DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS 4131–F]

RIN 0938–AP24

Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Final Marketing Provisions

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

ACTION: Final rule.

SUMMARY: This final rule revises the Medicare Advantage (MA) program (Part C) and Medicare Prescription Drug Benefit Program (Part D). The regulation contains new regulatory provisions regarding marketing processes for both programs. The revisions to the Part C and Part D programs are based on lessons we have learned since 2006, the initial year of the prescription drug program and the revised MA program.

DATES: *Effective Date:* The provisions of this regulation are effective September 18, 2008.

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SUPPLEMENTARY INFORMATION:

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 program 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 through 4741 and 70 FR 4194 through 4585, 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 have gained more experience with the MA and the Part D programs, we are revising areas of both programs. Many of these revisions clarify existing policies or codify current guidance for both programs. We believe that these changes will help plans understand and comply with our policies for both programs and aid MA organizations and Part D plan sponsors in implementing their health care and prescription drug benefit plans.

B. Relevant Legislative History and Overview

The Balanced Budget Act of 1997 (BBA), Public Law 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 M+C program which was established by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33). Title II of the MMA renamed the M+C program the MA program and included new payment and bidding provisions, added authority for 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 to the provisions of Part C. 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 through 46977) and the Medicare Prescription Drug Benefit Program (69 FR 46632 through 46863). 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 4588–4741) and (70 FR 4194–4585).

Based on what we learned in program experience subsequent to the promulgation of the initial regulations implementing the MMA, on May 16, 2008, we proposed additional revisions to the Part C and D regulations that proposed to incorporate certain existing policies into the regulations, and make some revisions to policies based on program experience (73 FR 28556). The proposals in this May 16, 2008, notice of proposed rulemaking (proposed rule) included proposals addressing the marketing of Part C and Part D plans to Medicare beneficiaries. While the proposed rule also included a wide range of other proposals, in this final rule, we are only finalizing certain proposals in the May 16, 2008, proposed rule relating to marketing.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Public Law 110–275 was enacted on July 15, 2008, and amended titles XVIII and XIX of the Social Security Act to make various revisions to the Medicare statute intended to improve the Medicare program. Section 103 established new statutory prohibitions and limitations for MA plans and Medicare Prescription Drug plans (PDPs) on certain sales and marketing activities. Many of these new statutory marketing provisions were similar (or identical) to provisions that we proposed in our May 16, 2008, proposed rule. For example, MIPPA specifically prohibits, while performing marketing activities to promote or sell MA plans or PDPs, any unsolicited means of direct contact with beneficiaries, cross-selling of non-health related products, and providing meals. It also prohibits sales and marketing

activities in health care settings (excluding common areas) and at educational events.

MIPPA also places limits on other marketing activities. Specifically, it limits the following: the scope of the discussion during an appointment set with a beneficiary to discuss an MA plan or PDP to what was agreed upon with the beneficiary in advance; the ability to use names and logos of co-branded network providers on plan membership and marketing materials; the value of gifts and promotional items provided to beneficiaries; and the compensation paid by plans to agents for selling MA and Part D products. In addition, it requires the training and testing of agents and brokers selling MA and Part D products. MIPPA also requires plans and CMS to collaborate and share information with the States.

The above MIPPA provisions enact into statute provisions we proposed through our authority to establish marketing rules through rulemaking, and thus effectively would supersede our regulatory proposals. Pursuant to MIPPA, the marketing prohibitions provisions mentioned above apply to the plan year beginning on January 1, 2009. In keeping with statutory intent and based on policy concerns related to inappropriate marketing activity, we believe that regulations setting forth important protections for beneficiaries should be in effect before the 2009 plan year marketing campaign begins this fall on October 1, 2008. We are finalizing our May 16, 2008 proposals in these areas in this final rule so that the marketing rules in question can be effective for the 2009 benefit year marketing campaign, beginning October 1, 2008. These provisions are set forth in this final rule at § 422.2268, § 423.2268, 422.111(b) and 423.128(b).

Specifically, this final rule finalizes six new marketing provisions and modifies the disclosure and dissemination of Part D information provisions and the file and use provision set forth in the May 16, 2008, proposed rule. The remaining proposals in the proposed rule either were superseded by statutory provisions that we will reflect in the regulations as part of an interim final rule, or will be finalized in a future final regulation in which we will respond to any public comments on those proposals in the May 16th proposed rule that were not superseded by MIPPA provisions.

II. Provisions of the Proposed Regulations

Because this final rule finalizes only the recodification and modification of existing sections of the marketing regulations at § 422.80, § 423.50, § 422.111, and § 423.128 and finalizes only six of the new provisions from the proposed rule, we shall only discuss these aspects of the May 16, 2008 proposed rule here. The following table displays how the proposed rule proposed to recodify existing marketing provisions, and the bullets that follow the table set forth those proposals in the May 16, 2008 proposed rule that we are addressing in this final rule.

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
Marketing: Definitions	Subpart V (all marketing sections)	422.2260	Subpart V (all marketing sections)	423.2260
Review and Distribution of Marketing Materials.		422.2262		423.2262
Guidelines for CMS Review		422.2264		423.2264
Deemed Approval		422.2266		423.2266
Marketing: Standards for MA/Part D marketing.		422.2268		423.2268
Marketing: Licensing of marketing representatives and confirmation of marketing resources.		422.2272		423.2272
Marketing: Employer group retiree marketing.		422.2276		423.2276
Disclosure requirements and Dissemination of Part D information.	Subpart C	422.111	Subpart C	423.128

• § 422.2262(b) and § 423.2262(b)—we proposed to eliminate the file and use eligibility process.

• § 422.2268(b) and § 423.2268(b)—we proposed to prohibit the offering of gifts to potential enrollees unless the gifts are of nominal value, and prohibit providing meals to beneficiaries while conducting marketing activities. We are only finalizing the prohibition on meals in this final rule, and thus are separating these two prohibitions. The nominal gifts provision will be addressed in a separate rule that implements the requirement that new MIPPA rules be in place no later than November 15, 2008.

• § 422.2268(d) and § 423.2268(d)—we proposed to extend the prohibition against door-to-door solicitation to include other instances of unsolicited direct contact including outbound telemarketing without the beneficiary initiating contact.

• § 422.2268(f) and § 423.2268(f)—we proposed to prohibit the cross-selling of non-health care related products during any sales, marketing, or presentation for an MA plan or PDP.

• § 422.2268(k) and § 423.2268(k)—we proposed to prohibit conducting sales presentations or distributing and accepting plan applications in provider offices or other places where health care is delivered.

• § 422.2268(l) and § 423.2268(l)—we proposed to prohibit conducting sales activities, distributing, or collecting applications at education events.

• § 422.2272(c) and § 423.2272(c)—we proposed that plans must appoint and use only State licensed representatives to conduct direct marketing activities in accordance with applicable State appointment laws.

• § 422.111 and § 423.128—we proposed that plans must disclose the information specified in §§ 422.111(b) and 423.128(b) to its members both at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

III. Analysis of and Response to Public Comments

We received a total of 405 timely comments on the May 16, 2008 proposed rule, and will only address here those comments that pertain to the proposals we are finalizing in this final rule. We received comments from managed care organizations and other insurance industry representatives, pharmacy benefit management firms,

pharmacies and pharmacy education and practice-related organizations, beneficiary advocacy groups, representatives of health care providers, States, employers and benefits consulting firms, members of Congress, beneficiaries, and others. The comments ranged from general support or opposition to the proposed provisions to very specific questions or comments regarding the proposed changes.

Brief summaries of each proposed provision, a summary of the public comments we received, and our responses to the comments are set forth below.

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

A. General

In order to implement standards consistent with ''fair marketing'' practices in accordance with sections 1851(h) and 1860D–1(b)(1)(B)(vi) of the Act, and to ensure beneficiaries receive the necessary information to make informed choices during the annual election period, we proposed to amend and expand our marketing regulations for both the MA and the Part D programs. Moreover, due to the proposed addition of new marketing provisions and the need to clarify current marketing regulations, we proposed to remove §§ 422.80 and 423.50 of subpart B, which currently specify the requirements related to the approval of marketing materials and instead include this core of our marketing requirements in a new subpart V at 42 CFR parts 422 and 423 specific to the marketing regulations for each program.

