Private Fee-for-Service Plan

a. Clarification Regarding Utilization

The revised section 422.114(a)(2)(ii)(A) requires that for plan year 2010 and subsequent plan years, a PFFS plan that meets access requirements, with respect to a particular category of provider, by establishing contracts or agreements with a sufficient number and range of providers must meet the network accessibility and adequacy requirements described in Section 1852(d)(1) of the Act. This section of the statute describes the network adequacy requirements that coordinated care plans currently must meet when contracting with providers to furnish benefits covered under the plan.

CMS currently uses the network adequacy standards established for coordinated care plans in order to determine whether PFFS plans who want to meet access requirements under section 422.114(a)(2)(ii) satisfactorily meet those requirements. Therefore, we believe that there will be no additional burden on PFFS plans in order to comply with section 422.114(a)(2)(ii)(A).

b. Requirement for Certain Non-Employer PFFS Plans To Use Contract Providers

Section 422.114(a)(3) requires that for plan year 2011 and subsequent plan years, an MA organization that offers a PFFS plan that is operating in a network area as defined in section 422.114(a)(3)(i) meets the access requirements in section 422.114(a)(1) only if the MA organization has contracts or agreements with providers in accordance with the network accessibility and availability requirements described in Section 1852(d)(1) of the Act.

The burden associated with this requirement is that beginning in plan year 2011, an MA organization offering a PFFS plan will be required to create separate plans within its existing service area based on whether the counties located in that service area are considered network areas or not. We have 77 MA organizations currently offering 838 non-employer MA PFFS plans. We estimate that an additional 300 plans will be created as a result of organizations creating separate plan benefit packages for their network area and non-network area plans. We estimate that it will take 2 hours to create a new plan benefit package for a total of 600 hours to create 300 plan benefit packages.

c. Requirement for all Employer/Union-Sponsored PFFS Plans To Use Contracts With Providers

Section 422.114(a)(4) requires that an employer/union sponsored PFFS plan operating on or after plan year 2011 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 network accessibility and availability requirements described in Section 1852(d)(1) of the Act.

The burden associated with this requirement is the time and effort necessary for an organization offering an employer/union sponsored PFFS plan to submit the required application to CMS according to section 422.501. We estimate that approximately 100 hours would be required to complete an application. We project approximately 5 organizations will submit applications for a year, requiring 1000 hours of time by all applicants on an annual basis. This burden associated with the requirement under section 422.501 is captured in OMB #0938–0935.

Section 422.152 Quality Improvement Program

Section 422.152(g) states that MA organizations offering special needs plans must conduct a quality improvement program that (1) provides for the collection, analysis, and reporting of data that measures health outcomes and indices of quality at the plan level; (2) measures the effectiveness of its model of care; and (3) makes available to CMS information on quality and outcomes measures that will enable (i) beneficiaries to compare health coverage options, and (ii) CMS to monitor the plan's model of care performance.

The burden associated with this requirement is the time and effort put forth by the special needs plan to develop, collect, and analyze the quality and health outcomes measures that meet the requirements under Section 422.152(g). In the initial year of development, we estimate it would take one special needs plan 120 hours per year to meet this requirement. In subsequent years, we estimate that it would take 40 hours per year to revise the quality and health outcomes measures based on performance data analysis through the plan's quality improvement program.

The cumulative burden on SNPs is reflected in two parts: The burden on existing plans; and the burden on new SNPs approved to operate beginning on January 1, 2010. First, we estimate that, in calendar year 2009, the 335 existing SNPs would have a cumulative annual burden of 40,200 hours (120 hours × 335 plans) to develop the quality and health outcomes measures needed to evaluate their model of care and overall plan performance. In calendar year 2010 and subsequent years, the existing SNPs would have a cumulative annual burden of 13,400 hours (40 hours × 335 plans) to revise the quality and health outcomes measures based on performance data analysis through the plan's quality improvement program. Second, by January 1, 2010, we anticipate that CMS will approve 150 new SNPs. We estimate the 150 new SNPs would have a cumulative initial year (calendar year 2010) burden of 18,000 hours (120 hours × 150 plans) to develop their quality and health outcomes measures needed to evaluate their model of care and overall plan performance, and a cumulative annual burden of 6,000 hours (40 hours × 150 plans) to revise their model of care in subsequent years.

In summary, we project the cumulative annual burden in calendar year 2009 to be 40,200 hours. In calendar year 2010, we project the total annual burden to be 31,400 hours (13,400 hours for existing SNPs revising their measures, and 18,000 hours for new SNPs developing their measures).

Section 163 of MIPPA, as codified in new § 422.152(h), newly applies a general rule for quality improvement programs at § 422.152(a) to PFFS and MSA plans in 2010. Each MA organization that offers one or more MA plans must have, for each of those plans, an ongoing quality improvement program that meets the applicable requirements of this section for the services it furnishes to its MA enrollees. As part of its ongoing quality improvement program, a plan must—

- (1) Have a chronic care improvement program that meets the requirements of paragraph (c) of this section concerning elements of a chronic care program;
- (2) Conduct quality improvement projects that can be expected to have a favorable effect on health outcomes and enrollee satisfaction, and meet the requirements of paragraph (d) of this section; and
- (3) Encourage its providers to participate in CMS and HHS quality improvement initiatives.

Section 163 of MIPPA, as codified in § 422.152(h), also newly applies § 422.152(e)(2) to PFFS and MSA plans in 2011. Section 422.152(e)(2) are requirements that are currently applicable to local PPO organizations with contracted networks: § 422.152(e)(2) requires that MA organizations offering an MA regional plan or local PPO plan as defined in this section—

- (i) Measure performance under the plan using standard measures required by CMS and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.
- (ii) Evaluate the continuity and coordination of care furnished to enrollees.
- (iii) If the organization uses written protocols for utilization review, the organization must—
- (A) Base those protocols on current standards of medical practice; and
- (B) Have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.

These requirements relate to measuring of performance under the plans using standard measures required by CMS and to reporting this performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS and will relate to clinical areas including effectiveness of care, enrollee perception of care, and use of services and to non-clinical areas including access to and availability of services, appeals and grievances, and organizational characteristics.

The burden associated with this new reporting provision is the time it takes affected MA organizations to gather and submit the information. Reporting is usually required annually. Currently, the standard measures that will be required will most likely be those already captured in HEDIS and CAHPS, approved under OMB # 0938–0701. Note that CMS administers the CAHPS survey, and so the burden for CAHPS is minimal on plans.

The currently approved annual burden, per plan, for § 422.152 is estimated to be 400.53 hours.

Therefore, the total hours burden associated with this requirement, as estimated based on current numbers for each plan type = 400 hours for 1028 PFFS (employer and non-employer) plans and 400 hours for 10 MSA plans for 2010 and thereafter for a total of 415,200 hours.

Section 422.504 Contract Provisions

Section 422.504(g)(1) states that each MA organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of fees that are the legal obligation of the MA organization. This may be done by the establishment of identified liaison staff of the MA plan and the State Medicaid agency, and by conducting regular meetings for the purpose of enrollee review.

