DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS-4138-IFC2]

[RIN 0938-AP52]

Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs: Clarification of Compensation Plans

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), and prescription drug benefit program (Part D). 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. The new marketing requirements, which set forth new limits on the compensation that can be paid to agents or brokers with respect to Part C and Part D plans, are based on authority under provisions in the Medicare Improvements for Patients and Providers Act (MIPPA) that became law on July 15, 2008.

DATES: ***Effective date***: These regulations are effective on November 10, 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 **[**OFR--insert date 30 days after date of publication in the **Federal Register]**.

ADDRESSES: In commenting, please refer to file code CMS-4138-IFC2. 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-IFC2,

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-IFC2,

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:

Camille Brown, 410-786-0274, or

Chevell Thomas, 410-786-1387

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 were 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 superseded our rulemaking in these areas.

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), Pub. L. 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).

As noted above, on July 15, 2008, the Medicare Improvements for Patients and Providers Act became law, making several significant new revisions to the MA and Part D prescription drug benefit programs.

On September 18, 2008, we published an interim final rule with comment period, Revisions to the Medicare Advantage and Prescription Drug Benefit Programs (73 FR 54226), that revised the regulations governing the MA program, prescription drug benefit program, and section 1876 cost plans to reflect new statutory requirements enacted in MIPPA. This included new requirements governing the marketing of Part C and Part D plans. Specifically, among other things, the September 18, 2008 regulations established requirements governing MA plan and prescription drug plan (PDP) compensation structures designed to ensure that agents and brokers enroll individuals in the MA plan or PDP that best meets their health care needs. The provisions regarding compensation structures in the September 18, 2008 rule were

effective upon publication, and public comments are being accepted until November 17, 2008.

II. Provisions of the Interim Final Rule

In the section that follows, we discuss the revisions made in this interim final rule with comment period to the regulations in 42 CFR 422 and 423 governing, respectively, the MA and prescription drug benefit programs.

Medicare Advantage and Prescription Drug Program Marketing Requirements (Subparts V)--Broker and Agent compensation (§422.2274 and §423.2274)

Section 103(b)(1)(B) of MIPPA charged 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 applies these same guidelines to PDP sponsors.

On September 18, 2008 we published the new Medicare regulations, Medicare Advantage and Prescription Drug Benefit Programs; Final Marketing Provisions (73 FR 54208) and Revisions to the Medicare Advantage and Prescription Drug Benefit Programs (73 FR 54226), and a guidance document to assist plans in implementing these new regulations. Among other things, these new rules were intended to implement the MIPAA requirement to ensure that agents or

brokers enroll beneficiaries based on the plan that "best meet[s] their health care needs" by imposing requirements pertaining to agent and broker compensation designed to reduce existing financial incentives to enroll a beneficiary in a new plan based on the agent or broker's financial interests rather than the beneficiary's health care needs. These rules provided that, after a beneficiary is enrolled in an MA plan or PDP by an agent or broker, a renewal compensation would be paid for five years after the initial compensation, and that if any agent or broker enrolls the beneficiary in a different plan of a "like plan type" during this five-year period, renewal compensation would be paid. A "like plan type" refers to PDP, MA or MA-PD, or cost plan (as defined in 422.2274(a)(3)(i) and 423.2274(a)(3)(i)). This renewal compensation will apply whether or not the new enrollment is in the same or a new (receiving) organization. The renewal compensation will be paid by the organization offering the plan into which the enrollment occurs, and the amount of the renewal compensation will be based on that organization's compensation structure. That organization will pay renewal compensation for the remainder of the cycle provided that the enrollment remains with that organization. Thus, the agent or broker will receive compensation at the renewal rate, as described above, whether the enrollee stays in the same plan, or moves to a different plan of a like

type, regardless of whether the move is within the existing organization or to a different organization. However, if an enrollee moves to a plan of a different plan type (as defined in 422.2274(a)(3)(ii) and 423.2274(a)(3)(ii)) within the existing organization, the agent or broker may receive compensation at the initial rate. This is designed to ensure that recommendations will be based on the best interests of the beneficiary as MIPPA required.

