OMB Approved Number: 0938-0753
CMS-R-267
Supporting Statement for the Medicare Advantage Program and Supporting Regulations

A. Background

1. Revisions to the Medicare Advantage and Prescription Drug Benefit Programs (4131-F)

In **[year of publication]** final rule we revised several areas of the Medicare Advantage (MA) and Prescription Drug Benefit programs. The MA changes affect especially special needs plans, and issues related to payment and marketing. Provisions affecting the MA program and any burden related to them are captured in this updated supporting statement. The paperwork burden for the prescription drug benefit-related provisions are specified in the information collection package for those provisions.

2. 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. Title II of the MMA makes important changes to the current Medicare+Choice (M+C) program by replacing it with a new Medicare Advantage (MA) program under Part C of Medicare. On August 3, 2004, we published a proposed rule in the Federal Register (69 FR 46866) that set forth the provisions that would implement Title II of the MMA. The final rule was published on January 28, 2005. The program is designed to--

- Provide for regional plans that may make private plan options available to many more beneficiaries, especially those in rural areas.
- Expand the number and type of plans provided for, so that beneficiaries can choose from Health Maintenance Organizations (HMOs), Preferred Provider Organization (PPO) plans (the most popular type of employer-sponsored plan), Fee-for-Service (FFS) plans, and Medical Savings Account (MSA) plans, if available where the beneficiary lives.
- Enrich the range of benefit choices available to enrollees including improved prescription drug benefits, other benefits not covered by original Medicare, and the opportunity for the government to share in savings where MA plans can deliver benefits at lower costs.
- Provide incentives to add specialized plans to coordinate and manage care in ways that comprehensively serve those with complex and disabling diseases and conditions.
- Use open season competition among MA plans to improve service, improve benefits, invest in preventive care, and hold costs down in ways that attract enrollees.

- Enhance and stabilize payments to organizations, improve program design, introduce new flexibility for plans, and reduce impediments to plan participation.
- Advance the goal of improving quality and increasing efficiency in the overall health care system. Medicare is the largest payer of health care in the world. Medicare can drive changes in the entire health care system.

3. Balanced Budget Act of 1997

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Public Law 105-33) enacted August 5, 1997, added sections 1851 through 1859 to the Social Security Act (the Act) to establish a new Part C of the Medicare program, known as the Medicare+Choice program. The Centers for Medicare & Medicaid Services (CMS) published an interim final rule to establish the Medicare+Choice program on June 26, 1998. A final rule revising these sections was published on February 17, 1999 and again on June 29, 2000. Information supplied by organizations was used to determine eligibility for contracting with CMS, for determining compliance with contract requirements, and for calculating proper payment to the organizations. Information supplied by Medicare beneficiaries is used to determine eligibility to enroll in the M+C organization and to determine proper payment to the organization that enrolled the beneficiary. Separate OMB approval was sought for each form as required.

We are revising this currently OMB approved information collection to reflect the new and revised information collection requirements referenced in the Title II Final Rule (4069-F) which published in the Federal Register on January 28, 2005.

Most of the information collection requirements are currently approved. The new and revised information collections in the January 28, 2005 final rule concerned enrollment (§422.80), benefits (§§422.101 and 422.106), disclosure requirements (§422.111), access to services (§422.112), submission of bids (§422.254), cost sharing(§422.270), monthly payments to MA organizations(§422.304), risk adjustment data (§422.310), special rules for beneficiaries enrolled in MA MSA plans (§422.314), special rules for hospice care (§422.320), risk sharing with regional MA organizations for 2006 and 2007 (§422.458), application requirements(§422.501), and §422.564, grievance procedures.

B. **Justification**

1. Need and Legal Basis

The information collection requirements are mandated by 42 CFR 422. Section 4001 of the Balanced Budget Act of 1997 (BBA) added sections 1851 through 1859 to the Social Security Act to establish this new program. The Medicare, Medicaid, and SCHIP Benefits Improvement Act and Protection Act of 2000, P. L. 106-554 added new requirements. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P. L. 108-173)

added the new requirements specified in this statement.

2. Information Users

Medicare Advantage (MA) organizations (formerly M+C organizations) and potential MA organizations (applicants) use the information discussed below to comply with the application requirements and the MA contract requirements. CMS will use this information to approve contract applications, monitor compliance with contract requirements, make proper payment to MA organizations, determine compliance with the new prescription drug benefit requirements established by the MMA, and to ensure that correct information is disclosed to Medicare beneficiaries, both potential enrollees and enrollees.

3. Improved Information Technology

Where feasible the collection of information covered by this regulation does involve the use of automated, electronic, mechanical, or other technological collection techniques designed to reduce burden and enhance accuracy. Specifically, the submission of enrollment/disenrollment data by MA organizations is electronic (§422.66), , future collection of outpatient data is proposed to use direct transmission from providers to CMS with common PC-based technology, forms connected with submission of benefit packages and associated pricing (subpart C) have been electronically automated. Section 422.101, requires electronic disclosure, through the Internet, of information related to basic benefits. Section 422.111 requires, to the extent that a MA plan has a website, annual notification through the website of written, hard copy notifications sent the beneficiary. The requirements of section 422.112, which notifies beneficiaries about access to services, may be met either electronically or by written, hard copy.

4. Duplication of Similar Information

The information collection requirements contained in the regulations are not duplicated through any other effort.

5. Small Businesses

A fraction of MA organizations are small businesses. For an analysis to be necessary 3-5 percent of their revenue would have to be affected by the provisions and we do not believe that any of these provisions rise to that threshold. Most of the provisions clarify existing policy or require minimal costs.

6. Less Frequent Collection

This information is collected as needed. If it were to be collected less frequently, CMS would not be able to obtain this data. Some of the consequences would be improper or erroneous payment to MA organizations, improper enrollment of beneficiaries in an MA organization, the release of misleading information regarding health care coverage through an MA plan to potential members, and inadequate provision of patients' rights to Medicare-covered services.

7. Special Circumstances

Generally, information collections contained in the MA program occur annually or quarterly. Special circumstances that would require information to be submitted to the agency more often than quarterly include:

Approval of marketing materials and election forms (§422.80) - An MA organization may not distribute any marketing materials, as defined in this section, unless CMS has approved the materials in advance. While most marketing materials are developed and reviewed annually, such as the evidence of coverage or the member handbook, most MA organizations are continuously developing new advertising materials such as TV and radio ads. These materials must be submitted to CMS as approval is requested and thus information may be collected more frequently than quarterly. In addition, other materials requiring CMS review and approval, such as official notices pertaining to enrollment, disenrollment, appeals procedures, etc. may be modified by MA organizations at any time during the year and will need to be submitted at that time.

8. Federal Register Notice/Outside Consultation

A 60-day Federal Register notice was published on February 15, 2008 for collection CMS-R-267. No comments were received on the 60-day notice.

We published a 60-day Federal Notice in the proposed rule on May 16, 2008 for CMS-4131-P. Comments received on 4131-P will be responded to in the final rule.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

The collection of information from the MA applicants and contracting organizations that pertain to their financial records and submission of data to comply with the requirements concerning enrollment, applications, and bids have been determined by CMS's Freedom of Information officer to be proprietary and confidential. The information collected from MA organizations for the purposes of disclosing to the potential enrollees their health care coverage choices is public information and in fact is being collected for purposes of the National Medicare Education Program, whose purpose is to broadly disseminate to the public objective, comparative information on benefits, program rules, and premiums of the contracting MA organizations. The information collected from Medicare beneficiaries and contained in medical records, and other health and enrollment information must conform with all requirements at §422.118, including all Federal and State laws regarding confidentiality and disclosure. Contracted MA organizations must adhere to the HIPAA privacy rule on sharing patient health information during a change of ownership or a novation agreement.

11. Sensitive Questions

There are no sensitive questions included in this collection effort.

12. Burden Estimate (Total Hours & Wages)

The following material is from Section V. Collection of Information Requirements, contained in the preamble of the Final Rule published on January 28, 2005, and Section V, Collection of Information Requirements, contained in the preamble of the Final Rule published on **[insert date 4131-F publishes, citation].**

Source: The HPMS extracts.

*** The following wage burden estimates for the regulatory activities are not listed sequentially but are grouped according to the various wage/salary groups as determined by the divisions in CMS responsible for the regulatory knowledge areas, and new sections (Mini-reg provisions are also listed separately as they are based on bureau of labor wage data)**

§**422.60**: The estimated wage / salary cost associated with these requirements, i.e., to file and retain election forms and the prompt written notice to beneficiaries to be performed by an employee who is the equivalent of the GS 8 Step 5 ($19.09/hr in 2007) and electronic submission to CMS to be performed by an employee who is the equivalent of the GS 12 Step 10 ($35.07/hr in 2007). Thus, the hourly wage is ($19.09 x 750,000 hours = $214,317,500) + ($19.09 x 32,160 hours = $613,943) + ($19.09 x 150,000 hours = $2,863,500) = $17,794,934.

Electronic submission to CMS: $35.07x 150,000 hours = $5,260,000.

Grand total: $23,055,434.

§**422.64**: The estimated wage /salary cost associated with this requirement is $35.07 x 30,396 hours = $1,065,988.

§**422.66**: The estimated wage /salary cost associated with each of the activities noted in this requirement is expected to be performed by a plan employee who is compensated at the equivalent of the Grade 8 Step 5 in 2007, i.e., at $19.09 per hour. Thus, the estimated wage / salary cost associated with this requirement is ($19.09 x 65,000 hours = $1,240,850) + ($19.09 x 546 hours = $10,423) + ($19.09 x 32,760 hours = $625,388) + ($19.09 x 163,800 hours = $3,126,942) = Grand Total – 262,106 hours = $5,003,603.

§**422.80**: We expect the notification to the general public and the submission of the designated marketing materials to be performed by a plan employee who is the equivalent of the GS 12 Step 10 in 2007 ($35.07 per hour). Thus, the hourly wage is $35.07 x 13,400 = $469,938.

Note: For those tasks that can be performed by competent clerical staff the 2007 GS schedule GS 8 employees step 1 with a rounded pay rate of $25.00 hourly salary is used. For those tasks requiring a greater level of expertise a GS 12 step 1 with a $35.00 hourly salary figure is used for the following group of regulations:

§422.101: The estimated wage / salary cost associated with this requirement is 670 hours @ $25.00 per hour = $16,750

§422.105: The estimated wage / salary cost associated with this requirement is 892 hours @ $25.00 per hour = $22,300

§422.106: The estimated wage / salary cost associated with this requirement is 400 hours @ $35.00 per hour = $14,000

§422.111: The estimated wage / salary cost associated with this requirement is exempt from PRA.

§422.112(c): The estimated wage / salary cost associated with this requirement is 800 hours @ $35.00 hour = $28,000

§422.118: The estimated wage / salary cost associated with this requirement is 1 @ $35.00 = $35.00

§422.128: The estimated wage / salary associated with this requirement is 121,550 hours @ $25.00 per hour = $3,058,750.

§422.132: The estimated wage / salary associated with this requirement is 26,800 hours @ $35.00 per hour = $938,000

§422.152: The estimated wage / salary associated with this requirement is 26,800 + 1,340 (28,140) hours @ $35.00 per hour = $98,350.