The burden associated with this requirement is the time and effort put forth by the each MA plan to adopt and

maintain arrangements. We estimate it would take one MA plan 208 hours to comply with this requirement. We estimate 3400 plans would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 707,200 hours.

Section 422.2268 Standards for MA Organization Marketing

Section 422.2268(g) states MA organizations cannot market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

The burden associated with this requirement is the time and effort put forth by the MA organization to document a beneficiary's signed acknowledgement confirming the specific types of choices that the marketing representative is authorized to discuss. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 422.2272 Licensing of Marketing Representatives and Confirmation of Marketing Resources

Section 422.2272(d) states that MA organizations must report to the State in which the MAO appoints an agent or broker, the termination of any such agent or broker, including the reasons for such termination if State law requires that the reasons for the termination be reported.

The burden associated with this requirement is the time and effort put forth by the MA organization to comply with the State requests for information. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 422.2274 Broker and Agent Compensation and Training of Sales Agents

Section 422.2274(b) states that if a MA organization markets through independent brokers or agents, they must train and test agents selling Medicare products concerning Medicare rules and regulations specific to the plan products they intend to sell.

The burden associated with this requirement is the time and effort put forth by the MA organization to provide training and test agents. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 422.2274(d) states that upon CMS' request, the organization must provide to CMS the information necessary for it to conduct oversight of marketing activities.

The burden associated with this requirement is the time and effort put forth by the organization to provide the requested information to CMS. We anticipate it would take 1 organization 480 minutes/8 hours to fulfill this requirement. We estimate 670 MA organizations would be affected annually by this requirement, therefore the total annual burden associated with this requirement is 5360 hours.

Section 423.520 Prompt Payment for Part D Sponsors

Section 423.520(a)(ii)(2) requires the Part D sponsor to notify the submitting network pharmacy that a submitted claim is not a clean claim. Such notification must specify all defects or improprieties in the claim and must list all additional information necessary for the proper processing and payment of the claim.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to provide proper notification to the network pharmacy. While there is burden associated with this requirement, we believe the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act (PRA) of 1995, as defined in 5 CFR 1320.3(b)(2), because the time, effort, and financial resources necessary to comply with this requirement would be incurred by persons in the normal course of their activities.

Section 423.2268 Standards for Part D Marketing

Section 423.2268(g) states Part D organizations cannot market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

The burden associated with this requirement is the time and effort put forth by the Part D organization to document a beneficiary's signed acknowledgement confirming the specific types of choices that the marketing representative is authorized to discuss. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 423.2272 Licensing of Marketing Representatives and Confirmation of Marketing Resources

Section 423.2272(d) states that Part D sponsors must report to the State in which the Part D sponsor appoints an agent or broker, the termination of any such agent or broker, including the reasons for such termination if State law requires that the reasons for the termination be reported.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to comply with the State requests for information. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 423.2274 Broker and Agent Compensation and Training of Sales Agents

Section 423.2274(b) requires the Part D sponsor to ensure agents selling Medicare products are trained on Medicare rules and regulations specific to the plan products they intend to sell.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to provide training and test agents. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the

requirement would be incurred by persons in the normal course of their activities.

Section 423.2274(d) states that the Part D sponsor provide information for it to conduct oversight of marketing activities upon CMS' request.

The burden associated with this requirement is the time and effort put forth the by the Part D sponsor to provide information to CMS. We anticipate it would take 1 Part D sponsor 480 minutes/8 hours to fulfill this requirement. We estimate 87 Part D sponsors would be affected annually by this requirement; therefore the total annual burden associated with this requirement is 696 hours.

Please note, CMS will revise the currently OMB approved PRA packages that contain Part 422—Medicare Advantage Program and Part 423—Voluntary Medicare Prescription Drug Benefit to include any new and/or revised burden requirements. The OMB approval numbers for those PRA packages are 0938–0753 and 0938–0964.

As reflected in the table that follows, the aggregate annual burden associated with the collection of information section for this rule totals 1,194,766.

TABLE 2—AGGREGATE ANNUAL BURDEN

OMB No.	Requirements	Number of respondents	Burden hours	Total annual burden
0938–0753	422.101(f)(1)	335	24	[1] 3,350
0938–0753	422.107(a)	460	20	16,560
0938–0753	422.111(b)(2)	460	10	[1] 4,600
0938–0753	422.114(a)(3)	300	2	600
0938–0753	422.114(a)(4)	10	100	1,000
0938–0753	422.152(g)	335	120	[1] 40,200
0938–0753	422.152(h)	1,038	400	415,200
0938–0753	422.504(g)(1)	3,400	208	[1] 707,200
0938–0753	422.2268(a)	N/A	N/A	N/A
0938–0964	422.2272(d)	N/A	N/A	N/A
0938–0964	422.2274(b)(d)	670	8	5,360
0938–0964	423.520	N/A	N/A	N/A
0938–0964	423.2268(a)	N/A	N/A	N/A
0938–0964	423.2272(d)	N/A	N/A	N/A
0938–0964	423.2274(b)(d)	87	8	696
Total Aggregate Burden				[1] 1,194,766

[1] = hours.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this rule; or

2. Mail copies to the address specified in the **ADDRESSES** section of this rule and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: CMS Desk Officer, CMS–4138–IFC *Brenda_Aguilar@omb.eop.gov*. Fax (202) 395–6974.

VI. Regulatory Impact Analysis

A. Overall Impact

Executive Order 12866 (as amended) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate the prompt payment provisions to have an impact to the federal budget in an amount exceeding $100 million as specified in Table 3 which indicates $670 million in costs to the Federal government associated with these provisions from calendar year (CY) 2010 through CY 2018. Costs for provisions not related to prompt payment, which are indicated in Table 5, total $26.7 million, and will affect MA organizations and prescription drug plan sponsors. In addition, we project an incurred savings (before the Part B premium offset) ranging from $780 million in CY 2011 to $1.59 billion in CY 2018, representing savings to the Federal government of $8.1 billion over this period, as the result of the requirement for certain non-employer and all employer private-fee-for-service plans to establish contracts with providers (see Table 4). Including both the costs and savings to the Federal government as a result of the provisions in this IFC, we estimate a net savings of $7.43 billion to the Federal government over the period estimated. As a result, this interim final rule meets the threshold of being economically significant and is consequently a major rule.

B. Regulatory Flexibility Analysis

1. General

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has significant impact on a substantial number of small entities. Under the RFA, we are not required to conduct an initial regulatory flexibility analysis for interim final rules. However, it is our longstanding policy to provide an analysis whenever we believe it would aid understanding of the effects of the IFC. As a result, we provide, in separate sections below, an analysis of the prompt payment provisions and other provisions in the IFC that are not associated with these. For purposes of RFA, a small business (as determined by the Small Business Administration (SBA)), is a non-profit entity of any size that is not dominant in its field, or a small government jurisdiction. HHS uses an impact change of 3 to 5 percent on revenues in its threshold measure of a significant economic impact on a substantial number of small entities. Individuals and States are not included in the definition of a small entity. Small entities affected include small retail pharmacies, which we believe will have positive cost impacts; pharmacy benefit managers, which we believe will have

some additional costs; and MA organizations and Part D sponsors, which are not typically considered small entities. Cost impacts for these entities are discussed in further detail below.