Comment: We received several comments recommending changes to the content of the existing requirements contained in § 422.80 and § 423.50.

Response: In the proposed rule we made no changes to the requirements in §§ 422.80 and 423.50 other than to include them in a new subpart V (§§ 422.2260 and 423.2260). Because we did not propose modifications to the content of this section in the proposed rule other than relocating the text to a new subpart, the comments are beyond the scope of this regulation. However, there is one exception. A commenter requested that we remove the second sentence at §§ 422.2268(a) and 423.2268(a) because it creates ambiguity with respect to the prohibition outlined in the first sentence. We agree and are removing the sentence.

Comment: One commenter expressed concern about the time frame for implementing certain provisions prior to the annual election period (AEP) and open enrollment period (OEP) and recommended that the effective date of any provisions of the final regulations be effective after the 2009 AEP and OEP (April 1 or later). Other commenters expressed their desire for the provisions to be effective no sooner than 2010.

Response: This final rule contains the six provisions from the May 2008 proposed rule that we believe should be implemented prior to October 1, 2008, the beginning of the marketing period for contract year 2009, in order to protect beneficiaries during the annual election period. These six provisions are in accordance with requirements contained in section 103 of MIPPA that will take effect by operation of statute on January 1, 2009. In light of our program experience, we believe that the beneficiary protections in these six provisions should be put into effect before the 2009 benefit year marketing campaign and annual election period. Other provisions from the May 2008 proposed rule will be addressed in separate regulations, one will reflect other statutory provisions in MIPAA, and one will respond to comments on the other provisions in the May 2008 proposed rule that were not addressed in MIPAA. We will consider this comment in relation to the latter remaining provisions.

Comment: A few commenters requested clarification of the extent to which the proposed marketing requirements apply to cost plans or employer group plans; recommending that, if the proposed marketing requirements do not apply to cost plans or employer group plans, CMS modify the regulations to apply the proposed marketing requirements to such plans.

Response: Cost plans are subject to provisions found in § 417.28 and the guidance contained in the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans.* Employer group plans are MA and Part D plans. Additional guidance on employer group plans will be forthcoming in chapter 9 of the *Medicare Managed Care Manual.* The statutory provisions that the provisions of this final rule mirror only apply to MA plans under Part C and PDPs under Part D.

B. Review and Distribution of Marketing Materials: File and Use (§ 422.2262(b), § 423.2263(b))

In addition to moving our requirements concerning the approval of marketing materials and election forms to §§ 422.2262 and 423.2262 of the Part C and Part D program regulations, respectively, we are proposing to modify the ''file and use'' review process.

While the statute requires the submission of marketing materials to CMS for a 45 day period of CMS review, based on years of program experience CMS recognized that some MA organizations consistently met all marketing standards, and that their marketing materials warranted less scrutiny. CMS accordingly established a file and use policy that was designed to streamline the marketing materials approval process for these MA plans. Under this file and use policy, Medicare health plans that demonstrated to the satisfaction of CMS that they continually met a particular high standard of performance were able to publish and distribute certain marketing materials within 5 days of submission to CMS under section 1851(h)(1), without waiting for a response from CMS.

In effect, these materials were deemed approved by CMS after 5 days based on CMS's prior review of earlier materials. The criteria in order to be eligible for the original file and use policy were that a contracting entity had to have submitted at least eighteen months of marketing materials for CMS review, and at least ninety percent of the materials submitted within the past six months had to meet applicable marketing standards.

In the regulations implementing the MMA, CMS adopted a separate file and use policy that was based on the nature of the marketing materials in question, rather than the track record of the MA organization or PDP sponsor. Under this policy, an MA organization or PDP sponsor certifies that it is using either model language already reviewed and approved by CMS, or types of marketing materials that CMS has identified as not containing substantive content. As with the original policy that focused on the organization, the materials covered by this new file and use certification policy could be used 5 days after submission, without any explicit approval from CMS. In the case of MA organizations, this certification is made at the time of submission, while PDP sponsors are permitted to so certify in their contracts.

In order to level the playing field among contractors, eliminate redundancies, and focus resources on materials that have content that warrants CMS scrutiny, we are proposing to eliminate file and use status based on an organization's track record, and apply a uniform policy of applying the file and use policy to marketing materials that either use model language without substantive modification, or materials that are

identified by CMS as not containing substantive content warranting CMS review. The same approach to certifying that these types of materials are being used would apply for both MA organizations and Part D sponsors. We would include the proposed file and use provision in § 422.2262(b) and § 423.2262(b) of the MA and Part D programs, respectively.

Comment: There were several general comments on the CMS review process for marketing materials, including a request for further definition of ''substantive content.''

Response: Over the past 2 years CMS has implemented several mechanisms to enhance the consistency of our review process, and we will continue to refine our processes. We consider the suggestion to make more materials eligible for file and use a good one, and we have done so recently and may continue to do so in the future. A list of materials CMS has identified as ''not containing substantive content'' and eligible for file and use is available in the Health Plan Management System (HPMS) marketing module. With respect to shortening the review period to 30 days, the statute requires the submission of marketing materials to CMS for a 45-day period of review. Materials that are not deemed eligible for the 5-day file and use policy must be submitted for a 45-day review period. Finally, CMS will take under consideration suggestions to clarify the review process for plans that operate in more than one geographic area, and to allow such plans to submit materials to the lead office only for review.

Comment: One commenter agrees with the 45-day rule for marketing materials, but suggests that CMS attach the civil monetary penalty (per enrollee affected) as penalty for violating the certification without exceptions.

Response: CMS may impose a civil monetary penalty (CMP) on an organization when the organization's conduct adversely affects or has the substantial likelihood of adversely affecting one or more enrollees. One of the violations for which a CMP can be assessed is that the organization substantially fails to comply with marketing requirements (§§ 422.510(a)(12) and 423.509(a)(9)). If CMS determines an organization's substantial failure to adhere to marketing requirements has adversely affected or has the substantial likelihood of adversely affecting one or more enrollees, CMS may impose a CMP. It is important to note that CMS has other enforcement options, such as marketing and enrollment sanctions, for organizations that fail to adhere to marketing requirements. Under these sanctions, CMS may restrict a plan from marketing during marketing season or from accepting new enrollments for a period of time. For example, since marketing season begins on October 1st of every year, CMS may decide to impose a sanction against a plan for a marketing violation that prevents the plan from marketing until a later date, such as October 15th or November 1st. Similarly, CMS may prohibit a plan from accepting new enrollments for several months.

Comment: We received several comments in support of this rule change, and one comment opposing our elimination of the file and use policy for marketing materials.

Response: Section 423.2262 does not eliminate the file and use process, it only eliminates the file and use status based on an organization's track record. Instead a uniform policy will be applied, so that all contractors are eligible to submit any material deemed file and use qualified.

Comment: CMS received one comment that this change will over burden CMS and could lead to a negative impact on members. CMS must release models in time for document preparation and review time to be allowed.

Response: The elimination of file and use based on status will not increase the number of documents that CMS must review through the 45-day review process—model documents previously eligible for file and use will remain eligible for file and use. In addition, CMS is moving towards more standardization of certain model documents, which will then increase the number of documents eligible for file and use, thereby significantly shortening the amount of time required for CMS review. CMS has successfully released several model documents for plan review and modification earlier in the year, and will continue towards that goal.

Comment: Several comments suggested that CMS should add a requirement that plan sponsors file marketing materials with State regulators, so that States will be able to differentiate between CMS-approved and unapproved material and take action accordingly.

Response: It is not necessary for plans to file marketing materials with State regulators. All CMS approved marketing materials contain a unique material identification number. If anyone has a question about the legitimacy of plan marketing material, they can report it to CMS and it will be verified. If CMS determines that the material was not reviewed and approved prior to use, we will initiate a compliance action. If CMS determines that the material was appropriately submitted and approved, but determines as a result of a complaint that there is a problem with the material, it will contact the plan to have the material taken out of use.