§422.156: The cost associated with this requirement is captured in §422.158

§422.157: The cost associated with this requirement is captured in §422.158

§422.158: The estimated wage / salary associated with this requirement is 192 hours @ $35.00 per hour = $6,720

§422.202: The estimated wage / salary associated with this requirement is 12,060 hours + 6,700 hours for total hours of 18,760 @ $25.00 per hour = $469,000

§422.204: The estimated wage / salary associated with this requirement is 20 hours + 510 hours + 510 hours + 3.35 hours for total hours of 1044 @ $25.00 per hour = $26,100

§422.205: The estimated wage / salary associated with this requirement is 6,700 hours @ $25.00 per hour = $167,500

§422.206: The estimated wage / salary associated with this requirement is 335 hours @ $35.00 per hour = $11,725

§422.216: The estimated wage / salary associated with this requirement is 232,400 hours + 1,400,000 hours + 1,200,000 hours + 1,667 hours = a total burden hours of 2,834,067 hours @ $25 per hour = $70,851,675.

§422.320: The estimated wage / salary associated with this requirement is 750 hours @ $25.00 per hour = $18,750

§422.400: The estimated wage / salary associated with this requirement is 42 hours @ $25.00 per hour = $1050.00

§422.501: The estimated wage / salary associated with this requirement is 3000 hours @ $35.00 per hour = $105,000

§422.503 & 504: The estimated wage / salary associated with these requirements is 1340 hours @ $35.00 per hour = $46,900

§422.506: The estimated wage / salary associated with this requirement is 220 hours @ $35.00 per hour = $7,700.

§422.508: The estimated wage / salary associated with this requirement is 20 hours @ $35.00 per hour = $700

§**422.516**: The estimated wage /salary associated with this requirement is 4,690 hours @ $35.00 per hour = $164,150.

§422.624: The estimated wage / salary associated with this requirement is 515,069 hours @ $35.00 per hour = $18,027,415.

Note: The activities associated with the following regulatory cites assumes the expertise level of a plan employee at the equivalent of the hourly rate of the base of a GS 12 Step 10 in 2007, i.e., $35.07:

§**422.254:** The estimated wage / salary associated with this requirement is 341,000 hours x $35.07/hr = $ 11,958,870.

§**422.270**: The estimated wage /salary associated with this requirement is 100 hours x $35.07/hr = $3,507.

§**422.310**: The estimated wage / salary associated with this requirement is 121,270 hours x $35.07/hr = $4,252,939.

§**422.314**: The estimated wage / salary associated with this requirement is 1,668 hours x $35.07/hr = $58,497.

Note: The activities associated with the following regulatory cites assumes an expertise level of a plan enrollee who is the equivalent of the hourly rate of the GS 12 Step 10 in 2008, i.e., $35.95.

§422.564: The estimated wage / salary associated with this requirement is 70,380 hours x $35.95/hr = $2,530,161.

§422.568: The estimated wage / salary associated with this requirement is 117,250 hours x $35.95/hr = $4,215,138.

§422.572: The estimated wage / salary associated with this requirement is 154,188 hours x $35.95/hr = $5,543,059.

§422.584: The estimated wage / salary associated with this requirement is 335 hours x $35.95/hr = $12,043.

§422.590: The estimated wage / salary associated with this requirement is 405,000 hours x $35.95 = $14,559,750.

§422.622: The estimated wage / salary associated with this requirement is 25,500 hours x $35.95 = $916,725.

§422.626: The estimated wage / salary associated with this requirement is 20,850 hours x $35.95 = $749,558.

Note: the paperwork burden sections below are based on 4131-F, Revisions to the Medicare Advantage and Prescription Drug Benefit Programs. We use, as appropriate, the figures of $14.68 (based on the United States Department of Labor (DOL) statistics for the hourly wages of word processors and typists) and $37.15 (based on DOL statistics for a management analyst)[1] plus the added OMB figures of 12 percent for overhead and 36 percent for benefits, respectively, to represent average costs to plans, sponsors and downstream entities for the provisions discussed in proposed mini-reg. (note that the wages cited for the provisions below include the hourly wage + an additional 48 percent to reflect overhead, benefit costs for total wages of $21.73 and $54.98, respectively).

§422.4:

The estimated wage/salary associated with this requirement is 9504 hours x $54.98 = $517,031

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

§422.52

The estimated wage/salary associated with this requirement is 60,000 hours x $21.73 = $1,303,800.

§422.60(g)

The estimated wage/salary associated with notifying dual eligible beneficiaries of enrollment options in addition to automatic enrollment is 8694 hours x $21.73 = $188,920.

§422.101 (f)

The estimated wage/salary associated with the model of care requirement is 8040 hours x $54.98 = $442,039.

§422.103 (e)

The estimated wage/salary associated with MSA cost and quality reporting requirements is 100 hours the first year of the plan's participation as an MSA. We expect 20 plans in 2009 so the total of the requirement is 2000 hours x $54.98= $109,960.

§422.107

The estimated wage/salary for dual eligible SNPs to establish a documented relationship with the state in which the plan is located is 8280 hours x $54.98 = $455, 234.

§422.504 (g)

The estimated wage/salary for ensuring that provider contracts contain language holding dual eligible beneficiaries not liable for costs that are not their responsibility is 707,200 hours x $54.98 = $38,881,856.

§422.2262

The estimated wage/salary to develop and submit marketing materials is 8040 hours x $21.73 = $174, 709.

§422.2274

The estimated wage/salary for the training and testing of agents selling Medicare MA products is 32160 hours x $54.98 = $1,768,157.

Types of MA plans (§ 422.4)

MA organizations offering disproportionate percentage SNPs must limit new enrollment of non-special needs members to no more than 10 percent of new enrollees, and that 90 percent of new enrollees thus be special needs individuals as defined in §422.2.

The burden associated with this requirement is the time and effort put forth by the MA organization to monitor the percentage of non-special needs individuals in the SNP and ensure that this level remains below the established threshold. It will take one MA organization an initial burden of 2 hours to comply with this requirement. Therefore, with 176 disproportionate percentage SNPs in the market, the initial burden associated with this requirement is 352 hours. We estimate it would take one MA organization an additional burden of 1 hour/week to comply with this requirement on an ongoing basis for a total annual burden of 52 hours/year. We estimate 176 MA organizations would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 9152 hours.

Eligibility to elect an MA plan (§ 422.50)

A beneficiary, who is a new enrollee, must complete and sign an election form or complete another CMS approved election method offered by the MA organization and provide information required for enrollment.

The burden associated with this requirement is the time it takes for a new enrollee to complete an enrollment form. The enrollment form varies for each organization, but similar identifying information is collected. It is estimated that in 2008 it will take an estimated 9,000,000 beneficiaries 10 minutes for an annual burden of 90,000,000 minutes = 1,500,000 hours.

Eligibility to elect an MA plan for special needs individuals (§ 422.52)

Special needs plans must establish a process to verify the Medicaid eligibility and special needs status of an individual prior to enrolling the individual in a form and manner specified by CMS. This may require collaborative meetings between MA plan staff and State Medicaid staff to establish the process. This process could include calling the Medicaid eligibility verification system (EVS) and reviewing appropriate used to determine an individual's special need.

The burden associated with this requirement is the time and effort put forth by the SNP to establish a process and to verify eligibility. We estimate it would take one SNP approximately (4680 minutes/78 hours) to comply with this requirement. The total number of respondents affected would be 776 SNPs; therefore, the total annual burden is estimated to be 60,000 hours.

Continuation of enrollment (§ 422.54)

An MA organization that wishes to offer a continuation of enrollment option must submit its marketing materials to CMS for approval that describe the option and include the MA organization's assurances of access to services as set forth in this section. An MA organization that offers a continuation of enrollment option must also convey all enrollee rights conferred under this rule.

The burden associated with this requirement is captured below in § 422.64 and § 422.80.

Election process (§ 422.60)

The election form or another CMS approved election method offered by the MA organization must be completed by the MA eligible individual beneficiary (or the individual who will soon become entitled to Medicare benefits) and include authorization for disclosure and exchange of necessary information between CMS and the MA organization.

The burden associated with this requirement is captured above in the § 422.50 discussion.

The MA organization must file and retain MA plan election forms for the period specified in

CMS instructions and submit beneficiary MA plan and optional supplemental benefit elections to CMS.

The burden associated with this requirement is the time required for each organization to perform record keeping on each new application filed. It is estimated that it will take each organization 5 minutes for each of 9,000,000 beneficiaries estimated to enroll in 2008. The total annual burden is estimated at 45,000,000 minutes = 750,000 hours.
On average, MA organizational level burden is 750,000/670 = 1119 annual hours. In addition, it is estimated to take each MA organization 4 hours per month to electronically submit a subset of beneficiary MA plan and optional supplemental benefit election information to CMS, for a total annual burden of 32,160 hours (670 x 4 x 12).

The MA organization must give the beneficiary prompt written notice of acceptance or denial in a format specified by CMS that meets the requirements set forth in this section.

The burden associated with each organization providing the beneficiary prompt written notice, performed by an automated system, is estimated at 1 minute per application processed. The annual total burden is estimated at 9,000,000 minutes = 150,000 hours. On average, MA organizational level burden is 150,000/670 = 224 annual hours.

The burden associated with electronic submission of information to CMS is estimated at 1 minute per application processed, for an annual burden of 9,000,000 minutes = 150,000 hours. On average, MA organizational level burden is 150,000/670 = 224 annual hours.

Paragraph (b) of the section states that MA organizations may submit information on enrollment capacity of plans they offer by July 1 of each year as provided by Sec. 422.306(a)(1). The burden associated with this reporting provision is captured under Sec. 422.306.

Paragraph (g) of the section states that organizations receiving enrollments provide notification to beneficiaries describing costs and benefits of the plan and the process of accessing care under the plan.

The burden associated with the requirement to provide notification that meets CMS requirements is 30 minutes. It is estimated that 5 organizations will be affected in 2009 for a total burden of 2.5 hours.

<u>Election of coverage under an MA plan (§ 422.62)</u>

An individual may enroll or disenroll from an MA plan only during allowed election periods, such as initial coverage election period, annual coordinated election period, open enrollment period, and special election periods.

The burden associated with the requirement to make an election is captured under § 422.66.

<u>Information about the MA program (§ 422.64)</u>

Each MA organization must provide, on an annual basis and in a format and using standard terminology that may be specified by CMS, the information necessary that meets the general and content requirements set forth in § 422.64, to enable CMS to provide to current and potential beneficiaries the information they need to make informed decisions with respect to the available choices for Medicare coverage. MA organizations must submit the data for each plan they propose to offer. An MA organization can offer multiple MA plans. We expect the 670 estimated MA organizations to submit approximately 3400 plans a year – approximately 5.1 plans per MA organization.

The burden associated with this requirement is the time required for the organization to provide the information to CMS. It is estimated that it will take 670 organizations 12 hours per

plan (estimating 3400) for an annual burden of 40,800 hours, or approximately 61 hours per organization.

Coordination of enrollment and disenrollment through MA organizations (§ 422.66)

An individual who wishes to elect an MA plan offered by an MA organization may make or change his or her election during the election periods specified in § 422.62 by filing the appropriate election form with the organization or through other mechanisms as determined by CMS.