2. Prompt Payment Provisions

The Secretary has determined that this rule will have a significant impact on a substantial number of small entities and that the prompt payment revisions will positively impact retail pharmacies while adding some additional cost impacts to Part D sponsors and pharmacy benefit managers (PBMs).

With respect to the provisions contained in this interim final rule, we discuss in further detail impacts to retail pharmacies, Part D sponsors, and pharmacy benefit managers (PBMs). The Small Business Administration (SBA) considers pharmacies with firm revenues less than $6.5 million to be small businesses. The 2004 Business Census (the latest available detailed data) indicated that there were approximately 19,443 firms operating about 40,115 retail pharmacies and drug store establishments (NAICS code 44611). Of these firms, 17,835 had revenues under $6.5 million and operated a total of 17,835 establishments. As a result, we estimate that more than 90 percent of retail pharmacy firms are small businesses (as defined by the SBA size standards).

Given this assumption, we estimate that the prompt payment provisions will positively impact a substantial number of small retail pharmacies. Our conversations with retail pharmacies indicate that those pharmacies able to provide remittances to wholesalers for invoices for drugs within a contractual 14 day period will receive a rebate of 1–3% off the total invoice price. The new prompt payment provisions requiring the payment by Part D plan sponsors of clean claims from pharmacies within 14 days of electronic submission will facilitate the payment of pharmacies' wholesalers for drugs within their contractual window and receiving the related discount. We do not anticipate that there will be any additional costs to pharmacies related to this provision.

The other small businesses that may be impacted by the provisions in this interim final rule are pharmacy benefit managers (PBMs). In our 2005 Part D final rule, we estimated approximately one hundred PBM firms. Since that time we have seen continued consolidation in this industry and believe there to be even a small number of PBMs, even thought there have been a handful of new entrants in the industry. We have no information on the size of the smaller firms in the industry, but it is likely that none of them, or at most a very small number would fall below the $6.5 million annual revenue threshold used by the SBA for defining ''small entities'' in the insurance industry. We address the impact of these provisions on health plans and PBMs with revenues greater than the $6.5 million dollar threshold in section B. However, we do believe that the prompt payment provisions may put small PBMs at a disadvantage as more frequent payments may result in a shorter float on cash and a loss of investment income.

Section 1102(b) of the Social Security Act requires us to prepare a regulatory flexibility impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This rule will not affect small rural hospitals since the program will be directed at outpatient prescription drugs, not drugs provided during a hospital stay. As required by law, prescription drugs provided during hospital stays are covered under a separate Medicare payment system. Therefore, we are not providing an analysis in this rule.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. That threshold level is currently approximately $130 million. We anticipate that this interim final rule would not impose costs above the $130 million UMRA threshold on State, local, tribal governments, in the aggregate or by the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. The changes and additions contained in this interim final rule do not impose new costs on states or local governments. Thus, there are no anticipated Federalism implications.

Anticipated Effects on Health Plans and Pharmacy Benefit Managers (PBM)

Part D sponsors and their PBM subcontractors will be significantly impacted by a number of provisions contained in this interim final rule. We estimate that the prompt payment provisions contained this interim final rule will impose significant costs to PDPs, MA–PD plans, and their subcontractors. The industry expects that the shortened payment period will likely require sponsors to hold more cash reserves and lose the opportunity for accumulating interest. We estimate the loss of investment income resulting from the prompt payment provisions to increase the costs of the Part D program by $670 million from CY 2010 through CY 2018.

CMS requests comments and information on the accuracy and completeness of our estimates.

3. Other Provisions

Although other provisions of this rule do not exceed $100 million, because there are costs to plans and sponsors associated with several provisions of this rule, we indicate in Table 5 general areas affected and specify the cost impacts associated with these other provisions of the rule. For specific burden associated with the proposed requirements and the bases for our estimates, see section IV, Collection of Information Requirements, of this rule.

For the cost impact estimates for provisions other than the prompt payment provisions, we use, as appropriate, the figures of $14.68 (based on the United States Department of Labor (DOL) statistics for the hourly wages of word processors and typists) and $37.15 (based on DOL statistics for a management analyst) [1] plus the added OMB figures of 12 percent for overhead and 36 percent for benefits, respectively, to represent average costs to plans, sponsors and downstream entities for the provisions discussed in this proposed rule with comment period (note that the wages cited for the provisions below include the hourly wage + an additional 48 percent to reflect overhead, benefit costs for total wages of $21.73 and $54.98, respectively). Also, it should be noted that while we believe there may be costs for special needs plans to hire medical personnel or senior staff not captured above for the state contracting and model of care provisions, we are unsure of the costs for these and thus are

[1] The hourly rates for the burden requirement were developed using the Department of Labor, Bureau of Labor Statistics for May 2006 (National Occupational Employment and Wage Estimates).

requesting comments on additional cost impacts for these provisions.

In the Regulatory Impact Analysis of the January 28, 2005 final rule (70 FR 4695) revising the Medicare Advantage program, we noted that costs associated with the MA program would be approximately $18.3 billion from 2004 through 2009, 10 percent of which we estimated will be administrative costs. The rule establishing the prescription drug benefit program published on January 28, 2005 (70 FR 4194) made a similar calculation in its Regulatory Impact Statement. Administrative costs associated with the provisions of this final rule, then, add negligibly to the total administrative costs of the MA or Part D programs.

With respect to economic benefits, we have no reliable basis for estimating the effects of these proposals. Many of the proposed changes clarify or codify existing policies though such clarification could contribute to greater plan efficiency and compliance with program regulations. Accordingly, we estimate that while there could be economic benefits associated with these proposals, they are difficult to gauge at this time.

Special Needs Plans (Part C)

Several of our provisions concern special needs plans and strengthening coordination between plans and States to better coordinate care, developing models of care, and ensuring that enrollees are not charged for costs that are the responsibility of the State. A breakdown of costs for each provision are as follows:

- Developing models of care ($54.98 × 3,350 hours = $184,183).
- Contracting with States ($54.98 × 16,560 hours = $910,469).
- Developing dual-eligible written information on both Medicare and Medicaid cost-sharing and benefits ($21.73 × 4,600 hours = $99,958).
- Collecting, analyzing, and reporting data that measures health outcomes and indices of quality on its model of care ($54.98 × 40,200 hours = $2,210,196).

Private Fee-for-Service Plans (Part C)

CMS estimates an incurred savings (before the Part B premium offset) of $780 million for CY 2011 to $1.59 billion in CY 2018 as a result of the requirement that certain non-employer and all employer PFFS plans establish contracts with providers.

To do the estimates, we considered the number of counties that had PFFS plans, and the number of members. We then saw how many coordinated care plans were currently operating in each of these counties (excluding regional PPOs). This gave us a basis to project how many PFFS plans and members would be subject to the new requirement to set up networks of providers by 2011.

Based on the information, as well as the level of payments that these plans receive from CMS, we estimated how many members would end up in PFFS plans that did not need to form networks; how many would be in plans that converted to network PFFS plans, how many would end up in a coordinated care plan; and how many would switch to original Medicare. We used different assumptions for individual plans and for group plans. However, for both group and individual plans, we assumed that most members would remain in a PFFS plan (either network or non-network).

