Supporting Statement Part A
Medicare Advantage Program and Supporting Regulations
CMS-R-267, OMB 0938-0753

Background

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

This section mentions four contributing factors to this package.

I. The original 2005 final rule which accompanied CMS-R-267
II. Corrections of numerous errors in the 2013 version of CMS-R-267
III. Final rule (CMS-4182-F, RIN 0938-AT08), published April 16, 2018 (83 FR 16440)
IV. Proposed rule CMS-4185-P (RIN 0938-AT59), published November 1, 2018 (83 FR 54982).

I: In the 2005 final rule we revised several areas of the Medicare Advantage (MA) and Prescription Drug Benefit programs. The MA changes affect specifically 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.

II: This 2017 collection corrects numerous errors and form from the 2013 collection including the following:

- Two sections per provision vs. one: The 2013 collection scored dollar cost and hour cost separately in two sections. First, this was confusing since the reader had to review two sections for each provision. Additionally, the two sections in arriving at total cost (total dollars x total hours) misquoted the other section resulting in errors. Furthermore, at times there were omissions (citations were made without any defense of the numbers in the other section). The 2017 version scores each provision once.
- Narrative vs bullet and table: The 2013 collection used a narrative format to score making it hard for the reader to quickly locate items. This narrative format was replaced by a bullet format at the end of each provision scoring the provision. Additionally, a summary table was placed at the end.
- Numerical errors: The 2013 collection had numerical (mathematical) errors which have all been corrected.
- Cross-referencing other OMB packages: The 2013 collection ignored ongoing paper reduction work packages in other areas. In this 2017 collection, proper referencing to other OMB packages are made and duplicative calculations are eliminated.
- Voluntary marketing: While preparing the 2017 collection it was discovered that the voluntary marketing provisions had never been scored in any OMB package, neither previous versions of CMS-R-267 nor other packages. This came as a complete surprise. This omission was complicated by the fact that the NPRM, CMS-4182-P (RIN 0938-AT08), published Nov. 28, 2017, made changes to the voluntary marketing provision. This omission resulted in

numerous high-level internal discussions at CMS, between the division responsible for marketing and the Office of Strategic Operations and Regulatory Affairs (OSORA) on where and how to place the scoring (which OMB package). It was finally decided to group voluntary and mandatory marketing (for which there is an ongoing OMB package) together. Mandatory marketing provisions are scored in paper reduction act package, CMS-10260, OMB control number 0938-1051.

- NPRM, CMS-4182-P (RIN 0938-AT08): While updating this package, work on NPRM, CMS-4182-P (RIN 0938-AT08) published November 28, 2017 began. Changes to provisions in CMS-4182-P affected corresponding provisions in CMS-R-267.

The above mentioned factors delayed updating this 2017 package by close to a year past its expiration date. Additionally, certain minor (not time intensive) changes were made to CMS-R-267 such as grouping provisions by subpart, were also added.

III: This 2018 collection request subsumes revisions that are set out under CMS-4182-F (RIN 0938-AT08), published April 16, 2018 (83 FR 16440). A major task of the Part C and Part D programs is to provide ease of access to Original Medicare beneficiaries who wish to enroll in a Medicare Advantage Plan. In this regulatory proposal we further provide ease of access to beneficiaries by proposing to:

i) Add new provisions at § 422.60(g) which would allow CMS, in consultation with a state Medicaid agency, to implement passive enrollment procedures in situations where criteria identified in the regulation text are met. This change would impact under ten entities and would be exempt from PRA.

ii) Modify § 422.66 and 422.68 by codifying the requirements for default enrollment that are currently set out in subregulatory guidance, revising current practice to limit the use of this type of enrollment mechanism, and clarifying the effective date for ICEP elections. This would provide an MA organization the option to enroll its Medicaid managed care enrollees who are newly eligible for Medicare into an integrated Dual Eligible Special Needs Plan (D-SNP) administered by the same MA organization that operates the Medicaid managed care plan. We do not expect this change to have impact.

iii) Modify 422.60, 422.62, 422.68, to codify the requirements for open enrollment and disenrollment opportunities by eliminating the existing MADP and establishing a Medicare Advantage Open Enrollment Period (OEP). This new OEP revises a previous OEP which would allow MA-enrolled individuals the opportunity to make a one-time election during the first 3 months of the calendar year to switch MA plans, or disenroll from an MA plan and obtain coverage through Original Medicare. Although no new data would be collected, the burden associated with this requirement would be the time and effort that it takes an MA organization to process an increased number of enrollment and disenrollment requests by individuals using this OEP, which is first available in 2019. This burden will be estimated below.

IV: Proposed rule (CMS-4185-P, RIN 0938-AT59), published November 1, 2018 (83 FR 54982) responds to the amendment of Section 50311(b) of the Bipartisan Budget Act of 2018 which amends section 1859(f)(8) of the Act to stipulate that dual eligible special needs plans (D-SNPs)

meet certain new minimum criteria for Medicare and Medicaid integration. This integrations improves care coordination, quality of care, and beneficiary satisfaction while reducing administrative burden. This proposed regulation proposes new requirements in accordance with these amendments by:

i. Adding new provisions at §§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752 to establish minimum criteria for Medicare and Medicaid integration in D-SNPs. These provisions require D-SNPs to meet the integration criteria either by (1) covering Medicaid long-term services and supports and/or behavioral health services through a capitated payment from a state Medicaid agency; or (2) notifying the state Medicaid agency (or its designee) of hospital and skilled nursing facility admissions for at least one group of high-risk full-benefit dual eligible individuals, as determined by the state Medicaid agency.

ii. Modifying and adding §§ 422.560 – 562, 422.566, 422.629 – 634, 438.210, 438.400, and 438.402 to unify Medicare and Medicaid grievance and plan-level appeals processes for certain D-SNPs and affiliated Medicaid managed care plans. The unified processes would apply only to D-SNPs with exclusively aligned enrollment, where one organization is responsible for managing Medicare and Medicaid benefits for all enrollees. In such D-SNPs, enrollees will have simpler, more straightforward grievance and appeals processes. The proposed rules would take effect for 2021.

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.

A. 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 the Managed Care program. The Medicare, Medicaid, and SCHIP Benefits Improvement Act and Protection Act of 2000, P. L. 106-554 added requirements to the Managed Care program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P. L. 108-173) created the Medicare Advantage program.

A major goal of the Medicare Advantage program is to provide ease of access for Original Medicare beneficiaries who wish to enroll in a Medicare Advantage program. Certain

populations of beneficiaries such as the dually eligible population (those beneficiaries enrolled in both Medicaid and Medicare) have grown since the program was created and these populations require more flexibilities.

Proposed rule (CMS-4185-P, RIN 0938-AT59), published November 1, 2018 (83 FR 54982) responds to the amendment of Section 50311(b) of the Bipartisan Budget Act of 2018 which amends section 1859(f)(8) of the Act to stipulate that dual eligible special needs plans (D-SNPs) meet certain new minimum criteria for Medicare and Medicaid integration. This integrations improves care coordination, quality of care, and beneficiary satisfaction while reducing administrative burden. This proposed regulation proposes new requirements in accordance with these amendments by:

iii. Adding new provisions at §§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752 to establish minimum criteria for Medicare and Medicaid integration in D-SNPs. These provisions require D-SNPs to meet the integration criteria either by (1) covering Medicaid long-term services and supports and/or behavioral health services through a capitated payment from a state Medicaid agency; or (2) notifying the state Medicaid agency (or its designee) of hospital and skilled nursing facility admissions for at least one group of high-risk full-benefit dual eligible individuals, as determined by the state Medicaid agency.

iv. Modifying and adding §§ 422.560 – 562, 422.566, 422.629 – 634, 438.210, 438.400, and 438.402 to unify Medicare and Medicaid grievance and plan-level appeals processes for certain D-SNPs and affiliated Medicaid managed care plans. The unified processes would apply only to D-SNPs with exclusively aligned enrollment, where one organization is responsible for managing Medicare and Medicaid benefits for all enrollees. In such D-SNPs, enrollees will have simpler, more straightforward grievance and appeals processes. The proposed rules would take effect for 2021.

Proposed rule CMS-4182-P (RIN 0938-AT08), published Nov. 28, 2017, explains the need to use passive and default enrollment to create flexibilities for our dually eligible population which has grown in the last 12 years. The purpose of passive and default enrollment is to allow beneficiaries a smoother transition, thereby ensuring no delay or loss of services. Our partnership with Medicaid has resulted in a population of dually eligible beneficiaries who are in need of these flexibilities. Similarly, the creation of a new open enrollment period gives greater flexibility to beneficiaries who are dissatisfied with their Medicare Advantage plan to return sooner to Original Medicare.

2. Information Users

The information users of the regulations at 42 CFR 422 are i) the MA organizations, ii) CMS, and iii) applicants to MAOs.

Medicare Advantage (MA) organizations (formerly M+C organizations) and potential MA organizations (applicants) use the information collected based on the regulations at 42 CFR 422 to comply with the application requirements and the MA contract requirements. CMS uses the

information collected based on the regulations at 42 CFR 422 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 involves 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 (§422.60,64,66,74)
- Several collection requirements in 42 CFR part 422, now covered by other Paper Reduction Act packages, collect information electronically. This includes collection of outpatient data, submission of benefit packages and under final rule CMS-4182-F (RIN 0938-AT08) published April 16, 2018 (83 FR 16440) disclosure requirements.

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

Many of the provisions in 42 CFR 422 are done “as they occur”. This collection does not set out any daily, weekly, monthly, or annual requirements; rather this information is collected as needed. More specifically, as explained in the next section some information is collected more frequently and some information is only collected annually. 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 "as they occur" include i) enrollment, ii) disenrollment, iii) marketing, iv) filing and all processing of grievances by enrollees, and v) notifications dependent on hospitalizations.

More specifically, except for the exceptions listed above, neither the Medicare Modernization Act, the added enrollment flexibilities proposed by CMS-4182-P (RIN 0938-AT08), nor requirements for Dual Special Needs Plans proposed by CMS-4185-P (RIN 0938-AT59):

- Require respondents to report information to the agency more often than annually;
- Require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Require respondents to submit more than an original and two copies of any document;
- Require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Make use of a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Require the use of a statistical data classification that has not been reviewed and approved by OMB;
- Includes a pledge of confidentiality that is not supported by authority established in statue or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Require respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect die information's confidentiality to the extent permitted by law.

8. Federal Register Notice/Outside Consultation

The November 1, 2018 (83 FR 54982), proposed rule (CMS-4185-P, RIN 0938-AT59) serves as the 60-day Federal Register notice.

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. . Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, and other matters that are commonly considered private.

Religious beliefs are not collected except in the following circumstances: i) For a beneficiary wishing to join a Religious Fraternal Plan (42 CFR 422.2) and ii) when an MA plan has conscientious objection to covering a procedure on religious grounds (42 CFR 422.206).

12. Burden Estimate (Total Hours & Wages)

Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Salary	Allowance for Fringe benefits	Cost per hour
Lawyer	23-1011	68.22	68.22	136.44
Software Developers and Programmers	15-1130	49.27	49.27	98.54
All other business operation specialists	13-1199	36.42	36.42	72.84
Office and Administrative Support Workers, All	43-9199	17.96	17.96	35.92

Other				

Wages for Individuals: To derive average costs for individuals, we used data from the May 2017 National Occupational Employment and Wage Estimates for our salary estimate. We believe that the burden will be addressed under All Occupations (occupation code 00-0000) at $24.34/hr since the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of employment, and educational attainment, etc.

Unlike our private sector adjustment to the respondent hourly wage, we are not adjusting this figure for fringe benefits and overhead since the individuals' activities would occur outside the scope of their employment.

Information Collection Requirements and Associated Burden Estimates

Subpart B of CFR 422, Eligibility, Election and Enrollment

Eligibility to elect an MA plan (§ 422.50)

To elect an MA plan an individual 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 or other CMS approved election method offered by the MA organization. The enrollment form and other election methods vary for each organization, but similar identifying information is collected.

The annual burden is estimated at

- ½ hour, the time for a prospective beneficiary to fill out an enrollment form, times
- 6,523,944, the number of new enrollments processed by MAOs in 2016, resulting in
- An annual burden of 3,261,972 hours with an associated cost to a business operation specialist to perform the task of
- 3,261,972 hours x $23.86 (minimum hourly wage) = $77,830,652.

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

Special needs plans (SNPs) must employ a process approved by CMS to verify the eligibility of each individual enrolling in the SNP.

The burden associated with this requirement is the time and effort put forth by the SNP to determine an applicant's eligibility for the SNP. We estimate it would take the SNP approximately 1/4 of an hour for each of the 153,000 beneficiaries estimated to request enrollment annually. The total annual burden is estimated at

- 1/2 hour per enrollment form, times
- 153,000 beneficiaries estimated to request enrollment annually, resulting in an annual

aggregate burden of

- 76,500 hours, with a consequent aggregate impact for a business operation specialist to perform the task of
- 76,500 hours x $23.86 (hourly wage of a business operations specialist) = $1,825,290.

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.

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) or the MA eligible individual's authorized representative and include authorization for disclosure and exchange of necessary information between CMS and the MA organization.

The burden associated with this requirement is the burden for beneficiaries to fill out enrollment requests. The burden for all beneficiaries is estimated

- 0.5 hour, the time we estimate it takes for an enrollee to fill out an enrollment form, times
- 6,523,944, the number of new enrollments processed by MAOs in 2016,
- Resulting in an annual burden of 3,261,972 hours (6,523,944 x 0.5 hours), with a consequent burden of $77,830,652 (3,261,972 x $7.25).

