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

Background

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. Title II of The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) enacted on December 8, 2003 made 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.

In this 2020 collection of information request the standard ("long") model enrollment form to elect an MA plan established at 42 CFR 422.50 and 422.60 has been extracted into its own stand-alone information collection request (CMS-10718; OMB control number: 0938-1378).

This iteration also requests approval of our new minimum criteria for dual eligible special needs plans (D-SNPs) to integrate Medicare and Medicaid benefits detailed in Section 50311(b) of the Bipartisan Budget Act of 2018 and set forth in our April 16, 2019 (84 FR 15680) final rule CMS-4185-F (RIN 0938-AT59) for CY2020 and 2021. The integration requirements improve care coordination, quality of care, and beneficiary satisfaction while reducing administrative burden.

Lastly, this collection request subsumes revisions that are set out under our June 2, 2020 (85 FR 33796) final rule (CMS-4190-F; RIN 0938-AT97). The revisions account for the addition of burden for:

- 42 CFR 422.62 and 423.38 the addition of the burden for determining an applicant's eligibility for an election period.
- 42 CFR 422.514, the addition of a contract requirement limiting CMS contracts to MA plans consisting of 80 percent or more dually eligible enrollees if such plans are non-special needs plans (SNPs)
- 42 CFR 422.2440, accounting for certain costs associated with anticipated enrollment changes attributable to the addition of a deductible-based adjustment to the medical loss ratio (MLR) for MA Medical Savings Account (MSA) contracts with relatively low enrollment.

A. Justification

1. Need and Legal Basis

The information collection requirements are mandated by 42 CFR part 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.

Our April 16, 2019 (84 FR 15680) final rule (CMS-4185-F, RIN 0938-AT59) 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 regulation establishes 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 §§ 422.560–422.562, 422.566, 422.629422.634, 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. These rules take effect in 2021.

Our June 2, 2020 (85 FR 33796) final rule (CMS-4190-F, RIN 0938-AT97) (hereinafter referred to as the "June 2020 final rule") revises regulations for the MA program, Medicare Prescription Drug Benefit (Part D) program, and Medicare Cost Plan program to implement recent changes in statute, codify several existing CMS policies, and implement other technical changes. This final rule implements a subset of the proposals from the February 18, 2020 (85 FR 9002) proposed rule (CMS-4190-P, RIN 0938-AT97). We intend to address all of the remaining proposals in subsequent rulemaking, with an effective date of 2021 and enforcement deferred to 2022.

2. Information Users

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

MA organizations (formerly M+C organizations) and potential MA organizations (applicants) use the information collected based on the regulations at 42 CFR part 422 to comply with the application requirements and the MA contract requirements. CMS uses the information collected based on the regulations at 42 CFR part 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 (§§ 422.64, 422.66, and 422.74)
- Several collection requirements in 42 CFR part 422, now covered by other OMB 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

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.

Except for the exceptions listed above, there are no other special circumstances that would require the information collections to be conducted in a manner that requires respondents to:

- 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

For this 2020 iteration, we published the following proposed and final rules for the provisions associated with CMS-4190-P and –F. We also published standard 60- and 30-day non-rulemaking notices for the changes associated with CMS-10718 (OMB 0938-1378) and CMS-4185-F.

CMS-4190-P and –F

The proposed rule (CMS-4190-P, RIN 0938-AT97), filed for public inspection on February 5, 2020 and published in the Federal Register on February 18 (85 FR 9002). Comments were due on/by April 6, 2020, but no comments were received.

The final rule (CMS-4190-F, RIN 0938-AT97) published in the Federal Register on June 2, 2020 (85 FR 33796).

Non-rulemaking Changes

The 60-day notice published in the Federal Register February 24, 2020 (85 FR 10444). No comments were received.

The 30-day notice published in the Federal Register June 4, 2020 (85 FR 34450).

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 to 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 (§ 422.2) and ii) when an MA plan has conscientious objection to covering a procedure on religious grounds (§ 422.206).