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

We proposed making an organizational change for this section, consistent with our proposal to create a new subpart V at 42 CFR part 422 and part 423 specific to marketing regulations. We are redesignating §§ 422.80 and 423.50 as §§ 422.2268 and 423.2268, respectively.

Comment: We received several comments requesting that we clarify that pharmacies are not obligated to distribute plan information to beneficiaries for Part D plans with which they do not have contracts. One commenter stated they do not believe that pharmacies should be prevented from providing comparative Part D plan information to patients if they do not accept and display marketing materials from all Part D sponsors. A commenter stated that some pharmacies may not contract with some Part D plans, and as a result may not be familiar with their terms and conditions nor have ready access to those plans' marketing materials. Some commenters also stated that the regulatory language in proposed § 422.2268(j) was not consistent with § 423.2268(j). Commenters stated that the final Part D technical rule that published April 15, 2008, (73 FR 20486) modified 42 CFR 423.50(f) requiring providers such as a pharmacy provider to display and distribute comparative plan marketing materials only from plans with which the provider contracts. One commenter recommended that CMS retain the recently amended § 423.50(f) and remove the language proposed in § 422.2268(j) and § 423.2268(j). There were also some commenters that opposed the existing provision.

Response: We are revising proposed § 423.2268(j) to be consistent with § 423.50(f)(v) as published in the Policy and Technical Changes to the Medicare Prescription Drug Benefit final rule (73 FR 20486) to include '' accept and display materials from MA organizations or Part D plan sponsors with which the provider, provider group or pharmacy is contracted.'' We are also modifying the regulatory language in § 422.2268(j) to be consistent with the language provided in § 423.2268(j). With respect to commenters that opposed the provision, as opposed to seeking

clarification, these comments are outside the scope of this rulemaking.

Comment: One commenter contended that this provision does not reflect guidance CMS issued October 30, 2006, that allows comparisons to be limited to SNPs as long as the remaining MA plans are identified. The Commenter recommended having this guidance explicitly recognized in the new regulation.

Response: The guidance released on October 30, 2006, references provider affiliation announcements in which SNPs may announce an ongoing affiliation or arrangement. This guidance will be included in the updated *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans and other guidance.* This guidance requires that all affiliated plans be listed on affiliation announcements. In some cases, a disclaimer indicating that other plans are available is required. Highlighting the affiliated SNP plans within the list of all affiliated plans or listing the affiliated SNP plans along with the disclaimer is consistent with our guidance.

Comment: One commenter requested that CMS continue to allow providers to use an objective third party to create MA health plan benefit comparisons (all or a subset) that are distributed to beneficiaries/patients consistent with the Medicare marketing guidelines.

Response: This is still allowed. The *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* provides specific guidance for materials created by third parties.

D. Employer Group Retiree Marketing (§§ 422.2276, 423.2276)

We proposed an organizational change for this section, consistent with our proposal to create a new subpart V at 42 CFR part 422 and part 423 specific to marketing regulations. We are redesignating § 422.80(f) as § 422.2276 and, to be consistent, are adding § 423.2276.

Comment: We received no comments about the reorganization or the addition of § 423.2276. The only comments received expressed a concern about employer group marketing materials not being subject to prior review and approval.

Response: We have considered this comment and believe that employer group marketing is very different from marketing individual plans. Therefore, we are finalizing the provision without modification.

E. Licensing of Marketing Representatives and Confirmation of Marketing Resources (§§ 422.2272, 423.2272)

In response to questions from the Part D industry regarding State licensure of marketing representatives, we adopted in our *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* the requirement that MA organizations and Part D sponsors that conduct marketing through employees or independent agents use State-licensed, certified, or registered individuals to do so, if a State licenses such agents. The use of only State-licensed marketing representatives helps ensure that the marketing representatives meet minimum standards of integrity and professionalism in order to market to Medicare-eligible beneficiaries. This Medicare requirement permits Medicare to benefit from State efforts to deny licensure to under-educated, unscrupulous or otherwise substandard individuals, and helps ensure that Medicare beneficiaries are not the victims of substandard or inappropriate marketing activities.

Based on the experience we have gained since the start of the Part D program, and continued experience with the Medicare Advantage program, we proposed to codify in the regulation our existing requirement that MA organizations and Part D sponsors utilize only State-licensed marketing representatives to do marketing in the States that license such agents.

We further proposed to add a regulatory requirement to §§ 422.2272 and 423.2272 that MA organizations and PDP sponsors that market through agents, not only be required to use licensed agents, but would be required to report to States that they are using such agents, in a manner consistent with State appointment laws. State appointment laws require MA and PDP sponsors to appoint marketing representatives before the agent can market a plan's product. Appointment laws may require an insurance plan to maintain a registry of marketers who sell their plans, including maintaining a list of license numbers, dates the individual began selling policies for the insurance company, and stopped selling plans for the insurance company. While we previously required only that licensed agents be used, and did not require that the appointment of such agents be reported to the State agency that regulates agents, we believe this latter requirement would enable States to monitor the agents' activities in connection with their Medicare marketing for the purpose of monitoring the agent's fitness to engage in marketing in the State. We believe Medicare beneficiaries would benefit from this State monitoring.

We recognize that, under the preemption provisions in section 1856(b)(3) of the Act (incorporated for PDPs under section 1860D–12(g)), States do not have the authority to regulate the marketing of Medicare Part C and D plans. However, as noted, any abuses by an agent in marketing such plans would have direct relevance to the State's oversight of the agent generally, and implications for the agent's marketing of products over which the State has jurisdiction, and Medicare beneficiaries would benefit from having the agents who engage in Medicare marketing subject to this State oversight.

In the context of the requirement that MA organizations and Part D sponsors utilize only State-licensed marketing representatives, and report the appointment of such agents to States consistent with the procedures under State appointment laws, it is important to discuss the activities that would not trigger the need for using State-licensed marketing representatives. As standard practice, MA organizations and Part D sponsors employ customer service representatives who answer questions and accept enrollments on behalf of enrollees who have decided to enroll in a particular plan offered by the organization. We recognize that plan customer service representatives play an important role in disseminating information by answering factual questions posed by beneficiaries, and that such an activity is distinguishable from the act of steering to a plan (''marketing,'' as defined in the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans*).

Additionally, taking demographic information from someone who has decided to enroll in the plan, in order to complete an application, is not steering in that the beneficiary has already made a choice to enroll in a plan. Accordingly, we believe providing factual information, fulfilling a request for materials, and taking demographic information in order to complete an enrollment application at the initiative of the enrollee by a customer service representative (CSR), are legitimate customer service activities that would

not trigger the need for using State-licensed marketing representatives.

Comment: Many commenters agreed with the requirement that MA organizations and Part D sponsors that conduct marketing through agents must use State-licensed, certified, or registered individuals.

One commenter urged that the proposed rule on licensed agents include clarifying language similar to the language in the preamble, and in the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans.*

Response: We have considered this comment and have determined that the proposed provision should be finalized without modification. The *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* provide the clarification requested and we believe that the guidelines are the appropriate vehicle to do this.

Comment: A few commenters asked if the appointment of agents/brokers was warranted for stand-alone prescription drug plans (PDPs), because the marketing of these plans differs significantly from MA and MA–PD marketing.

Response: We believe that while the marketing of MA plans may differ from PDPs, in accordance with provisions in section 103 of MIPPA that will take effect on January 1, 2009, we are, in this final rule, requiring effective October 1, 2008, that MA organizations and PDP sponsors appoint their marketing representatives before the agents can begin to market a plan's product.

Comment: A few commenters would like the requirement for the licensing and appointment of independent agents/brokers to be effective on January 1, 2010 or later.

Response: As we have learned from our experience over the past several years and in order to better protect Medicare beneficiaries from practices that could mislead or confuse them, we believe that this requirement must be implemented before the fall 2008 marketing period during which plans for 2009 are marketed. These provisions would take effect by operation of MIPAA effective January 1, 2009, even if we had not acted to finalize these provisions of the proposed rule in this regulation. Therefore, we will proceed with implementing these rules as final and effective October 1, 2008.