The MA organization must file and retain MA plan election forms, as well as records of MA enrollment requests made by any other enrollment request mechanism, for the period specified in CMS instructions

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

- 1/12 th of an hour (5 minutes) times
- 6,523,944, the number of new enrollments processed by MAOs in 2016,
- Resulting in an annual burden of 6,523,944 x 1/12=543,662 hours,
- Resulting in an annual cost of 543,662 hours x $34.66 (hourly wage of an administrative and support worker) = $18,843,325.

The MA Organization must submit beneficiary MA plan to CMS. It is estimated to take each MA organization 4 hours per month to electronically submit a subset of beneficiary MA plan enrollment elections to CMS. The total annual burden is estimated at

- 4 hours per month, per Medicare Advantage Organization, to electronically submit,

times
- 12 months per year, times
- 468 MAO contracts
- Resulting in an annual burden of 4 x 12 x 468 =22,464 hours
- Resulting in an annual cost of 22,464 hours x $69.08 (hourly wage of Business Operation Specialist) = $1,551,813.

The MA organization must give the beneficiary prompt written notice of acceptance or denial of the enrollment request 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 1/60th of an hour (1 minute) per application processed. The annual total burden is estimated at
- 1/60th of an hour (1 minute), to provide prompt notices, times
- 6,523,944 new enrollments processed by MAOs in 2016, resulting in
- An annual burden of 6,523,944/60 = 108,732 hours, resulting in
- An annual cost of 108,372 hours x $69.08 (hourly wage of a business operation specialist)=$7,511,207.

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 this section states that organizations receiving passive enrollments provide notification to beneficiaries describing costs and benefits of the plan and the process of accessing care under the plan. In recent years, we have received only 1 to 2 contract terminations a year where CMS allows passive enrollment. Under the limited expansion of passive enrollment authority to promote integrated care for dually eligible beneficiaries, we anticipate 4 additional instances in which CMS allows passive enrollment each year. The notifications are sent as a batch process from the parent organization.. Thus the burden associated with this provision affects less than 10 entities per year and therefore this requirement is not subject to the PRA as stipulated at 5 CFR 1320.3(c).

The Medicare Advantage Open Enrollment Period (OEP allows MA-enrolled individuals the opportunity to make a one-time election during the first 3 months of the calendar year to switch MA plans, or disenroll from an MA plan and obtain coverage through Original Medicare. The burden for all beneficiaries is estimated at 279,000 hours (558,000 beneficiaries x 0.5 hr) at a cost of $6,656,940 (279,000 hr x $23.86/hr) or $11.93 per beneficiary ($6,656,940 / 558,000 beneficiaries).

There are currently 468 MA organizations in 2017. Not all MA organizations are required to be open for enrollment during the OEP; however, for those that are, we estimate that this enrollment period would result in approximately 1,192 enrollments per organization (558,000 individuals / 468 organizations) during the OEP each year.

We estimate it would take approximately 5 minutes at $69.08/hr for a business operations specialist to determine eligibility and effectuate the changes for open enrollment. The burden for all organizations is estimated at 46,500 hours (558,000 beneficiaries x 5 min/60) at a cost of $3,212,220 (46,500 hr x $69.08(hourly wage of a business operation specialist)) or $6,864 per organization ($3,347,070 / 468 MA organizations).

Once the enrollment change is completed, CMS estimates that it will take 1 minute at $69.08 / hr for a business operations specialist to electronically generate and submit a notice to convey the enrollment or disenrollment decision for each of the 558,000 beneficiaries. The total burden to complete the notices is 9,300 hours (558,000 notices x 1 min/60) at a cost of $642,444 (9,300 hr x $69.08/hr) or $1.15 per notice ($642,444 / 558,000 notices) or $1,373 per organization ($642,444 / 468 MA organizations).

The burden associated with electronic submission of enrollment information to CMS is estimated at 1 minute at $69.08/hr for a business operations specialist to submit the enrollment information to CMS during the open enrollment period. The total burden is estimated at 9,300 hours (558,000 notices x 1 min/60) at a cost of $642,444 (9,300 hr x $69.08/hr) or $1.15 per notice ($642,444 / 558,000 notices) or $1,373 per organization ($642,444 / 468 MA organizations).

Additionally, MA organizations will have to retain a copy of the notice in the beneficiary's records. The burden associated with this task is estimated at 5 minutes at $34.66/hr for an office and administrative support worker to perform record retention for the open enrollment period. In aggregate we estimate an annual burden of 46,500 hours (558,000 beneficiaries x 5 min/60) at a cost of $1,611,690 (46,500 hr x $34.66/hr) or $3,444 per organization **(**$1,611,690 / 468 MA organizations).

We estimate a total annual burden for all MA organizations resulting from this proposed provision to be 111,600 hours (46,500 hr + 9,300 hr + 9,300 hr + 46,500 hr) at a cost of $6,108,798 ($3,212,220 + $642,444 + $642,444+$1,611,690). Per organization, we estimate an annual burden of 238 hours (111,600 hr / 468 MA organizations) at a cost of $13,053 ($6,108,798/ 468 organizations). For beneficiaries we estimate a total annual burden of 279,000 hours at a cost of $2,022,750 and a per beneficiary burden of 30 min at $3.63

The total burden to MA plans of 422.60 is 786,458 hours (543,662 + 22,464 + 108,732 + 111,600) at a total cost of $34,015,143 (18,843,325+1,551,813+7,511,207+6,108,798).

The total burden to beneficiaries wishing to enroll in MA plans is estimated at 3,540,972 hours (3,261,972+279,000) at an annual cost of $25,672,047 ($23,649,297+$2,022,750).

Although we received some comments on the preamble, none of them affect the provision and we are therefore finalizing our proposal as is.

The following lists required information to be collected from the beneficiary for enrollment into a Medicare Advantage Plan

Per 42 CFR §§ 422.53 and 422.60, individuals who meet the eligibility criteria may enroll in a Medicare Advantage (MA) plan, and requests for enrollment must comply with CMS instructions and be approved by CMS. CMS permits multiple ways in which a beneficiary can submit an enrollment request to the MA organization of his or her choice, such as paper, telephonic and electronic. In all instances the MA organization is required to determine eligibility for enrollment based on the required collection of information.

While each MA organization develops their own enrollment collection (or "form"), the guidance in Chapter 2 of the Medicare Managed Care Manual outlines the items required to be collected for each enrollment request. These items are required for the MA organization to determine if the beneficiary is eligible for plan enrollment per statutory and regulatory requirements and to submit the enrollment transaction to CMS. The following chart outlines the data to be collected for the enrollment request to be valid and processed. It also includes items asked (but beneficiary not required to answer) to aid the MA organization in efficiently processing the request and setting up beneficiary preferences for services.

Data Elements Required for MA plan enrollment		**Required to be Asked?**	**Response Required?**	**Reason for Collection**
	Required for enrollment eligibility per law and regulation			
1	Beneficiary name	Yes	Yes	Required so that MA organization can identify the correct beneficiary in CMS' systems and properly process the enrollment request.
2	Permanent residence address (with the exception of "County" – see below)	Yes	Yes	Required for MA organization to determine if beneficiary resides in the plan's services area.
3	Beneficiary's Medicare Number	Yes	Yes	Required for the MA organization to identify the correct beneficiary in CMS' systems and verify enrollment in both Part A and Part

Data Elements Required for MA plan enrollment		Required to be Asked?	Response Required?	Reason for Collection
				B.
4	Response to question regarding if beneficiary has ESRD	Yes	Yes	Required for the MA organization to determine if beneficiary eligibility for enrollment based on restrictions of ESRD enrollments.
5	Beneficiary agrees to abide by the rules of the MA organization. This includes: • Understanding of requirement to continue to keep Medicare Parts A&B • Agreement to abide by MA plan membership rules (pay premiums timely, see network providers, etc.) • Consent to disclosure and exchange of information necessary for operation of MA program • Understanding that he/she can be enrolled in only one Medicare health plan and that enrolled in the MA plan automatically disenrolls him/her from any other Medicare health plan and Rx drug plan • Understanding the right to appeal service and payment denials made by organization.	Yes	Yes	Required for the MA organization to determine that the enrollment request is complete per regulation.
6	Beneficiary signature	Yes	Yes	Required for the MA organization

Data Elements Required for MA plan enrollment		Required to be Asked?	Response Required?	Reason for Collection
	and/or authorized representative signature			to determine that the enrollment request was made by the beneficiary and is valid.
7	Date of signature	Yes	No[1]	Requested to aid MA organizations in determining if the election is valid.
8	Authorized representative contact information	Yes	Yes	Required for the MA organization to determine that the enrollment request is valid.
9	For Special Needs Plans (SNP), description of SNP eligibility criteria	Yes	Yes	Required for the MA organization offering a Special Needs Plan to determine eligibility for enrollment based on additional requirements for Special Needs Plans (chronic condition, dually eligible for Medicare and Medicaid, or institutionalized).
10	For Medical Savings Account (MSA) plans, all additional elements including proof that MSA bank account has been established. This includes: • Assurance that beneficiary will reside in U.S. for at least 183 days during the year • Beneficiary is not covered under another	Yes	Yes	Required for the MA organization offering the MSA plan to determine eligibility for enrollment.

[1] The beneficiary and/or legal representative should write the date he or she signed the enrollment form; however, if he/she fails to include the date on the enrollment form, then the stamped date of receipt that the MA organization places on the enrollment form may serve as the signature date of the form. Therefore, the signature date is not a necessary element. For employer group MA enrollments outlined in Ch. 2 of the Medicare Managed Care Manual, the "signature date" is the date the employer's process was completed as recorded.

Data Elements Required for MA plan enrollment		Required to be Asked?	Response Required?	Reason for Collection
	health benefit program (Federal Employee Health Benefit, Veterans Administration, the Department of Defense, or Medicaid • Beneficiary does not receive health benefits that cover part or all of the annual MSA plan deductible (could be retiree coverage, other coverage, supplemental insurance policies) • Beneficiary receiving hospice benefits.			
11	For MA organizations offering employer/union health plan coverage, employer or union name and group number	Yes	Yes	Required for MA organization to determine eligibility for enrollment into an employer group sponsored MA plan.

Data Elements Required for MA plan enrollment		Required to be Asked?	Response Required?	Reason for Collection
12	For enrollment requests the MA organization receives outside of the Annual Election Period, beneficiary attestation of being in a valid enrollment period. This includes indicating if beneficiary meets certain situations to permit enrollment at the time of the request and in some cases, dates of situations. (e.g., person changed permanent residence)	Yes	No	Law and regulations require that enrollments occur only in prescribed enrollment periods. Response aids MA organization in determining eligibility for enrollment at the time the request is received. In the event the beneficiary does not provide a response, MA organization can use CMS systems data to determine eligibility. Lack of response or data information can result in denial of enrollment request.
13	For MA organizations who offer a shortened enrollment "form" for beneficiaries selecting a different MA plan within the same MA organization, information regarding which MA plan the beneficiary is currently a member of and to which MA plan the beneficiary is changing	Yes	Yes	In this case, the MA organization already has much of the information required due to the existing enrollment in another of their MA plans. Required so that MA organization can easily identify the correct beneficiary in its systems and to determine if the beneficiary is eligible to use the shortened enrollment mechanism or needs to provide additional required information.
	Additional information required for MA organization to submit enrollment transaction to CMS			
14	MA plan name[2]	Yes	Yes	Required so that MA organization knows which plan the beneficiary wants to enroll. Most MA

[2] If enrollment mechanism will be used for multiple plans, all plan names must be listed in a way that permits the applicant to clearly indicate his/her plan choice.