For members who stayed in either a network or non-network PFFS plan, we assumed a higher plan bid and, therefore, cost to Medicare. In contrast, we assumed a savings for those that we estimate will go to a coordinated care plan, and a larger savings for those who go to original Medicare.

We indicate the estimated incurred savings over this period in Table 4.

Costs for each provision, as shown in Table 5, affecting private fee-for-service (PFFS) plans are as follows:

- Certain non-employer PFFS plans establishing contracts with providers ($54.98 × 600 hours = $32,988).
- Employer/union sponsored PFFS plans establishing contracts with providers ($54.98 × 1,000 hours = $54,980).
- PFFS and MSA plans developing quality improvement programs ($54.98 × 415,200 hours) = $22,827,696.

Marketing (Parts C and D)

Costs for each marketing provision, in the context of each program, are as follows:

- Training and testing of agents selling Medicare products, MA program ($54.98 × 5,360 hours = $294,692).
- Training and testing of agents selling Medicare products, Part D ($54.98 × 696 hours = $38,266)

CMS requests comments and information on the accuracy and completeness of our estimates.

TABLE 3—PROJECTED PART D (NON-MARKETING) COSTS FOR CY 2010–2018

[Millions of dollars]

	CY 2010	CY 2011	CY 2012	CY 2013	CY 2014	CY 2015	CY 2016	CY 2017	CY 2018	CY 2010–2018
Prompt payment by prescription drug plans and MA–PD plans under Part D	50	50	60	60	70	80	90	100	110	670

TABLE 4—PROJECTED INCURRED SAVINGS FOR NON-EMPLOYER AND EMPLOYER PFFS NETWORK PROVISION

[Millions of dollars]

	CY 2011	CY 2012	CY 2013	CY 2014	CY 2015	CY 2016	CY 2017	CY 2018	CY 2011–2018
Total HI (MC and FFS)	420	470	520	580	640	690	760	830	4,910
Total SMI (MC and FFS)	360	400	460	490	540	600	670	760	4,280
Total Medicare (before Part B premium offset)	780	870	980	1,070	1,180	1,290	1,430	1,590	9,190
Total Medicare (after Part B premium offset)	690	770	860	950	1,040	1,140	1,260	1,400	8,110

TABLE 5—PROJECTED ANNUAL COSTS TO MAOS AND PDP SPONSORS: OTHER PROVISIONS

Provision	CY effective	Projected costs
Special needs plan: developing models of care	2010	$184,183
Special needs plan: contracting with States	2010	910,469
Special needs plan: developing written information on both Medicare and Medicaid cost-sharing and benefits for dual-eligible beneficiaries.	2010	99,958
Special needs plan: collecting, analyzing, and reporting data related to model of care concerning health outcomes and indices of quality.	2010	2,210,196
Training and testing of agents and brokers (Part C and Part D programs)	October 2008	332,958
Certain non-employer PFFS plans establishing contracts with providers	2011	32,988
Employer/union sponsored PFFS plans establishing contracts with providers	2011	54,980
PFFS and MSA plans developing quality improvement programs	2010	22,827,696
Total		26,653,428

C. Alternatives Considered

All of the economically significant provisions in this interim final rule are a result of the recent passage of MIPPA and are self-implementing. While we had no discretion with these statutory provisions, we desired to make our resulting regulations available to industry and the public as soon as possible to facilitate continued, efficient operation of the Part C and D programs. Regarding the other provisions contained in this interim final rule, we considered not issuing further guidance in these areas, but we believed that in order to ensure public awareness of our policies, as well as to avoid potential confusion regarding them, we should codify our policies in this interim final rule.

D. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/index.html*), in Table 6 below, we have prepared an accounting statement showing the classification of the expenditures associated with the prompt payment provisions of this final rule and the benefits associated with the PFFS network provisions. This table provides our best estimate of the costs and savings as a result of the changes presented in this interim final rule. All costs are classified as transfers by the Federal Government to PDP sponsors or MAOs.

TABLE 6—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers ($ millions)
Incurred savings for the Non-Employer and Employer PFFS Network Provision, CYs 2011–2018	
Undiscounted Annualized Monetized Transfers	$1,013.8.
Annualized Monetized Transfers Using 7% Discount Rate	$838.4.
Annualized Monetized Transfers Using 3% Discount Rate	$873.9.
From Whom to Whom? (Represents a reduction of transfers from the Federal Government to non-network/network PFFS Plans.).	PFFS Plans to the Federal Government.
Prompt payment by prescription drug plans and MA–PD plans under Part D, CYs 2010–2018	
Undiscounted Annualized Monetized Transfers	$74.4.
Annualized Monetized Transfers Using 7% Discount Rate	$71.0.
Annualized Monetized Transfers Using 3% Discount Rate	$72.9.
From Whom to Whom?	Federal Government to Part D Sponsors.
Costs for all other (non-marketing) provisions not related to Part D	
Undiscounted Annualized Monetized Costs	$26.7.
Who Is Affected?	MAOs/PDP Sponsors.

E. Conclusion

Given that we expect the cost of implementing a number of the provisions contained in this interim final rule, as specified in Table 3, will exceed the $100 million threshold within a single year between CY 2010 and CY 2018, we conducted an economic impact analysis with regard to those entities potentially impacted by these provisions. As we stated previously, we expect that entities such as pharmacies will benefit from these changes, whereas other entities, such as PBMs and Part D sponsors, will experience additional costs which they will pass on to CMS through direct subsidy payments and beneficiaries through additional premiums as reflected in their bids. The prompt payment provisions account for the primary cost impacts associated with this IFC, ranging from $50 million in CY 2010 to $110 million in CY 2018. Cost impacts for the other provisions of this IFC will total slightly more than $26.7 million in the years indicated when the provisions become effective. As discussed, we also estimate a savings ranging from $780 million in CY 2011 to $1.59 billion in CY 2018 as a result of the requirement that non-employer private-fee-for-service plans have networks beginning in 2011.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority citation for part 417 continues to read as follows:

Authority: Sec. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

Subpart J—Qualifying Conditions for Medicare Contracts

■ 2. Amend § 417.402 by—
■ A. Revising paragraph (c)(1).
■ B. Revising paragraph (c)(2).
■ C. Revising paragraph (c)(3).
The revisions read as follows:

§ 417.402 Effective date of initial regulations.

* * * * *

(c) * * *

(1) There were two or more coordinated care plan-model MA regional plans not offered by the same MA organization in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph(c)(3) of this section; or

(2) There were two or more coordinated care plan-model MA local plans not offered by the same MA organization in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph (c)(3) of this section.

(3) *Minimum enrollment requirements.* With respect to any service area or portion of a service area that is within a Metropolitan Statistical Area (MSA) with a population of more than 250,000 and counties contiguous to the MSA that are not in another MSA with a population of more than 250,000, 5000 enrolled individuals. If the service area includes a portion in more than one MSA with a population of more than 250,000, the minimum enrollment determination is made with respect to each such MSA and counties contiguous to the MSA.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 3. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

■ 4. Amend § 422.4 by—
■ A. Republishing paragraph (a) introductory text.
■ B. Revising paragraph (a)(3)(ii).
The revision reads as follows:

§ 422.4 Types of MA plans.