Comment: Many commenters suggested that all MA and PDP enrollment applications should include the National Insurance Producer Registry (NIPR) license number. A few commenters urged more expansive CMS oversight and greater investment of resources in enforcement.

Response: We believe that States currently provide appropriate oversight, and have the necessary reporting mechanisms in place to track and monitor agent activity. The intent of this requirement is to strengthen our ability to collaborate with States in addressing fraudulent and inappropriate marketing practices.

Comment: A number of commenters requested that CMS develop guidance specifying the information that Plans must provide to States and establish a streamlined process for data submission.

Response: We believe States currently provide appropriate oversight and have the necessary reporting mechanisms in place to track and monitor agent activity. The intent of this requirement is to provide support to States as they exercise their oversight authority and we note that the requirement we are finalizing is generally in accordance with the Medicare Improvements for Patients and Providers Act (MIPPA). We will consider this comment when updating marketing guidance in the future.

Comment: Many commenters noted that our proposed regulatory language did not clearly state that CMS is requiring action that parallels information requirements under State appointment laws, because the regulation did not require compliance with all aspects of the State appointment process. By preventing the application of any State fees pursuant to the State appointment process, and requiring plans only to report to States that they are acting ''consistent with the appointment process'' may undermine States' ability to enforce their own appointment laws.

A few commenters believed CMS should revise this section to clarify that State agent appointment laws are enforceable against MA and Part D plan sponsors.

Response: We have considered these comments. Section 103 of MIPPA requires that plans pay fees to States under appointment laws, effective January 1, 2009.

Comment: A commenter questioned if CSRs who respond to beneficiaries' requests for a meeting with an agent need to be licensed.

Response: As discussed in the preamble, we recognize that CSRs play an important role disseminating information by performing activities like answering factual questions posed by beneficiaries. These activities are activities that we distinguish from activities that could result in steering a beneficiary to a particular plan. In keeping with that context, Customer Service Representatives (CSRs) scheduling agent appointments in response to a beneficiary request is not an activity that would require a licensed agent to fulfill.

Comment: A commenter asked if a CSR could answer questions about plans offered by a sponsor.

Response: Section 422.2272 permits CSRs to answer factual questions posed by beneficiaries.

Comment: A few commenters asked whether employees of external agents and brokers who perform ''customer service'' functions, but are not involved in the actual selling of plan products, could also do so without being State-licensed or appointed.

Response: Individuals performing customer service functions such as providing factual information, fulfilling a request for material, and taking demographic information are considered CSRs. When performing these functions, they do not need to be State-licensed or appointed.

E. Standards for MA/Part D Marketing (§§ 422.2268 and 423.2268)

In addition, we also proposed to clarify in §§ 422.2268 and 423.2268 several standards for MA and PDP marketing. In §§ 422.2268(d) and 423.2268(d) we clarify that the prohibition on door-to-door solicitation includes other instances of unsolicited direct contact, such as outbound calling without the beneficiary initiating contact, calling to confirm that the beneficiary is in receipt of mailed information, and accepting appointments made by third parties or independent agents without the beneficiary initiating contact; but does not include calling existing members. Although, plans may not contact former members who have disenrolled or are in the process of disenrolling. We believe this clarification would help prevent inappropriate conduct on the part of agents in aggressively pursuing the marketing of MA plans and PDPs to beneficiaries outside of approved common areas that may be used for marketing displays and presentations (for example, approaching beneficiaries directly in parking lots).

We also proposed to clarify in §§ 422.2268(l) and 423.2268(l) that plans may not engage in sales or marketing activities, including the distribution or collection of plan applications, at educational events. These events may be sponsored by plans or by outside entities, and are events

that are promoted to be educational in nature and have multiple vendors, such as health information fairs, conference expositions, State-or community-sponsored events, etc. In §§ 422.2268(k) and 423.2268(k) we clarified that sales and marketing activities, including the distribution or collection of plan applications, are only permitted in common areas of health care settings (for example, hospital cafeterias or conference rooms), and would be prohibited in areas where patients primarily intend to receive health care services (for example, waiting rooms and pharmacy counter areas). The term ''health care setting'' refers to all settings where providers operate, including but not limited to pharmacies, physicians' offices, hospitals, and long-term care facilities. In the proposed rule, we added § 423.2268(i) to be consistent with § 422.2268(i). We received no comments on this change.

We further proposed a regulatory requirement in §§ 422.2268 and 423.2268, providing additional protections to ensure beneficiaries are not the victims of inappropriate marketing techniques. In §§ 422.2268(f) and (b) and § 423.2268(f) and (b), we proposed to prohibit in any MA or Part D sales activity or presentation, the provision of meals or the cross-selling of non-health care related products to a prospective enrollee.

Comment: Commenters that supported the unsolicited contact prohibition requested that CMS further define cold calls by clarifying if calls are permissible to the following: (1) Existing membership and beneficiaries that have an existing relationship with a producer, (2) business reply cards, and (3) follow-up calls on plan mailings.

Response: These clarifications will be updated in the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, and 1876 Cost Plans and other guidance.*

Comment: Many of the comments were not wholly opposed to the prohibition on meals, and instead were requesting clarification on the definition of meals.

Response: Comments received will be taken under consideration when updating the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, and 1876 Cost Plans and other guidance.*

Comment: Several commenters opposed the provision prohibiting outbound calls. Some stated that it is too restrictive, minimizes growth in the program, and is inconsistent with common marketing practices. Commenters stated that restricting calls will prevent beneficiaries from learning about their full range of healthcare options and is considered discriminatory since it creates an imbalance with Medigap plans. Some commenters stated this provision impacts low-income and non-English speaking populations where communication through mailings has been less effective, specifically beneficiaries with Medicare and Medicaid. Commenters also stated that the current CMS rules in the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* provides adequate protection. Commenters that supported the provision on unsolicited contacts recommended that CMS implement reporting requirements to identify and prevent unsolicited door-to-door sales and require documentation on how an invitation was secured for an in-home presentation.

Response: We believe that this change is necessary to ensure the protection of beneficiaries from inappropriate or fraudulent marketing activities such as high-pressure sales tactics or inappropriate use of beneficiary information. Section 103 of MIPPA prohibits unsolicited means of direct contact including door-to-door solicitation or any outbound telemarketing, and therefore we will proceed without modification in the final regulation. The *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* and other guidance are also in the process of being updated and will set forth in detail requirements for outbound calls to existing membership and plan mailings.

In response to the comment regarding reporting requirements for door-to-door solicitation and in-home appointments, we will consider including detailed guidance in the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans and other guidance.* However, organizations should have internal reporting requirements established to maintain appropriate oversight of these and all marketing activities.

Comment: Some commenters opposed the provision that prohibits sales activities at educational events. One commenter suggested that CMS require agents and brokers to register with their carrier and CMS at seminars and group sales events. Enrollments should be allowed to take place as a result of the seminar at the end or at a later date. Many commenters stated that enrollment materials should be available for distribution only. Commenters supporting the provision also suggested that there should be a disclaimer provided at education events that states, ''This is an education event only and no sales activity will be conducted, including distribution or collection of plan applications.'' Many commenters requested additional clarification on the difference between sales events and education events. Commenters also stated they are concerned with CMS' ability to enforce this provision.

Response: We believe the sole purpose of an education event is to provide objective information about the Medicare program, not steering an enrollee towards a specific plan or limited number of plans. When a beneficiary receives informational materials used to promote an organization or materials that include enrollment information for an organization, this is considered a marketing activity. Additionally, section 103 of MIPPA prohibits sales or marketing activities for enrollment in MA plans in the healthcare setting or at educational events except in common areas of healthcare settings. Therefore, we are finalizing the provision as proposed. We will also further clarify here that sales activities or sales events are marketing activities that steer or attempt to steer, an undecided potential enrollee towards a plan, or limited number of plans, including an effort that involves compensation directly or indirectly to the party conducting the effort if it may lead to enrollment in a plan. In response to the disclaimer requirement for education events, we will consider this requirement when updating the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans and other guidance.*

Comment: One commenter suggested that CMS develop easy to understand educational materials and require plans to distribute those materials to beneficiaries, regarding the disenrollment options available to beneficiaries who may have erroneously or inappropriately enrolled in an MA–PD or a Private-Fee-for-Service Plan.