Data Elements Required for MA plan enrollment		Required to be Asked?	Response Required?	Reason for Collection
				organizations offer multiple plans and some have additional eligibility requirements based on the MA plan type.
15	Beneficiary gender	Yes	Yes	Required so that MA organization can identify the correct beneficiary in CMS' systems and properly process the enrollment request.
16	Beneficiary date of birth	Yes	Yes	Required so that MA organization can easily identify the correct beneficiary in CMS' systems and properly process the enrollment request.
	Required and optional items the MA organization may ask, but not required to be answered by beneficiary			
17	County	No	No	Requested to aid MA organization in determining if beneficiary permanently resides in plan's service area, when zip code occurs in more than one county.
18	Mailing address	Yes	No	Requested to provide the beneficiary an option to have their written communications from the MA organization be delivered to an address that is not his or her permanent address. Some rural areas only deliver mail to P.O. Boxes, and helpful for beneficiaries with legal/authorized representatives.
19	Beneficiary telephone number(s)	Yes	No	Requested to aid MA organization in communicating with

Data Elements Required for MA plan enrollment		Required to be Asked?	Response Required?	Reason for Collection
				beneficiary via his or her preferred method. Also aids in circumstances where the enrollment request is missing required information and MA organization needs to contact beneficiary to obtain it.
20	E-mail address	No	No	Aids MA organization in communicating with beneficiary via his or her preferred method.
21	Option to request materials in language other than English or in other alternate formats (e.g., Braille, large print, etc.)	Yes	No	Aids MA organization in communicating with beneficiary via his or her preferred method.
22	Name of person to contact in emergency, including phone number and relationship to beneficiary	No	No	Aids MA organization in contacting beneficiary-selected individual in case of emergency. This is especially helpful for beneficiaries with legal/authorized representatives.
23	Additional Medicare information contained on Medicare card, or copy of card (e.g., Part A and Part B start dates, name as it appears on card)	No	No	Aids beneficiaries in providing their Medicare number. Many beneficiaries find it helpful to see a picture of their Medicare card in order to provide his or her Medicare information.
24	For MA plan with premiums, selection of plan premium payment option	Yes	No	Requested to aid MA organization in efficiently processing how the beneficiary wishes to pay their premiums (e.g., automatic payment, withholding from Social Security or Railroad Retirement

Data Elements Required for MA plan enrollment		Required to be Asked?	Response Required?	Reason for Collection
				benefit, direct bill). Lack of response results in beneficiary being placed in direct billing.
25	Information related to residing in a long term care facility and facility information, if applicable	No	No	Requested to aid MA organization in efficiently coordinating care for beneficiary and establishing special services (e.g., health assessments for institutionalized individuals, etc.)
26	Other insurance coordination of benefits information (e.g., other commercial coverage, Veterans Administration, TRICARE, etc.)	Yes	No	Requested to aid MA organization in determining proper payer for services while beneficiary is member of plan.
27	For MA organizations offering employer/union health plan coverage, annotation of whether beneficiary is retiree, including retirement date and name of retiree (if not the beneficiary)	No	No	Requested to aid MA organization to determine if beneficiary is part of employer/union group and determining proper payer for services.
28	For MA organizations offering employer/union health plan coverage, information regarding if spouse or dependents are covered under the plan and name of spouse or dependents, if applicable	No	No	Requested to aid MA organization to determine if beneficiary is part of employer/union group and determining proper payer for services.
29	For MA organizations offering employer/union health plan coverage,	No	No	Requested to aid MA organization to determine if beneficiary is part of employer/union group and

Data Elements Required for MA plan enrollment		Required to be Asked?	Response Required?	Reason for Collection
	information regarding if beneficiary is currently a member of the plan and plan identification number, if applicable			determining proper payer for services.
30	Name of chosen primary care physician, clinic or health center	No	No	Requested to aid MA organization to efficiently process the beneficiary's choice of preferred provider, if the MA plan requires a selection within their provider network.

The following lists required information to be collected from the beneficiary for disenrollment from a Medicare Advantage Plan

Per 42 CFR 422.66, a beneficiary can disenroll from a Medicare Advantage (MA) plan by enrolling in another plan or making a disenrollment request to the MA plan or other approved ways established by CMS (e.g., calling 1-800-MEDICARE). Any new requests for enrollment to leave a MA plan or disenrollment requests must occur during a prescribed enrollment period. In instances where the beneficiary requests disenrollment directly from the MA plan, the MA organization is required to determine eligibility for disenrollment based on the required collection of information. In instances where the beneficiary requests disenrollment by making a new enrollment request into a different plan, the MA organization that received the enrollment request will determine eligibility for enrollment, and if approved, the switch will automatically disenroll the beneficiary from their prior MA plan.

While each Medicare Advantage (MA) organization develops their own disenrollment collection (or "form"), the following items are required to be collected for a disenrollment request made by the beneficiary directly to the MA plan. These items are required for the MA organization to determine if the beneficiary is eligible for plan disenrollment per statutory and regulatory requirements and to submit the enrollment transaction to CMS. The following chart outlines the data to be collected for the disenrollment request to be valid and processed. It also includes items asked (but beneficiary not required to answer) to aid the MA organization in efficiently processing the request.

Data Elements Required for MA plan disenrollment		**Required to be Asked?**	**Response Required?**	**Reason for Collection**
1	Beneficiary name	Yes	Yes	Required so that MA organization can identify the correct beneficiary in its and CMS' systems and properly process the disenrollment request.
2	Beneficiary's Medicare Number	Yes	Yes	Required for the MA organization to identify the correct beneficiary in its and CMS' systems to submit the disenrollment transaction to

Data Elements Required for MA plan disenrollment		Required to be Asked?	Response Required?	Reason for Collection
				CMS.
3	Beneficiary gender	Yes	Yes	Required so that MA organization can identify the correct beneficiary in CMS' systems and properly process the disenrollment request.
4	Beneficiary date of birth	Yes	Yes	Required so that MA organization can easily identify the correct beneficiary in CMS' systems and properly process the disenrollment request.
5	Beneficiary telephone number	Yes	No	Requested to aid MA organization in circumstances where the disenrollment request is missing required information and MA organization needs to contact beneficiary to obtain it.
6	Language related to impacts of disenrollment. This includes a statement of beneficiary understanding that: • Enrolling in another plan will cancel the membership in the MA plan as if the date the coverage in the new plan starts • Beneficiary may not be able to enroll in another	No	No	Encouraged for the MA organization to convey ramifications of disenrollment to beneficiary. Signature in element #7 serves as indication that beneficiary understands ramifications.

Data Elements Required for MA plan disenrollment		Required to be Asked?	Response Required?	Reason for Collection
	plan at this time • If the MA plan includes Part D coverage and beneficiary wants Part D coverage later, beneficiary may be subject to a late enrollment penalty			
7	Beneficiary signature and/or authorized representative Signature	Yes	Yes	Required for the MA organization to determine that the disenrollment request was made by the beneficiary and is valid.
8	Date of signature	Yes	No[3]	Requested to aid MA organizations in determining if the disenrollment request is valid.
9	Authorized representative contact information	Yes	Yes	Required for the MA organization to determine that the disenrollment request is valid.
10	For disenrollment requests the MA organization receives outside of the Annual Election Period, beneficiary attestation of being in a valid enrollment period. This includes indicating if beneficiary meets certain situations to permit disenrollment at the time of the request and in some cases, dates of	Yes	No	Law and regulations require that disenrollments occur only in prescribed enrollment periods. Response aids MA organization in determining eligibility for disenrollment at the time the request is received. In the event the beneficiary does not provide a response, MA organization can use CMS systems data to determine eligibility. Lack of response or data information can

[3] The beneficiary and/or legal representative should write the date he or she signed the enrollment form; however, if he/she fails to include the date on the enrollment form, then the stamped date of receipt that the MA organization places on the enrollment form may serve as the signature date of the form. Therefore, the signature date is not a necessary element. For employer group MA enrollments outlined in Ch. 2 of the Medicare Managed Care Manual, the "signature date" is the date the employer's process was completed as recorded.

Data Elements Required for MA plan disenrollment		Required to be Asked?	Response Required?	Reason for Collection
	situations. (e.g., person changed permanent residence)			result in denial of disenrollment request.

Election of coverage under an MA plan (§ 422.62)

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, Medicare Advantage disenrollment period and special election periods.

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

Information about the MA program (§ 422.64)

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.

As part of the annual bid submission to CMS, each MAO submits benefit and cost-sharing information for each Plan Benefit Package (PBP). CMS uses this information to populate Medicare Compare which is used to provide to current and potential beneficiaries the information they need to make informed decisions with respect to the available choices for Medicare coverage. The burden associated with the PBP submission is contained in PRA package CMS R 262, OMB Control number 0938-0763,

In addition to the PBP submission, Medicare Compare draws data from Medigap files, State Pharmaceutical Assistance Program (SPAP) and the Part D pricing files. The information for Medigap and SPAP come from sources external to MAOs. However, each MAO offering part D must submit a Part D pricing file. We estimate that each Part D sponsor will spend 2 hours gathering and submitting the data to CMS. There are 468 MAOs. Most MAOs offer at least one Part D plan. However, the three MSAs are prohibited from offering Part D. The PFFS MAOs have the option to offer Part D or not but there are only six of them. So we assume 465 MAOs. Thus the annual burden is estimated at

- 2 hours, the time estimated to submit a Part D Pricing File, times
- 465 MAOs, an upper estimate for the number of Part D sponsors, resulting in

- An annual hourly burden of 2 x 465 = 930 hours, resulting in
- An annual cost of 930 x $69.08 (hourly wage of business operation specialist) = $64,244.

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 submitting an election form or other CMS approved enrollment mechanism to the organization.

An individual who wishes to disenroll from an MA plan may do so by 1) electing a different MA plan by submitting an enrollment request to another MA organization, 2) submitting a signed and dated request for disenrollment to the MA organization in the form and manner prescribed by CMS or, 3) calling 1-800-Medicare.

The burden associated with electing a different plan is included in §422.50. The burden associated with disenrolling is the time it takes for an enrollee to complete a disenrollment form or other CMS approved method. It is estimated that

- 162,000 enrollees will voluntarily disenroll times
- 0.0333 hours (2 minutes), resulting in an annual burden of
- 5400 hours the time it takes to complete a disenrollment form, resulting in
- An annual cost of 5400 x $23.86 (minimum hourly wage) = $128,844

The MA organization must submit each disenrollment transaction to CMS promptly. The burden associated with electronic submission of disenrollment information to CMS is estimated at

- 1 minute per disenrollment processed times
- 162,000 voluntarily disenrollees, resulting in an annual burden of
- 162,000 / 60 = 2,700 hours, resulting in
- An annual cost of 2,700 x $69.08 (hourly wage of business operations specialist)= $186,516.

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, except for emergency or urgently needed services or out-of-area dialysis services.

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. The annual burden is estimated at

- 162,000 voluntarily disenrollees, times
- 0.0166 hours (1 minutes), the time it takes to notify an enrollee, resulting in
- An annual burden of 162,000 / 60 = 2,700 hours, resulting in
- An annual cost of 2,700 x $69.08 (hourly wage of a business operations specialist) =

$186,516.

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 for each disenrollment record. The annual burden is estimated at

- 162,000 enrollees, voluntarily disenrollees, times
- 0.08333 hours (5 minutes), the time it takes to retain disenrollment records,
- Resulting in an annual burden of 162,000/12 =13,500 hours, resulting in
- An annual cost of 13,500 x $69.08 (hourly wage of a business operations specialist)= $467,910.

The total annual burden of § 422.66 is estimated at 18,900 hours (2700+ 2700 + 13,500) at an annual cost of $905,186 ($186,516+$186,516+$467,910) for plans and an annual hourly burden of 5,400 hours at an annual cost of $39,150 for enrollees.

Disenrollment by the MA organization (§ 422.74)

If the disenrollment is for any reason other than death, loss of entitlement to Part A or Part B, or lack of lawful presence in the United States, 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), and (b)(3) 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 OMB control number 0938-0763.

A MA organization may disenroll an individual from the MA plan for failure to pay any basic and supplementary premiums following a minimum 2-month grace period if the MA organization can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount and if the MA organization sends a written notice of nonpayment to the enrollee stating that nonpayment of premiums will result in disenrollment and providing information about the lock-in requirements of the MA plan.

The burden associated with this requirement is the time and effort necessary for the organization to effectuate the disenrollment and provide the beneficiary the disenrollment notice. We estimate that it will take a MA organization 5 minutes (0.083 hours) to submit the required transaction to CMS for each occurrence and 1 minute (0.017 hours) to assemble and disseminate the notice for each disenrollment. Thus the total time required for each disenrollment is 0.1 hours (6 minutes). We estimate that on an annual basis 13,500 individuals will be disenrolled for failure to pay plan premiums. Thus we estimate the total annual burden as

- 13,500 disenrollments for failure to pay plan premiums, times
- 0.1 hours (6 minutes), the time it takes notify CMS (5 minutes) and the enrollee (1 minute), resulting in an annual burden of 13,500 x 0.1 = 1,350 hours, resulting in

- Annual cost of 1,350 x $69.08 (hourly wage of business operations specialist)= $93,258.

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 and effort necessary for a MA organization to document and retain the documentation that meets the requirements set forth in this section. We estimate that it will take a MA organization 3 hours to capture and retain the required documentation for each occurrence. Based on actual experience, CMS receives approximately 1-2 total requests for involuntary disenrollment due to disruptive behavior annually. Thus, the burden to MA organizations is negligible and per 5 CFR 1320.3(c) not subject to PRA because it involves less than 10 entities per year.

An MA organization may request to cancel the enrollment of a member who knowingly provides, on the enrollment request form or by another enrollment request mechanism, fraudulent information that materially affects the determination of an individual's eligibility to enroll in the plan. The organization may also request to disenroll a member who intentionally permits others to use his/her enrollment card to obtain services or supplies from the plan or any authorized plan provider.

The burden associated with this requirement is the time and effort necessary for a MA organization to document and retain the documentation that meets the requirements set forth in this section. We estimate that it will take a MA organization 3 hours to capture and retain the required documentation for each occurrence. Based on actual experience, CMS receives approximately 1-2 total requests for involuntary disenrollment due to fraud annually. Thus, the burden to MA organizations is negligible and per 5 CFR 1320.3(c) not subject to PRA because it involves less than 10 entities per year.

The MA organization must disenroll a member from an MA plan if the MA organization contract is terminated or if the MA organization discontinues offering the plan or reduces its service area to exclude the member. The MA organization must give each affected Medicare enrollee a written notice of the effective date of the plan termination or service 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 below in § 422.506.

Thus the total burden for §422.74 is 1,350 hours at a cost of $93,258.

Subpart C of CFR 422, Benefits and Beneficiary Protections

Requirements relating to basic benefits (§422.101)

(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.

This information is given to the enrollees through the annual notice of change (ANOC) and Evidence of Coverage (EOC) documents annually presented to the enrollees. The burden with producing and delivering the ANOC and EOC is captured in PRA package CMS-10260, OMB control number 0938-1051.