(a) *General rule.* An MA plan may be a coordinated care plan, a combination of an MA MSA plan and a contribution into an MA MSA established in accordance with § 422.262, or an MA private fee-for-service plan.

(3) * * *

(ii) Subject to paragraphs (a)(3)(ii)(A) and (B) of this section, does not vary the rates for a provider based on the utilization of that provider's services; and

(A) May vary the 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 and do not violate § 422.205 of this part.

(B) May increase the rates for a provider based on increased utilization of specified preventive or screening services.

* * * * *

Subpart C—Benefits and Beneficiary Protections

■ 5. Amend § 422.101 by adding paragraph (f) to read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(f) *Special Needs Plan Model of Care.* (1) MA organizations offering special needs plans (SNP) must implement an evidence-based model of care with appropriate networks of providers and specialists designed to meet the specialized needs of the plan's targeted enrollees. The MA organization must, with respect to each individual enrolled—

(i) Conduct a comprehensive initial health risk assessment of the individual's physical, psychosocial, and functional needs as well as annual health risk reassessment, using a comprehensive risk assessment tool that CMS will review during oversight activities.

(ii) Develop and implement a comprehensive individualized plan of care through an interdisciplinary care team in consultation with the beneficiary, as feasible, indentifying goals and objectives including measurable outcomes as well as specific services and benefits to be provided.

(iii) Use an interdisciplinary team in the management of care.

(2) [Reserved]

■ 6. Add new section § 422.107 to read as follows:

§ 422.107 Special needs plans and dual-eligibles: Contract with State Medicaid Agency.

(a) *Definition.* For the purpose of this section, a contract with a State Medicaid agency means a formal written agreement between an MA organization and the State Medicaid agency documenting each entity's roles and responsibilities with regard to dual-eligible individuals.

(b) *General rule.* MA organizations seeking to offer a special needs plan serving beneficiaries eligible for both Medicare and Medicaid (dual-eligible) must have a contract with the State Medicaid agency. The MA organization retains responsibility under the contract for providing benefits, or arranging for benefits to be provided, for individuals entitled to receive medical assistance under title XIX. Such benefits may include long-term care services consistent with State policy.

(c) *Minimum contract requirements.* At a minimum, the contract must document—

(1) The MA organization's responsibility, including financial obligations, to provide or arrange for Medicaid benefits.

(2) The category(ies) of eligibility for dual-eligible beneficiaries to be enrolled under the SNP, as described under the Statute at sections 1902(a), 1902(f), 1902(p), and 1905.

(3) The Medicaid benefits covered under the SNP.

(4) The cost-sharing protections covered under the SNP.

(5) The identification and sharing of information on Medicaid provider participation.

(6) The verification of enrollee's eligibility for both Medicare and Medicaid.

(7) The service area covered by the SNP.

(8) The contract period for the SNP.

(d) *Date of Compliance.* (1) Effective January 1, 2010—

(i) MA organizations offering a new dual-eligible SNP must have a State Medicaid agency contract.

(ii) MA organizations with an existing dual-eligible SNP without a State Medicaid agency contract may continue to operate through 2010 provided they meet all other statutory requirements, that is, care management and quality improvement program requirements. However, they cannot expand their service areas during 2010.

(2) [Reserved]

■ 7.Amend § 422.111 by—

■ A. Redesignating paragraph (b)(2)(iii) as (b)(2)(iv).

■ B. Adding new paragraph (b)(2)(iii) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(2) * * *

(iii) For a Special Needs Plan for dual-eligible individuals, prior to enrollment, for each prospective enrollee, a comprehensive written statement describing cost sharing protections and benefits that the individual is entitled to under title XVIII and the State Medicaid program under title XIX.

* * * * *

■ 8. Amend § 422.114 by—

■ A. Revising paragraph (a)(2) introductory text.

■ B. Revising paragraph (a)(2)(ii).

■ C. Adding paragraph (a)(3).

■ D. Adding paragraph (a)(4).

The revisions and additions read as follows:

§ 422.114 Access to services under an MA private fee-for-service plan.

(a) * * *

(2) Subject to paragraphs (a)(3) and (a)(4) of this section, CMS finds that an MA organization meets the requirement in paragraph (a)(1) of this section if, with respect to a particular category of health care providers, the MA organization has—

(i) * * *

(ii) Subject to paragraph (A) of section (a)(2)(ii), contracts or agreements with a sufficient number and range of providers to furnish the services covered under the MA private fee-for-service plan; or

(A) For plan year 2010 and subsequent plan years, contracts or agreements with a sufficient number and range of providers to meet the access standards described in section 1852(d)(1) of the Act.

(B) [Reserved]

* * * * *

(3) For plan year 2011 and subsequent plan years, an MA organization that offers an MA private fee-for-service plan (other than a plan described in section 1857(i)(1) or (2) of the Act) that is operating in a network area (as defined in paragraph (a)(3)(i) of this section) meets the requirement in paragraph (a)(1) of this section only if the MA organization has contracts or agreements with providers in accordance with paragraph (a)(2)(ii)(A) of this section.

(i) Network area is defined, 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 2 network-based plans (as defined in paragraph (a)(3)(ii) of this section) with enrollment as of the first day of the year in which the announcement is made.

(ii) Network-based plan is defined as a coordinated care plan as described in § 422.4(a)(1)(ii), a network-based MSA plan, or a section 1876 reasonable cost plan. A network-based plan excludes a MA regional plan that meets access requirements substantially through the authority of § 422.112(a)(1)(ii) instead of written contracts.

(4) For plan year 2011 and subsequent plan years, an MA organization that offers an MA private fee-for-service plan that is described in section 1857(i)(1) or (2) of the Act meets the requirement in paragraph (a)(1) of this section only if the MA organization has contracts or agreements with providers in accordance with paragraph (a)(2)(ii)(A) of this section.

* * * * *

Subpart D—Quality Improvement

■ 9. Amend § 422.152 by—

■ A. Revising paragraph (a) introductory text.

■ B. Adding paragraph (g).

■ C. Adding paragraph (h).

The revisions read as follows:

§ 422.152 Quality improvement program.

(a) *General rule.* Each MA organization that offers one or more MA plans must have, for each of those plans, an ongoing quality improvement program that meets applicable requirements of this section for the service it furnishes to its MA enrollees. As part of its ongoing quality improvement program, a plan must—

* * * * *

(g) *Special requirements for specialized MA Plans for special needs individuals.* A SNP must conduct a quality improvement program that—

(1) Provides for the collection, analysis, and reporting of data that measures health outcomes and indices of quality pertaining to its targeted special needs population (that is, dual-eligible, institutionalized, or chronic condition) at the plan level.

(2) Measures the effectiveness of its model of care through the collection, aggregation, analysis, and reporting of data that demonstrate the following:

(i) Access to care as evidenced by measures from the care coordination domain (for example, service and benefit utilization rates, or timeliness of referrals or treatment).

(ii) Improvement in beneficiary health status as evidenced by measures from functional, psychosocial, or clinical domains (for example, quality of life indicators, depression scales, or chronic disease outcomes).