Under the September 18th regulations, compensation in the initial year in this six-year cycle could not exceed 200 percent of the amount paid for renewal years. We released additional guidance on October 8 and 17, 2008 to further clarify the marketing requirements contained in these new rules. On October 24, 2008, we rescinded the October 8, 2008 guidance memorandum in light of concerns about how the compensation guidance was being interpreted. Based on comments and complaints about how the September 18, 2008 regulations were being implemented, we became concerned that MA and Part D plans were misinterpreting our intent in the compensation structure requirements in §422.2274(a) and §423.2274(a) by proposing structures under which compensation in the initial year in the cycle was less than the renewal years and renewal compensation varied from year to year.

First, in limiting the amount by which the initial year

compensation can exceed the compensation paid for the five renewal years in the six-year cycle, the regulations clearly contemplated that the initial year compensation would be higher than the renewal compensation level. The very purpose of the regulatory scheme, ensuring that an entity does not get the benefit of a initial year level of compensation for moving a member to another plan after the first year, is clearly premised on this assumption.

In addition, we believed that the words of the regulation text made clear that, once a plan chooses an appropriate renewal amount, this fixed renewal amount would be paid for all five renewal years of the six-year cycle in question. Sections 422.2274(a)(1) and 423.2274(a)(1) refer to the "first year compensation" amount being "no more than 200 percent of the compensation paid for selling or servicing the enrollee in *each* individual subsequent renewal year…." (Emphasis added) Thus, we believed that the current regulations made clear that the renewal "compensation paid" for a renewal year, whatever that amount is, be paid for "each" of the five "individual" renewal years of the six-year cycle.

Because, as noted, we have received reports of compensation structures that are inconsistent with the intent of the September 18 interim final rule with comment period, we are revising the regulations to expressly specify

in §§422.2274(a)(1) and 423.2274(a)(1) that the aggregate (commissions, bonuses, etc.) of the compensation amount paid for selling or servicing an enrollee during each of the 5 individual renewal years of a six-year cycle must be fair-market value for the work performed and no more, and no less, than 50 percent of the aggregate (commissions, bonuses, etc.) of the compensation amount paid for that beneficiary in the initial year of the six-year cycle. These new regulations are necessary to achieve the original intent of the September 18, 2008 regulations. We recognize this is a significant change in approach to a compensation structure from September 18, 2008, interim final rule with comment period, where the first year in the six-year cycle could not exceed 200 percent of the amount paid for renewal years, which was modeled after the National Association of Insurance Commissioner's compensation requirements for Medicare supplemental policies. We are making this change, however, to modify the difference between initial year compensation rates and renewal rates to better ensure that agents and brokers enroll beneficiaries in a plan that is intended to best meet the beneficiaries' health care needs.

We do not currently have the administrative capability to communicate to plans as part of our enrollment acceptance process whether an individual enrolling in a plan in 2009 is a new enrollee to Part C or Part D, or an individual who,

under the compensation structure provided for in this interim final rule, is subject to the renewal compensation level rather than the initial compensation level. Thus, we are in this interim final rule, for 2009 only, initially deeming all individuals enrolling in a plan to be in the first year of the five renewal years in the six-year cycle provided for under these regulations.

This means that for enrollments with effective dates in 2009, the MA or PDP plan initially pays the renewal compensation amount to the broker or agent enrolling an individual. Several times in 2009, we will run a report identifying those beneficiaries enrolled in an MA plan or PDP who were newly entitled or enrolled from original Medicare. We will sort the report by plan and send each organization the list of enrollees in a plan offered by that organization, for which, if an agent or broker wrote the policy, that agent or broker would be entitled to an initial compensation amount. Organizations can use the report to identify the agents or brokers who are entitled to an initial compensation amount.