(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. This burden is also captured in PRA package CMS-10260, OMB control number 0938-1051.

(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 Model of Care is submitted with MA application. Therefore the burden associated with this requirement is captured in the burden for SubPart K, §§422.500-422.527 Application Procedures and Contracts for Medicare Advantage Organizations.

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

MSAs fulfill this obligation of providing information on the cost and quality of services in their service area by creating and disseminating the Annual Notice of Change (ANOC) and the Evidence of Coverage (EOC) documents. The burden associated with production and dissemination of the ANOC and EOC is captured in PRA package CMS-10237, OMB control number 0938-0935.

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 of providing information on the cost and quality of services in their service area by creating and disseminating the Annual Notice of Change (ANOC) and the Evidence of Coverage (EOC) documents. The burden associated with production and dissemination of the ANOC and EOC is captured in PRA package CMS-10237, OMB control number 0938-0935.

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. Currently, CMS does not specifically collect POS data though it retains the right to so collect if it finds it necessary. Thus there is no current burden associated with this requirement.

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.

In the past few years the waiver process has been consolidated and we currently anticipate at most five waiver requests on an annual basis. As such, this requirement is not subject to the PRA as stipulated under 5 CFR 1320.3(c).

§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.

In the past few years the waiver process has been consolidated and we currently anticipate at mot five 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) Definition. For the purpose of this section, a contract with a State Medicaid agency means a formal written agreement between an MA organization and the State Medicaid agency documenting each entity's roles and responsibilities with regard to dual-eligible individuals.

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

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

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

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

(3) The Medicaid benefits covered under the SNP.

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

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

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

(7) The service area covered by the SNP.

(8) The contract period for the SNP.

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

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

(ii) Existing dual-eligible SNPs that do not have a State Medicaid agency contract—

(A) May continue to operate through the 2012 contract year provided they meet all other statutory and regulatory requirements.

(B) May not expand their service areas during contract years 2010 through 2012.

The burden associated with this requirement is the time and effort put forth by each Medicare Advantage organization (MAO) offering a dual eligible special needs plan (D-SNP) to have a contract with a state Medicaid agency. We estimate it would take one MAO offering a D-SNP 30 hours to comply with this requirement. We estimate 373 Dual Eligible SNPS, offered by 191 MAOs would be affected annually by this requirement. Therefore we estimate the burden as

- 373, the number of D-SNPs, times
- 30 hours, the time required per D-SNP to comply with the requirement, resulting in an annual hourly burden of 11,190 hours with a consequent annual aggregate cost of
- A total annual burden of 11,190 x $72.84 (hourly wage of a business operations specialist)= $815,080.

NEW BURDEN:

In CMS-4185-P (RIN 0938-AT59) we proposed the requirements for establish minimum criteria for Medicare and Medicaid integration in D-SNP at §§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752. Although no new data would be collected, the burden associated with this requirement has the following four components: The time and effort for

I. State Medicaid Agencies to update one-time their contracts
II. State Medicaid Agencies to update one-time their systems
III. Plans to update one-time their contacts
IV. Plans to update one-time their systems

I: One time update by State Medicaid Agencies to update their contracts: To update a contract, we estimate it would take 24 hours at $136.44/hr for a lawyer to update the state Medicaid agency's contract with every D-SNP in its market. Since half of the cost would be offset by

federal financial participation for Medicaid administrative activities, we have adjusted our estimates for State agencies by 50 percent. Given the market penetration of D-SNPs in certain states relative to others, we recognize that this estimate reflects an average cost across all states and territories with D-SNPs. We expect that the state Medicaid agency would establish a uniform requirement for all D-SNPs operating in their market. As of June 2018, there were 42 states, plus the District of Columbia and one territory (Puerto Rico), in which D-SNPs were available to MA enrollees.

We estimate a one-time first year burden of 24 hours per state at a cost of $136.44/hr x 0.50 (due to federal matching) for a lawyer to update the contract. In an aggregate, we estimate a burden of 1,056 (44 x 24 hr) hours and a cost of $72,040 (1,056 hrs x $136.44 x 0.50).

While we recognize that, over time, states could modify this contract term, for example, by expanding the population of full-benefit dual eligible individuals to whom this notification applies, we do not think that such a contract change would have a material impact on time and effort and, therefore, would already be accounted for in the burden estimate for the overall contract that the state Medicaid agency has with each D-SNP.

Given the lack of material impact and the uncertainty involved in estimating state behavior, we are estimating a minimum of zero burden in subsequent years on plans. The maximum burden would be the estimated first year cost. However, we believe the maximum estimate is unlikely to be accurate since we expect any changes to contracting requirements to be iterative compared to the first year update.

II: State Medicaid Agencies updating their software: To address differences among the states in available infrastructure, population sizes, and mix of enrollees, this rule proposes broad flexibility identifying the groups for which the state Medicaid agency wishes to be notified and how the notification should take place. Flexibilities include: (1) consideration of certain groups who experience hospital and SNF admissions; (2) protocols and timeframes for the notification; (3) data sharing and automated or manual notifications; and (4) use of a stratified approach over several years starting at a small scale and increasing to a larger scale. We would also allow states to determine whether to receive notifications directly from D-SNPs or to require that D-SNPs notify a state designee such as a Medicaid managed care organization, section 1915(c) waiver case management entity, area agency on aging, or other organization.

Some states, using a rich infrastructure and a well-developed automated system, may fulfill this requirement with minimal burden, while states with less developed or no infrastructure or automated systems may incur greater burden. Furthermore, the burden, especially to those states starting on a small scale, may differ significantly from year to year. Because of the flexibilities provided in this proposed rule, we expect states to choose strategies that are within their budget and best fit their existing or already-planned capabilities. We would expect any state choosing to receive notification itself of such admissions to claim federal financial participation under Medicaid for that administrative activity.

As of June 2018, there were 42 states, plus the District of Columbia and one territory (Puerto Rico), in which D-SNPs were available to MA enrollees. We estimate that there are nine states and territories with D-SNPs that all are expected to qualify as either FIDE SNPs or HIDE SNPs – Arizona, Florida, Hawaii, Idaho, Massachusetts, Minnesota, New Jersey, New Mexico, and Puerto Rico. We do not expect these states to establish a notification system under this proposal. We estimate that nine additional states that primarily use managed care for long-term services and supports (LTSS) (Michigan, North Carolina, New York, Ohio, Oregon, Pennsylvania, Tennessee, Texas, and Virginia) would delegate receipt of this information to their Medicaid managed care organizations. We further estimate that approximately half of the remaining 26 states – that is, 13 states – would build an automated system for receiving notification of hospital and SNF admissions consistent with this proposed rule.

We estimate that, on average, this work could be accomplished in a month with one programmer and one business analyst to define requirements. In making these estimates we assume half of the cost would be offset by 50 percent federal financial participation for Medicaid Administrative activities.

Accordingly, we estimate a one-time burden of a programmer working for 160 hours at $98.54/hr to build and program a notification system and a business analyst working for 160 hours at $72.84 an hour to define notification requirements for 13 states. The aggregate hourly burden is 4,160 hours (2,080 hr for a programmer + 2,080 hr for a business analyst) and at an aggregate cost is $178,236 ($102,482 for a programmer + $75,754 for a business analyst) for the update.

We believe that we have no reasonable way of estimating or illustrating burden in later years. The expected behavior among states is unknown relative to how often they will modify their notification mechanisms. Given the uncertainty involved in estimating state behavior, we are estimating a minimum of zero burden in future years on plans. The maximum burden would be the estimated first -year cost. However, we believe the maximum estimate is unlikely to be accurate since it would involve developing an automated notification system from the beginning rather than modifying an existing system.

III: Plans making a one-time update to contacts: For plans making contract modifications with state Medicaid agencies in the initial year, we expect it would take 8 hours at $136.44/hr for a lawyer to update their plan's contract with the state Medicaid agency. Since states are identifying the high-risk populations for which they wish to be notified, it is reasonable to project that every D-SNP contract would negotiate one contract modification with the state Medicaid agency. There are 190 D-SNP contracts as of June 2018, of which 37 contracts, or 12.7 percent (about one-eighth), are FIDE SNPs. We do not have a precise count of D-SNPs that will likely meet the proposed definition of a HIDE SNP. We assume another 12.7 percent of the 190 D-SNP contracts would be HIDE SNP contracts. Since the notification requirements are only applicable to D-SNPs that are not FIDE SNPs or HIDE SNPs, we expect that the number of contracts needing modification is 190 D-SNP contracts, less 37 FIDE SNP contracts, less 37 HIDE SNP contracts, or 116 D SNP contracts.

We estimate a one-time first year burden of a lawyer working at a wage of $136.44/hr each working for 8 hours. We estimate the aggregate burden is 928 hours (116 D-SNPs x 8 hr) at an aggregate cost of $126,616 (928 hr x $136.44/hr).

We believe that we have no reasonable way of estimating or illustrating burden in later years. The expected behavior among states is unknown relative to how often they will modify their contracts with D-SNPs on this particular matter. For example, state Medicaid agencies may remain satisfied with the initial year selection of high-risk groups and see no reason to modify their contracts in later years. In contrast, other state Medicaid agencies may seek to expand the notification requirement to encompass additional groups of high-risk dually eligible individuals and may therefore modify their contracts on this basis.

Given the uncertainty involved in estimating state behavior, we are estimating a minimum of zero burden in subsequent years on plans. The maximum burden would be the first year costs. However, we believe this estimate is unlikely to be accurate given our expectation that contractual changes after the first year would be iterative at most.

IV: Plans making a one-time update to their software: We have noted in CMS-4185-F the broad flexibility in notification options for states. We also note that MA organizations are already required to have systems that are sufficient to organize, implement, control, and evaluate financial and marketing activities, the furnishing of services, the quality improvement program, and the administrative and management aspects of the organization (§ 422.503(b)(4)(ii)). Independent of the state Medicaid agency's selection of high-risk populations, protocols, and notification schedules, an MA organization's most likely method of sharing this notification would be through the use of an automated system that could identify enrollees with criteria stipulated by the states and issue electronic alerts to specified entities. We do not believe that this work is very complex. Therefore, we estimate it could be accomplished in a month with one programmer and one business analyst to define requirements. The burden would be at the contract, not the plan, level and we estimate 116 affected D-SNP contracts.

Accordingly, we estimate a first year burden of a programmer working for 160 hours at $98.54/hr to build and program a notification system and a business analyst working for 160 hours at $72.84 an hour to define notification requirements for 116 D SNPs. The aggregate burden is (37,120 hours (18,560 hrs for a programmer and 18,560 hrs for a business analyst) at a cost $3,180,812 ($1,828,902 for a programmer + $1,351,910 for a business analyst).

Summary: The total burden to MA plans of the new provision at §422.107 is an aggregate hourly burden of 54,454 (11,190+ 1056+2080+2080+928+18,560+18,560)hours at an aggregate cost of $4,372,784 ($815,80+$72,040+$102,482+$75,754+$126,616+$1,828,902+$1,351,910).

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.

This information is disclosed through the Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents which are annually sent to all enrolled beneficiaries. The burden associated with production and dissemination of the ANOC and EOC is captured in PRA package CMS-10237, OMB control number 0938-0935.

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 § 422.111(d)(3). However, CMS no longer allows midyear changes in benefits since such a change would challenge the integrity of the bid. Thus CMS receives under 10 requests annually for change of rules. Consequently, this provision is exempt from the PRA as stated in 5 CFR 1320.3(c).

The plan must also give notice to all enrollees 30 days before the intended effective date of the changes. As just indicated, change of rules is currently very rare. Consequently, this provision is exempt from the PRA per 5 CFR 1320.3(c).

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 of creating an adequate network of providers capable of meeting CMS access standards is part of the Application process. The burden of the application process is captured in PRA package, CMS-10237, OMB control number 0938-0935. The additional burden of translating this network into a directory which is posted on the plan website as well as the update and maintenance of this directory is part of the usual and customary normal business activities and as such is exempt from PRA by 5 CFR 1320.3(b)(2).

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 8 hours to submit the materials to CMS for each non-contracting hospital that is requested to be an essential hospital. In the past few years only one Regional PPO makes these requests for about 30 hospitals. Consequently, this provision is exempt from the PRA per 5 CFR 1320(3) (c).

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 which are captured by the application process. The burden of the application process is captured in PRA package, CMS-10237, OMB control number 0938-0935

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).

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. The currently approved requirements encompass a larger universe of provider types than just managed care organizations. However, MAOs fulfill their obligation of notifying enrollees about advanced directive through the Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents annually distributed to enrolled beneficiaries. The burden of creating and disseminating the ANOC and EOC is captured in PRA package CMS-10260 and OMB control number 0938-1051.

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

- 40 hours, the time for completion and submission of an insolvency plan, times
- 468, the number of MAOs, resulting in an annual hourly burden of 18,720 hours, with a consequent annual aggregate cost of
- 18,720 x $69.08 = $1,293,178.

Subpart D of CFR 422, Quality Improvement Program

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

All 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 we will request the status and results of each organization's projects annually. 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.

§422.152(f) (4) –This section requires MA organizations' quality assurance programs to have a separate focus on racial and ethnic minorities.

The burden associated with all quality requirements is being captured in PRA packages CMS-10209 and CMS-10379.