(iii) Staff implementation of the SNP model of care as evidenced by measures of care structure and process from the continuity of care domain (for example, National Committee for Quality Assurance accreditation measures or medication reconciliation associated with care setting transitions indicators).

(iv) Comprehensive health risk assessment as evidenced by measures from the care coordination domain (for example, accuracy of acuity stratification, safety indicators, or timeliness of initial assessments or annual reassessments).

(v) Implementation of an individualized plan of care as evidenced by measures from functional, psychosocial, or clinical domains (for example, rate of participation by IDT members and beneficiaries in care planning).

(vi) A provider network having targeted clinical expertise as evidenced by measures from medication management, disease management, or behavioral health domains.

(vii) Delivery of services across the continuum of care.

(viii) Delivery of extra services and benefits that meet the specialized needs of the most vulnerable beneficiaries as evidenced by measures from the psychosocial, functional, and end-of-life domains.

(ix) Use of evidence-based practices and nationally recognized clinical protocols.

(x) Use of integrated systems of communication as evidenced by

measures from the care coordination domain (for example, call center utilization rates, rates of beneficiary involvement in care plan development, etc.).

(3) Makes available to CMS information on quality and outcomes measures that will—

(i) Enable beneficiaries to compare health coverage options; and

(ii) Enable CMS to monitor the plan's model of care performance.

(h) *Requirements for MA private-fee-for-service plans and Medicare medical savings account plans.* (1) Subject to paragraph (h)(2) of this section, MA PFFS and MSA plans are subject to requirements that may not exceed the requirements specified in § 422.152(e).

(2) For plan year 2010, MA PFFS and MSA plans are not subject to the limitations under § 422.152(e)(1)(i) and must meet the requirements using administrative claims data only.

Subpart E—Relationships With Providers

■ 10. Revise paragraph (a) of § 422.216 as follows:

§ 422.216 Special Rules for MA private-fee-for-service plans.

(a) *Payment to Providers*—(1) *Payment Rate.* (i) The MA organization must establish payment rates for plan covered items and services that apply to deemed providers. The MA organization may vary payment rates for providers in accordance with § 422.4(a)(3).

(ii) Providers must be reimbursed on a fee-for-service basis.

(iii) The MA organization must make information on its payment rates available to providers that furnish services that may be covered under the MA private fee-for-service plan.

(2) *Noncontract providers.* The organization pays for services of noncontract providers in accordance with § 422.100(b)(2).

(3) *Services furnished by providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA private fee-for-service plan must receive, and accept as payment in full, at least the amount (less any payments under §§ 412.105(g) and 413.76 of this chapter) that it could collect if the beneficiary were enrolled in original Medicare.

* * * * *

Subpart G—Payments to Medicare Advantage Organizations

■ 11. Amend § 422.306 by—

■ A. Revising the introductory text.

■ B. Adding paragraph (c).

The revisions and additions read as follows:

§ 422.306 Annual MA capitation rates.

Subject to adjustments at § 422.308(b) and § 422.308(g), the annual capitation rate for each MA local area is determined under paragraph (a) of this section for 2005 and each succeeding year, except for years when CMS announces under § 422.312(b) that the annual capitation rates will be determined under paragraph (b) of this section, and is then adjusted to exclude the applicable phase-in percentage of the standardized costs for payments under section 1886(d)(5)(B) of the Act in the area for the year under paragraph (c) of this section.

* * * * *

(c) *Phase-out of the indirect costs of medical education from MA capitation rates.* Beginning with 2010, after the annual capitation rate for each MA local area is determined under paragraph (a) or (b), the amount is adjusted in accordance with section 1853(k)(4) of the Act to exclude from such amount the phase-in percentage for the year of the estimated costs for payments under section 1886(d)(5)(B) of the Act in the area for the year.

Subpart K—Contracts With Medicare Advantage Organizations

■ 12. Amend § 422.504 by adding paragraph (g)(1)(iii) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(g) * * *

(1) * * *

(iii) For full-benefit dual-eligible individuals or qualified Medicare beneficiaries, plans may not impose cost sharing exceeding the amount that would be permitted to the individual under title XIX if the individual were not enrolled in the SNP.

* * * * *

Subpart V—Medicare Advantage Marketing Requirements

■ 13. Amend § 422.2268 by—

■ A. Adding paragraph (b)

■ B. Adding paragraph (g).

■ C. Adding paragraph (h).

■ D. Adding paragraph (n).

■ E. Adding paragraph (q).

The additions to read as follows:

§ 422.2268 Standards for MA organization marketing.

* * * * *

(b) Offer gifts to potential enrollees, unless the gifts are of nominal (as defined in the CMS Marketing Guidelines) value, are offered to all potential enrollees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

* * * * *

(g) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

(h) Market additional health related lines of plan business not identified prior to an in-home appointment without a separate appointment that may not be scheduled until 48 hours after the initial appointment.

* * * * *

(n) Display the names and/or logos of co-branded network providers on the organization's member identification card, unless the provider names, and/or logos are related to the member selection of specific provider organizations (for example, physicians, hospitals). Other marketing materials (as defined in § 422.2260) that include names and/or logos of provider co-branding partners must clearly indicate that other providers are available in the network.

* * * * *

(q) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name.

■ 14. Amend § 422.2272 by adding paragraph (d) to read as follows:

§ 422.2272 Licensing of marketing representatives and confirmation of marketing resources.

* * * * *

(d) Report to the State in which the MAO appoints an agent or broker, the termination of any such agent or broker, including the reasons for such termination if State law requires that the reasons for the termination be reported.

■ 15. Add § 422.2274 to read as follows:

§ 422.2274 Broker and agent requirements.

If a Medicare Advantage organization markets through employed or independent brokers or agents—

(a) Agents and brokers must be compensated as follows:

(1) An MA plan (or other entity on its behalf) may provide compensation to a broker or agent for the sale of a MA product only if the aggregate of the first year compensation is no more than 200 percent of the aggregate of the compensation paid for selling or servicing the enrollee in each individual subsequent renewal year, of which there

must be a total of five renewal years (creating a 6-year compensation cycle). For purposes of this section, ''compensation''—

(i) Includes pecuniary or non-pecuniary remuneration of any kind relating to the sale or renewal of the policy including but not limited to commissions, bonuses, gifts, prizes, awards and finders fees.

(ii) Does not include salary or other benefits related to employment, except to the extent that the salary or other benefits are related to the volume of sales.

(iii) Does not include the payment of fees to comply with State appointment laws, training, certification, and testing costs; and reimbursement for mileage to and from appointments with beneficiaries and reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

(2) If compensation is paid in the first year, renewal compensation must be paid for no fewer than 5 renewal years (6-year compensation cycle), provided that the enrollee remains enrolled in the plan.

(3) No entity shall provide aggregate compensation to its agents or brokers and no agent or broker shall receive aggregate 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 (6-year compensation cycle).

(i) For purposes of this section, ''like plan type'' means PDP replaced with another PDP, MA or MA–PD replaced with another MA or MA–PD, or cost plan replaced with another cost plan.

(ii) Replacements between different plan types (for which a new compensation is paid) include—PDP and MA–PD, PDP and cost plans, or MA–PD and cost plans.