12. Burden Estimates

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates for all salary estimates (https://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 Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Wage ($/hr)

All Occupations*	00-0000	25.72	n/a	n/a
Business Operation Specialists, All Other	13-1198	38.57	38.57	77.14
Lawyer	23-1011	69.86	69.86	139.72
Office and Administrative Support Workers, All Other	43-9199	18.41	18.41	36.82
Software Developers and Programmers	15-1250	51.44	51.44	102.88

*Represents the mean hourly rate for individuals which, as explained above, is not adjusted for fringe benefits and overhead.

Wages for Individuals: To derive average costs for individuals, we used data from the May 2019 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 $25.72/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 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 in 2018. The total annual burden is estimated at

- 0.25 hour for an administrative support worker to determine the beneficiary's eligibility to enroll, times
- 153,000 beneficiaries estimated to request enrollment in a SNP annually, resulting in an annual burden of

- 38,250 hours (153,000 x 0.25 hours), with a consequent burden of $1,408,365 (38,250 x $36.82).

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)

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. The burden associated with this reporting provision is contained in PRA package CMS-10237, OMB Control number 0938-0935.

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).

Election of coverage under an MA plan (§ 422.62)

An individual may enroll in or disenroll from an MA plan only during allowed election periods, such as initial coverage election period, annual coordinated election period, Medicare Advantage Open Enrollment period and special election periods.

The burden associated with the requirement to process disenrollment elections is captured under § 422.66.

For each enrollment or disenrollment election received, the MA organization must determine the individual’s eligibility for an election period. We estimate it would take approximately 5 minutes (0.0833 hr) at $77.14/hr for a business operations specialist to determine an applicant’s eligibility for an election period.

The burden for all MA organizations is estimated at 142,497 hours (1,710,650 beneficiary SEP elections x 0.0833 hr) at a cost of $10,992,219 (142,497 hr x $77.14/hr) or $60,731 per organization ($10,544,778/181 MA parent organizations).

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 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 Plan Finder (MPF) 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 Plan Finder 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 503 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 500 MAOs. Thus the annual burden is estimated at

- 2 hours, the time estimated to submit a Part D Pricing File, times
- 563 MAOs, an upper estimate for the number of Part D sponsors, resulting in
- An annual hourly burden of 2 x 563 = 1,126 hours, resulting in
- An annual cost of 1,126 x $77.14 (hourly wage of business operation specialist) = $86,860.

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. The burden for beneficiaries associated with electing a different plan is included in CMS-10718.

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
- 226,339 voluntary disenrollees, resulting in an annual burden of
- 226,339 / 60 = 3,772 hours, resulting in
- An annual cost of 3,772 x $77.14 (hourly wage of business operations specialist) = $291,589.

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

- 226,339 voluntary disenrollees, times
- 0.0166 hours (1 minute), the time it takes to notify an enrollee, resulting in
- An annual burden of 226,339 / 60 = 3,772 hours, resulting in
- An annual cost of 3,772 x $77.14 (hourly wage of a business operations specialist) = $291,589.

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

- 226,339 voluntary disenrollees, times
- 0.08333 hours (5 minutes), the time it takes to retain disenrollment records,
- Resulting in an annual burden of 226,339/12 =18,862 hours, resulting in
- An annual cost of 18,862 x $36.82 (hourly wage of an administrative and support worker) = $694,204.

The total annual burden of § 422.66 is estimated at 26,406 hours (3,772+ 3,772 + 18,862) at an annual cost of $1,277,382 ($291,589 + $291,589 + $694,204) for plans.

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 PRA package CMS-R-262, OMB control number 0938-0763.

An 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 an 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 27,313 individuals will be disenrolled for failure to pay plan premiums. Thus we estimate the total annual burden as

- 27,313 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 27,313 x 0.1 = 2,731 hours, resulting in
- Annual cost of 2,731 x $77.14 (hourly wage of business operations specialist) = $210,669.

An 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 fewer 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 fewer 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 2,731 hours at a cost of $210,669.

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)

(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).

(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).

(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: Contract with state Medicaid agency (§ 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.
(9) For each dual eligible special needs plan that is an applicable integrated plan as defined in § 422.561, a requirement for the use of the unified appeals and grievance procedures under §§ 422.629 through 422.634, 438.210, 438.400, and 438.402.