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. CMS currently recognizes 10 approved accrediting organizations. 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 or on the average 16 hours per year 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 per year. Thus the total hours per year per deeming organization is 64 hours. Thus we estimate total burden as

- 64 hours, the time for initial application and annual updates, times
- 10, the number of deeming organizations, resulting in an annual aggregate burden of
- 640 hours, with a consequent annual aggregate cost of
- 640 x $71.98 (hourly wage for business operations specialist) = $46,067.

Subpart E of CFR 422, Relations With Providers

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).

Section 422.202(d)(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.

Section 422.202 (d)(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.

Nowadays, most MA organizations have no-cause clauses allowing the MA organization to terminate the provider without a statement of cause. Thus the only remaining 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.

To estimate this burden we note that MA organizations frequently terminate low numbers of providers, for example, providers who do not treat enrollees or providers about whom they have received substantive complaints. Because of technology, the MA organization can group-batch the terminations and have the notifications sent out automatically. Thus we estimate one termination per week. We further estimate that each termination requires 10 minutes, the time required to indicate the individuals or groups in an electronic list of providers that are being terminated. The notification itself would come from an electronically stored template and would require no additional burden.

Thus we estimate

- 50 batch terminations per year (one per week), by each of the
- 468 MA organizations, times
- 0.166 (10 minutes) to electronically identify the selected individuals or provider groups,
- Resulting in 3900 hours annual hourly burden, with a consequent annual aggregate cost of

- 3900 x $69.08 (hourly wage of a business operations specialist) = $269,412.

Section 422.204(e) requires that notifications take place at least 60 days prior to any termination. There is no additional burden in this 60 day requirement since the time and resources required for notification are the same.

Provider selection and credentialing (§ 422.204)

An MA organization must have written policies and procedures for the selection and evaluation of providers. These requirements include the requirement that the physician is licensed to operate in the state and that the physician's credentials are approved by an accrediting body or meet the standards established by the organization itself and several similar requirements.

CMS believes that these requirements of licensure and accreditation are business requirements that any insurer would require of staff providing services and do not reflect anything special about the Medicare program. Thus these requirements are reasonable and customary business practices and therefore the burden of meeting these requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2).

Provider antidiscrimination rules (§422.205)

The reporting requirement of this section requires that, if an MA organization declines to include, in its network a given provider or group of providers, acting within their scope of license and certification, it must furnish written notice to the affected provider(s) of the reason for the decision and may not base the decision solely on the basis of license and certification.

CMS believes these requirements relating to selecting staff are normal course of business activities that are usual and customary. There is no extra burden in requiring that such decisions not be based solely on the basis of license and certification. Therefore, the burden associated with these requirements is exempt from the PRA as defined in 5 CFR 1320.3(b) (2).

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 § 422.64.

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

- 0.5 hours (30 minutes) per notification, times
- 468 MA organizations, for a total of
- 234 hours on an annual basis, with a total cost of
- 234 x $69.08 (hourly wage of a business operations specialist) = $16,165.

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 6 PFFS contracts currently offering 52 MA PFFS plans, about 9 plans per PFFS organization. Although each plan has its own Terms and Conditions of payment (T&C), all the T&Cs are posted on the website owned by the PFFS contract. Since each contract will use a template T&C with information filled in from its systems, we do not believe there is considerable extra burden in producing 9 T&Cs versus 1. Since there are only 6 PFFS contracts the burden associated with producing the T&C is exempt from PRA per 5 CFR 1320.(3)(c)

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 1% of all MA PFFS plans will have one case per year. Since there are only 52 plans, it follows that the expected burden is under ten and typically zero. In fact, consistent with this estimate, CMS has not recently experienced such violations. Thus the burden associated with this provision is exempt from PRA per 1320(3) (c).

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.

Currently, all MA plans must submit EOMB or summary statements. The burden for submitting such EOMB statements for all MA plans is captured in PRA package CMS-10453, OMB control number 0938-1228.

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 there on average there will be 10 hospitalizations per plan per year with 80% of all hospitalizations requiring these notices. Furthermore, we expect the $500 tolerance to always be exceeded. We estimate that each notice requires 5 minutes. Thus the total annual burden is estimated at

- $1/12^{th}$ of an hour (5 minutes), the time to prepare and deliver the notice, times
- 80% x 52 plans x 10 hospitalizations per plan= 416 hospitalizations per year that would require such notices, resulting in an annual hourly burden of
- 35 hours with a consequent aggregate annual cost of
- 35 x $69.08(hourly wage of a business operations specialist) = $2,418 dollars.

Subpart F of 422, Submission of Bids, Premiums, and Related Information

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. The burden for submitting a bid is captured in PRA package CMS-R-262, OMB control number 0938-0263.

(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.

We currently have 3 MSA contracts with only 6 plans. Hence, the burden for this requirement is exempt from the PRA per 5 CFR 405.1320(3)(c).

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.

Nowadays, premiums and cost-sharing is typically done electronically significantly reducing the possibility of error. Thus we experience the application of this provision very rarely if at all. Hence, per 5 CFR 1320.3(c) this provision is exempt from PRA.

Subpart G of CFR 422, Payments to Medicare Advantage Organizations

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.

(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 for these provisions is captured in PRA package CMS-10062, OMB control number 0938-0878, which discusses the burden of the risk-adjustment provisions.

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.

There are currently 3 MSA contracts with 6 plans. Consequently, per 5 CFR 1320.3(c) this provision is exempt from the PRA.

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 Medicare managed care enrollees have elected the hospice option.

We estimate that informing beneficiaries about their hospice choices would take about ten minutes. Consequently the burden associated with this provision is estimated at

- $1/20^{th}$ of 1% of 18,584,920 = 9292, the number of MA enrollees expected to have elected hospice, times
- 0.1667 hours (10 minutes), resulting in a total annual hourly burden of

- 1,549 hours and a total annual cost of
- 1,549 x $69.08 (hourly wage of a business operations specialist) = $107,005.

Subpart I of CFR 422, Organization Compliance with State Law and Preemption by Federal Law

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).

The burden for complying with this provision is captured in the overall burden of applying to CMS. This burden is captured in PRA package, CMS-10237, OMB control number 0938-0935.

Subpart J of CFR 422, Special Rules for MA Regional Plans

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

Since the provisions at 422.458 only apply to contract years 2006 and 2007, they are not applicable today and there is no need to score them in the PRA.

Subpart K of CFR 422, Application Procedures and Contracts for Medicare Advantage Organizations

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. The burden associated with this requirement is captured in PRA package CMS-10237, OMB control number 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. The burden associated with this requirement is captured in PRA package CMS-10237, OMB control number 0938-0935.

(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.
The burden associated with this requirement is captured in PRA package CMS-10237, OMB control number 0938-0935.

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 –about 1 to 2 dozen notifications of non-renewal on an annual basis.

We estimate that the burden of notifying CMS is 2 hours per notification.

We estimate the burden associated with drafting and disseminating through mass mailings information of changes to affected beneficiaries would be 3 hours per plan.

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. Thus the total annual hourly burden is estimated at

- 2+3+4=9 hours, the time for notification to CMS, enrollees and the general public, times
- 468, the number of MAOs, resulting in an annual hourly burden of
- 4,212 hours, resulting in an aggregate cost of
- 4,212 x $69.08 (hourly wage of a business operations specialist) = $290,965.

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 than 10 notifications of modification or termination on an annual basis that would require notification of Medicare enrollees or the general public

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.

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.

Subpart L of CFR 422, Effects of Change of Ownership or Leasing of Facilities During Term of Contract

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 is currently captured under National Data Reporting Requirements, form CMS-906, OMB # 0938-0469.

Subpart M of CFR 422, Grievances, Organization Determinations and Appeals

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.

The burden for this requirement is captured in the estimation of the burden for **§422.564.**

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.

MA enrollees are currently notified about their rights to file a grievance and appeal through the Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents that they receive annually. The burden for production and dissemination of the ANOC and EOC is captured in PRA package in CMS-10260, OMB control #0938-1051.

NEW BURDEN:
In CMS-4185-P (RIN 0938-AT59), we proposed the requirements for all D-SNPs to assist enrollees with filing of their grievance or appeal as required in proposed § 422.562(a)(5). We did not calculate the burden of this requirement, as we are assuming that providing assistance is a usual and customary business practice that is exempt from the PRA (5 CFR 1320.3(b)(2)).

Grievance procedures (§422.564)

An enrollee dissatisfied with some aspect of the MA plan to which they belong has the right to file a grievance. MA organizations receiving an oral or written grievance are required to respond to it.

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.

Based on previous grievance requirements analysis (See 66 Fed. Reg. 7,593, 7600), we estimate that 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. Of those requests, we believe that approximately 10% of enrollees will request a follow-up written response.

We estimate that it will take MA organizations 15 minutes to prepare and furnish each written response

Consequently we estimate the total annual burden associated with this requirement at

- 1/4 hour, (15 minutes) the time to prepare a written response to an oral request, times
- 18,584,920, the number of expected MA enrollees, times
- 17%, the percent of enrollees who are dissatisfied, times
- 40%, the percent of dissatisfied enrollees who will file an oral or written grievance, times
- 60%, the percent of grievance filers who will request a grievance orally, times
- 10%, the percent of oral filers of grievances who request a follow up written response, time, resulting in an annual hourly burden of
- 18,957 hours, with
- An annual aggregate cost 18,957 hours x $69.08 (hourly wage of a business operations specialist) = $1,309,550.

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 provision will require 30 hours for each MAO to perform notifications. Thus the total annual hourly burden is estimated at

- 30 hours, the time required for the notifications to enrollees, times
- 468, the number of MAOs, resulting in a total annual hourly burden of
- 14,040 hours, resulting in an annual aggregate cost of
- 14,040 x $69.08 (hourly wage of a business operations specialist) =$969,883.

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. CMS estimates that approximately 1% of all MA enrollees will experience a denial. Thus we expect 1% x 18.5 million enrollees divided by 468 MA contracts or about 400 denials per contract for which a detailed decision must be provided. CMS further estimates each notification will take an average of 60 minutes

Thus, the aggregate annual cost associated with this burden is estimated at

- 1 hour, the time required for notifying enrollees about the denial and possible follow-up, times
- 185,849, 1% of the number of MA enrollees, the estimated number of enrollees requiring a written notice because of a denial, resulting in an annual hourly burden of
- 185,849 hours, with a consequent annual cost of
- $12,838,449 = 185,849 x $69.08 (hourly wage of a business operations specialist).

The total burden associated with 422.568 is 199,889 hours (14,040+185,849) at a cost of $13,808,332 (12,838,449+969,883)

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 all MA enrollees may make a request for an organization determination in a year, with an estimated burden of 2 minutes per request. The estimated notification burden associated with these requests is 5 minutes per request. Consequently, we estimate the total annual burden of this requirement at

- 0.1166 hours (7 minutes, the sum of 2 minutes for the organization determination and 5 minutes for the notification), times
- 20%*18,584,920 or 3,716,984, the number of enrollees requesting organization determinations, resulting in an annual hourly burden of
- 433,648 hours, with a consequent aggregate annual cost of
- 433,648 x $69.08 (hourly wage of a business operations specialist) =$29,956,404.

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
3% of enrollees requesting organization determinations will be provided with extension notices an annual basis. Each of these extension notices will take an average of 5 minutes per notification.

The aggregate annual MA organization cost associated with this burden is estimated at

- 0.0833 hours (5 minutes), the time required for enrollee notification, times
- 3%*20%*18,584,920 or 111,510, the number of enrollees receiving extension requests, times, resulting in an annual total burden of
- 9,292 hours , with a consequent annual aggregate cost of
- $641,891 = 9,292 x $69.08 (hourly wage of a business operations specialist).

Thus the total burden of 422.572 is 442,941 hours (433,648+9,292) at a cost of $30,598,295 ($29,956,404+$641,891).

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 an average of 30 minutes to add the language to its current letter for notifying beneficiaries. .

The aggregate annual cost associated with this burden is estimated at.

- 0.5 hours (30 minutes), the time required for adding language to form letters, times
- 468, the number of MAOs, resulting in an annual hourly burden of
- 234 hours, with a consequent aggregate annual cost of
- $16,165 = 234 x $69.08 (hourly wage of a business operations specialist).

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 - 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.

- 4 hours, the time required for dealing with a reconsideration, times
- 5%*20%*18,584,920 or 5%*3,716,984=185,489 the number of organization determinations reaching the reconsideration stage, resulting in an annual burden of
- 743,397 hours, resulting in an aggregate annual cost of
- $51,353,865 = 743,397 x $69.08 (hourly wage of a business operations specialist).

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 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.

The aggregate annual cost associated with this burden is estimated at

- 2 hours, the time required for forwarding a case to an independent entity, times
- 25%*185489=46,462, the number of reconsideration cases with a decision adverse to the enrollee, resulting in an annual hourly burden of
- 92,924 hours, resulting in an annual aggregate cost of
- $6,419,259 = 92,924 x $69.08 (hourly wage of a business operations specialist) for forwarding adverse reconsiderations of organization determinations to an independent entity.

The total burden of 422.490 is 836,321 hours (743,397+92,924) at an annual cost of $57,773,124 (51,353,865+6,419,259).

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 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 86% of 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 estimate that 20% of all MA enrollees will require inpatient care every year. We further estimate that 1 percent of the enrollees admitted for inpatient care, 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. Therefore the total annual burden is

- 0.0833 hours (5 minutes), the time required for an enrollee to contact the QIO, times
- 1%*20%*18,584,920=37,170, the number of enrollees admitted to inpatient hospitals who are expected to request reviews, resulting in an annual hourly burden of
- 3097 hours, with a consequent annual aggregate cost of
- $73,894 = 3097 x $23.86 (minimum hourly wage) for requesting an immediate review

from a QIO.