Under this interim final rule, organizations will be required to adjust the compensation from renewal compensation in these cases only to the amount that would have been paid in compensation for an initial enrollment under the six year cycle in question. For the remainder of

2009, this interim final rule requires that organizations pay agents and brokers an initial compensation when a beneficiary enrolls in an MA plan during the beneficiary's Initial Coverage Election Period (ICEP) or in a PDP during the Initial Enrollment Period (IEP). This approach enables organizations to compensate agents and brokers for the additional work involved in explaining all of the attributes of an MA plan (and the Part C program generally) or a PDP (and the Part D program generally) to a beneficiary who has had no prior experience with Part C or Part D, while at the same time reducing the financial incentive for moving a beneficiary who is in a renewal cycle (and is thus already familiar with these types of products) to a new plan that may be contrary to his or her health care needs.

In addition to the above changes to the September 18, 2008 regulations, we are also in this interim final rule addressing the amount paid in agent and broker compensation for 2009 and beyond. We have received information that some organizations are proposing to offer extremely generous compensation in 2009 far in excess of amounts paid for the previous three years by the organization in question, or substantially in excess of the amounts paid generally in the area for the plan type involved. We are concerned about the financial incentive to enroll beneficiaries in a new plan that is created by the potential for an agent or broker to

receive such a substantial increase in compensation relative to the amount he or she would be paid for a renewal in the beneficiary's current plan. We also believe that these excessive compensation structures are detrimental to sustaining an enrollee's long term relationship with the plan in which he or she is enrolled.

In order to protect against the incentive that such a substantially higher compensation level may create to enroll beneficiaries in a different plan even when doing so might not be in their best interest, and to ensure that beneficiaries' long term relationships with their plans are preserved for as long as they are in the beneficiary's interest, we are also in this interim final rule establishing a requirement that compensation levels under the new regulatory scheme must satisfy one of two regulatory standards. For an organization that offered plans in 2006, and used agents and brokers to sell its Medicare products, the MA organization or PDP sponsor offering the plan can comply with our new rules if the "initial year" compensation under the six-year cycle provided for under this rule is the same, adjusted for inflation, that was paid for the same plan type in the same area by the MA or PDP organization, as applicable, in 2006, and the MA or PDP organization certifies to that effect. The inflation adjustment will be based on the average change in MA plan growth rates for MA

organizations and Part D growth rates for Part D organizations, as published in the MA and Part D rate announcements published on the first Monday in April. Because 2009 is initially deemed to be the first renewal year in the six-year cycle, this means that the organization will initially pay 50 percent of the inflation adjusted amount of the initial enrollment compensation it paid in 2006 for the plan type in question. Unless the 2009 compensation amount is adjusted to be changed to an initial enrollment compensation amount as discussed above, this renewal amount will also be paid by the current organization for the remainder of the renewal years in the six-year cycle (for example, 2010 through 2013), assuming that the enrollee remained enrolled in the current organization in the same plan type. If an agent or broker moves the enrollee to a like-plan type in a different organization, the new organization will pay renewal compensation for the remainder of the cycle at the new (receiving) organization's renewal compensation amount.

Organizations that offered plans in an area in 2006 will also have another option, which will be the only option for organizations that did not offer a plan of the type in question in the area involved in 2006 or did offer a plan of the type in question in 2006, but did not use agents and brokers to sell that product. Under this alternate test,

renewal compensation initially paid in 2009 must be 50 percent of an initial rate that was determined, based on market analysis to be commensurate with the "market" rates paid by all organizations in the geographic area for an initial enrollment in the plan type in question during 2006 and 2007, also adjusted for inflation based on changes in MA and Part D growth rates. Essentially, any rates in excess of what was paid by organizations in the area must be justified. We will reserve the right to determine, based on data we receive from MA and Part D contractors, whether the compensation amount proposed meets this test. See the chart below for a reference regarding the required six-year compensation cycle. We note that for purposes of both of the foregoing tests, the "area" in which the plan is offered corresponds to the area the organization uses to determine any geographic adjustments to the amount of compensation paid. If the organization pays the same amount in each county, or MSA, or Statewide, that would be the area in question.