(d) Additional minimum contract requirement. For any dual eligible special needs plan that is not a fully integrated or highly integrated dual eligible special needs plan, the contract must also stipulate that, for the purpose of coordinating Medicare and Medicaid-covered services between settings of care, the SNP notifies, or arranges for another entity or entities to notify, the State Medicaid agency, individuals or entities designated by the State Medicaid agency, or both, of hospital and skilled nursing facility admissions for at least one group of high-risk full-benefit dual eligible individuals, identified by the State Medicaid agency. The State Medicaid agency must establish the timeframe(s) and method(s) by which notice is provided. In the event that a SNP authorizes another entity or entities to perform this notification, the SNP must retain responsibility for complying with this requirement.

(e) 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.

(2) MA organizations offering a dual eligible SNP must comply with paragraphs (c)(9) and (d) of this section beginning January 1, 2021.

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 277 MAOs will submit 351 Dual Eligible SNP contracts annually in compliance with this requirement. Therefore we estimate the burden as

- 351, the number of D-SNP contracts, times
- 30 hours, the time required per D-SNP to comply with the requirement, resulting in an annual hourly burden of 10,530 hours with a consequent annual aggregate cost of
- A total annual burden of 10,530 x $77.14 (hourly wage of a business operations specialist)= $812,284.

In CMS-4185-F (RIN 0938-AT59), we codified the requirements to 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 information burden associated with this requirement, subject to the PRA, 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: State Medicaid Agencies to update one-time their contracts

For the initial year, we expect it will take 24 hours at $139.72/hr for a lawyer to update the state Medicaid agency’s contract with every D-SNP in its market to address the changes to § 422.107 made by the final rule. Since half of the cost will 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 will establish uniform contracting requirements for all D-SNPs operating in their market. As of September 2019, there were 42 states, plus the District of Columbia and Puerto Rico, in which D-SNPs were available to MA enrollees. In aggregate, we estimate a one-time burden of 1,056 hours (44 respondents x 24 hr/response) at an adjusted cost of $73,772 (1,056 hr x $139.72/hr x 0.50). Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 352 hours (1,056 hr x 1/3) at a cost of $24,591 ($73,722 x 1/3). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

In future years, we anticipate minimal burden associated with modifications to contract terms consistent with the changes we finalized to § 422.107(c)(1) through (3). While it is possible more states will move toward increased integration by contracting with applicable integrated plans and would therefore need to modify their state Medicaid agency contracts with D-SNPs consistent with the changes we finalized to § 422.107(c)(9), we are unable to reliably estimate the additional burden in subsequent years. In addition, while we recognize that, over time, states could modify the newly required contract term at § 422.107(d) to require notification about admissions for certain high-risk enrollees (for example, by expanding the population of high-risk full-benefit dual eligible individuals to whom this notification applies), we do not believe that such a contract change will have a material impact on time and effort and, therefore, will 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 will 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 to update one-time their systems

To address differences among the states in available infrastructure, population sizes, and mix of enrollees, this rule provides broad flexibility to identify the groups for which the state Medicaid agency wishes to be notified and how the notification should take place. These 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. The final rule also allows 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 some other organization.

Some states, using a rich infrastructure and a well-developed automated system, may fulfill this notification 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 the final rule, we expect that states will choose strategies that are within their budget and best fit their existing or already-planned capabilities. We 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 Puerto Rico, in which D-SNPs were available to MA enrollees. We estimate that there are nine (9) states and territories with D-SNPs that are all 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 the final rule because none of their D-SNPs will be subject to the state notification requirement at § 422.107(d). We estimate that nine additional states that primarily use managed care for long-term services and supports

(LTSS) (Michigan, New York, North Carolina, Ohio, Oregon, Pennsylvania, Tennessee, Texas, and Virginia) will delegate receipt of this information to their Medicaid managed care organizations. We also estimate that approximately half of the remaining 26 states (42 states – 16 states, excluding the District of Columbia and Puerto Rico) or 13 states will build an automated system for receiving notification of hospital and SNF admissions consistent with the final rule.