An individual who wishes to disenroll from an MA plan may do so by 1) electing a different MA plan by filing an election form with the MA organization or through other mechanisms as determined by CMS, 2) submitting a signed and dated request for disenrollment to the MA organization in the form and manner prescribed by CMS or, 3) filing the appropriate disenrollment form through other mechanisms as determined by CMS.

The burden associated with electing a different plan is included in 422.50. The burden associated with disenrolling is the time to complete a disenrollment form or other CMS approved method. It is estimated that 1,965,600 disenrollments in 2008 will take 2 minutes each for an annual burden of 3,931,200 minutes = 65,000 hours. On average, MA organizational level burden is 65,000/670 = 97 annual hours.

The MA organization must submit each disenrollment notice to CMS promptly.

The burden associated with electronic submission of information to CMS is estimated at 1 second per disenrollment processed, for an annual burden of 32,760 = 546 hours.

On average, MA organizational level burden is 32,760/670 = .81 annual hours.

In the case of a plan where lock-in applies, the MA organization must provide the enrollee with a statement explaining that he or she remains enrolled until the effective date of disenrollments, and until that date, neither the MA organization nor CMS pays for services not provided or arranged for by the MA plan in which the enrollee is enrolled.

The burden associated with each organization providing the beneficiary prompt written notice of disenrollment and lock-in, produced by an automated system, is estimated at 1 minute per disenrollment processed, for an annual burden of 1,965,600 minutes = 32,760 hours. On average, MA organizational level burden is 32,760/670 = 48.9 annual hours.

The MA organization must file and retain disenrollment requests for the period specified in CMS instructions.

The burden associated for each disenrollment request is the time required for each organization to perform record keeping on each disenrollment request filed. It is estimated that it will take 5 minutes each for 1,965,600 disenrollments processed for an annual burden of 9828,000 minutes = 163,800 hours. On average, MA organizational level burden is 163,800/670 = 244 annual hours.

Disenrollment by the MA organization (§ 422.74)

If the disenrollment is for any reason other than death or loss of entitlement to Part A or Part B, the MA organization must give the individual a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) must include an explanation of the individual's right to a hearing under the MA organization's grievance procedures. This requirement is currently approved under 0938-0763.

There is a burden associated with the requirement for the organization to notify the

beneficiary about an involuntary disenrollment, and to separately notify the beneficiary of the effective date of the disenrollment. It is estimated that fewer than 100 such notices will be issued and that each notice will take 1 minute for an annual burden of less than 100 minutes = or less than 1.5 hours.

A MA organization may disenroll an individual from the MA plan for failure to pay any basic and supplementary premiums if the MA organization sends a written notice of nonpayment to the enrollee stating that nonpayment of premiums will result in disenrollment and information about the lock-in requirements of the MA plan.

There is a burden associated with the requirement for the organization to notify the beneficiary of disenrollment because of nonpayment, etc., and it is estimated that fewer than 500 of these notices are provided annually at 1 minute per notification, resulting in an estimated burden of 500 minutes, or approximately 80 hours.

A MA organization may disenroll an individual from the MA plan if the individual's behavior substantially impairs the plan's ability to arrange or provide services for the individual or other plan members. The MA organization must make serious efforts to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS. The MA organization must document the enrollee's behavior, its own effort to resolve any problems, and any extenuating circumstances. The MA organization may request from CMS the ability to decline future enrollment by the individual. The MA organization must submit this information and any documentation received by the beneficiary to CMS.

The burden associated with this requirement is the time for the organization to document the behavior of the beneficiary and document the efforts of the organization to resolve any problems and provide information to CMS concerning the involuntary disenrollment request. The burden reflects documentation and transmission of documentation to CMS by the managed care plans. It is estimated that fewer than 100 such notices are provided annually (based on estimate of regional office collection of such information), and it is estimated that each request will take 1 hour to manually collect the data and 15 minutes to transmit the data to CMS, for a burden of 125 hours.

A MA organization must report to CMS any disenrollment based on fraud or abuse by the individual.

There is a burden associated with the requirement for the organization to report to CMS any disenrollment based on fraud or abuse by the individual. It is estimated that only 1% of all involuntary disenrollments, or 10 involve fraud or abuse, and the reporting burden would be 1 minute each, for a total burden of less than 1 hour.

If a MA organization terminates or is terminated or the service area or continuation area is reduced with respect to all MA enrollees in the area in which they reside, the MA organization must give each Medicare enrollee a written notice of the effective date of the plan termination or area reduction and a description of alternatives for obtaining benefits under the MA program. The notice must be sent before the effective date of the plan termination or area reduction.

The burden associated with this requirement is captured in below in § 422.506.

<u>Requirements relating to basic benefits (§422.101)</u>

(b)(5) An MA organization, an MA local plan, or regional MA plan, as described in this section, must make information on the selected local coverage policy readily available to the enrollees and health care providers.

The burden associated with this requirement is the time and effort necessary for the plan to make information on the selected local coverage policy readily available to the enrollees and

health care providers. We estimate that it will require 670 MA organizations 1 hour each on an annual basis to make the necessary information available.

(d)(4) MA regional plans are required to track the deductible (if any) and catastrophic limits in paragraphs (d)(1) through (d)(3) of this section based on incurred out-of-pocket beneficiary costs for original Medicare covered services, and are also required to notify members and health care providers when the deductible (if any) or a limit has been reached.

The burden associated with this requirement is the time and effort necessary for the plan to notify members when the deductible (if any) or a limit has been reached. While this requirement is subject to the PRA, we believe that this requirement meets the requirements of 5 CFR 1320.3(b)(2), and, as such, the burden associated with this requirement is exempt from the PRA.

(f)(1) MA organizations offering special needs plans must have a model of care plan specifying how the plan coordinates and delivers care for the plan's enrollees.

The burden associated with this requirement is the time and effort put forth by the special needs plan to establish a model that meets CMS requirements. We estimate that it will take one special needs plan 24 hours to meet this requirement. We estimate 335 special needs plans will be affected by this requirement annually for a total burden of 8,040 hours.

Benefits under an MA MSA plan (§ 422.103)

(e) All MA organizations offering MSA plans must provide enrollees with available information on the cost and quality of services in their service area, and submit to CMS for approval a proposed approach to providing such information.

The burden associated with this requirement is the time and effort necessary for each plan to develop the information and submit this information to CMS. We estimate that there will be a start-up cost of 100 hours per plan to develop this information for a total of 2000 hours in the first year the plan participates as an MSA plan.

Special rules for point of service option (§ 422.105)

MA organizations must maintain written rules on how to obtain health benefits through the POS benefit. While the maintenance of written rules is a record keeping requirement subject to the PRA, the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2) and (b)(3).

The MA organization must provide to beneficiaries enrolling in a plan with a POS benefit an "evidence of coverage" document, or otherwise provide written documentation, that specifies all costs and possible financial risks to the enrollee, including the requirements set forth in (d)(2)(i) through (d)(2)(iv) of this section.

The burden associated with this requirement is captured above in § 422.64.

An MA organization that offers a POS benefit must report data on the POS benefit in the form and manner prescribed by CMS.

The special rules for MA organizations offering a POS benefit as stipulated in § 422.105 require that MA organizations provide to CMS POS data relating to the utilization of the POS benefit by plan members. This is not a new data requirement since MA organizations that offer a POS benefit would need to have this data in the normal course of business in order to pay POS claims. We estimate that providing this data to CMS would require 1 hour per quarterly submission. Thus, the annual burden would be 1 hour x 4 = 4 hours per MA organization in providing the required POS data. We estimate one-third of all MA organizations offer a POS

benefit. (670 divided by 3 = 223 x 4 hours = 892 hours)

Coordination of benefits with employer or union group health plans and Medicaid. (§422.106)

§422.106(c)(1) – MA organizations may request, in writing, a waiver or modification of those requirements in part 422 that hinder the design of, the offering of, or the enrollment in, MA plans under contracts between MA organizations and employers, labor organizations, or the trustees of benefits funds.

We believe that the burden associated with this requirement is minimal. We anticipate approximately 200 requests for waivers or modifications submitted on an annual basis and that it will take approximately 2 hours to prepare each request. The total annual burden associated with this requirement is estimated to be 400 hours. This information is used by CMS to determine whether or not to approve waiver requests.

§422.106(c)(2) – This section states that approved waivers or modifications under this paragraph may be used by any MA organization in developing its bid. Any MA organization using a waiver or modification must include that information in the cover letter of its bid proposal submission.

The burden associated with this requirement is the time and effort for the MA organization to include the information in the cover letter of its bid proposal submission. Although this requirement is subject to the PRA, the burden is minimal; the burden is captured in the analysis for §422.106(c)(1).

§422.106(d)(1) To facilitate the offering of MA plans by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof), or members or former members (or combination thereof), of the labor organizations, those MA plans may request, in writing, from CMS, a waiver or modification of those requirements in this part that hinder the design of, the offering of, or the enrollment in, those plans by those individuals.

The burden associated with this requirement is the time and effort necessary for the plan to submit a waiver to CMS.

We estimate that on an annual basis it will take plans 2 hours to submit the waiver to CMS. However, we do not anticipate more than ten waiver requests on an annual basis. As such, this requirement is not subject to the PRA as stipulated under 5 CFR 1320.3(c).

Special Needs Plans and dual eligibles: arrangements with states (§ 422.107)

(a) An MA organization seeking to offer or currently offering a special needs plan primarily serving beneficiaries eligible for both Medicare and Medicaid (dual eligible SNPs) must have a documented relationship with the State Medicaid agency for the State in which the SNP is operating. At minimum, documented arrangements must include the means to (1) verify enrollees' eligibility for both Medicare and Medicaid, (2) identify and share information on Medicaid participation, and (3) identify Medicaid benefits which are not covered by Medicare.

The burden associated with this requirement is the time and effort put forth by each special needs plans to have a documented relationship. We estimate it would take one special needs plan 18 hours to comply with this requirement. We estimate 460 special needs plans would be affected annually by this requirement; therefore the total annual burden is 8,280 hours.

Disclosure requirements (§ 422.111)

We require an MA organization to disclose the information specified in § 422.64 and in paragraph (b) of § 422.111 to each enrollee eligible for or electing an MA plan it offers. The information must be in clear, accurate, and standardized form, and provided at the time of enrollment and at least annually thereafter. The burden associated with this requirement is captured above in § 422.64.

If an MA organization intends to change its rules for an MA plan, it must submit the changes for CMS review under the procedures of § 422.80. The burden associated with this requirement is reflected in § 422.80 above.

The plan must also give notice to all enrollees 30 days before the intended effective date of the changes. The burden associated with this requirement is reflected above in § 422.80.

The MA organization must make a good faith effort to provide written notice of a termination of a contracted provider at least 30 working days of receipt or issuance of a notice of termination, as described in § 422.204(c)(4), to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must also be notified.

CMS has no basis to calculate the burden impact imposed by these requirements. Therefore, we explicitly seek comment on the impact of this notification requirement.

§ 422.111(f)(10). The names, addresses, and phone numbers of providers from whom the enrollee the enrollee may obtain in-network coverage in other areas.

The burden associated with this requirement is the time and effort necessary for the plan to notify members of the names, addresses, and phone numbers of providers from whom the enrollee may obtain in-network coverage in other areas. While this requirement is subject to the PRA, we believe that this requirement meets the requirements of 5 CFR 1320.3(b)(2) and, as such, the burden associated with this requirement is exempt from the PRA.