For 2010 and subsequent years, the compensation amount paid to an agent or broker for an initial enrollment of a Medicare beneficiary into an MA or PDP plan is the prior year's compensation adjusted by the change in MA rates for MA plans as published in the MA rate announcement and the change in the Part D rates for PDP plans as published in the

Part D rate announcement. CMS releases annually the rate announcements for MA and Part D publish on the first Monday in April.

We have removed and reserved §422.2274(a)(2) and §423.2274(a)(2) as it is redundant to §422.2274(a)(1)(iii) and §423.2274(a)(1)(iii) in this rule.

We invite comment on the extent to which the compensation structure, or some alternative compensation structure, will promote long-term relationships (that are based on the beneficiaries' interests) between beneficiaries and the plans in which they are enrolled. We are particularly interested in comments on whether this goal would be served (1) by providing for higher levels of compensation for an initial enrollment in Part C or Part D (given the added costs of explaining how the programs work) than for a change in enrollment from one Part C plan or Part D plan to another, (2) by establishing a flat fee schedule, or (3) by providing for lower payments in early years and higher payments in the renewal years, or in later renewal years, to incentivize agents or brokers to keep enrollees in the same plan rather than giving them an incentive to move enrollees.

We note that, to the extent that the high levels of agent or broker compensation that have been reported are already in place for 2008, and were not included in bids for

2008, we intend to ensure in our review of bids for 2010 that these additional uncovered costs are not included in 2010 bid amounts. Similarly, if the compensation paid for 2009, even under this new interim final rule, exceeds the amount assumed in the bids submitted this spring for 2009, we will similarly ensure in our bid review that these 2009 costs are not built into bids for 2010.

These new requirements will apply to the compensation paid to the agent or broker who actually enrolls the beneficiary, whether that agent or broker is paid directly by the MA organization or PDP sponsor, or by an intermediate entity, such as a "Field Marketing Organization" (FMO) or similar type entity that has been retained to sell a plan's Medicare products on its behalf.

We are also concerned about amounts paid to FMOs or other similar type entities for their services that do not necessarily flow down to the agent or broker who deals with the beneficiary. Examples of such services are training, material development, customer service, direct mail, and agent recruitment. Specifically, we are concerned that these FMOs or other similar entities could engage in a "bidding war" with respect to payments they retain, agree to contract to recruit agents, or perform other services only for MA and PDP organizations that are the "highest bidders" for their services. Thus, in this interim final rule, in

addition to limiting the compensation that is ultimately paid to agents or brokers as set forth above, we are requiring that, for organizations that contract with FMOs or pay other similar type entities, any amount paid to such a third party must be fair-market value and may not exceed an amount that is commensurate with the amount that organization paid to a third party for similar services in each of the prior two years.

Finally, we have learned that some organizations did not post their compensation structures by October 15, 2008, but instead posted them after they had the opportunity to review competitors' compensation structure postings. In fact, it appears that some organizations have yet to post their compensation levels. In light of the new requirements set forth in this interim final rule with comment period, MA and PDP organizations must submit compensation structures paid for the 3 previous years, and the compensation structures for the upcoming plan year in accordance with our instructions. This information must be submitted to the following mailbox MA_PDPSalesCompensation@cms.hhs.gov (there is an underscore between "MA_PDP") no later than the date we specify. For MA and PDP organizations that did not sell products through agents and brokers in any of these years, they would not be required to provide information for those years. Nevertheless, all MA and PDP organizations must

respond to the data requests in accordance with our instructions. In addition, if the MA and PDP organization contracts with an FMO or other third party, the compensation structure paid to each third party in each of the past three years, and the compensation structure for 2009, should be reported.

We will consider an organization that does not submit compensation structure information for the appropriate years to us by the date indicated to be out of compliance with our marketing requirements and the organization will face potential sanctions and/or other penalties. An organization's submission must include a signed certification from its CEO or CFO (or other authorized senior official). MA and PDP organizations must distribute their rates by November 15, 2008 to agents, brokers, and other third parties under contract to sell Medicare Advantage and Part D plans. Once plans distribute their 2009 compensation rates and submit that information to CMS, they cannot change the rate without prior CMS approval.