We estimate that, on average, this work could be accomplished in a month with one software developer/programmer to build an automated system and one business operations specialist to define requirements. We estimate a one-time burden of 4,160 hours (13 states x 40 hr/week x 4 weeks x 2 FTEs). Since half of the cost will be offset by 50 percent federal financial participation for Medicaid administrative activities, we estimate an adjusted cost of $187,221 [((2,080 hr x $102.88/hr) + (2,080 hr x $77.14/hr)) x 0.50]. Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 1,387 hours (4,160 hr x 1/3) at a cost of $62,422 ($187,221x 1/3). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

Because of the possible wide variability in states' approaches in implementing this requirement, we solicited comment in the proposed rule and requested suggestions for modeling state approaches and costs related to this provision. Given the uncertainty involved in estimating state behavior, we estimated a minimum of zero burden in subsequent years on plans and a maximum burden that is the estimated first-year cost. We received no comments and finalized our time estimates without change.

III: Plans to update one-time their contacts

For the initial year, we expect it will take 8 hours at $139.72/hr for a lawyer to update their plan's contract with the state Medicaid agency to reflect the revised and new provisions finalized in this rule at § 422.107(c)(1) – (3), (c)(9), and (d). We are unable to differentiate how these provisions impact individual D-SNP contracts due to the ways contracts are structured. For example, some contracts will include FIDE SNPs, HIDE SNPs, and other D-SNPs, while others may include only a subset of these D-SNP types. The specific requirements for the content of and scope of changes to the contract vary somewhat based on the type of D-SNP the plan is. However, it is reasonable to project that every D-SNP contract will require contract modifications with the state Medicaid agency.

There are 277 D-SNP contracts for CY 2021. In aggregate, we estimate a one-time burden of 2,216 hours (277 D-SNPs x 8 hr/modification) at a cost of $309,620, (2,216 hr x $139.72/hr). Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 739 hours (2,216 hr x 1/3) at a cost of $103,253, ($309,620 x 1/3). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

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. By contrast, other state Medicaid agencies may seek to expand the notification requirement to encompass additional groups of high-risk dual 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 will be the first year costs.

IV: Plans to update one-time their systems

We have noted previously in Section II.A.2.a. of the final rule, CMS-4185-F (RIN: 0938-AT59) 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 their 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 will 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 believe that this work has only minimal one-time cost, as detailed immediately below.

Therefore, we estimate it could be accomplished in a month with one software developer/programmer to update systems and one business operations specialist to define requirements. The burden will be at the contract, not the plan, level for a subset of D-SNP contracts that are not FIDE SNPs or HIDE SNPs and to which the notification requirements are applicable. As noted previously, there are 277 D SNP contracts for CY2021, 176 contracts have at least one plans that is not a FIDE SNP or HIDE SNP. Accordingly, we estimate a one-time burden of 56,496 hours (176 contracts x 40 hr x 4 weeks x 2 FTEs) or 320 hours per MOA, at a cost of $5,085,204 [(28,248 hr x $102.88/hr) + (28,248 hr x $77.14/hr)]. Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 18,832 hours (56,496 hr x 1/3) at a cost of $1,695,068 ($5,085,204 x 1/3). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

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).

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

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, 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
- 563, the number of MAOs, resulting in an annual hourly burden of 18,773 hours, with a consequent annual aggregate cost of
- 18,773 x $77.14 = $1,737,193.

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; (3) 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 (4) 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 $77.14 (hourly wage for business operations specialist) = $49,370.

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
- 563 MA organizations, times

- 0.166 (10 minutes) to electronically identify the selected individuals or provider groups,
- Resulting in 4,693 hours annual hourly burden, with a consequent annual aggregate cost of
- 4,693 x $77.14 (hourly wage of a business operations specialist) = $361,988.

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
- 563 MA organizations, for a total of
- 282 hours on an annual basis, with a total cost of
- 282 x $77.14 (hourly wage of a business operations specialist) = $21,753.