Access to services (§ 422.112)

In the case of involuntary termination of an MA plan or specialist(s) for a reason other than for cause, the MA organization must inform beneficiaries of their right to maintain access to specialists and provide the names of other MA plans in the area that contract with specialists of the beneficiary's choice, as well as an explanation of the process the beneficiary would need to follow should he or she decide to return to original Medicare.

The requirements imposed by this section would be pursuant to an administrative action and therefore are exempt from the PRA as defined in 5 CFR 1320.4.

An MA plan seeking a service area expansion must demonstrate that the number and type of providers available to plan enrollees are sufficient to meet projected needs of the population to be served. The burden associated with meeting this requirement is captured above in 422.6.

An MA plan must demonstrate to CMS that its providers are credentialed through the process set forth at § 422.204(a). The burden associated with meeting this requirement is captured above in 422.6.

Plans must have procedures approved by CMS for (1) identification of individuals with complex or serious medical conditions; (2) assessment of those conditions, including medical procedures to diagnose and/or monitor them on an ongoing basis; and (3) establishment of a treatment plan appropriate to those conditions, with an adequate number of direct access visits to specialists to accommodate the treatment plan. Treatment plans must be time-specific and

updated periodically by the PCP.

Plans must also: 1) establish written standards for the timeliness of access to care and member services that meet or exceed standards established by CMS, 2) continuously monitor and document the timely access to care and member services within a plan's provider network to ensure compliance with these standards, and take corrective action as necessary, 3) establish written policies and procedures (coverage rules, practice guidelines, payment policies, and utilization management) that allow for individual medical necessity determinations, and 4) ensure that providers consider and document beneficiary input into the provider's proposed treatment plan.

Plans must maintain written procedures to ensure that: 1) the MA organization and its provider network have the information required for effective and continuous patient care and quality review, including procedures to ensure that each provider, supplier, and practitioner furnishing services to enrollees maintains an enrollee health record in accordance with standards established by the MA organization, taking into account professional standards, and there is appropriate and confidential exchange of information among provider network components, 2) there are written procedures to ensure that enrollees are informed of specific health care needs that require follow-up and receive, as appropriate, training in self-care and other measures they may take to promote their own health; and 3) there is documentation demonstrating that systems to address barriers to enrollee compliance with prescribed treatments or regimens.

CMS believes these requirements are reasonable and customary business practices and the burden associated with these requirements is exempt from the PRA as defined in 5 CFR 1320.3(b)(2). Therefore, we are assigning one token hour of burden for these requirements.

§ 422.112(c) An MA regional plan may seek, upon application to CMS, to designate a noncontracting hospital as an essential hospital, as defined in section 1858(h) of the Act, that meets the conditions set forth in this section.

The burden associated with this requirement is the time and effort necessary for the plan to submit the required materials to CMS. We estimate that on an annual basis it will take 100 plans 8 hours each to submit the materials to CMS for a total burden of 800 hours.

Section 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services

In addition, instructions to seek prior authorization for emergency services and/or before the enrollee has been stabilized may not be included in any materials furnished to the enrollee. We anticipate that these requirements will be provided as part of standard enrollment disclosures. Therefore, the burden associated with this requirement is contained in section 422.64.

Confidentiality and accuracy of enrollee records (§ 422.118)

For any medical records or other health and enrollment information it maintains with respect to enrollees, an MA organization must establish and maintain procedures set forth in (a) through (c) of this section.

While the maintenance of health records is a record keeping requirement subject to the PRA, we believe the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2) and (b)(3), and are assigning 1 token hour of burden for this requirement.

Information on advance directives (§ 422.128)

Each MA organization must maintain written policies and procedures that meet the

requirements for advance directives, as set forth in 43 CFR part 489 subpart I.

An MA organization must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care by or through the MA organization.

An MA organization must provide written information to those individuals with respect to the requirement set forth in this section.

These requirements are identical to the requirements currently approved under OMB# 0938-0610. Since the currently approved requirements encompass a larger universe of provider types than just managed care organizations it is difficult to estimate the burden on the MA organizational level. However, the per beneficiary encounter burden is estimated to be 3 minutes. With 3,400 MA plans with average enrollment of 715 the time burden for this requirement is 121,550 hours

Protection against liability and loss of benefits (§ 422.132)

Each MA organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the MA organization. The burden associated with demonstrating this requirement is captured below under § 422.306.

Each MA organization must have an insolvency protection plan that provides for continuation of benefits. Each MA organization must submit an insolvency plan to CMS for approval. The reporting requirements are similar to the insolvency plan reporting requirements submitted by 1876 organizations. The burden associated with completing and submitting an insolvency plan is estimated to be 40 hours per organization on an annual basis. Therefore, the total annual burden associated with this requirement is 26,800 hours (40 hours x 670 MA organizations).

Quality improvement program (§ 422.152)

All Medicare Advantage organizations are required to measure performance under their plans, using standard measures required by CMS, and report their performance to CMS. Reporting is required annually. The standard measures that will be required will most likely be those already captured in HEDIS and CAHPS, approved under OMB # 0938-0701. In the near future CMS will resubmit this collection to OMB for approval for use by MA organizations.

The organization must report the status and results of each performance improvement project to CMS as requested.

All 670 MA organizations offering coordinated care plans are required to undertake performance improvement projects relative to those plans. Each organization must report the status and results of each project to CMS as requested. We expect that, in any given year, each organization will complete two projects, and will have two others underway, relative to each plan. We expect that we will request the status and results of each organization's projects annually. We estimate that it will take an organization 5 hours to prepare its report for each project. Therefore, we estimate that the total annual hours involved per organization to be 20 and an overall annual burden for all organizations offering coordinated care plans of 7,400 hours. (670 x 20 hours = 13,400).

For all types of plans that it offers, an organization must: (1) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality assessment and performance improvement program, (2) Ensure that the information it receives from providers of services is reliable and complete, and (3) Make all collected information

available to CMS.

All MA organizations must maintain a health information system, and must make all collected information available to CMS. The requirement guarantees our access to organization information: it does not impose an obligation for routine organization submission of information. At this time, we do not anticipate requesting information other than that relating to the standard measures and performance improvement projects discussed above.

Paragraph (e) of this section requires an organization offering an MA plan to measure performance under the plan using standard measures required by CMS and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS and will relate to clinical areas including effectiveness of care, enrollee perception of care, and use of services and to non-clinical areas including access to and availability of services, appeals and grievances, and organizational characteristics.

The burden associated with this reporting provision is the time it takes an MA organization to gather and submit the information. All MA organizations will be required to measure performance under their plans, using standard measures required by CMS, and report their performance to CMS. Reporting is required annually. Currently, the standard measures that will be required will most likely be those already captured in HEDIS and CAHPS, approved under OMB # 0938-0701. The currently approved annual per plan burden is estimated to be 200 hours. Therefore, the total burden associated with this requirement is 13,400 hours (200 hours x 670 plans)

§422.152(f)(4) –This section requires MA organizations' quality assurance programs to have a separate focus on racial and ethnic minorities. We estimate that it will take each MA organization approximately 2 hours to add a separate focus on racial and ethnic minorities to its quality assurance program. Since we currently contract with approximately 670 MA organizations, we estimate the annual burden associated with this requirement to be approximately 1340 hours. This information is used by CMS to determine whether or not the MA organization has made quality improvements.

Compliance deemed on the basis of accreditation (§ 422.156)

An MA organization deemed to meet Medicare requirements must: (1) Submit to surveys by CMS to validate its accreditation organization's accreditation process, and (2) authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

The burden associated with this requirement is captured below in § 422.158.

Accreditation organizations (§ 422.157)

An accreditation organization approved by CMS must undertake the following activities on an ongoing basis: (1) Provide to CMS in written form and on a monthly basis all of the information required in paragraphs (c)(1)(i) through (c)(1)(v) of § 422.157, (2) Within 30 days of a change in CMS requirements, submit to CMS all of the information required in paragraphs (c)(2)(i) through (c)(2)(iii) of § 422.157, (4) Within 3 days of identifying, in an accredited MA organization, a deficiency that poses immediate jeopardy to the organization's enrollees or to the general public, give CMS written notice of the deficiency, and (5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited MA

organizations. The burden associated with this requirement is captured below in § 422.158.

Procedures for approval of accreditation as a basis for deeming compliance (§ 422.158)

A private, national accreditation organization applying for approval must furnish to CMS all of the information and materials referenced in this section. However, when reapplying for approval, the organization need furnish only the particular information and materials requested by CMS.

The BBA allows CMS to deem that a MA organization meets certain Medicare requirements if that organization is accredited by an accreditation organization approved by CMS. We expect that four national accreditation organizations will eventually be approved. The application and oversight procedures that we have developed for deeming in the managed care arena mirror those already in place in the fee-for-service arena as currently approved under OMB # 0938-0690. Therefore, much of the burden estimate prepared for the fee-for-service deeming regulations in 42 CFR part 488, Subpart A, would also apply here. The initial application burden associated with obtaining deeming authority is 96 hours every six years. Since we anticipate that four organizations will apply, the total burden is 386 hours over a six year period. The ongoing burden of supplying CMS with data on the status of its deemed facilities is estimated to be 48 annual hours per deeming organization for a total annual burden of 192 hours.

Participation procedures (§ 422.202)

An MA organization that operates a coordinated care plan must provide for the participation of individual health care professionals and of the management and members of groups through reasonable written procedures that include the following: (1) written notice of rules of participation such as terms for payment, utilization review, quality improvement programs, credentialing, data reporting, confidentiality, guidelines or criteria for the furnishing of particular services, and other rules related to administrative policy; (2) written notice of material changes in participation rules before the changes are put into effect; (3) written notice of participation decisions that are adverse to health care professionals; and (4) a process for appealing adverse decisions, including the right of physicians and other health care professionals to present information and their views on the decision.

The MA organization must maintain documentation demonstrating that: (1) practice guidelines and utilization management guidelines meet the requirements of (1)(i) through (iv) of this section; (2) the guidelines have been communicated to providers and, as appropriate, to enrollees; (3) decisions with respect to utilization management, enrollee education, coverage of services, and other areas in which the guidelines apply are consistent with the guidelines; and (4) an MA organization that operates an MA plan through subcontracted physician groups or other subcontracted networks of health care professionals ensures that the participation procedures in this section apply equally to physicians and other health care professionals within those subcontracted groups.

The burden associated with these requirements is the time required to maintain documentation demonstrating that the requirements have been met and, as necessary, the time necessary to communicate the guidelines to providers and enrollees. CMS believes that these requirements are reasonable and customary business practices and the burden of meeting these requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2). Paragraph (d) of this section requires that an MA organization that suspends or terminates an agreement under which the physician provides services to MA plan enrollees give the affected individual written notice as

required by this section.

This section also requires that an MA organization that suspends or terminates a contract with a physician because of deficiencies in the quality of care give written notice of that action to licensing or disciplinary bodies or to other appropriate authorities.

The burden associated with these reporting provisions is the time it takes an MA organization to write the notice and give it to the practitioner and the appropriate licensing, or disciplinary bodies or to other appropriate authorities. We estimate that it will take 670 organizations 18 hours to produce and disclose 10 notices on an annual basis, for a national annual burden of 12,060 hours.