Based on public comments and discussions with the industry, we realize that while our current compensation regulations are relevant to the way independent agents and brokers are compensated, the relationship and compensation arrangements between MA and Part D organizations and employed agents is very different. As a result, the new

compensation requirements in this interim final rule will not apply to employed agents. CMS considers agents employed if the employed agent sells exclusively for one organization and receives a set salary in addition to any compensation tied to volume of sales. We are interested in receiving public comments on what, if any, compensation requirements should apply to employed agents.

In accordance with the above new requirements, we will investigate outliers whose current compensation is not reasonable in light of the compensation paid during the previous three years and compensation paid in that geographic area by similar plan types to ensure that organizations are in compliance with our requirements and take enforcement action as appropriate, including requiring organizations to be prepared to adjust the compensation rates submitted to CMS, or to take other steps to ensure that beneficiaries' interests are not harmed by the excessive compensation paid. In addition, as noted in the preamble to the September 18, 2008 interim final rule (73 FR 54239), all parties should be mindful that their compensation arrangements including arrangements with FMOs and other similar type entities must comply with the fraud and abuse laws, including the anti-kickback statute.

Required Six-Year Compensation Cycle					
Year 1 – "Initial Year Compensation"	Year 2 – "Renewal Compensation "(2009)	Year 3 – "Renewal Compensation "	Year 4 – "Renewal Compensation "	Year 5 – "Renewal Compensation "	Year 6 – "Renewal Compensation "
While not initially applicable for 2009, the first year compensation assumed as part of the six-year cycle will either be the amount paid by the MA organization or PDP sponsor for the plan type in question in the area for 2006, or an amount commensurate with the market rate in the area for the plan type in 2006 and 2007, adjusted for inflation. This rate will apply in 2009 if an adjustment is required in the case of a beneficiary new to Part C or Part D	This amount must be no more and no less than half the assumed initial amount under the six-year cycle.	Same amount as year 2.	Same amount as year 2.	Same amount as year 2.	Same amount as year 2.

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, Full 60-day Comment Period, and Delay in Effective Date

A. Waiver of proposed rulemaking and full 60-day comment period

We ordinarily publish a notice of proposed rulemaking

in the **Federal Register** and allow a 60-day 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. In addition, 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 MIPPA was enacted on July 15, 2008. The deadline for issuing the compensation rules included in this interim final rule with comment period are required by MIPAA to be in effect on a date specified by the Secretary, but no later than November 15, 2008, which is less than 150 days after enactment of MIPAA. For this reason, we find good cause to waive the proposed rulemaking requirement and to shorten the customary 60-day comment period to 30 days.

B. Waiver of delay of effective date

In addition, since the provision discussed above which

is 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 including the provision related to agent/broker compensation 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).

A. ICRs Regarding Broker and agent compensation and training of sales agents (§422.2274)

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. Specifically, we are requiring all Medicare Advantage plans to post revised compensation structures to brokers or agents that conform precisely to our regulations and guidance (for 2009, these rates must be posted by November 15, 2008). We are further requiring organizations to submit their compensation structures for the previous years plus the current year to CMS (for example, 2009 plans must submit 2006 through 2009). In addition to the compensation structures, every complete submission must include a signed certification from the organization's CEO or CFO (or other authorized senior official). The burden associated with this requirement is the time and effort put forth by the organization to post the compensation structures and to provide the structures and certification to CMS.

We anticipate it would take 1 organization 56 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 37,520 hours.

In this interim final rule with comment period, we are collecting additional information to implement 422.2274(d). We submitted a revision of the currently approved information collection request assigned to OMB control number 0938-0753. The information collection requirements contained in 422.2274(d) will be included in the revised information collection request.