Response: We will consider additional methods for ensuring beneficiaries are aware of their options to disenroll if the beneficiary has been erroneously or inappropriately enrolled in an MA–PD or a Private-Fee-for-Service Plan. However, CMS currently provides several resources that

organizations can access to provide educational information on the Medicare Program. For example, plans may refer to the CMS partnership Web site for general outreach and education information at *http://www.cms.hhs.gov/partnerships.* Also beneficiaries may be referred to 1–800–MEDICARE if they have been inappropriately enrolled in a health plan.

Comment: We received several comments stating that the provision for plan sales activities in a healthcare setting is inconsistent with the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* and is overly restrictive. Commenters requested clarification on the phrase ''other places where healthcare is delivered'', and suggested instead to prohibit such activities in ''provider offices, other places where a healthcare provider delivers healthcare services to a Medicare beneficiary''. One commenter suggested that CMS model the language included in the recently passed Medicare bill (MIPPA). Some commenters stated that sales activities and applications should be prohibited at pharmacies and any part of a retail store in which a pharmacy is located.

Response: We have reviewed this comment and will revise §§ 422.2268(k) and 423.2268(k) to include the following language from section 103 of MIPPA ''areas where health care is delivered to individuals, except in the case where such activities are conducted in common areas in health care settings.''

Comment: Commenters recommended that CMS amend the rule to clarify that marketing may not take place in areas within healthcare settings where individuals receive care, rather than in the entire building.

Response: We have considered the comment; however, we will retain the provision as proposed. Clarification is provided in the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* where we state ''Common areas, where marketing activities are allowed, include areas such as hospital or nursing home cafeterias, community or recreational rooms and conference rooms. If a pharmacy counter is located within a retail store, common areas would include the space outside of where patients wait for services or interact with pharmacy providers and obtain medications.''

Comment: Commenters stated that CMS did not address in the preamble or proposed regulation sales activities in hospitals or skilled nursing facilities. Some commenters stated that the provisions will impact seniors who are hospitalized or living in long-term care facilities, and that a waiver should be signed to allow marketing in any section that is available. Commenters also stated that this provision would impact beneficiaries that receive care from dialysis facilities where they lack common areas such as lobbies or patient-accessible areas.

Response: In response to the first comment, the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* clarifies that upon request by the beneficiary, plans are permitted to schedule appointments with beneficiaries residing in long-term care facilities just as with other individuals living in a private residence. In response to the comments regarding marketing to patients that are hospitalized or receiving care in a dialysis center, these are areas where patients receive care primarily and therefore are prohibited areas. The preamble provides clarification on activities that can be permitted in common areas and activities that would be prohibited. Furthermore, the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* also provide detail on the requirements for plan activities in a healthcare setting.

Comment: One commenter recommended that CMS provide clarification as to whether providers could provide printed materials in waiting rooms regarding MA or Part D plans, which do not compare or contrast different health plans but focus instead on a single health plan.

Response: The clarification is provided in the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* where it is stated that ''providers are permitted to make available and/or distribute plan marketing materials for all plans with which the provider participates.'' Therefore, if a provider is only contracted with one health plan they are only obligated to display materials for that plan. Otherwise, the provider must display information from all plans with which the provider contracts.

Comment: CMS received many comments on the prohibition on providing meals at marketing events, both in favor and opposed. Commenters in favor of the prohibition expressed that the inclusion of meals as a prohibited item would help protect beneficiaries by preventing mass enrollments without personal attention to the appropriateness of the plan. Comments opposed to the provision on meals were varied. Some stated it is overly restrictive, while others stated that there is no relationship between offering meals at an enrollment event and inappropriate sales tactics, and that meal settings can allow beneficiaries to feel more comfortable and less pressured than an in-home visit. Commenters stated that hosting meal events is a key marketing strategy, and the provision will have a significant impact on beneficiary attendance in marketing seminars. Several commenters stated that the current marketing guidance is sufficient. Some comments requested clarification on the term meals and the limitation—for example, is it acceptable if the beneficiary purchases their own meal or if a volunteer association arranges the meals, or if the meals are provided at an event where no enrollment forms are distributed or collected. One commenter stated that limiting food to snacks would be difficult to enforce. Several organizations made recommendations on different strategies of implementation, including the suggestions that organizations should be prohibited from advertising that a meal will be provided at a plan sponsored event, that meals be allowed at events where applications are not accepted, that a disclaimer be required that the meal is not a contingency for signing up for a plan, or that organizations should be prohibited from spending a dollar limit per person on all food and beverage items at a given event. Comments were received that this provision would deny restaurants an important source of revenue, and that beneficiaries also benefit from the opportunity to get free meals.

Response: Based on oversight activities, we believe it is important to protect the integrity of the sales and marketing process by moving forward with this prohibition. Furthermore, MIPPA prohibits meals at marketing events. Therefore, we adopt the prohibition on meals as proposed. The *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* and other guidance will provide more detail on this requirement. As, noted, the issue of gifts will be addressed separately.

Comment: One commenter argued that cross-selling of all non-Medicare

products should be prohibited, not just non-healthcare related products. In this commenter's view, a prohibition on all non-Medicare products would ensure that beneficiaries focus on Medicare related products. Several commenters were in agreement with prohibiting the marketing of non-health care related products during a sale of Medicare Products, but similarly recommended that regulations governing cross-selling be expanded to bar the cross-selling of all non-Medicare related products. One commenter recommended that plans be permitted to cross sell health related items on inbound calls when a beneficiary has initiated the call. Some commenters requested clarification on what is considered health related products for the purposes of Medicare cross-selling requirements. A commenter believed that the agent oversight would be a huge administrative burden, and that the prohibition of cross selling would be inconvenient for potential members who are seeking to purchase other products.

Response: We welcome the support for banning the marketing of non-health care related products. We are not changing this language to refer to non-Medicare related products however, for two reasons. First, non-Medicare health care coverage is subject to Medigap restrictions, and we would not expect MA organizations or PDP sponsors to attempt to sell non-Medicare health care products. Also, Congress has addressed the issue of cross-selling in a new section 1851(j)(2) that, effective January 1, 2009, prohibits the sale of ''non-health care related products (such as annuities and life insurance).'' We believe that our final rule should track the statute in this area.

F. Disclosure of Plan Information (§§ 422.111 and 423.128)

We are finalizing our proposal in our May 16, 2008 proposed rule to specify in §§ 422.111(a)(3) and 423.128(a)(3) that plans must disclose the information specified in §§ 422.111(b) and 423.128(b) of the MA and Part D program regulations, respectively, both at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period. This is essential to ensuring that current enrollees receive comprehensive information necessary for making an informed decision regarding their health care options prior to the annual coordinated election period. Note that MIPPA made a related change affecting special needs plans disclosure requirements which we will discuss in a regulation to be published at or about the same time as this final rule.

Comment: A commenter suggested that new enrollees receive comprehensive information about their benefit package prior to their purchase rather than after the sale. The commenter stated that more comprehensive information is essential for the consumer and the agent to know ahead of time in order to determine if a product is suitable for a particular individual.

Response: We agree that disclosure of plan information continues to be an important feature that allows beneficiaries to make an informed decision about their healthcare options. MA plans and PDPs are obligated to provide details on benefits and rules prior to enrollment through pre-enrollment materials including the Summary of Benefits. The Summary of Benefits provides comparative information of Original Medicare and the benefits of the MA plan or PDP. We also believe that the Medicare & You Handbook along with other information channels such as the State Health Insurance Assistance Programs (SHIPs) and 1–800–MEDICARE provides an opportunity for Medicare beneficiaries to receive comprehensive information prior to enrollment on the choices available to them. Therefore, we will continue to allow plans the option of providing the Annual Notice of Change/Evidence of Coverage (ANOC/EOC) prior to enrollment and upon beneficiary request.