(4) Compensation shall be earned for months 4 through 12 of the enrollment year.

(i) Plans may pay agents and brokers up-front or prorate compensation payments over 12 months or over months 4 through 12, but

(ii) When a beneficiary disenrolls from the plan, the plan must recover all compensation paid: for months in which the beneficiary is not enrolled; and during months 1 through 3 if the beneficiary disenrolls during the first three months.

(5) Organizations and sponsors must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year. Compensation structures must be in place by the beginning of the plan marketing period, October 1.

(6) Compensation structures must be available upon CMS request including for audits, investigations, and to resolve complaints.

(b) It must ensure agents selling Medicare products are trained annually on Medicare rules and regulations specific to the plan products they intend to sell.

(c) It must ensure agents selling Medicare products are tested annually, as specified in CMS guidance.

(d) Upon CMS' request, the organization must provide to CMS, in a form consistent with current CMS guidance, the information necessary for it to conduct oversight of marketing activities.

(e) It must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 16. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

Subpart B—Eligibility and Enrollment

■ 17. Amend § 423.46 by revising paragraph (a) introductory text to read as follows:

§ 423.46 Late enrollment penalty.

(a) *General.* A Part D eligible individual must pay the late penalty described under § 423.286(d)(3), except as described at § 423.780(e), if there is a continuous period of 63 days or longer at any time after the end of the individual's initial enrollment period during which the individual meets all of the following conditions:

* * * * *

Subpart G—Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage

■ 18. Amend § 423.322 by revising paragraph (b) to read as follows:

§ 423.322 Requirement for disclosure of information.

* * * * *

(b) *Restrictions on use of information.* Officers, employees and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this subpart only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments, and payment-related oversight, and program integrity activities.

(1) This restriction does not limit OIG's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

(2) This restriction does not limit CMS' ability to use data regarding drug claims in accordance with section 1848(m) of the Act.

Subpart K—Application Procedures and Contracts with Part D Plan Sponsors

■ 19. Amend § 423.505 by—
■ A. Adding paragraph (b)(19).
■ B. Adding paragraph (b)(20).
■ C. Adding paragraph (b) (21).
■ D. Adding paragraph (i)(3)(iv) through (vi).
■ E. Revising paragraph (m)(1) introductory text.
■ F. Revising (m)(1)(iii)(A).
■ G. Revising paragraph (m)(1)(iv).
■ H. Adding paragraph (m)(3).

The additions and revisions read as follows.

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(19) Effective contract year 2010, include the prompt payment provisions described in § 423.520.

(20) Effective contract year 2010, provide that pharmacies located in, or having a contract with, a long-term care facility (as defined in § 423.100) must have not less than 30 days, nor more than 90 days, to submit to the Part D sponsor claims for reimbursement under the plan.

(21) Effective contract year 2009, update any prescription drug pricing standard for reimbursement of network pharmacies based on the cost of a drug used by the Part D sponsor on—

(i) January 1 of each contract year; and

(ii) Not less frequently than once every 7 days after the date in paragraph (b)(21)(i) of this section.

* * * * *

(i) * * *

(3) * * *

(iv) A provision requiring prompt payment of clean claims by the Part D sponsor, consistent with § 423.520.

(v) A provision that establishes timeframes, consistent with § 423.505(b)(20), for long-term care

pharmacies to submit claims to the Part D sponsor for reimbursement under the plan.

(vi) If applicable, a provision—

(A) Establishing regular updates of any prescription drug pricing standard used by the Part D sponsor consistent with § 423.505(b)(21); and

(B) Indicating the source used by the Part D sponsor for making any such pricing updates.

* * * * *

(m)(1) CMS may release the minimum data necessary for a given purpose from the data collected under paragraph (f)(3) of this section to Federal executive branch agencies, States, and external entities in accordance with the following:

* * * * *

(iii) * * *

(A) Subject to the restrictions in this paragraph, all elements on the claim are available to HHS.

* * * * *

(iv) For purposes of paragraph (m)(1)(iii) of this section, States and executive-branch Federal agencies are not considered to be external entities.

* * * * *

(3) CMS shall make available to Congressional support agencies (the Congressional Budget Office, the Government Accountability Office, the Medicare Payment Advisory Commission, and the Congressional Research Service when it is acting on behalf of a Congressional committee in accordance with 2 U.S.C. 166(d)(1)) all information collected under paragraph (f)(3) of this section for the purposes of conducting congressional oversight, monitoring, making recommendations, and analysis of the Medicare program.

■ 20. Add 423.520 to read as follows:

§ 423.520 Prompt payment by Part D sponsors.

(a) *Contract between CMS and the Part D sponsor.* (1) Effective contract year 2010, the contract between the Part D sponsor and CMS must provide that the Part D sponsor will issue, mail, or otherwise transmit payment with respect to all clean claims, as defined in paragraph (b) of this section, submitted by network pharmacies (other than mail-order and long-term care pharmacies) within—

(i) 14 days after the date on which the claim is received, as defined in paragraph (a)(2)(i) of this section, for an electronic claim; or

(ii) 30 days after the date on which the claim is received, as defined in paragraph (a)(2)(ii) of this section, for any other claim.

(2) *Date of receipt of claim.* A claim is considered to have been received—

(i) On the date on which the claim is transferred, for an electronic claim; or

(ii) On the 5th day after the postmark day of the claim or the date specified in the time stamp of the transmission, for any other claim, whichever is sooner.

(b) *Clean claim.* A clean claim means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment of the claim from being made under this section.

(c) *Procedures involving claims*—(1) *Claims determined to be clean.* A claim is deemed to be a clean claim if the Part D sponsor receiving the claim does not provide notice to the submitting network pharmacy of any deficiency in the claim within—

(i) 10 days after the date on which the claim is received, as defined in paragraph (a)(2)(i) of this section, for an electronic claim; or

(ii) 15 days after the date on which the claim is received, as defined in paragraph (a)(2)(ii) of this section, for any other claim.

(2) *Claims determined not to be clean*—(i) *General.* If a Part D sponsor determines that a submitted claim is not a clean claim, as defined in paragraph (b) of this section, the Part D sponsor must notify the submitting network pharmacy of such determination within the period described in paragraph (c)(1) of this section. Such notification must specify all defects or improprieties in the claim and must list all additional information necessary for the proper processing and payment of the claim.

(ii) *Determination after submission of additional information.* A claim is deemed to be a clean claim under paragraph (b) of this section if the Part D sponsor that receives the claim does not provide notice to the submitting network pharmacy of any defect or impropriety in the claim within 10 days of the date on which additional information is received under paragraph (c)(2)(i) of this section.

(3) *Obligation to pay.* A claim submitted to a Part D sponsor that is not paid or contested by the Part D sponsor within the timeframes specified in paragraphs (a)(1)(i) and (ii) of this section must be deemed to be a clean claim and must be paid by the Part D sponsor in accordance with paragraph (a) of this section.

(d) *Date of payment of claim.* Payment of a clean claim under paragraph (c)(3) of this section is considered to have been made on the date on which—

(1) The payment is transferred, for an electronic claim; or

(2) The payment is submitted to the United States Postal Service or common carrier for delivery, for any other claim.