B. ICRs Regarding Broker and agent compensation and training of sales agents (§423.2274)

Section 423.2274(d) states that the Part D sponsor provide information for it to conduct oversight of marketing activities upon CMS' request. Specifically, we are requiring all Medicare Prescription Drug Plans to post revised compensation structures to brokers or agents that conform precisely to our regulations and guidance (for 2009, these rates must be posted by November 15, 2008). We are further requiring organizations to submit their compensation structures for the 3 previous years plus the current year to CMS (for example, 2009 plans must submit 2006 through 2009). In addition to the compensation structures, every complete submission must include a signed certification from the organization's CEO or CFO (or other authorized senior official). The burden associated with this requirement is

the time and effort put forth by the organization to post the compensation structures and to provide the structures and certification to CMS.

We anticipate it would take 1 Part D sponsor 49 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 4,263 hours.

The information collection requirements contained in §423.2274 were submitted to OMB for approval as part of an emergency revision of the currently approved information collection request assigned to OMB control number 0938-0964.

As reflected in the table that follows, the aggregate annual burden associated with the collection of information section for this rule totals 41,783 hours.

Table 2
Aggregate Annual Burden

OMB Control Number	Requirements	Number of Respondents	Burden per Response (hours)	Total Annual Burden (hours)
0938-0753	422.2274(d)	670	56	37,520
0938-0964	423.2274(d)	87	49	4,263
Total				41,783

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-IFC2

Fax (202) 395-6974.

VI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258) 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). As a result of our analysis, this interim final rule does not meet the threshold of being economically significant and is consequently not a major rule.

B. Regulatory Flexibility Analysis

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 when we believe it would aid understanding of the effects of the interim final rule. We are providing a summary of the minimal costs associated with this interim final rule. Costs for preparing and reporting compensation structures to CMS is as follows: MA program $54.98 x 37,520 hours = $2,062,849. Costs for the PDP program are $54.98 x 4,263 hours = $234,379. The aggregate new burden costs are estimated to be $2,297,228.

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.

C. Conclusion

Given that we expect the cost of implementing this provision to be minimal and under the $100 million threshold; we did not conduct a full economic impact analysis with regard to those entities potentially impacted by these provisions, as outlines by the regulatory flexibility analysis or Section 1102(b) of the Act.

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 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 422—MEDICARE ADVANTAGE PROGRAM

1. 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 V—Medicare Advantage Marketing Requirements

2. Section 422.2274 is amended by—

A. Revising the introductory paragraph.

B. Revising paragraph (a)(1).

C. Removing and reserving paragraph (a)(2).

The revisions read as follows:

§422.2274 Broker and agent requirements.

For purposes of this section "compensation" includes pecuniary or non-pecuniary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes, awards and finders fees. "Compensation" does not include the payment of fees to comply with State appointment laws, training, certification, and testing costs; reimbursement for mileage to, and from, appointments with beneficiaries; or reimbursement for actual costs associated with beneficiary

sales appointments such as venue rent, snacks, and materials. If a Medicare Advantage organization markets through independent (i.e., non-employee) brokers or agents, the following requirements must be met:

(a) * * *

(1) An MA organization (or other entity on its behalf) may provide compensation to a broker or agent for the sale of an MA product if the following requirements are met:

(i) The compensation amount paid to the broker or agent for an initial enrollment of a Medicare beneficiary into an MA plan in 2009 is one of the following:

(A) The compensation paid by the MA organization in the geographic area for initial enrollment for the plan type in question in 2006, adjusted by the average change in MA rates as published by CMS in the MA rate announcement; or

(B) A compensation amount commensurate with the market rate for initial enrollments paid by (or on behalf of) MA organizations offering plans in the geographic area for the plan type in question during 2006 and 2007, adjusted by the average change in MA rates as published by CMS in the MA rate announcement.

(ii) For 2010 and subsequent years, the compensation amount paid to an agent or broker for enrollment of a Medicare beneficiary into an MA plan is:

(A) For an initial enrollment, the prior year’s

initial compensation adjusted by the change in MA rates that CMS announces each year.

(B) For renewals, an amount equal to 50 percent of the initial compensation in (A) above.