Comment: Several commenters suggested that CMS articulate penalties for plans that do not adhere to the disclosure requirement for the ANOC/EOC, since there have been plans that have made these disclosures far too late in each of the past 3 years.

Response: Pursuant to §§ 422.752(c) and 423.752(c), CMS may impose CMPs on an organization for any of the determinations at § 422.510(a) (except §§ 422.510(a)(4)) or 423.509(a) (except § 423.509(a)(4)) if CMS determines that the organization's conduct has adversely affected or has the substantial likelihood of adversely affecting one or more enrollees. Determinations that would justify the imposition of CMPs include the MA organization or Part D sponsor failing substantially to carry out the terms of its contract with CMS, the MA organization or Part D sponsor carrying out its contract with CMS in a manner that is inconsistent with the effective and efficient implementation of this part, and the MA organization substantially failing to comply with the marketing requirements at § 422.80 or the Part D sponsor substantially failing to comply with the dissemination of information requirements at § 423.128. Therefore, if CMS determines an organization's failure to comply with marketing disclosure requirements supports a determination pursuant to § 422.510(a) or § 423.509(a) and adversely affects or has the substantial likelihood of adversely affecting one or more enrollees, CMS may consider imposing a CMP.

Comment: One commenter that supported the disclosure of plan information requested that CMS extend the proposal to require that plans disclose information 30 days before the annual coordinated election period.

Response: We have reviewed this comment and we believe this provision will allow beneficiaries adequate time to make an informed decision about their health care options. Therefore, we will proceed with this provision in the final regulation without modification.

Comment: One commenter stated thirty days prior to the benefit becoming effective is a more appropriate requirement with respect to employer groups, when the annual coordinated period is not specified.

Response: Employer sponsored ''800 series'' plans, Direct Contract plans or individual MA plans that are subject to Medicare marketing and disclosure requirements are subject to any applicable timing requirements for issuance of annual disclosure materials prior to the Annual Election Period (AEP). CMS has waived or modified applicable timing requirements in certain circumstances where a particular employer/union sponsor has an open enrollment period that differs from Medicare's AEP. Under these circumstances, the timing for issuance of these materials would be based on the employer/union sponsor's open enrollment period. In circumstances where there is no specified open enrollment period, CMS will clarify in the Medicare Managed Care Manual for Employer Groups and the Prescription Drug Benefits Manual for Employer Groups that disclosure materials based on the AEP must be received by beneficiaries no later than 15 days before the beginning of the plan year.

IV. Provisions of the Final Regulations

This final rule relocates to the new subpart V, sections from subparts B and C related to marketing definitions, marketing materials, and other marketing requirements:

A. Definitions Concerning Marketing Materials (§§ 422.2260, 423.2260)

We are making an organizational change for this section, consistent with

our proposal to create a new subpart V of 42 CFR parts 422 and 423 specific to marketing. We are moving the definition of marketing materials to §§ 422.2260 and 423.2260 of the Part C and D program regulations, respectively.

B. Reviews and Distribution of Marketing Materials: File and Use (§§ 422.2262, 423.2262)

• We are making an organizational change for this section, consistent with our proposal to create a new subpart V of 42 CFR parts 422 and 423 specific to marketing. We are moving §§ 422.80(a) and 423.50(a), which describe the review and distribution of marketing materials, to §§ 422.2264 and 423.2264, respectively, and making the language consistent between the two sections as 423.50 was missing the provision now located at § 423.2264(a)(2)(i); allowing Part D sponsors to distribute their marketing materials 5 days following their submission to CMS provided the Part D sponsor is deemed to meet certain performance requirements established by CMS. In addition to moving these requirements to §§ 422.2262 and 423.2262 of the Part C and D program regulations, respectively, we proposed to modify the ''file and use'' review process. We are moving forward with our proposal to eliminate the file and use eligibility process.

C. Guidelines for CMS (§§ 422.2264, 423.2264)

We are making an organizational change for this section, consistent with our proposal to create a new subpart V of 42 CFR parts 422 and 423 specific to marketing regulations. We are moving §§ 422.80(c) and 423.50(d), which describe specific guidelines for CMS review of marketing materials and election forms, to §§ 422.2264 and 423.2264, respectively.

D. Deemed Approval (§§ 422.2266, 423.2266)

Consistent with our proposal to create a new subpart V of 42 CFR parts 422 and 423 specific to marketing regulations, we are making an organizational change for this section. We are removing §§ 422.80(d) and 423.50(e) and adding §§ 422.2266 and 423.2266, respectively. The provision concerns CMS' deemed approval of the distribution of marketing materials.

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

This final rule also incorporates six of the new provisions from the proposed rule and relocates several of the provisions that already existed in §§ 422.80 and 423.50. The remaining provisions from the May 2008 proposed rule will be incorporated into regulations that will be released later this year. There are four provisions of this final rule that differ from the May 16, 2008, proposed rule:

• Sections 422.2268(a) and 423.2268(a) in the proposed rule have been modified by removing the sentence, ''This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the MA plan, such as eligibility to enroll in a supplemental benefit plan that covers deductibles and coinsurance, or preventive services'' and ''This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the Part D plan,'' respectively. This was done because each sentence creates ambiguity with respect to the prohibition against cash inducements in the respective first sentence of the provision.

• Sections 422.2268(b) and 423.2268(b) have been redesignated as § 422.2268(p) and 423.2268(p), respectively. This modification separates the prohibition against providing meals to prospective enrollees at promotional and sales activities from the proposed nominal gifts provision. The nominal gifts provision will be addressed in a separate rule that implements the requirement that new MIPPA rules be in place no later than November 15, 2008.

• Sections 422.2268(j) and 423.2268(j) in the proposed rule have been revised in this final rule to be consistent with each other and with § 423.50(f)(v) published in the April 15, 2008, Policy and Technical Changes to the Medicare Prescription Drug Benefit final rule.

• Sections 422.2268(k) and 423.2268(k) in the proposed rule have been revised in this final rule to be consistent with the language in section 103 of MIPPA.

F. Licensing of Marketing Representatives and Confirmation of Marketing (§§ 422.2272, 423.2272)

We are making an organizational change for this section, consistent with our proposal to create a new subpart V of 42 CFR 422 and 423 specific to marketing regulations. We are moving §§ 422.80(e)(2) and 423.50(f)(2), which describe standards of marketing, to §§ 422.2272 and 423.2272, respectively. We are adding §§ 422.2272(c) and 423.2272(c) which require plans to appoint and use only State-licensed representatives to conduct direct marketing activities in accordance with State appointment laws.

G. Employer Group Retiree Marketing (§§ 422.2276, 423.2276)

We are making an organizational change for this section, consistent with our proposal to create a new subpart V of 42 CFR 422 and 423 specific to marketing regulations. We are moving §§ 422.80(f) to § 422.2276 and adding § 423.2276, which describe requirements for employer group retiree marketing.

H. Disclosure of Plan Information (§§ 422.111 and 423.128)

We are finalizing our proposal in our May 16, 2008, proposed rule to specify in §§ 422.111(a)(3) and 423.128(a)(3) that plans must disclose the information specified in §§ 422.111(b) and 423.128(b) of the MA and Part D program regulations, respectively, both at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

V. Waiver of 30-Day Delay in Effective Date

Section 553(d) of the APA (5 U.S.C. section 553(d)) ordinarily requires a 30-day delay in the effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the finding and its reasons in the rule issued.

In this case, we believe it is in the public interest to implement these provisions upon publication in order to be effective by October 1, 2008, when MA and PDP marketing season begins. Failure to implement these provisions prior to the beginning of the marketing season would hinder CMS's ability to protect its beneficiaries by ensuring that they receive the necessary information to make informed choices during the annual election period. These provisions prevent agents and brokers from engaging in sales and marketing activities that may pressure beneficiaries to make plan choices for reasons other than those that best meet their health care needs. Without this waiver, these provisions would not be effective until January 1, 2009 as specified in MIPPA.