(e) *Interest payment*—(1) *General.* Subject to paragraph (e)(2) of this section, if payment is not issued, mailed or otherwise transmitted for a clean claim as required under paragraph (a) of this section, the Part D sponsor must pay interest to the network pharmacy that submitted the claim at a rate equal to the weighted average of interest on 3-month marketable Treasury securities determined for such period, increased by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which the payment is made, as determined under paragraph (d). Interest amounts paid under this paragraph will not count against the Part D sponsor's administrative costs, as defined in § 423.308, and will not be treated as allowable risk corridor costs, as defined in § 423.308.

(2) *Authority not to charge interest.* As CMS determines appropriate, including in exigent circumstances such as natural disasters and other unique and unexpected events that prevent the timely processing of claims, a Part D sponsor will not be charged interest under paragraph (e)(1) of this section.

(f) *Electronic transfer of funds.* A Part D sponsor must pay all clean claims submitted electronically by electronic transfer of funds provided the submitting network pharmacy so requests or has so requested previously that contract year. When such payment is made electronically, remittance may also be made electronically by the Part D sponsor.

(g) *Protecting the rights of the claimants.* (1) *General.* Nothing in this section may be construed to prohibit or limit a claim or action that any individual or organization has against a pharmacy, provider, or Part D sponsor that is not covered by the subject matter of this section.

(2) *Anti-retaliation.* Consistent with applicable Federal or State law, a Part D sponsor may not retaliate against an individual, pharmacy, or provider for exercising a right of action under paragraph (g)(1) of this section.

(h) *Construction.* A determination under this section that a claim submitted by a network pharmacy is a clean claim shall not be construed as a positive determination regarding eligibility for payment under title XVIII of the Act, nor is it an indication of government approval of, or acquiescence regarding, the claim submitted. The determination does not relieve any party of civil or criminal liability with respect to the claim, nor

does it offer a defense to any administrative, civil, or criminal action with respect to the claim.

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

■ 21. Amend § 423.772 by revising the definitions of ''income'' and ''resources'' to read as follows:

§ 423.772 Definitions.

* * * * *

Income means income as described under section 1905(p)(1) of the Act without use of any more liberal disregards under section 1902(r)(2) of the Act (that is defined by section 1612 of the Act) and exempts support and maintenance furnished in kind. This definition includes the income of the applicant and spouse who is living in the same household, if any, regardless of whether the spouse is also an applicant.

* * * * *

Resources means liquid resources of the applicant (and, if married, his or her spouse who is living in the same household), such as checking and savings accounts, stocks, bonds, and other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act, and real estate that is not the applicant's primary residence or the land on which the primary residence is located. It exempts the value of any life insurance policy.

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■ 22. Amend § 423.780 by revising paragraph (e) to read as follows:

§ 423.780 Premium subsidy.

* * * * *

(e) *Waiver of Late Enrollment Penalty for Subsidy-Eligible Individuals.* Subsidy eligible individuals, as defined in § 423.773, are not subject to a late enrollment penalty, as defined in § 423.46.

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Subpart V—Part D Marketing Requirements

■ 23. Amend § 423.2268 by—
■ A. Adding paragraph (b)
■ B. Adding paragraph (g).
■ C. Adding paragraph (h).
■ D. Adding paragraph (n).
■ E. Adding paragraph (q).

The additions and revisions read as follows:

§ 423.2268 Standards for Part D marketing.

* * * * *

(b) Offer gifts to potential enrollees, unless the gifts are of nominal (as defined in the CMS Marketing Guidelines) value, are offered to all potential enrollees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

* * * * *

(g) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

(h) Market additional health related lines of plan business not identified prior to an in-home appointment without a separate appointment that may not be scheduled until 48 hours after the initial appointment.

* * * * *

(n) Display the names and/or logos of co-branded network providers on the organization's member identification card. Other marketing materials (as defined in § 423.2260) that include names and/or logos of provider co-branding partners must clearly indicate that other providers are available in the network.

* * * * *

(q) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name.

■ 24. Amend § 423.2272 by adding new paragraph (d) to read as follows:

§ 423.2272 Licensing of marketing representatives and confirmation of marketing resources.

* * * * *

(d) Report to the State in which the MAO appoints an agent or broker, the termination of any such agent or broker, including the reasons for such termination if State law requires that the reasons for the termination be reported.

■ 25. Add new § 423.2274 to read as follows:

§ 423.2274 Broker and agent requirements.

If a Part D sponsor markets through employed or independent brokers or agents—

(a) Agents and brokers must be compensated as follows:

(1) A Part D sponsor (or other entity on its behalf) may provide compensation to a broker or agent for the sale of a Part D plan only if the aggregate of the first year compensation is no more than 200 percent of the aggregate of the compensation paid for selling or servicing the enrollee in each individual subsequent renewal year, of which there must be a total of five renewal years (creating a 6-year compensation cycle). For purposes of this section ''compensation''—

(i) Includes pecuniary or non-pecuniary remuneration of any kind relating to the sale or renewal of the policy including but not limited to commissions, bonuses, gifts, prizes, awards and finders fees.

(ii) Does not include salary or other benefits related to employment, except to the extent that the salary or other benefits are related to the volume of sales.

(iii) Does not include the payment of fees to comply with State appointment laws, training, certification, and testing costs; and reimbursement for mileage to and from appointments with beneficiaries and reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

(2) If compensation is paid in the first year, compensation must be paid for no fewer than 5 renewal years (6-year compensation cycle), provided that the enrollee remains enrolled in the plan.

(3) No entity shall provide aggregate compensation to its agents or brokers and no agent or broker shall receive aggregate 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 (6-year compensation cycle).

(i) For purposes of this section, ''like plan type'' means PDP replaced with another PDP, MA or MA–PD replaced with another MA or MA–PD, or cost plan replaced with another cost plan.

(ii) Replacements between different plan types (for which a new compensation is paid) include—PDP and MA–PD, PDP and cost plans, or MA–PD and cost plans.

(iii) When a PDP is added to an MA-only plan, a new commission would be paid for the enrollment in the PDP during the first year.

(4) Compensation shall be earned for months 4 through 12 of the enrollment year.

(i) Plans may pay agents and brokers up-front or prorate compensation payments over 12 months or over months 4 through 12, but

(ii) When a beneficiary disenrolls from the plan, the plan must recover all compensation paid: for months in which the beneficiary is not enrolled; and during months 1 through 3 if the beneficiary disenrolls during the first three months.

(5) Organizations and sponsors must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year. Compensation structures must be in

place by the beginning of the marketing period, October 1.

(6) Compensation structures must be available upon CMS request including for audits, investigations, and to resolve complaints.

(b) It must ensure agents selling Medicare products are trained annually on Medicare rules and regulations specific to the plan products they intend to sell.

(c) It must ensure agents selling Medicare products are tested annually, as specified in CMS guidance.

(d) Upon CMS' request, the organization must provide to CMS, in a form consistent with current CMS guidance, the information necessary for it to conduct oversight of marketing activities.

(e) It must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 19, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: September 2, 2008.

Michael O. Leavitt,

Secretary.

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