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. We estimate that 20% of all MA enrollees will require inpatient care every year. We further estimate that 1 percent of the enrollees admitted for inpatient care, will request an immediate review Therefore, we estimate total annual burden at

- 1.5 hours (90 minutes), the time required to complete, fill out and deliver the DND, times
- 1%*20%*18,584,920=37,170, the number of enrollees admitted to inpatient hospitals who are expected to appeal their discharge or being moved to a lower level of care, resulting in an annual hourly burden of
- 55,755 hours ,resulting in an annual aggregate cost of
- 55,755 x $69.08 (hourly wage of a business operations specialist) = $3,851,555.

Thus the total annual burden of 422.622 is 55,755 hours at an annual cost of $3,851,555 for plans and total annual burden of 3,097 hours at an annual cost of $22,457 to enrollees..

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 5 minutes to deliver the standardized notice; we further estimate that this 7.7% (1 in 13) of all MA enrollees will have their provider services terminated. Thus the total annual burden is estimated at

- 0.0833 hours (5 minutes), the time required to complete, fill out and deliver the standardized notice, times
- 7.69%*18,584,920=1,429,629, the number of enrollees experiencing terminations of SNF, HHA or CORF services, resulting in an annual hourly burden of
- 119,098 hours, with a consequent annual aggregate cost of
- $8,227,290 = 119,134 hours x $69.08 (hourly wage of a business operations specialist)

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 of MA 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 annual hourly burden associated with this provision based on a 90 minute timeframe) is

- 1.5 hours (90 minutes), the time required to complete, fill out and deliver the standardized notice, times
- 2%*7.69%*18,584,920=28,584, the number of enrollees experiencing terminations of SNF, HHA or CORF services who appeal to the IRE, resulting in an annual hourly burden of
- 42,875 hours (28,584 x 1.5 hours), with a consequent aggregate annual cost of
- 2,961,805 =42,875 hours x $69.08 (hourly wage of a business operations specialist)

NEW BURDEN: General requirements for applicable integrated plans (§ 422.629)

(a) Scope. The provisions in this section and in §§ 422.630 through 422.634 set forth requirements for unified appeals and grievance processes with which applicable integrated plans must comply.

(1) These provisions apply to an applicable integrated plan in lieu of §§ 422.564, 422.566(c) and (d), and 422.568 through 422.590 and §§ 438.404 through 438.424.

(b) General process. An applicable integrated plan must create integrated processes for enrollees for integrated grievances and for integrated organization determinations, and for integrated reconsiderations.

(c) State flexibilities. A State may, at its discretion, implement standards for timeframes or notice requirements that are more protective for the enrollee than required by this section and §§ 422.630 through 422.634. The contract under § 422.107 must include any standards that differ from the standards set forth in this section.
(d) Evidence. The applicable integrated plan must provide the enrollee a reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments for integrated grievances, integrated reconsiderations. The applicable integrated plan must inform the enrollee of the limited time available for presenting evidence sufficiently in advance of the resolution timeframe for appeals as specified in this section if the case is being considered under an expedited timeframe for the integrated grievance or integrated reconsideration.

(e) Assistance. In addition to the requirements in § 422.562(a)(5), the applicable integrated plan must provide an enrollee reasonable assistance in completing forms and taking other procedural steps related to integrated grievances and integrated appeals.

(f) Applicable requirements. The requirements in §§ 422.560, 422.561, 422.562, 422.566, and 422.592 through 422.626 apply to an applicable integrated plan unless otherwise provided in this section or in §§ 422.630 through 422.634.

(g) Acknowledgement. The applicable integrated plan must send to the enrollee written acknowledgement of integrated grievances and integrated reconsiderations upon receiving the request.

(h) Recordkeeping. (1) The applicable integrated plan must maintain records of integrated grievances and integrated appeals. Each applicable integrated plan that is a Medicaid managed care organization must review the Medicaid-related information as part of its ongoing monitoring procedures, as well as for updates and revisions to the State quality strategy.

(2) The record of each integrated grievance or integrated appeal must contain, at a minimum:

(i) A general description of the reason for the integrated appeal or integrated grievance.

(ii) The date of receipt.

(iii) The date of each review or, if applicable, review meeting.

(iv) Resolution at each level of the integrated appeal or integrated grievance, if applicable.

(v) Date of resolution at each level, if applicable.

(vi) Name of the enrollee for whom the integrated appeal or integrated grievance was filed.

(vii) Date the applicable integrated plan notified the enrollee of the resolution.

(3) The record of each integrated grievance or integrated appeal must be accurately maintained in a manner accessible to the State and available upon request to CMS.

(i) Prohibition on punitive action. Each applicable integrated plan must ensure that no punitive action is taken against a provider that requests an integrated organization determination or integrated reconsideration, or supports an enrollee’s request for these actions.

(j) Information to providers and subcontractors. The applicable integrated plan must provide information about the integrated grievance and integrated appeal system to all providers and subcontractors at the time they enter into a contract including, at minimum, information on integrated grievance, integrated reconsideration, and fair hearing procedures and timeframes as applicable. Such information must include:

(1) The right to file an integrated grievance and integrated reconsideration.

(2) The requirements and timeframes for filing an integrated grievance or integrated reconsideration.

(3) The availability of assistance in the filing process.

(k) Review decision-making requirements. (1) General Rules. Individuals making decisions on integrated appeals and grievances must take into account all comments, documents, records, and other information submitted by the enrollee or their representative without regard to whether such information was submitted or considered in the initial adverse integrated organization determination.

(2) Integrated grievances. Individuals making decisions on integrated grievances must be individuals who:

(i) Were neither involved in any previous level of review or decision-making nor a subordinate of any such individual.

(ii) If deciding any of the following, have the appropriate clinical expertise in treating the enrollee's condition or disease:

(A) A grievance regarding denial of expedited resolution of an appeal.

(B) A grievance that involves clinical issues.

(3) Integrated organization determinations. If the applicable integrated plan expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the integrated organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare and Medicaid coverage criteria, before the applicable integrated plan issues the integrated organization determination. Any physician or other health care professional who reviews an integrated organization determination must have a current and unrestricted license to practice within the scope of his or her profession.

(4) Integrated reconsideration determinations. Individuals making an integrated reconsideration determination must be individuals who:

(i) Were neither involved in any previous level of review or decision-making nor a subordinate of any such individual.

(ii) If deciding an appeal of a denial that is based on lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), are a physician or other appropriate health care professional who have the appropriate clinical expertise, in

treating the enrollee's condition or disease, and knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision.

(l) Parties. (1) The individuals or entity who can request an integrated grievance and integrated organization determination and integrated reconsideration are:

(i) The enrollee or his or her representative;

(ii) An assignee of the enrollee (that is, a physician or other provider who has furnished or intends to furnish a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service), or any other provider or entity (other than the applicable integrated plan) who has an appealable interest in the proceeding. If the provider is requesting an integrated reconsideration on behalf of an enrollee, the provider must provide notice to the enrollee. If the provider or authorized representative requests that the benefits continue while the appeal is pending, pursuant to § 422.632 and consistent with state law, the provider or authorized representative must obtain the written consent of the enrollee to request the appeal on behalf of the enrollee; or

(iii) The legal representative of a deceased enrollee's estate.

(2) When the term “enrollee” is used throughout this section, it includes providers that file a request and authorized representatives consistent with this paragraph, unless otherwise specified.

(3) The parties who can request an expedited integrated organization determination are—

(i) The enrollee (including his or her representative); or

(ii) A provider.

The implementing regulations of the PRA at 5 CFR 1320.4 exclude information collection activities during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. We conclude that a beneficiary’s appeal of an adverse integrated coverage determination as proposed in this rule, and the subsequent information collection activities necessitated by that integrated appeal – for example, acknowledgement of integrated reconsiderations at § 422.629(g), recordkeeping related to integrated appeals at § 422.629(h), are exempt from the PRA on the basis that an appeal is submitted in response to an administrative action against a specific individual. Therefore, this exemption would cover any information collection activities undertaken after the integrated organization determination by an applicable integrated plan. The cost of storage is not expected to change under § 422.629(h)(3) since D-SNPs are currently required to store records (§ 422.504(d)), and the provision would not impose any new or revised storage requirements or burden. The remaining burden associated with these requirements are captured under § 422.631.

NEW BURDEN: Integrated grievances (§ 422.630)

Under § 422.630(b), applicable integrated plans would be required to accept grievances filed at any time consistent with the Medicaid standard at § 438.402(c)(2)(i). This change would have the net effect of permitting enrollees to file a grievance for a Medicare-covered service outside of the current 60-day timely filing standard, as measured from the date of the event or incident that precipitated the grievance. The provision would effectively eliminate the timely filing period for Medicare-related grievances. We do not expect this proposal to increase the volume of grievances that an applicable integrated plan would be responsible for handling since we believe that the timeframes for filing Medicare grievances were designed to be consistent with current practice and were set in place only to eliminate complaint outliers. Furthermore, as detailed in CMS-4185-P even a four-fold increase in grievance volume would still have a negligible aggregate burden because of the small number of contracts in states that currently require exclusively aligned enrollment.

Under § 422.630(c), enrollees of applicable integrated plans could file integrated grievances with the plan orally or in writing, in alignment with current Medicare and Medicaid requirements, or with the state, in states that have existing processes for accepting Medicaid grievances in place in accordance with § 438.402(c)(3). Because this proposed provision simply extends an existing avenue for filing grievances, in states where it exists, for enrollees to file Medicaid benefits grievances with the state, we do not expect this proposal to increase the volume of grievances that either states or applicable plans would be responsible for handling.

Section 422.630(d) would permit an enrollee to file an expedited grievance, which is available under current law for Medicare-covered, but not Medicaid-covered, benefits. We estimate that the availability of an expedited grievance for Medicaid benefits would have a negligible impact on information collection activities because applicable integrated plans would already have procedures in place to handle expedited grievances for Medicare-covered services, which could be leveraged for Medicaid-covered services. Furthermore, the availability of the expedited resolution pathway (where under current law there is only one resolution pathway for Medicaid-covered services) would have no impact on the volume of grievances.

Section 422.630(e)(1) would require that an applicable integrated plan resolve a standard (non-expedited) grievance within 30 days consistent with the MA standard; under Medicaid, the timeframe is established by the state but may not exceed 90 calendar days from day the plan receives the grievance. We estimate that this change in timeframe would have a negligible impact on information collection activities because applicable integrated plans already have business processes in place to comply with a 30-day timeframe under MA.

Section 422.630(e)(2) would require the applicable integrated plan, when extending the grievance resolution timeframe, to make reasonable efforts to notify the enrollee orally and send written notice of the reasons for the delay within 2 calendar days. We do not believe that this provision would have more than a negligible impact on plans since this proposal adopts MA requirements for how an applicable integrated plan must notify an enrollee of an extension and

the Medicaid managed care requirement for the timeliness standard. Thus, applicable integrated plans would already have business processes in place to comply with these requirements.

Although we do not estimate cost impacts for applicable integrated plans related to information collection activities involved in unifying grievances associated with our proposed provisions at § 422.630, some of the individual provisions in §§ 422.630 and 422.631 would necessitate operational and systems changes on the part of applicable integrated plans, and others would result in savings to applicable integrated plans. We estimate both the burden and savings associated with changes to policies and procedures, record maintenance, grievance notice consolidations, and savings for our proposed integrated organization determination procedures at § 422.631 and integrated grievance procedures at § 422.630. The burden associated with these requirements are captured under § 422.631.

NEW: Integrated organization determinations (§ 422.631)

Applicable integrated plans are required to update policies and procedures to subject all requests for covered benefits to the same integrated organization determination process. Enrollee may request an integrated organization determination either orally in writing, but must make a request for payment in writing. Enrollees can also file an expedited grievance orally or in writing. Applicable integrated plans must send a written integrated notice when the organization determination (standard or expedited) is adverse to the enrollee. Applicable integrated plan must send an integrated determination notice when it fails to make a timely decision, since such a failure constitutes an adverse decision, and that the enrollee may then request an integrated reconsideration.

Applicable integrated plans are required to update policies and procedures to subject all requests for covered benefits to the same integrated organization determination process.

The burden associated with this requirement is the burden for plans to update their policies and procedures to reflect the proposed new integrated organization determination and grievance procedures.

The one-time burden associated with this requirement is estimated at hourly burden of 8 hours for a business operations specialist to revise current policies and procedures times at a cost of $72.84 an hour. With an aggregate burden of 272 hours (34 contracts x 8 hours) with a consequent aggregate cost of 19,812 (272 hours x $72.84).

Applicable integrated plans are required to revise their systems for record keeping related to integrated grievances.

The one-time burden associated with this requirement is estimated as 3 hours for a programmer to revise record keeping systems (consistent with the per- response time estimated in CMS-2390-F RIN-0938-AS25 (81 FR 27498)) times at a cost of $98.54/hr. In aggregate, we estimate a one-

time burden of 102 hours (34 contracts x 3 hours) and a one-time cost of $10,051 (102 hours x $98.54).

Applicable integrated plans must issue a notice upon resolution of the integrated grievance, unless the grievance was made orally and the enrollee did not request a written response. The cost of notification and the cost of grievance review are added to calculate the savings. The burden associated with production and dissemination of this notice will be captured in future PRA submission.