In addition this paragraph requires that an MA organization and a contracting provider must provide at least 60 days written notice to each other before terminating the contract without cause.

The burden associated with this reporting provision is the time it takes an MA organization and provider to write the notice and furnish it to the other party. We estimate that 670 entities will be required to write 10 notices, at 1 hour per notice, for a national annual burden of 6,700 hours.

Provider selection and credentialing (§ 422.204)

An MA organization that operates a coordinated care plan that provides benefits through contracting health care professionals must provide notice to contracting professionals when the organization denies, suspends, or terminates their agreement with the professional and include: (1) the reason for the action; (2) the standards and the profiling data the organization used to evaluate the professionals; (3) the numbers and mix of health care professionals needed for the organization to provide adequate access to services; and (4) the professional's right to appeal the action and the timing for requesting a hearing.

The burden associated with this requirement is the time required for an organization to prepare a written notification of the denial, suspension, or termination of their agreement with the organization. In discussions with CMS plan managers, it was predicted that approximately 4 organizations) would find it necessary to take such action for about 1 percent of the contracted professionals within a single year and if the organization was already established and doing business. The range of number of contracted professionals extends from 3 contracted professionals to 67,000. Excluding outliers on both ends of the range, we estimate that an organization contracts with an average of 3,000 health care professionals. Using an estimate of 10 minutes per instance to generate and furnish a notice of such action, the total burden on contractors (670) would be 4 organizations x 30 x 10 minutes = 1200 minutes or 20 hours annually.

In addition, CMS expects to receive approximately 100 additional applications for contracts with new entities to be processed. For organizations creating new networks, they would probably all have at least one instance of denial the first year affecting approximately 1 percent of the number of contracting professionals. Using an estimate of 10 minutes per instance to generate and furnish a notice of such action, the total burden on new contractors would be 100 organizations x 30 x 10 minutes = 30,000 minutes or 500 hours. The total burden with current applications and expected applications for contracts would be 510 hours annually.

The number of new organizations is expected to increase by 100, on an annual basis creating an expected burden for current contracts [350(x.005(organization-rounded to the nearest whole number) x30x10)/60 =]10 hours + new contracts [100x30x10 /60 =]500 hours = 510 hours.

An MA organization is required to notify any licensing or disciplinary bodies or other

appropriate authorities when it suspends or terminates a contract with a health care professional because of deficiencies in the quality of care provided by the professional.

The burden associated with this requirement is the time required for the organization to prepare a written notification to the appropriate authorities. No exact data is available to estimate how often this situation might occur. CMS estimates that this situation might occur in 3 percent of the MA organizations once during an annual period. The amount of time estimated to prepare the written notification is 10 minutes. The annual burden associated with this requirement is estimated to be [670 x .03 x 1 x10 /60] = 3.35 hours.

Section 422.204(c)(1) requires an MA organization that suspends or terminates an agreement under which the physician provides services to MA plan enrollees must give the affected individual written notice of the reasons for the action, including, if relevant, the standards and profiling data used to evaluate the physician and the numbers and mix of physicians needed by the MA organization, and the affected physician's right to appeal the action and the process and timing for requesting a hearing. We estimate 10 hours of annual burden per MA organization. Section 422.204 (c)(3) requires an MA organization that suspends or terminates a contract with a physician because of deficiencies in the quality of care to give written notice of that action to licensing or disciplinary bodies or to other appropriate authorities. We estimate an average burden of 2.25 hours per MA organization.

Provider antidiscrimination rules (§422.205)

The reporting requirement of this section requires that, if an MA organization declines to include a given provider or group of providers in its network, it furnish written notice to the affected provider(s) of the reason for the decision.

The burden associated with this reporting provision is the time it takes an MA organization to write and provide the required notice. We estimate that it will take 670 organizations 30 minutes to produce and disclose 20 notices on an annual basis, for a national annual burden of 6,700 hours.

Interference with health care professionals' advice to enrollees prohibited (§ 422.206)

Section 422.206 prohibits the MA organization from restricting the provision of treatment advice by health care professionals to enrollees. However, the prohibition against interference is not construed as requiring counseling by a professional or a referral to a service by that professional, if there is an objection based on moral and religious grounds. Section 422.206 requires MA organizations to notify CMS during the application process, and later to all current and prospective enrollees, through appropriate written means, if the organization has such a conscience protection policy regarding counseling in effect or if the policy is changed subsequent to the application. The expected number of MA organizations exercising this option is not expected to exceed 10 in any given year. The amount of burden imposed in the application process, which is captured in the application burden and in the preparation of the contents of the subscriber agreement or member handbook or a subsequent written notice to enrollees, is reflected above in § 422.6 and § 422.64.

The reporting requirement in paragraph (b)(2) requires that, through appropriate written means, an MA organization make available information on any conscience protected policies to CMS, with its application for a Medicare contract, within 10 days of submitting its bid proposal or, for policy changes, in accordance with §422.80 (concerning approval of marketing materials and election forms) and with §422.111.

This information collection provision requires the MA organization to make available policy changes. We estimate that it will take 30 minutes for each of the 670 MA organizations to comply, for a total of 335 hours nationally on an annual basis.

Special rules for MA private fee-for-service plans (§ 422.216)

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

We expect the MA PFFS plan to provide written information to contracting providers and to make the information available via a website or toll free number to noncontracting providers who inquire. We have 69 MA organizations currently offering 2,800 MA PFFS plans. We estimate that these 2,800 MA PFFS will each be required to provide 1000 annual responses at an estimated 5 minutes per disclosure (average of phone calls, website time, mailing time for hard copies to contracting providers) for a total annual burden of 83 hours per MA plan and an overall annual 83 x 2,800 = 232,400 hours.

An MA organization that offers an MA fee-for-service plan must enforce the limit specified in paragraph (b)(1) of this section. Specifically, an MA organization that offers an MA private fee-for-service plan must monitor the amount collected by non-contract providers to ensure that those amounts do not exceed the amounts permitted to be collected under paragraph (b)(2) of this section. The MA organization must develop and document violations specified in instructions and must forward documented cases to CMS.

MA private fee-for-service plans must investigate and send to CMS documentation of excessive charges by providers. It is estimated that 2,800 MA private fee-for-service plans will have 25 cases per year, at 20 hours per case (to contact the enrollee who complained, acquire and review documents, contact the provider, prepare report to CMS). Therefore, the total burden associated with this requirement is 25 cases x 20 hours = 500 annual hours per plan (for a total annual burden of 1,400,000 hours.

An MA organization that offers an MA private fee-for-service plan must provide to plan enrollees, for each claim filed by the enrollee or the provider that furnished the service, an appropriate explanation of benefits. The explanation must include a clear statement of the enrollee's liability for deductibles, coinsurance, copayment, and balance billing.

This requirement is akin to the Medicare EOMB or summary statement and must be furnished on a regular basis for every claim paid or denied by the MA private fee-for-service plan. It is estimated that 24 million notices will be disseminated by MA private fee-for-service plans. This estimate is determined by multiplying 715 enrollees per plan by 12 (one notice per month) or 8580, multiplied by an estimated 2,800 plans for a total of 24 million notices. At an estimated 3 minutes of burden per notice, the total burden is 720 million minutes or 1,200,000 burden hours. On a plan level the average annual burden is estimated to be 428 hours.

In its terms and conditions of payment to hospitals, the MA organization must require the hospital, if it imposes balance billing, to provide to the enrollee, before furnishing any services for which balance billing could amount to not less than $500 the following: (1) notice that balance billing is permitted for those services; (2) a good faith estimate of the likely amount of balance billing, based on the enrollees presenting condition; and (3) the amount of any deductible, coinsurance, and copayment that may be due in addition to the balance billing amount.

It is estimated that 20,000 of 25,000 estimated hospitalizations will require these notices. The $500 tolerance will be exceeded each time the plan payment rate for the inpatient stay would exceed $3333.33 -- which is probably almost all of them -- if the plan lets the hospital balance

bill. At 5 minutes of burden per notice times 20,000 annual notices, the total burden is 100,000 minutes or 1,667 hours of burden.

Submission of bids (§422.254)

(a)(1) No later than the first Monday in June, each MA organization must submit to CMS an aggregate monthly bid amount for each MA plan (other than an MSA plan) the organization intends to offer in the upcoming year in the service area (or segment of such an area if permitted under § 422.262(c)(2)) that meets the requirements in paragraph (b) of this section. With each bid submitted, the MA organization must provide the information required in paragraph (c) of this section. In addition, regional MA plans have the option to submit additional cost factors in order to receive their geographic payment adjustment.

The burden associated with this requirement is the time and effort necessary for the plan to submit the required bid materials to CMS. We estimate that 670 MA organizations offering an estimated 3,400 plans will take 100 hours per plan bid submission to CMS, for a total annual burden of 340,000 hours.

(e) For MSA plans, MA organizations must submit the following information: the monthly MSA premium, the plan deductible amount, and the beneficiary supplemental premium, if any. Since CMS does not review or approach MSA plan submissions, we estimate that the submission burden is half that for other MA plans. Under the M+C program, no MSA plans were offered. We estimate that under the MA program 20 organizations will offer an MSA plan and require 50 hours for submission of the above information, for a total annual burden of 1000 hours.

Incorrect collections of premiums and cost sharing (§422.270)

(b) An MA organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf.

The burden associated with this requirement is the time and effort necessary for the MA organization to provide written assurance to CMS that they will refund all amounts incorrectly collected from its Medicare enrollees or other representatives. We estimate that on an annual basis it will take 200 MA organizations 30 minutes for a total of 100 hours to submit a written agreement to CMS.

Monthly Payments (§422.304)

(e)(2) A State's chief executive may request, no later than February 1 of any year, a geographic adjustment of the State's payment areas, as outlined in this section, for MA local plans for the following calendar year.

The burden associated with this requirement is the time and effort necessary for a State to provide a written request for geographic adjustment to CMS. Under the M+C program, we received inquiries from 2 States and requests from none. Thus, we estimate that on an annual basis we may receive 2 State submissions. As such this requirement is not subject to the PRA as stipulated under 5 CFR 1320.3(c).

Risk adjustment data (§422.310)

(b) Each MA organization must submit to CMS (in accordance with CMS instructions) all data necessary to characterize the context and purposes of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. CMS may also collect data

necessary to characterize the functional limitations of enrollees of each MA organization. The PRA impact on MA organizations offering MA Prescription Drug Plans is addressed in the companion document, the Title I regulation.

The burden association with this requirement is the time and effort necessary for a plan to submit the required risk adjustment data to CMS. We estimate that on an annual basis it will take 670 MA organizations 121 hours each to submit the required data to CMS for a total of 81,070 hours.

(d)(1) MA organizations must electronically submit data that conform to the requirements for equivalent data for Medicare fee-for-service when appropriate, and to all relevant national standards. Alternatively, MA organizations may submit data according to an abbreviated format, as specified by CMS.

The burden associated with this requirement is the time and effort necessary for a plan to submit the required risk adjustment data to CMS. The estimate for submission of the abbreviated format data is included in the above estimate.

(e) MA organizations and their providers and practitioners will be required to submit medical records for the validation of risk adjustment data, as required by CMS.

The burden associated with this requirement is the time and effort necessary for a plan to submit the required validation data to CMS. We estimate that on average 670 MA organizations will each submit 60 medical records to CMS, requiring 1 hour per record, for a total annual burden of 40,200 hours.