(iii) The broker or agent is paid a renewal compensation for each of the next 5 years the enrollee remains in the plan in an amount equal to 50 percent of the initial year compensation amount (creating a 6-year compensation cycle). For purposes of paragraph (a)(1)(i), individuals enrolling in an MA plan in 2009 are initially deemed to be in the first renewal year (the second year) in the 6-year cycle. With respect to an individual identified by the MA organization as in an Initial Coverage Election Period (ICEP) or subsequently identified by CMS as in an ICEP or new to the MA program, the individual is considered to be in the initial year of the 6-year cycle. The MA organization must adjust the compensation paid for these new enrollees from renewal compensation to the amount that would have been paid for an initial enrollment under the 6-year compensation structure initiated in the year the enrollment occurred.

(iv) If the MA organization contracts with a third party entity such as a Field Marketing Organization or similar type entity to sell its insurance products, or perform services (for example, training, customer service,

or agent recruitment), the amount paid to the third party must be fair-market value and must not exceed an amount that is commensurate with the amounts paid by the MA organization to a third party for similar services during each of the previous 2 years.

(2) Reserved

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

3. 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 V—Part D Marketing Requirements

4. Section 423.2274 is amended by—

A. Revising the introductory paragraph.

B. Revising paragraph (a)(1).

C. Removing and reserving (a)(2).

The revisions read as follows:

§423.2274 Broker and agent requirements.

For purposes of this section "compensation" includes pecuniary or non-pecuniary remuneration of any kind relating to the sale or renewal of a policy including, but not limited, to commissions, bonuses, gifts, prizes, awards and finders fees. "Compensation" does not include the payment of

fees to comply with State appointment laws, training, certification, and testing costs; reimbursement for mileage to, and from, appointments with beneficiaries; or reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials. If a Part D sponsor markets through independent (i.e., non-employee) brokers or agents, the following requirements must be met:

(a) * * *

(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 following requirements are met:

(i) The compensation amount paid to the broker or agent for an initial enrollment of a Medicare beneficiary into a PDP in 2009 is either one of the following:

(A) The compensation paid by the Part D sponsor in the area for an initial enrollment for the plan type in question in 2006, adjusted by the average change in Part D rates as published by CMS in the Part D rate announcement; or

(B) A compensation amount commensurate with the market rate for initial enrollments paid by (or on behalf of) Part D sponsors offering plans in the geographic area for the plan type in question during 2006 and 2007, adjusted by the average change in Part D rates as published in the Part D rate announcement by CMS.

(ii) For 2010 and subsequent years, the compensation amount paid to an agent or broker for enrollment of a Medicare beneficiary into an PDP is:

(A) For an initial enrollment, the prior year's initial compensation adjusted by the change in Part D rates that CMS announces each year.

(B) For renewals, an amount equal to 50 percent of the initial compensation in (A) above.

(iii) The broker or agent is paid a renewal compensation for each of the next 5 years the enrollee remains in the plan in an amount equal to 50 percent of the initial year compensation paid (creating a 6-year compensation cycle). For purposes of paragraph (a)(1)(i), individuals enrolling in a PDP in 2009 are initially deemed to be in the first renewal year (the second year) in the 6-year cycle. With respect to an individual identified by the PDP sponsor as in an Initial Enrollment Period (IEP) or subsequently identified by CMS as in an IEP or new to the Part D program, the individual is considered to be in the initial year of the 6-year cycle. The PDP Sponsor must adjust the compensation paid for these new enrollees from renewal compensation to the amount that would have been paid for an initial enrollment under the 6-year compensation structure initiated in the year the enrollment occurred.

(iv) If the Part D sponsor contracts with a third party entity such as a Field Management Organization or similar type entity to sell its insurance products or perform services (for example, training, customer service, or agent recruitment), the amount paid to the third party must be fair-market value and must not exceed an amount that is commensurate with the amounts paid by the PDP organization to a third party for similar services during each of the previous 2 years.

(2) Reserved

* * * * *

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

Dated: October 31, 2008

Kerry Weems,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Approved: November 7, 2008

Michael O. Leavitt,

Secretary.

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