The following figures are used to calculate the savings due to Medicare and Medicaid notice consolidation: (1) the number of enrollees in the exclusively aligned plans in contract year 2021, which is 172,000; (2) the time of notification using either a standard notice or a copy of the decision prepared by the reviewer (traditionally such a routine notification is estimated as 1 minute per notification (1/60 of an hour)); (3) the hourly wage for a business operations specialist; and (4) the percent of total enrollees expected to file a grievance (the recent Medicaid Managed Care May 2016 final rule (81 FR 27498) estimates a 2 percent filing rate, while the burden under OMB control number 0938-0753 (CMS-R-267) estimates 6.8 percent (17 percent of enrollees that are dissatisfied x 40 percent of dissatisfied enrollees who file a grievance)). For purposes of specificity, we assume the average of these two estimates, 4.4 percent (1/2 x [6.8 percent + 2 percent]) represents the percent of enrollees filing a grievance with the integrated plan.

Therefore, the annual savings due to notifications is estimated at 126 hours (1 minute x 172,000 enrollees x 0.044) and an aggregate savings of $9,188 (126 hours x $72.84/hr for a business operations specialist).

The annual savings for review of a grievance filed by an enrollee is estimated at 784 hours (172,000 enrollees x * 0.044 x * 0.5 hr). The annual aggregate savings is estimated at $275,627 (3,784 hours x $72.84/hr for a business operations specialist).

Integrated reconsideration (§ 422.633)

The implementing regulations of the PRA at 5 CFR 1320.4 exclude information collection activities during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. We conclude that a beneficiary's appeal of an adverse integrated coverage determination as proposed in this rule, and the subsequent information collection activities necessitated by that integrated appeal – such as notification of the applicable integrated plan's integrated reconsideration determination at § 422.633(f)(4) – are exempt from the PRA on the basis that an appeal is submitted in response to an administrative action against a specific individual. Therefore, this exemption would cover any information collection activities undertaken after the integrated organization determination by an applicable integrated plan.

Subpart N of CFR 422, Medicare Contract Determinations and Appeals

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.

Subpart V of CFR 422, Medicare Advantage Marketing Requirements

Definitions (§ 422.2260)

This section defines the marketing materials that an MA organization must provide to Medicare beneficiaries. An MA organization that, durinig the year, discloses additional information on benefits including advertisements or promotional materials may distribute marketing materials to its enrollees. These marketing materials are subject to certain requirements. The burden

associated with production and dissemination of Marketing materials is captured in PRA package CMS-10237, OMB control number 0938-0935.

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.

There are several disclosures that are mandatory for MAOs to disclose, for example, explanations of benefits and plan rules. These mandatory disclosures are disclosed in the Annual Notice of Change and Evidence of Coverage documents. The burden for producing and disseminating these documents is captured in PRA package CMS-10260, OMB control number 0938-1051.

Other marketing materials produced and disseminated by the MAO, for example, promotional materials, are voluntary, that is, they are not required by Federal law. The burden associated with production and dissemination of Marketing materials is captured in PRA package CMS-10237, OMB control number 0938-0935.

(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. The burden associated with production and dissemination of Marketing materials is captured in PRA package CMS-10237, OMB control number 0938-0935.

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.

The burden associated with production and dissemination of Marketing materials is captured in PRA package CMS-10237, OMB control number 0938-0935.

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. The burden associated with production and dissemination of Marketing materials is captured in PRA package CMS-10237, OMB control number 0938-0935.

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.

(d) Upon CMS request and 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.

Currently, mandatory marketing materials are produced from templates, significantly reducing the burden of communication between plans and CMS. Furthermore, all marketing materials are uploaded to the CMS HPMS system.

The mandatory disclosures are disclosed in the Annual Notice of Change and Evidence of Coverage documents. The burden for producing and disseminating these documents is captured in PRA package CMS-10260, OMB control number 0938-1051.

Other marketing materials produced and disseminated by the MAO, for example, promotional materials, are voluntary, that is, they are not required by Federal law. While there is burden associated with the production and dissemination of these materials, either to the public or to CMS, this burden of promoting a product is a customary and usual activity conducted in the normal course of business. Consequently, this burden is exempt from the requirements of the PRA per 5 CFR 1320.3(b)(2).

(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.

The following table summarizes the annual burden by hour and dollars for all provisions scored in this PRA package.

Table I summarizes hourly and dollar burden for all provisions listed in this PRA package. Positive numbers indicate costs.

Table 1: Summary of hourly and dollar burden for all provisions (Positive numbers indicate cost)

Regulatory Citation	Annual Frequency	Number of respondents	Numbers of responses per respondent	Total Responses	Hourly Burden per Hour	Total Hourly Burden	Wages	Total cost (Labor)
422.60(e)	As occurs	6,523,944	1	6,523,944	0.0833	543,662	35.92	$18,843,325
422.60(e)(5)	Monthly	468	12	5,616	4	22,464	$72.84	$1,551,813
422.60(e)(3)	As occurs	6,523,944	1	6,523,944	0.0167	108,732	$72.84	$7,511,207
422.60(g)	As occurs	558,000	1	558,000	0.0833	46,500	$72.84	$3,212,220
422.60(g)	As occurs	558,000	1	558,000	0.0167	9,300	$72.84	$642,444

422.60(g)	As occurs	558,000	1	558,000	0.0167	9,300	$72.84	$642,444
422.60(g)	As occurs	558,000	1	558,000	0.0833	46,500	35.92	$1,611,690
422.64	Annually	465	1	465	2	930	$72.84	$64,244
422.66(b)(3)(i)	As occurs	162,000	1	162,000	0.0167	2,700	$72.84	$186,516
422.66(b)(3)(iii)	As occurs	162,000	1	162,000	0.0167	2,700	$72.84	$186,516
422.66(b)(3)(iv)	As occurs	162,000	1	162,000	0.0833	13,500	$34.66	$467,910
422.74	As occurs	13,500	1	13,500	0.1	1,350	$72.84	$93,258
422.107	One time	44	1	44	24	1,056	$136.44	72,040
422.107	One time	13	1	13	160	2,080	98.54	102,482
422.107	One time	13	1	13	160	2,080	72.84	75,754
422.107	One time	116	1	116	8	928	136.44	126,616
422.107	One time	116	1	116	160	18,560	98.54	1,828,902
422.107	One time	116	1	116	160	18,560	72.84	1,351,910
422.107	Annually	373	1	373	30	11,190	72.84	815,080
422.132	Annually	468	1	468	40	18,720	$72.84	$1,293,178
422.202	Weekly	468	50	23,400	0.1667	3,900	$72.84	$269,412
422.206	As occurs	468	1	468	0.5	234	$72.84	$16,165
422.216	As occurs	42	10	416	0.0833	35	$72.84	$2,418
422.32	As occurs	9,292	1	9,292	0.1667	1,549	$72.84	$107,005
422.506	Annually	468	1	468	9	4,212	$72.84	$290,965
422.564	As occurs	75,826	1	75,826	0.25	18,957	$72.84	$1,309,550
422.568(b)	As occurs	468	1	468	30	14,040	$72.84	$969,883
422.568(d)	As occurs	185,849	1	185,849	1	185,849	$72.84	$12,838,449
422.572	As occurs	3,716,984	1	3,716,984	0.1167	433,648	$72.84	$29,956,404
422.572	As occurs	111,510	1	111,510	0.0833	9,292	$72.84	$641,891
422.584	As occurs	468	1	468	0.5	234	$72.84	$16,165
422.59	As occurs	185,849	1	185,849	4	743,397	$72.84	$51,353,865
422.59	As	46,462	1	46,462	2	92,925	$72.84	$6,419,259

	occurs							
422.622(e)	As occurs	37,170	1	37,170	1.5	55,755	$72.84	$3,851,555
422.624	As occurs	1,429,180	1	1,429,180	0.0833	119,098	$72.84	$8,227,290
422.626	As occurs	28,584	1	28,584	1.5	42,875	$72.84	$2,961,805
422.631	One time	34	1	34	8	272	72.84	19,812
422.631	One Time	34	1	34	3	102	98.54	10,051
422.631	As occurs	7568	1	7568	-0.0167	-126	72.84	(9,188)
422.631	As occurs	7568	1	7568	-0.5	-3784	72.84	(275,627)
Subtotal (Private Sector)	*Varies*	*468*	*Varies*	*21,654,326*	*varies*	*2,603,276*	*Varies*	*$159,656,680*
422.5	As occurs	6,523,944	1	6,523,944	0.5	3,261,972	$24.34	$77,830,652
422.52	As occurs	153,000	1	153,000	0.5	76,500	$24.34	$1,825,290
422.60(c)	As occurs	6,523,944	1	6,523,944	0.5	3,261,972	$24.34	$77,830,652
422.60(g)	As occurs	558,000	1	558,000	0.5	279,000	$24.34	$6,656,940
422.66(b)(ii)	As occurs	162,000	1	162,000	0.0333	5,400	$24.34	$128,844
422.622(b)	As occurs	37,170	1	37,170	0.0833	3,097	$24.34	$73,894
Subtotal (Beneficiaries)	*As occurs*	*13,958,058*	*1*	*13,958,058*	*Varies*	*6,887,941*	*$23.86*	*$164,346,272*
TOTAL	**varies**	**13,958,570**	**Varies**	**35,612,384**	**varies**	**9,491,217**	**varies**	**$324,002,952**

Collection of Information Instruments and Instruction/Guidance Documents

There are no specific information instruments or instruction/guidance documents.

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

Federal Burden under CMS-4182-F

The annualized cost associated with implementation of several specific MA requirements to the MAOs is detailed in separate PRA packages.

However, CMS-4182-F (RIN 0938-AT08) created of a new open enrollment period that created burden to the Federal government.

We expect that increasing the amount of time that MA-enrolled individuals are given to switch plans will result in slightly more beneficiaries selecting plans that receive Quality-Bonus Payments (QBP). This assessment reflects our observation that beneficiaries tend to choose plans with higher quality ratings when given the opportunity. The projected costs to the Government by extending the open enrollment period for the first three months of the calendar year are $9 million for calendar year 2019, $10 million in 2020, $10 million in 2021, $11 million in 2022, and $12 million in 2023.

In order to estimate the additional costs for the projection window 2019 – 2023, we first made an assumption that approximately 24,600 MA-enrolled individuals will switch health plans from one without a QBP to one with a QBP during the extended open enrollment period. The 24,600 enrollee assumption was determined by using a combination of published research and by observing historical enrollment information. Published research[1] shows that 10% of Medicare Advantage enrollees voluntarily switch Medicare Advantage Plans and that Medicare Advantage enrollees who voluntarily switch plans change to plans with slightly higher star ratings than their original plan, with a modest improvement of 0.11 stars, on average. The Office of the Actuary confirmed these findings by analyzing CMS enrollment data and provided further detail. We estimate that of the 10% of Medicare Advantage plan enrollees who switch plans, 15% move to a higher rated plan. Of those who go to a higher rated plan, we estimate 40% move from a non-QBP plan to a QBP plan. We also estimate that 1/5 of these enrollees would take advantage of the new open enrollment period.

We apply these assumptions to the estimated Medicare Advantage enrollment for 2019, 20,512,000, which can be obtained from the CMS Trustee's Report available at https://www.cms.gov/reportstrustfunds/. We find that 24,600 (20,512,000 x 10% x 15% x 40% x 20%) people are expected to enroll in the proposed open enrollment period.

The $9 million in additional costs for 2019 was calculated by multiplying the 24,600 impacted enrollment by the expected 2019 bonus amount ($637.20). The Office of the Actuary experiences an average rebate percentage of 66% and an 86% backing out of the projected Part B premium. Hence, the net savings to the trust funds is estimated as $9 million = 24,600 enrollees x $637.20 (Bonus payment) x 66% (rebate percentage) x 86% (Reduction in Part B premium), rounding to $9 million.

We can then apply trends from the Trustees Report to the 2019 estimate in order to project the costs for years 2020 – 2023. The data from the Medicare Payments to Private Health Plans, by Trust Fund (Table IV.C.2. of the 2017 Medicare Trustees Report) was used as the basis for the trends. The trend estimates presented below in Table II demonstrate the calculations and displays the cost estimates for each year 2019 – 2023.

Table II: Calculation of Net Costs for the Extended Open Enrollment Period

Year	2019 Base year	Trend Factor 2020	Trend Factor 2021	Trend Factor 2022	Trend Factor 2023	Net Costs (millions of dollars) Rounded to nearest million
2019	9 million					9
2020	9 million	1.078				10

2021	9 million	1.078	1.084			10
2022	9 million	1.078	1.084	1.089		11
2023	9 million	1.078	1.084	1.089	1.086	12

Federal Burden under CMS-4185-P

Integration

Many of the changes we are proposing streamline the burden of operations by unifying existing D-SNP requirements, and are therefore not expected to have impact. Table III notes which numbers are true savings or costs and which numbers or parts of estimates are transfers. Since the impacts are for services such as updating manuals or updating software, the cost and savings impact are true costs or savings (which in some cases reflect a transfer to the federal government). Table III also notes who bears the cost (states or MA plans). As can be seen, the aggregate cost of this provision is a first year cost of $3.4 million, $0.2 million of which are transfers between the Federal government and states. As noted in the section, although additional updates may be necessary in future years, we are scoring this as $0 as a best estimate given uncertainty regarding the need for additional changes by states and plans after the first year.