Special rules for beneficiaries enrolled in MA MSA plans (§422.314)

(b) For Medicare Advantage Medical Savings Account (MSA) plans, when a Medicare beneficiary enrolls into an MSA plan, Medicare pays a set amount of money to plans, and the plans then deposit some of this money into an MSA savings account for use by the enrollee. An entity that acts as a trustee for a beneficiary's MSA must: (1) register with CMS; (2) certify that it is a licensed bank, insurance company, or securities broker, or other entity qualified, under sections 408(a)(2) or 408(h) of the IRS Code, to act as a trustee of individual retirement accounts; (3) agree to comply with the MA MSA provisions of section 138 of the IRS Code of 1986; and (4) provide any other information that CMS may require. Enrollees must complete and submit to MSA plans an MSA registration form that would take no more than five minutes for plans to process.

We estimate that under the MA program 20 organizations will offer an MSA plan, each enrolling 1,000 beneficiaries. For 20,000 beneficiaries, registration would take 1,668 hours (i.e., 20,000 registration forms at 5 minutes each.)

Items 2 and 3, above, are IRS requirements and entail no reporting requirements for CMS. Under item 4, above, we anticipate no further MA MSA reporting requirements at this time.

Special rules for hospice care (§422.320)

(a) An MA organization that has a contract under Subpart K of part 422 must inform the enrollees of it MA plans eligible to elect hospice care under section 1812(d)(1) of the Act about the availability of hospice care (in a manner that objectively presents all available hospice providers, including a statement of any ownership interest in a hospice held by the MA organization or a related entity**)** if: (1) A Medicare hospice program is located within the organization's service area, or (2) It is common practice to refer patients to hospice programs outside that area.

Approximately one-twentieth of one percent four thousand five hundred) Medicare managed care enrollees have elected the hospice option.

We estimate that informing beneficiaries about their hospice choices would take about ten minutes. For 4,500 beneficiaries, this represents a total burden of 750 hours. On an organizational level, with 670 MA organizations, the annual burden would be 750 hours/670 MA organizations = 1.12 annual burden hours per entity.

State licensure requirement (§ 422.400)

Except in the case of a PSO granted a waiver under Subpart H of part 422, each MA organization must: (1) Be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity (as defined in § 422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more MA plans; (2) if not commercially licensed, obtain certification from the State that the organization meets a level of financial solvency and such other standards as the State may require for it to operate as an MA organization; and (3) demonstrate to CMS that--(i) The scope of its license or authority allows the organization to offer the type of MA plan or plans that it intends to offer in the State; and (ii) If applicable, it has obtained the State certification required under § 422.400(b).

The regulations at § 422.400 require health plans to demonstrate to CMS that they meet the State licensure requirement of section 1855(a)(1) of the Social Security Act. As explained in the preamble, organizations must meet both the basic requirement of State licensure as a risk-bearing entity, as well as the requirement that the scope of licensure be consistent with the type (or types) of MA plan(s) the organization will be offering. We ask new organizations (i.e., other than current contractors) to submit, as part of the process of applying for an MA contract, a written certification showing the organization's licensure status. A written statement containing the same type of information that is requested in the form we developed would also suffice to show compliance with the statutory requirement.

The written certification is a combination of information provided by the organization proposing to enter into an MA contract and information to be provided by the appropriate State regulatory body (e.g. the State department of insurance). This is necessary because the written certification serves two purposes. First, it provides us with written evidence of compliance with the State licensure requirement for all MA plans an organization may wish to offer. Second, it serves to inform State regulators of the intention of organizations doing business within the State with regard to MA offerings. The certification process enables the State to ensure that the organization is complying with the State's standards for licensure (for example, as noted in the preamble, an HMO that proposes to offer a Medicare point-of-service (POS) product may be informed by the State that HMO licensure does not allow an organization to offer POS products, and that licensure as an indemnity insurer is required in that State in order to offer a POS product).

The certification will have to be completed (or other written documentation provided) only once by each MA organization, unless the nature of the MA plan(s) offered by the organization differ from the original certification (e.g., an HMO may decide at some later date, after its initial application to offer a POS product—though even in such a case, a new certification may not be necessary to the extent that we are aware that applicable State law does not require a different licensure status). We estimate that the time burden for the MA organization is 10 minutes or less for completion of the certification form, or preparation of alternative written documentation. Similarly, we would estimate, that the time burden for the State regulatory body should be 15

minutes or less (including time necessary to verify information from electronic or paper files).

Because we are estimating that there will be an average of 100 new applicants for MA contracts over the next 5 years, and because this requirement will be imposed for nearly all organizations on a one-time basis, we estimate the annual total burden to be 25 minutes per respondent X 100 total responses for a total of 42 hours total or 8.4 annual hours.

Risk sharing with regional MA organizations for 2006 and 2007 (§422.458).

(d)(1) Each MA organization offering an MA regional plan must provide CMS with information as CMS determines is necessary to implement this section.

The burden associated with this requirement is the time and effort necessary for a plan to submit the required information to CMS. We estimate that on an annual basis it will take 30 to 100 organizations offering regional MA plans, 40 hours to submit the required information to CMS.

(d)(2) Pursuant to the existing §422.502(d)(1)(iii) (section 1857(d)(2)(B) of the Act), CMS has the right to inspect and audit any books and records of the organization that pertain to the information regarding costs provided to CMS under paragraph (b)(2) of this section.

This requirement is exempt from the PRA as stipulated under 5 CFR 1320.4.

Application requirements (§422.501)

(b)(1) In order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must complete and submit a certified application, in the form and manner required by CMS, that meets the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for an organization to submit the required application to CMS. We estimate that on an annual basis it will take 25 – 30 new organizations 100 hours each to submit the required application to CMS. This burden associated with this requirement is captured in OMB #0938-0935.

General provisions (§422.503)/Contract provisions (§422.504))

In order to qualify as an MA organization, enroll beneficiaries in any MA plans it offers, and be paid on behalf of Medicare beneficiaries enrolled in those plans, an MA organization must enter into a contract with CMS.

Since the contract requirements associated with these sections are reflective the requirements and associated burden set forth in other sections of Part 422, the remaining burden associated with the requirements of these sections is the time required for a MA organizations to read and sign the contract. It is estimated that it will take 670 MA organizations on an annual basis, 2 hours each for a total annual burden of 1,340 hours.

Contract provisions (§ 422.504)

(g) Each MA organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of fees that are the legal obligation of the MA organization.

The burden associated with this requirement is the time and effort put forth by each MA plan to adopt and maintain arrangements. We estimate it would take an MA plan 208 hours to comply with this requirement. We estimate 3400 plans would be affected annually by this requirement;

therefore, the total annual burden associated with this requirement is 707,200 hours.

Nonrenewal of contract (§ 422.506)

An MA organization that does not intend to renew its contract must notify CMS, each Medicare enrollee, and the general public, before the end of the contract. Based on current experience CMS receives 5 - 10 notifications of non-renewal on an annual basis.

We estimate that the burden of notifying CMS is 2 hours per notification for an annual burden of 20 hours.

We estimate the burden associated with notifying enrollees would take 16 hours per MA organization to draft and disseminate through mass mailings information of changes to affected beneficiaries for an annual burden of 160 hours.

We anticipate notification to the general public would be through the same notice published in a general circulation newspaper and would be an additional burden of 4 hours per organization for an annual burden of 40 hours.

Modification or termination of contract by mutual consent (§ 422.508)

An MA organization that modifies or terminates it contract by written mutual consent must notify CMS, each Medicare enrollee, and the general public, within timeframes specified by CMS.

Based on current experience CMS continues to receive less then 10 notifications of Modification or termination on an annual basis that would require notification of Medicare enrollees or the general public. However, we estimate that the burden of notifying CMS is 2 hours per notification for an annual burden of 20 hours.

Termination of contract by CMS (§ 422.510)

If CMS decides to terminate a contract for reasons other than the grounds specified in § 422.510(a)(5), the MA organization notifies its Medicare enrollees and the general public by publishing a notice in one or more newspapers of general circulation in each community or county located in the MA organization's geographic area of the termination by mail and at least 30 days before the effective date of the termination. Based upon current experience this requirement is imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.4 and 5 CFR 1320.3(c).

Termination of contract by the MA organization (§ 422.512)

The MA organization may terminate the MA contract if CMS fails to substantially carry out the terms of the contract. The MA organization must give advance notice as follows as required in paragraphs (a)(1) through (a)(3) of § 422.512. In summary, an MA organization that does not intend to renew its contract must notify CMS, each Medicare enrollee, and the general public, before the end of the contract.

Based upon current experience this requirement is imposed on fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c).

Reporting requirements (§ 422.516)

Each MA organization must report to CMS annually, within 120 days of the end of its fiscal year (unless for good cause shown, CMS authorizes an extension of time), the requirements in

§ 422.516 (b)(1) through (b)(3). The burden associate with these requirements is currently captured under form CMS-906, OMB # 0938-0469.

The burden associated with the completion of the CMS-906 differs by provider type. However, on average, the annual burden per provider for compilation is 17 annual hours, for a total burden of 4,690 (17 x 670) hours.

For any employees' health benefits plan that includes an MA organization in its offerings, the MA organization must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations under the Employee Retirement Income Security Act of 1974 (ERISA). The MA organization must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA.

These reporting requirements are currently imposed by the Department of Treasury and therefore impose no addition burden.

Each MA organization must make the information reported to CMS under § 422.502(f)(1) available to its enrollees upon reasonable request. This burden associated with this requirement is imposed pursuant to the dissemination of enrollment/disenrollment information referenced in Subpart B of this regulation.

Each organization must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

The burden associate with these requirements is currently captured under form CMS-906, OMB # 0938-0469.

General provisions (§ 422.550)

§ 422.550 requires in paragraph (b) that an MA organization must provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

The burden associated with these requirements, which is estimated to take 10 hours per respondent X 10 annual respondents, is currently captured under National Data Reporting Requirements, form CMS-906, OMB # 0938-0469.

General provisions (§ 422.562)

An MA organization, with respect to each MA plan that it offers, must establish and maintain written procedures related to: 1) the grievance procedures as described in § 422.564, (2) making timely organization determinations, 3) an appeal process that meets the requirements of this Subpart for issues that involve organization determinations. In addition, an MA organization must ensure that all enrollees receive written information about the grievance and appeal procedures that are available to them through the MA organization and complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

Grievance procedures (§422.564)

Based on the results of prior sampling of managed care enrollees, we extrapolate that approximately 17% of MA enrollees would likely experience some dissatisfaction with their MA organizations. Since we estimate that there will be approximately 9 million MA enrollees in 670 MA organizations (2008 projection), we estimate that approximately 1,530,000 enrollees likely will experience some dissatisfaction with their MA organizations in a given year.

Based on previous grievance requirements analysis (See 66 Fed. Reg. 7,593, 7600), we estimate that approximately 612,000 enrollees, that is, 40% of the total number of dissatisfied

enrollees, will file an oral or written grievance. We further estimate that 60% of those that file a grievance will request a grievance orally, that is, 367,200. Of those requests, we believe that approximately 10% of enrollees will request a follow-up written response, that is, 36,720 enrollees.