VI. 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 solicited public comment on each of these issues for the following sections of this document that contain information collection requirements:

Section 422.2260 Definitions concerning marketing materials.

Section 422.2260 defines the marketing materials that an MA organization must provide to Medicare beneficiaries. 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 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 422.2262 Review and distribution of marketing materials.

Section 422.2262(a)(i) states that at least 45 days before the date of distribution the MA organization submits the material or form to CMS for review under guidelines in Section 422.2264 of this Part.

The burden associated with this is the time and effort put forth by the MA organization to submit the material to CMS for review. We estimate it would take one MA organization 720 minutes/12 hours to comply with this requirement. We estimate 670 MA organizations would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 8,040 hours. The burden for this requirement is approved under OMB#: 0938–0753.

This section also requires the MA organization to certify that in the case of these certain marketing materials designated by CMS, it followed all applicable marketing guidelines or used model language specified by CMS without modification.

The burden associated with this requirement is the time and effort put forth by the MA organization to provide such certification. 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 of 1995 (PRA).

Section 422.2264 Guidelines for CMS review.

Section 422.2264 states that in reviewing marketing material or election forms under § 422.2262 of this Part, CMS determines that the marketing materials (a) provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(2) Adequate written description of any supplemental benefits and services.

(3) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(4) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(b) Notify the general Public of its enrollment period in an appropriate manner, through appropriate media, throughout its service and if applicable, continuation areas.

(c) Includes in the written materials notice that the MA organization is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the plan.

(d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations.

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

The burden with these guidelines is the time and effort put forth by the MA organization to provide adequate written descriptions of rules, of any supplemental benefits and services, explanation of the grievance and appeals process, and any other information necessary to enable beneficiaries to make an informed decision about enrollment. It also requires the MA organization to notify the general public of its enrollment period in an appropriate manner and include in the written materials notice that the MA organization is authorized by law to refuse to renew its contract with CMS. 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 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(b) states that an MA organization must establish and maintain a system for confirming that enrolled beneficiaries have, in fact, enrolled in the MA plan and understand the rules applicable under the plan.

The burden associated with this requirement is the time and effort put forth by the MA organization to establish and maintain such a system. 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 422.2276 Employer group retiree marketing.

Section 422.2276 describes the development of marketing materials for employer group retiree marketing. 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 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 423.2260 Definitions concerning marketing materials.

Section 423.2260 defines the marketing materials that a Part D Sponsor must provide to Medicare beneficiaries. 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 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 423.2262 Review and distribution of marketing materials.

Section 423.2262(a)(1)(i) requires the Part D sponsor to submit the marketing material or form to CMS for review under the guidelines in § 423.2264.

The burden associated with these requirements is the time and effort put forth by the Part D sponsor to submit the marketing materials to CMS and to provide certification. We estimate it would take one Part D sponsor (720 minutes/12 hours) to comply with 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 1044 hours. The burden for this requirement is approved under OMB#: 0938–0964.

Section 423.2264 Guidelines for CMS review.

Section 423.2264 reads that in reviewing marketing material or enrollment forms under § 423.2262, CMS determines (unless otherwise specified in additional guidance) that the marketing materials (a) provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(2) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(3) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(c) Include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.

(d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations.

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

The burden with these guidelines is the time and effort put forth by the Part D plan to provide adequate written descriptions of rules, of the grievance and appeals process, and any other information necessary to enable beneficiaries to make an informed decision about enrollment. It also requires the Part D plan to notify the general public of its enrollment period in an appropriate manner and include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS. 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 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(b) requires the Part D organization to establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to establish and maintain such a system. 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 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 423.2276 Employer group retiree marketing.

Section 423.2276 describes the development of marketing materials for employer group retiree marketing. 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 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.

As reflected in the table that follows, the aggregate burden associated with the collection of information section of this final rule totals 9,084 hours.

OMB No.	Requirements	Number of respondents	Burden hours	Total annual burden (hours)
Exempt/None	422.2260	N/A	N/A	N/A
0938–0753	422.2262(a)(i)	670	12	8,040
0938–0753	422.2264	N/A	N/A	N/A
0938–0753	422.2272(b)	N/A	N/A	N/A
Exempt/None	423.2260	N/A	N/A	N/A
0938–0964	423.2262(a)(1)(i)	87	12	1,044
0938–0964	423.2264	N/A	N/A	N/A
0938–0964	423.2272(b)	N/A	N/A	N/A
Total Aggregate Burden				9,084

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above.

VII. Regulatory Impact Statement

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

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). The provisions of this final rule require plans to submit marketing materials to CMS for review. We estimate the total cost (MA and Part D programs) of these provisions as $197,295. As a result, this final rule does not reach this economic threshold and thus is not considered a major rule.

We use the figure of $14.68 (based on the United States Department of Labor (DOL) (*http://www.bls.gov/oes2006.htm*) 2006 BLS occupational employment statistics for the hourly wages of word processors and typists) plus the added OMB figures of 12 percent for overhead and 36 percent for benefits to represent average costs to plans, sponsors and downstream entities. (Note that the wages cited below include the hourly wage + an additional 48 percent to reflect overhead, benefit costs for total wages of $21.73). The costs for these provisions, in the context of each program, are as follows:

- Submission of marketing materials, MA program ($21.73 × 8,040 hours = $174,709).
- Submission of marketing materials, Part D program ($21.73 × 1,044 hours = $22,686).

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6.5 million to $31.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. MA organizations and Part D sponsors, the only entities that will be affected by the final provisions, are not generally considered small business entities. Since they must follow minimum enrollment requirements (5,000 enrollees in urban areas and 1,500 enrollees in non-urban areas), the revenue generated from enrollment generally exceeds the revenue threshold required for analysis. While a very small rural plan could fall below the threshold, we do not believe that there are more than a handful of such plans.

A fraction of MA organizations and sponsors are considered small businesses because of their non-profit status. For an RFA analysis to be required, 3–5 percent of the identified small entities' revenue would have to be impacted by the final provisions. We do not believe that any of these provisions meet this threshold. Many of the provisions, discussed in section II, Analysis of and Response to Public Comments, are clarifications of existing policy or require minimal costs. Therefore, because the rule will not have a significant economic impact on a substantial number of small entities, we are not preparing an analysis for the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory 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. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year by State, local or tribal governments, in the aggregate, or by the private sector of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $130 million. This rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

In accordance with the provisions of Executive Order 12866, this regulation 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 B—Eligibility, Election, and Enrollment

§ 422.80 [Removed]

■ 2. Remove § 422.80.

Subpart C—Benefits and Beneficiary Protections

■ 3. Amend § 422.111 by revising paragraph (a)(3) to read as follows:

§ 422.111 Disclosure requirements

* * * * *

(a) * * *

(3) At the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

* * * * *

■ 4. New subpart V is added to read as follows:

Subpart V—Medicare Advantage Marketing Requirements

Sec.

Subpart V—Medicare Advantage Marketing Requirements

§ 422.2260 Definitions concerning marketing materials.

As used in this subpart—

Marketing materials. Marketing materials include any informational materials targeted to Medicare beneficiaries which:

(1) Promote the MA organization, or any MA plan offered by the MA organization.

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in, an MA plan offered by the MA organization.

(3) Explain the benefits of enrollment in an MA plan, or rules that apply to enrollees.

(4) Explain how Medicare services are covered under an MA plan, including conditions that apply to such coverage.

(5) May include, but are not limited to, the following:

(i) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.

(ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

(iv) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).

(v) Membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.

(vi) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(vii) Membership or claims processing activities (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or annual notification information).

§ 422.2262 Review and distribution of marketing materials.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (b) of this section, an MA organization may not distribute any marketing materials (as defined in § 422.2260 of this part), or election forms, or make such materials or forms available to individuals eligible to elect an MA organization unless—

(i) At least 45 days (or 10 days if using marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution the MA organization has submitted the material or form to CMS for review under the guidelines in § 422.2264 of this Part; and

(ii) CMS does not disapprove the distribution of new material or form.