TABLE III: COST OF INTEGRATION

Item	Respondents	Hours per Respondent	Total Hours	Cost per Hour	Total Cost	Nature of Cost Impact. To Whom and Whether True Impact or Transfer.
Initial update by state Medicaid agency of its contracts with D-SNPs*	44(States)	24	1,056	$136.44	$144,081	50% true cost of services to state; 50% transfer to Federal government through the Federal Medical Assistance Program to State agencies
Initial update by D-SNPs of their contracts with the state Medicaid agency	116 (D-SNPs)	8	928	$136.44	$126,616	True cost of services to Medicare Advantage Plans
Initial establishment of system for notification of hospital and skilled nursing facility admissions by state Medicaid agency*	13 (States)	160	2,080	$98.54	$204,963	50% true cost of services to State; 50% transfer to Federal government through the Federal Medical Assistance Program to State agencies
	13(States)	160	2,080	$72.84	$151,507	50% true cost of services to State; 50% transfer to Federal government through the Federal Medical Assistance Program to State agencies
Initial notification of hospital and skilled nursing facility admissions by D-SNPs to state Medicaid agency	116(D-SNPs)	160	18,560	$98.54	$1,828,902	True cost of services to Medicare Advantage Plans
	116 (D-SNPs)	160	18,560	$72.84	$1,351,910	True cost of services to Medicare Advantage Plans
Total	Varies	Varies	43,264	Varies	$3,807,979	

For purposes of clarity we have repeated Section 12 estimates in these tables.

Unified Grievances and appeals

There are three areas where the proposed unified grievances and appeals provision will have an impact on cost to the Federal Government; Furnishing Medicare Parts A and B Services during the pendency of appeals, creating new grievance and appeal notice templates, and issuing subregulatory guidance in CMS manuals on the new grievance and appeals procedures

a. Furnishing Medicare Parts A and B Services During the Pendency Of Appeals

One of the provisions related to appeals integration may marginally impact the ways MA sponsors bid for their D-SNPs, which could marginally impact Medicare spending. We propose that the existing standards for continuation of benefits at § 438.420 apply to applicable integrated plans for Medicare benefits under Parts A and B and Medicaid benefits in our proposed integrated appeals requirements at § 422.632. Under our proposal, and as is applicable to Medicaid managed care plans currently, if an applicable integrated plan decides to stop or reduce a benefit that the enrollee is currently authorized to receive, the enrollee could request that the benefit continue to be provided at the currently authorized level while the enrollee's appeal is

pending through the integrated reconsideration. Currently, MA plans in general are not required to provide benefits pending appeal, whereas in Medicaid it has been a long-standing feature.

It is our expectation that the new integrated appeals provisions will result in an increase in expenditures by applicable integrated plans for Medicare covered services because they will be required to continue coverage for services during the pendency of the reconsideration request, or first-level appeal under our proposal.

The estimate of impact of this continuation is based on calendar year (CY) 2016 appeal metrics, which are then trended to CY 2021.

The assumptions, sources and calculations are summarized in Table IV and Vin this PRA and further clarified as follows.

The first step in this estimation is to determine the number of applicable reconsiderations per 1,000 beneficiaries enrolled in integrated plans affected by this provision. Given the similarity of population characteristics, the reconsideration experience for the Medicare-Medicaid Plans (MMPs) participating in the Financial Alignment Initiative was used as a proxy for the applicable integrated plans. In 2016, MMP enrollees were impacted by 1,232 reconsiderations for services which were resolved adversely or partially favorably to the beneficiary. The corresponding MMP enrollment in 2016 was 368,841, which implies a rate of 3.3 applicable reconsiderations per 1,000 in 2016.

Then we projected D-SNP enrollment impacted by the unified procedures to grow from 150,000 in 2018 to 172,000 (150,000 * 1.145) in 2021 based on the estimated enrollment growth for all D-SNPs during the period of 14.5 percent. Applying the MMP appeal rate of 3.3 per 1,000 to the projected 2021 enrollment in applicable integrated plans of 172,000 results in an estimated 568 (172,000 * 3.3/1,000) service reconsiderations for the applicable integrated plans in 2020.

The next step is to determine the average level of benefit subject to the appeals. Table 1 in the report Medicare Part C QIC Reconsideration Data for 2016[4] contains data on the number and benefit amounts by service category for the second level appeals filed in 2016. Analysis of these data resulted in an estimated per-appeal benefit value of $737 for 2016. The determination of this value took into account that some services would not be subject to the regulatory extension of coverage due to the existence of immediate review rights (inpatient hospital, skilled nursing facility, and home health), other benefits would likely have been rendered already (emergency room, and ambulance), and other services are not covered as a D-SNP basic benefit (hospice and non-Medicare benefits). Accounting for 19.5 percent inflation in per-capita Medicare spending between 2016 and 2021, and carving out the 13.38 percent consumer price index inflation in years 2016 – 2020 inclusive, results in an estimated per-appeal benefit value of $774 (that is, $737 * 1.195 / 1.1338) for 2021.

[4] https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/IRE.html.

Taking the product of the number of applicable integrated plan service reconsiderations in 2021 (568) and average benefit value in 2021 ($774) yields an estimated cost in 2021 of $439,632 (that is, 568 * $774) due to an increase in Medicare expenditures stemming from the unified appeals procedures for applicable integrated plans. We believe that this figure represents an upper bound of the cost given that not all applicable services will be rendered during the extended period of benefit continuation being proposed in this regulation. These calculations are summarized in Table "Impact of Integrated Appeals provision of FIDE SNPs".

Using the 2021 estimates as a basis, estimates for 2021 through 2029 are presented in Table "Net Cost Per Year to the Medicare Trust Fund for Integrated Plan Appeals". The following assumptions were used in creating Table "Net Cost Per Year to the Medicare Trust Fund for Integrated Plan Appeals":

- As described earlier in this section, the numbers in the row for 2021 come from Table "Impact of Integrated Appeals provision of FIDE SNPs".
- The projected FIDE SNP enrollment for 2022 through 2029 was obtained by multiplying the estimated 2021 FIDE SNP enrollment of 172,000, using SNP enrollment growth factors inferred from Table IV.C1 in the 2018 Trustees Report.
- The projected cost per appeal for 2022 through 2029 was obtained by first multiplying the estimated 2021 cost per appeal of $774 by FFS per capita growth rates obtained from internal documentation for the Table of FFS USPCC, non-ESRD estimates in attachment II of the 2019 Rate Announcement and Call Letter (https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf).

The results are summarized in Table "Net Cost Per Year to the Medicare Trust Fund for Integrated Plan Appeals". As can be seen, there is an estimated true cost (reflecting purchase of goods and services) of $0.4 million in 2021 and $0.5 million in 2022-2024. Eighty-six percent of this cost is transferred from the plans to the Medicare Trust Fund. The remainder of this cost is born by beneficiary cost sharing. The cost of appeals between 2025 and 2029 is $0.5 to 0.6 million for the Medicare Trust Fund and $0.1 million for beneficiaries.

TABLE IV: IMPACT OF INTEGRATED APPEALS PROVISION OF FIDE SNPS

Row ID	Item Description	Number	Data Source
	MMP Appeals: 2016		
(A)	Appeals	1,232	2016 Parts C and D Reporting Requirements PUF (not incl. Part D MTM data) from site https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html Sum of service reconsiderations partially favorable and adverse for organization type "Demo"
(B)	Enrollment	368,841	2016 Parts C and D Reporting Requirements PUF (not incl. Part D MTM data) from site https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html Sum of enrollment for organization type "Demo"
(C)	MMP appeals per 1000	3.3	(C) =(A) / (B) * 1000
	FIDE SNP Appeals 2021		
(D)	Enrollment 2018	150,000	Internal CMS enrollment extract in HPMS data system for July 2018
(E)	DE SNP enrollment growth: '18-'21	14.5%	Table IV.C1, "Private Health Enrollment" in 2018 Trustee Report, accessible at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf
(F)	Enrollment 2021	172,000	(F) = (D)*(1+(E))
(G)	MMP Appeals per 1000 in 2016	3.3	Row (C)
(H)	FIDE SNP appeals 2021	568	(H) = (F)/1000 * (G)
	Cost of FIDE SNP Appeals: CY 2021		
(I)	Average benefit per appeal (2016)	$737	Data obtained from CMS Appeal & Grievance Contractor
(J)	Inflation: 2016 – 2021	19.5%	Ratio of CY 2021 and CY 2016 entries in table "Comparison of Current and Previous Estimates of the FFS USPCC - Non ESRD" in the 2019 Rate Announcement and Call letter accessible at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf
(K)	Carving out Ordinary Inflation 2016-2021	13.80%	Product of the urban consumer price index (CPI-U) increase factors for 2016-2020 inclusive. Data were obtained from Table V.B2 in the 2017 CMS Trustee Report accessible at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf
(L)	Average benefit per appeal (2021)	$774	(L) = (I) * (1 + (J)) / (1+(K))

Row ID	Item Description	Number	Data Source
(M)	Aggregate amount of appeal (2021)	$440,000	(M) = (L) * (H)

TABLE V: NET COST PER YEAR TO THE MEDICARE TRUST FUND FOR INTEGRATED PLAN APPEALS

Contract Year	Affected FIDE SNP Enrollment (A)	Appeals per 1,000 Affected Enrollees (B)	Number of Affected Appeals per Year (C) = (A) / 1000* (B)	Cost per Appeal (D)	Gross Cost of Appeals (millions $) (E) = (D)*(C)/ 1,000,000	Share of cost funded by Medicare Trust Funds (F)	Net Cost of Appeals to Medicare Trust Fund (millions $) (F)*(E)	Net Cost of Appeals to Beneficiaries (1-F)*(E)
2021	172,000	3.3	568	$774	$0.4	86%	$0.4	$-----
2022	179,000	3.3	591	$791	$0.5	86%	$0.4	$0.1
2023	185,000	3.3	611	$808	$0.5	86%	$0.4	$0.1
2024	191,000	3.3	630	$828	$0.5	86%	$0.4	$0.1
2025	197,000	3.3	650	$842	$0.5	86%	$0.5	$0.1
2026	203,000	3.3	670	$861	$0.6	85%	$0.5	$0.1
2027	209,000	3.3	690	$883	$0.6	85%	$0.5	$0.1
2028	215,000	3.3	710	$903	$0.6	85%	$0.5	$0.1
2029	220,000	3.3	726	$920	$0.7	85%	$0.6	$0.1

b. Creation of New Grievance and Appeal Notice Templates

When MA plans send out notifications to enrollees, they usually have the option to use templates created by CMS. To address the proposed new unified grievance and appeal procedures, CMS Central Office staff must create new notice templates. We estimate that three new notice templates must be created. We estimate each new template will require 3 hours of work by a GS level 13, step 5 (GS-13-5), employee. The 2018 hourly wages for a GS-13-5 Federal employee is $52.66.[5] We allow 100 percent for Fringe Benefits and overtime. Thus the expected one-time negligible initial cost is $1,000 (actually, $948 = 3 templates * 3 hours per template * $52.66 hourly wage * 2 for overtime and fringe benefits).

c. Subregulatory guidance in CMS Manuals on the New Grievance and Appeals Procedures

The CMS manuals present comprehensive sub-regulatory guidance on regulatory matters. Since these unified grievance and appeals procedures are new, we estimate it would require 20 hours to develop subregulatory guidance to be published in the CMS Medicare managed care manual. Thus we expect a negligible one-time cost of $2,000 (actually $2,106 = 20 hours of work * $52.66, hourly wage for a GS-13-5 * 2 for overtime and fringe benefits).

15. Program/Burden Changes

The following table contrasts the total hours and cost from the 2018 version of PRA package CMS-R-267 and the current one.

PRA Version	Total Hours	Total Cost
2018	9,451,489	$320,658,122
2019	9,491,217	$324,002,952

[5] https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/DCB_h.pdf
https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/DCB_h.pdf

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The above summary table is based on the following balance sheet comparing *by provision* the 2018 and 2019 version. Explanatory comments follow the Balance Sheet

BALANCE SHEET

	2019	Version	CMS R 267		2018		Version	CMS R-267
Regulatory Citation	Total Hourly Burden	Wages	Total cost (Labor)	Regulatory Citation	Total Hourly Burden	Wages	Total cost (Labor)	Reasons for change
422.107	11,190	$72.84	815,080	422.107	11,190	$69.08	$773,005	Wage estimate update
422.107	1,056	$136.44	72,040					NPRM CMS-4185-P
422.107	2,080	98.54	102,482					NPRM CMS-4185-P
422.107	2,080	72.84	75,754					NPRM CMS-4185-P
422.107	928	136.44	126,616					NPRM CMS-4185-P
422.107	18,560	98.54	1,828,902					NPRM CMS-4185-P
422.107	18,560	72.84	1,351,910					NPRM CMS-4185-P
422.631	272	72.84	19,812					NPRM CMS-4185-P
422.631	102	98.54	10,051					NPRM CMS-4185-P
422.631	-126	72.84	(9,188)					NPRM CMS-4185-P
422.631	-3784	72.84	(275,627)					NPRM CMS-4185-P
TOTAL			**159,240,789**	Total	**11,190**	**69.08**		

16. Publication/Tabulation Dates

Generally there are no publication or tabulation dates. However, required by §422.64, 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 Medicare Compare website. The Medicare Compare website allows interested beneficiaries to compare the benefits and costs of each plan. Beneficiaries use this information to select the plans they are interested in joining.

17. Expiration Date

CMS plans to publish the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

This collection does not employ statistical methods.