We estimate that it will take MA organizations 15 minutes to prepare and furnish each written response, and that MA organizations will be required to provide an estimated 36,720 written notices following oral requests. The total annual burden associated with this requirement is 70,380 hours.

We expect the notices to be developed and delivered by a plan employee who is the equivalent of a GS 12 Step 10 ($35.95 per hour). The aggregate annual cost associated with this burden is $2,530,161.

Standard timeframes and notice requirements for organization determinations (§ 422.568)

Under paragraph (a) of this section, when a party has made a request for a service, the MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The MA organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee. When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

We estimate that this requirement will add 30 hours for each of the 670 MA organizations, for an annual addition of 20,100 hours.

If an MA organization decides to deny service or payment in whole or in part, it must give the enrollee written notice of the determination. The notice of any denial must, in addition to currently approved requirements, (1) for service denials, describe both the standard and expedited reconsideration processes, including the enrollee’s right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process; and (2) for payment denials, describe the standard reconsideration process and the rest of the appeals process.

The burden associated with this reporting provision is the time it takes to write the detailed decision and provide it to the beneficiary. We estimate that there will be 145 occasions per entity (670) for which a detailed decision must be provided and that each notification will take an average of 60 minutes for a national annual burden of 97,150 hours.

The aggregate annual cost associated with this burden is $4,215,138.

Expediting certain organization determinations (§ 422.570)

When asking for an expedited determination, an enrollee or a health care professional must submit an oral or written request directly to the MA organization or, if applicable, to the entity responsible for making the determination, as directed by the MA organization. A physician may provide oral or written support for a request for an expedited determination.

If an MA organization denies a request for expedited determination, it must give the enrollee prompt oral notice of the denial and follow up, within 2 working days, with a written letter that:

(1) explains that the MA organization will process the request using the 30-calendar-day timeframe for standard determinations, (2) informs the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision not to expedite; and (3) provides instructions about the grievance process and its timeframes.

If an MA organization grants a request for expedited determination, it must make the determination and give notice in accordance with § 422.572.

The burden associated with this requirement is discussed in § 422.572.

Section ((d)(2)(iii)) requires that, if an MA organization denies a request for expedited determination, it must give the enrollee prompt oral notice of the denial and subsequently deliver, within 2 calendar days, a written letter that informs the enrollee of the right to resubmit a request for an expedited determination with a physician's support. The currently approved burden associated with this requirement has not changed.

Timeframes and notice requirements for expedited organization determinations (§ 422.572)

Except as provided in paragraph (b) of § 422.572, an MA organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician as warranted by the patient's medical condition or situation) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but not later than 72 hours after receiving the request.

The MA organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization finds that it needs additional information and the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence may change an MA organization's decision to deny), and notify the enrollee of the right to file an expedited grievance if he or she objects to the extension. The MA organization must notify the enrollee of its determination before or immediately upon expiration of the extension.

If the MA organization first notifies an enrollee of an unfavorable expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

Organizations that contract with CMS under the MA program are required to implement procedures for making timely organization determinations and for resolving reconsiderations and other levels of appeal with respect to these determinations. In general, organization determinations involve whether an enrollee is entitled to receive a health service or the amount the enrollee is expected to pay for that service. A reconsideration consists of a review of an adverse organization determination (a decision by an MA organization that is unfavorable to the MA enrollee, in whole or in part) by either the MA organization itself or an independent review entity. We use the term “appeal” to denote any of the procedures that deal with the review of organization determinations, including reconsiderations, hearings before administrative law judges (ALJs), reviews by the Medicare Appeals Council (MAC) and judicial review Sections 422.568, 422.570, and 422.572 contain the applicable requirements for initial organization determinations, which include submission of an oral or written request from an enrollee, and notification procedures that the MA organization must follow when it makes a determination. We estimate that approximately 20 percent of the approximately 9 million MA enrollees (projected for 2007) may make a request for an organization determination in a year, with an estimated burden of 2 minutes per request. Estimated notification burden associated with these requests is 5 minutes per request. The total overall annual burden for enrollee requests and organizational notification burden is 60,000 hours and 150,000 hours respectively.

Paragraph (b) requires that, when the MA organization extends the deadline, it notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension.

The additional burden associated with this requirement set forth in this section is the time it takes an MA organization to notify the beneficiary of the delay and the reasons for it. We estimate that 670 plans will provide extension notices to approximately 75 of their enrollees on an annual basis and it will take an average of 5 minutes per notification. Therefore, the annual national burden is estimated to be 4,187.5 hours.

The aggregate annual MA organization cost associated with this burden is $5,543,059.

Request for a standard reconsideration (§ 422.582)

A party to an organization determination must ask for a reconsideration of the determination by filing a written request with the MA organization that made the determination.

If the 60-day period in which to file a request for a reconsideration has expired, a party to the organization determination may file a request for an extension with the MA organization. The request for reconsideration and to extend the timeframe must: (1) be in writing; and (2) state why the request for reconsideration was not filed on time.

The party who files a request for reconsideration may withdraw it by filing a written request for withdrawal with the MA organization. The burden associated with this requirement is discussed below in § 422.590.

Expediting certain reconsiderations (§ 422.584)

When asking for an expedited reconsideration, an enrollee or a physician (on behalf of an enrollee) must submit an oral or written request directly to the MA organization or, if applicable, to the entity responsible for making the reconsideration, as directed by the MA organization. A physician may provide oral or written support for a request for an expedited reconsideration.

If an MA organization denies a request for expedited reconsideration, it must take the following actions: (1) automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe established in § 422.590(a); (2) give the enrollee prompt oral notice, and follow up, within 3 calendar days, with a written letter that--(i) explains that the MA organization will process the enrollee's request using the 30-day timeframe for standard reconsiderations, (ii) informs the enrollee of the right to file an expedited grievance if he or she disagrees with the organization's decision not to expedite, and (iii) provides instructions about the expedited grievance process and its timeframes.

If an MA organization grants a request for expedited reconsideration, it must conduct the reconsideration and give notice in accordance with § 422.590(d).

The burden associated with this requirement is discussed below in § 422.590.

This section requires that, if an MA organization denies a request for expedited reconsideration, it must give the enrollee prompt oral notice, and subsequently deliver, within 2 calendar days, a written letter that (in addition to currently approved disclosure requirements) informs the enrollee of the right to resubmit a request for an expedited reconsideration with a physician's support.

The one time burden associated with this disclosure requirement is the time it takes an MA organization to add the requisite language to the letter it furnishes to the beneficiary. We estimate that it will take each MA organization (670) an average of 30 minutes to add the language to its

current letter for notifying beneficiaries, for a national burden of 335 hours.

The aggregate annual cost associated with this burden is $12,043.

Timeframes and responsibility for reconsiderations (422.590)

If the MA organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration.

If the MA organization fails to provide the enrollee with a reconsidered determination within the timeframes specified in paragraph (a) or paragraph (b) of this section, or to obtain a good cause extension described in paragraph (e) of this section, this failure constitutes an affirmation of its adverse organization determination, and the MA organization must submit the file to the independent entity in the same manner as described under paragraphs (a)(2) and (b)(2) of this section.

The MA organization may extend the deadline by up to 14 calendar days if the enrollee requests the extension or if the organization finds that it needs additional information and the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence may change an MA organization's decision to deny). The MA organization must notify the enrollee of its determination, and the enrollee’s right to file an expedited grievance if he or she objects to extension.

If the MA organization first notifies an enrollee orally of a completely favorable expedited reconsideration, it must mail written confirmation to the enrollee within 2 working days.

If, as a result of its reconsideration, the MA organization affirms, in whole or in part, its adverse expedited organization determination, the MA organization must submit a written explanation and the case file to the independent entity contracted by CMS within 24 hours. If the MA organization refers the matter to the independent entity as described under this section, it must concurrently notify the enrollee of that action.

If the MA organization fails to provide the enrollee with the results of its reconsideration within the timeframe described in paragraph (d) of this section, this failure constitutes an adverse reconsidered determination, and the MA organization must submit the file to the independent entity within 24 hours of expiration of the timeframe set forth in paragraph (d) of this section.

Sections 422.582, 422.584, and 422.590 contain the applicable requirements for reconsiderations by an MA organization of adverse organization determinations. The required procedures generally involve a written request from an enrollee, preparation of a brief written explanation and case file by the MA organization, and notification of the decision by the MA organization. Only about 5 percent of organization determinations [that is, about 90,000 cases per year (2006 projection)], ever reach the reconsideration stage. For these cases, we estimate a burden on the requesting enrollee of approximately 20 minutes per case and a burden on the MA organization of approximately 4 hours, including both information collection and notification. Note that § 422.590 specifies that if an MA organization affirms, in whole or in part, its adverse organization determination, it must forward the case to an independent entity contracted by CMS for further review. We estimate that approximately 25 percent (22,500) of reconsidered cases result in a decision that is adverse to the enrollee, and thus review by the independent entity. For these cases, we estimate an additional burden on the MA organization of approximately 2 hours per case. Thus, the estimated total annual burden on MA organizations associated with

reconsiderations is 405,000 hours (4 hours times 99,000 cases plus 2 hours times 22,500 cases).

The aggregate annual cost associated with this burden is $14,559,750.

Notice of reconsidered determination by the independent entity (§ 422.594)

When the independent entity makes the reconsidered determination, it is responsible for mailing a notice of its reconsidered determination to the parties and for sending a copy to CMS.

Right to a hearing (§ 422.600)

(a) If the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary, any party to the reconsideration (except the MA organization) who is dissatisfied with the reconsidered determination has a right to a hearing before an ALJ.

Request for an ALJ hearing (§ 422.602)

A party must file a written request for a hearing at the place listed in the independent, outside entity's notice. The independent, outside entity is responsible for transferring the case to the appropriate ALJ hearing office.

We estimate that approximately 25 percent (16,500) of reconsidered cases result in a decision that is adverse to the enrollee, and thus review by the independent entity. About 14 percent of reconsideration requests that reach the independent entity level are resolved fully in favor of the enrollee. For the other 14,190 cases, an enrollee may pursue additional appeals, beginning with an appeal to an ALJ. However, these actions are exempt from the Paperwork Reduction Act process because they are pursuant to an administrative action, as outlined under 5 CFR 1320.4(b). This is due to the fact that the reconsideration process outlined under §§ 422.590 and 422.592 was initiated and thus, the actions flowing from the denial of payment and/or service and the subsequent request for reconsideration, such as the ALJ process at § 422.602 and judicial process, would also be exempt.

Medicare Appeals Council (MAC) review (§ 422.608)

Any party to the hearing, including the MA organization, who is dissatisfied with the ALJ hearing decision, may request that the MAC review the ALJ's decision or dismissal.

Judicial Review (§ 422.612)

(b) Any party, including the MA organization, may request judicial review (upon notifying the other parties) of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) In order to request judicial review, a party must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. See part 405, subpart I of this chapter for a description of the procedures to follow in requesting judicial review.

Notifying Enrollees of hospital discharge appeal rights (§ 422.620)

The hospital must provide, explain, and obtain the enrollee's signature (or that of the representative) on the revised Important Message from Medicare (IM) within 2 days of admission, followed by delivery of a copy of the signed IM no more than 2 calendar days before discharge in accordance with the requirements and procedures set forth in this rule. If the date the signed IM is delivered falls within 2 calendar days of discharge, no additional copy is given.