(2) [Reserved]

(b) *File and use.* The MA organization may distribute certain types of marketing materials, designated by CMS, 5 days following their submission to CMS if the MA organization certifies that in the case of these designated marketing materials, it followed all applicable marketing guidelines and, when applicable, used model language specified by CMS without modification.

§ 422.2264 Guidelines for CMS review.

In reviewing marketing material or election forms under § 422.2262 of this part, CMS determines that the marketing materials—

(a) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges;

(2) Adequate written description of any supplemental benefits and services;

(3) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each; and

(4) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area and if applicable, continuation areas.

(c) Include in written materials notice that the MA organization is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the plan.

(d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations.

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

§ 422.2266 Deemed approval.

If CMS has not disapproved the distribution of marketing materials or forms submitted by an MA organization with respect to an MA plan in an area, CMS is deemed not to have disapproved the distribution in all other areas covered by the MA plan and organization except with regard to any portion of the material or form that is specific to the particular area.

§ 422.2268 Standards for MA organization marketing.

In conducting marketing activities, MA organizations may not—

(a) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(b) [Reserved]

(c) Engage in any discriminatory activity such as, for example, attempts to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(d) Solicit door-to-door for Medicare beneficiaries or through other unsolicited means of direct contact, including calling a beneficiary without the beneficiary initiating the contact.

(e) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization. The MA organization may not claim it is recommended or endorsed by CMS or Medicare or that CMS or Medicare recommends that the beneficiary enroll in the MA plan. It may, however, explain that the organization is approved for participation in Medicare.

(f) Market non-health care related products to prospective enrollees during any MA or Part D sales activity or presentation. This is considered cross-selling and is prohibited.

(g) [Reserved]

(h) [Reserved]

(i) Distribute marketing materials for which, before expiration of the 45-day period, the MA organization receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the MA organization, its marketing representatives, or CMS.

(j) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the providers, provider groups, or pharmacies accept and display materials from all health plans with which the providers, provider groups, or pharmacies contract. The use of publicly available comparison information is permitted if approved by CMS in accordance with the Medicare marketing guidance.

(k) Conduct sales presentations or distribute and accept MA plan

enrollment forms in provider offices or other areas where health care is delivered to individuals, except in the case where such activities are conducted in common areas in health care settings.

(l) Conduct sales presentations or distribute and accept plan applications at educational events.

(m) Employ MA plan names that suggest that a plan is not available to all Medicare beneficiaries. This prohibition shall not apply to MA plan names in effect on July 31, 2000.

(n) [Reserved]

(o) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(p) Provide meals for potential enrollees, which is prohibited, regardless of value.

(q) [Reserved]

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

In its marketing, the MA organization must:

(a) Demonstrate to CMS' satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(b) Establish and maintain a system for confirming that enrolled beneficiaries have, in fact, enrolled in the MA plan, and understand the rules applicable under the plan.

(c) Employ as marketing representatives only individuals who are licensed by the State to conduct marketing activities (as defined in the Medicare Marketing Guidelines) in that State, and whom the organization has informed that State it has appointed, consistent with the appointment process provided for under State law.

§ 422.2274 [Reserved]

§ 422.2276 Employer group retiree marketing.

MA organizations may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the MA organization, and furnish these materials only to the group members. These materials are not subject to CMS prior review and approval.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 5. 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, Election, and Enrollment

§ 423.50 [Removed]

■ 6. Remove § 423.50.

Subpart C—Benefits and Beneficiary Protections

■ 7. Amend § 423.128 by revising paragraph (a)(3) to read as follows:

§ 423.128 Dissemination of Part D Plan Information.

(a) * * *

(3) At the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

■ 8. Add new subpart V to read as follows:

Subpart V—Part D Marketing Requirements

Sec.

Subpart V—Part D Marketing Requirements

§ 423.2260 Definitions concerning marketing materials.

As used in this subpart—

Marketing Materials. Marketing Materials include any informational materials targeted to Medicare beneficiaries which—

(1) Promote the Part D plan.

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in a Part D plan.

(3) Explain the benefits of enrollment in a Part D plan, or rules that apply to enrollees.

(4) Explain how Medicare services are covered under a Part D plan, including conditions that apply to such coverage.

(5) May include, but are not limited to—

(i) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.

(ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

(iv) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).

(v) Membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.

(vi) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(vii) Membership or claims processing activities.

§ 423.2262 Review and distribution of marketing materials.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (a)(2) of this section, a Part D plan may not distribute any marketing materials (as defined in § 423.2260 of this Part), or enrollment forms, or make such materials or forms available to Part D eligible individuals unless—

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution, the Part D sponsor submits the material or form to CMS for review under the guidelines in § 423.2264; and

(ii) CMS does not disapprove the distribution of new material or form.

(2) [Reserved]

(b) *File and use.* The Part D sponsor may distribute certain types of marketing material, designated by CMS, 5 days following their submission to CMS if the Part D sponsor certifies that in the case of these marketing materials, it followed all applicable marketing guidelines and, when applicable, used model language specified by CMS without modification.

§ 423.2264 Guidelines for CMS review.

In reviewing marketing material or enrollment forms under § 423.2262, CMS determines (unless otherwise specified in additional guidance) that the marketing materials—

(a) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges;

(2) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each; and

(3) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(c) Include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.

(d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations.

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

§ 423.2266 Deemed approval.

If CMS has not disapproved the distribution of marketing materials or forms submitted by a Part D sponsor for a Part D plan in a Part D region, CMS is deemed to not have disapproved the distribution of the marketing material or form in all other Part D regions covered by the Part D plan, with the exception of any portion of the material or form that is specific to the Part D region.

§ 423.2268 Standards for Part D marketing.

In conducting marketing activities, a Part D plan may not—

(a) Provide cash or other remuneration as an inducement for enrollment or otherwise.

(b) [Reserved]

(c) Engage in any discriminatory activity such as, for example, attempts to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(d) Solicit door-to-door for Medicare beneficiaries or through other unsolicited means of direct contact, including calling a beneficiary without the beneficiary initiating the contact.

(e) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor or its Part D plan. The Part D organization may not claim that it is recommended or endorsed by CMS or Medicare or that CMS or Medicare recommends that the beneficiary enroll in the Part D plan. The Part D organization may explain that the organization is approved for participation in Medicare.

(f) Market non-health care related products to prospective enrollees during any MA or Part D sales activity or presentation. This is considered cross-selling and is prohibited.

(g) [Reserved]

(h) [Reserved]

(i) Distribute marketing materials for which, before expiration of the 45-day period, the PDP Sponsor receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the PDP Sponsor, its marketing representatives, or CMS.

(j) Use providers, provider groups, or pharmacies to distribute printed information for beneficiaries to use when comparing the benefits of different Part D plans unless providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors with which the providers, provider groups or pharmacies contract. The use of publicly available comparison information is permitted if approved by CMS in accordance with the Medicare marketing guidelines.

(k) Conduct sales presentations or distribute and accept Part D plan enrollment forms in provider offices, pharmacies or other areas where health care is delivered to individuals, except in the case where such activities are conducted in common areas in health care settings.

(l) Conduct sales presentations or distribute and accept plan applications at educational events.

(m) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(n) [Reserved]

(o) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(p) Provide meals for potential enrollees, which are prohibited, regardless of value.

(q) [Reserved]

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

In its marketing, the Part D organization must—

(a) Demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(b) Establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

(c) Employ as marketing representatives only individuals who are licensed by the State to conduct direct marketing activities (as defined in the Medicare Marketing Guidelines) in that State, and whom the sponsor has informed that State it has appointed, consistent with the appointment process provided for under State law.

§ 423.2274 [Reserved]

§ 423.2276 Employer group retiree marketing.

Part D sponsors may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the Part D sponsor, and furnish these materials only to the group members. These materials are not subject to CMS prior review and approval.

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: August 27, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. E8–21674 Filed 9–15–08; 9:00 am]

BILLING CODE 4120–01–P