However, because this section only affects hospital requirements for Medicare health care enrollees, there is no burden estimate on Medicare health plans with this requirement.

Requesting immediate QIO review of decision to discharge from inpatient hospital care (§ 422.622)

This section states that an enrollee who wishes to appeal a determination by a Medicare health plan or hospital that inpatient care is no longer necessary, may request QIO review of the determination. On the date the QIO receives the enrollee's request, it must notify the plan that the enrollee has filed a request for immediate review. The plan in turn must deliver a Detailed Notice of Discharge (DND) to the enrollee.

We project that 1 percent of affected enrollees, that is, 17,000 enrollees, will request an immediate review. We estimate that it will take 5 minutes (average) for an enrollee who chooses to exercise his or her right to an immediate review to contact the QIO. For these 17,000 cases, the total estimated enrollee burden is 1,417 hours.

As specified in §422.622(c) and (d), Medicare health plans are required under this rule to deliver a DND to the enrollee and to make a copy of that notice and any necessary supporting documentation available to the QIO (and to the enrollee upon request). Plans were responsible for providing the NODMAR when an enrollee disagreed with the discharge or he or she was being moved to a lower level of care. Therefore, we believe that the DND essentially replaced the time associated with filling out and delivering the old NODMAR. We originally estimated that it would take 30 minutes to prepare and deliver the old NODMAR. We believe that, in addition to the time it took to complete the old NODMAR, an extra 60 minutes is needed for filling out and delivering the DND.

Therefore, we estimate that it takes plans 90 minutes to prepare the DND and to prepare a case file for the QIO. Based on an estimate that one percent of the 1.7 million enrollees admitted as inpatients each year would appeal their discharge decision, or 17,000 cases, the total annual burden associated with this requirement is approximately 25,500 hours.

The aggregate annual cost associated with this burden is $916,725.

Notifying enrollees of terminations of provider services §422.624

Section 422.624 sets forth the requirements for notifying enrollees when their SNF, HHA, or CORF services are being terminated. These procedures require that the provider deliver generally no later than two days before the termination of services, a standardized advance termination notice that informs enrollees of the date of termination and how to file an appeal. We estimate that it should take no more than 15 minutes to deliver the standardized notice to an estimated 2,060,277 enrollees, for an annual burden of 515,069 hours or 769 hours per MA organization.

Fast Track appeals of service terminations to the IRE §422.626

An enrollee who desires a fast-track appeal must submit a request for an appeal to the IRE, in writing or by telephone, by noon of the first calendar day after receipt of the written termination notice. We estimate that approximately 2 percent (13,900) of the 695,000 enrollees that receive a termination notice will appeal to the IRE. We therefore estimate that it will take MA organizations 60 to 90 minutes to gather and prepare a case file to send to the IRE. The total burden hours associated with this requirement between 13,900 and 20,850 hours.

The aggregate annual cost associated with this burden is $749,558 (based on a 90 minute timeframe).

Request for reconsideration (§ 422.650)

A request for reconsideration of a contract determination must be made in writing and filed with any CMS office within 15 days from the date of the notice of the initial determination. Based upon current experience this requirement is imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

The MA organization or MA contract applicant who filed the request for a reconsideration may withdraw it at any time before the notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with CMS. Based upon current experience this requirement is imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Request for hearing (§ 422.662)

A request for a hearing must be made in writing and filed by an authorized official of the applicant entity or MA organization that was the party to the determination under appeal. The request for a hearing must be filed with any CMS office within 15 days after the date of receipt of the notice of initial or reconsidered determination.

Based upon current experience this requirement is imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Disqualification of hearing officer (§ 422.668)

A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

Based upon current experience these requirements are imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Time and place of hearing (§ 422.670)

The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

Based upon current experience these requirements are imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Record of hearing (§ 422.686)

A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request. Based upon current experience these requirements are imposed pursuant to an administrative action against fewer than 10 organizations on an annual

basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Notice and effect of hearing decision (§ 422.690)

As soon as practical after the close of the hearing, the hearing officer issues a written decision that: (1) Is based upon the evidence of record, and (2) contains separately numbered findings of fact and conclusions of law. And, the hearing officer provides a copy of the hearing decision to each party. Based upon current experience these requirements are imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Effect of revised determination (§ 422.698)

The revision of an initial or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 422.662. Based upon current experience these requirements are imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Definitions (§ 422.2260)

This section defines the marketing materials that an MA organization must provide to Medicare beneficiaries. While there is burden associated with this requirement, the burden is exempt from the Paperwork Reduction Act of 1995 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.

Review and distribution of marketing materials (§ 422.2262)

(a) At least 45 days before the date of distribution of marketing materials, the MA organization must submit the material or form for review under guidelines in § 422.2264 of Title 42 of the CFR. This may require the development of written marketing materials used to promote an organization, provide enrollment information, explain benefits, rules, or various membership operational policies.

The burden associated with this requirement 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.

(b) MA organizations must certify that in the case of marketing materials designated by CMS, they followed all applicable marketing guidelines or, when applicable, 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 it is exempt from the requirements of the Paperwork Reduction Act of 1995.

Guidelines for CMS review and notification (§ 422.2264)

As part of the review of marketing materials under § 422.2262 of Title 42 of the CFR, MA

organizations must provide adequate written descriptions of rules, 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. In addition MA organizations must 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.

The burden associated with this requirement is the time and effort put forth by the MA organization to provide such materials and to notify the general public of its enrollment period. While there is a burden associated with these requirements, we believe they are exempt from the requirements of the Paperwork Reduction Act of 1995 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.

Standards for MA organization marketing (§ 422.2268)

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

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

Licensing of marketing representatives and confirmation of marketing resources (§ 422.2272)

(b) 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 a burden associated with this requirement, we believe the burden is exempt from the Paperwork Reduction Act of 1995 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.

Broker and agent commissions and training of sales agents (§ 422.2274)

(b) An MA organization that markets through independent agents and brokers must train and test agents selling Medicare products concerning Medicare rules and regulations specific to the plan products they intend to sell.

The burden associated with this requirement is the time and effort put forth by the MA organization to provide training and test agents. While there is a burden associated with this requirement, we believe the burden is exempt from the requirements of the Paperwork Reduction Act of 1995 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.

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

(d) Section 422.2274(d) states that upon CMS' request, the organization must provide to CMS the information necessary for it to conduct oversight of marketing activities. Specifically, we are requiring all Medicare Advantage Plans to post revised compensation structures to brokers or agents that conform precisely to our regulations and guidance. We are further requiring organizations to submit their 2006 through 2009 compensation structures to CMS. In addition to the compensation structures, every complete submission must include a signed certification from the organization's CEO or CFO (or other authorized senior official). Upon CMS request, an MA organization must provide CMS the information necessary to conduct oversight of marketing activities. This may include producing information for CMS on marketing materials submitted for review, file and use, and training or testing modules.

The burden associated with this requirement is the time and effort put forth by the MA organization to produce the information requested by CMS. The estimated average amount of time it would take one MA organization to comply with this requirement is 56 hours. We estimate that 670 MA organizations would affected annually by this requirement; therefore, the total annual burden associated with this requirement is 37,520 hours. Listed below is a detailed burden analysis.

Completing Attachment 1 through 3 for organizations w health plans in 2006 will take 48 hours. We assume that all the plans who can avail themselves to Option One will do so.
1 hour -- complete and submit CEO signatures on Attachments 1a and 1b.
5 hours – collect and submit compensation structures required under Attachments 2a and 2b
10 hours – collect and submit names of marketing contracting organizations, as well as counts of agents, by schedule under Attachments 2a and 2b.
2 hours – calculate and submit Year 2009 renewal schedules using Option One.
15 hours – derive values for actual initial compensations for years 2006 through 2008.
15 hours – derive values for expected compensation to be paid over life of schedule for years 2006 through 2008.
48 hours – TOTAL BURDEN

Completing Attachment 1 through 3 for organizations w new health plan types in 2007 will take 54 hours.
1 hour -- complete and submit CEO signatures on Attachments 1a and 1b.
5 hours – collect and submit compensation structures required under Attachments 2a and 2b
10 hours – collect and submit names of marketing contracting organizations, as well as counts of agents, by schedule under Attachments 2a and 2b.
16 hours – calculate and submit Year 2009 renewal schedules using Option Two.
10 hours – derive values for actual initial compensations for years 2007 through 2008.
10 hours – derive values for expected compensation to be paid over life of schedule for years 2007 through 2008.
54 hours TOTAL BURDEN

Completing Attachment 1 through 3 for organizations w new health plan types in 2008 will take 44 hours.
1 hour -- complete and submit CEO signatures on Attachments 1a and 1b.
5 hours – collect and submit compensation structures required under Attachments 2a and 2b
10 hours – collect and submit names of marketing contracting organizations, as well as counts of agents, by schedule under Attachments 2a and 2b.
16 hours – calculate and submit Year 2009 renewal schedules using Option Two.

5 hours – derive values for actual initial compensations for year 2008.
5 hours – derive values for expected compensation to be paid over life of schedule for year 2008.
44 hours TOTAL BURDEN

Completing Attachment 1 through 3 for organizations w new health plan types in 2009 will take 32 hours.
1 hour -- complete and submit CEO signatures on Attachments 1a and 1b.
5 hours – collect and submit compensation structures required under Attachments 2a and 2b
10 hours – collect and submit names of marketing contracting organizations, as well as counts of agents, by schedule under Attachments 2a and 2b.
16 hours – calculate and submit Year 2009 renewal schedules using Option Two.
32 hours TOTAL BURDEN

For MA plans, to fulfill this requirement the average burden would be 56 hours, for a total burden across all MA contracts of 37,520 hours. The cost would be $54.98 X 37,520 hours, for a total cost of $2,062,849.

(e) MA organizations must comply with state requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct.

The burden associated with this requirement is the time and effort put forth by the MA organization to comply with the state requests for information. While there is burden associated with this requirement, the burden is exempt from the requirements of the Paperwork Reduction Act of 1995 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.

13. Capital Costs

Not applicable. The entities that will offer coverage are ongoing health organizations and should have no or minimal total capital, startup, operational or maintenance costs resulting from this collection of information. .

14. Cost to the Federal Government

The annualized cost associated with implementation of the specific MA requirements to the MAOs is referenced in separate PRA packages. The cost to the Federal Government is $0.

15. Program/Burden Changes

This submission is a revision of the currently approved information collection request (ICR) and reflects an increase in the annual burden estimate due to program growth associated with the Title II MMA requirements and regulatory changes to the MA program. In addition, we revised the ICR to include the burden associated with the requirements contained in 42 CFR 422.2274(d). The implementation of this burden requirement is discussed in CMS-4138-IFC2.

16. Publication and Tabulation Dates

Generally there are no publication or tabulation dates. However, as part of the National Medicare Information Program, in connection with the annual election period in November of each year, information collected from MA organizations will be published in the Medicare Handbook and on the Internet. The schedule for the annual notices issued by CMS containing information regarding available choices for Medicare coverage is outlined in §422.64.

17. Expiration Date

This information collection contains very few forms; specifically, the forms are associated with the information collection requirements contained in §422.2274. Where applicable, CMS will display the expiration dates on the forms.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

Not applicable.