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 non-contracting providers who inquire. We have 5 PFFS contracts currently offering 44 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 5 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 44 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 44 plans x 10 hospitalizations per plan = 350 hospitalizations per year that would require such notices, resulting in an annual hourly burden of
- 29 hours with a consequent aggregate annual cost of
- 29 x $77.14 (hourly wage of a business operations specialist) = $2,237 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 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 MA 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 24,279,575 = 12,140, the number of MA enrollees expected to have elected hospice approximately 22 MA enrollee per MAO, times
- 0.1667 hours (10 minutes), resulting in a total annual hourly burden of
- 2,065 hours and a total annual cost of
- 2,065 x $77.14 (hourly wage of a business operations specialist) = $159,294.

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 an MA organization 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
- 563, the number of MAOs, resulting in an annual hourly burden of
- 5,067 hours, resulting in an aggregate cost of
- 5,067 x $77.14 (hourly wage of a business operations specialist) = $3390,868.

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 1320.3(c) and 1320.4 .

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).

NEW: Enrollment requirements (§ 422.514)

As described in Section II.B. of the June 2020 final rule, we finalized a prohibition for plan year 2023 and future years on CMS renewing an existing contract for any non-SNP MA plan that an

MA organization offers that has actual enrollment, as determined by CMS in January of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a state plan under title XIX of the Act, unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination. Additionally, our dually eligible enrollment threshold at § 422.514(d) applies to any plan that is not a SNP as defined in § 422.2 and only to MA plans in states where there is a D-SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals, such as a Medicare-Medicaid Plan (MMP).

Using data from the most recently available contract year, the 2020 bid submission process, we estimate that there are 67 MA plans that have enrollment of dually eligible individuals that is 80 percent or more of total enrollment. Of these 67 MA plans, 62 plans are in 19 states where there are D-SNPs or comparable managed care plans and will be subject to § 422.514(d). These 62 plans projected a total enrollment of 180,758 for contract year 2020.

At § 422.514(e), we finalized a process for an MA organization with a D-SNP look-alike to transition individuals who are enrolled in its D-SNP look-alike to another MA-PD plan offered by the MA organization, or by another MA organization with the same parent organization as the MA organization, to minimize disruption as a result of the prohibition on contract renewal for existing D-SNP look-alikes. Under this final rule, an MA organization with a non-SNP MA plan determined to meet the enrollment threshold in § 422.514(d)(2) could transition enrollees into another MA-PD plan offered by the same MA organization (or by another MA organization with the same parent organization as the MA organization), as long as that receiving MA-PD plan meets certain criteria specified in § 422.514(e)(1)(i) - (iv). The process finalized at § 422.514(e) allows, but does not require, the MA organization to transition dually eligible enrollees from D-SNP look-alikes into D-SNPs and other qualifying MA-PD plans for which the enrollees are eligible without the transitioned enrollees having to complete an election form.

While the contract limitation for existing D-SNP look-alikes begins in the 2023 plan year, we intend for the transition process to take effect in time for D-SNP look-alikes operating in 2020 and 2021 to utilize the transition process for enrollments effective January 1, 2021 or January 1, 2022, respectively. Based on the current landscape for D-SNP look-alikes, we believe the vast majority of D-SNP look-alikes are able to move current enrollees into another MA-PD plan using the transition process we are finalizing in this rule. We expect many of these plans will choose to transition membership for the 2022 and 2023 plan years. Therefore, we are assuming the burden of the 62 plans transitioning enrollees will happen for half the plans in 2021 (for a 2022 effective date) and half the plans in 2022 (for a 2023 effective date).

We estimate each plan will take a one-time amount of 2 hours at $77.14/hr for a business operations specialist to submit all enrollment changes to CMS necessary to complete the transition process. D-SNP look-alikes that transition enrollees into another non-SNP plan will take less time than D-SNP look-alikes that transition eligible beneficiaries into a D-SNP because they will not need to verify enrollees' Medicaid eligibility. The 2-hour time estimate accounts for any additional work to confirm an enrollee's Medicaid eligibility for D-SNP look-alikes transitioning eligible enrollees to a D-SNP. The burden for MA organizations to transition enrollees to other MA-PD plans during the 2021 and 2022 plan years is 124 hours (62 D-SNP look-alikes * 2 hr/plan) at a cost of $9,565 (124 hr * $77.14/hr). We averaged this burden for the

62 plans over the 2021 and 2022 plan years, resulting in an annual burden of 62 hours (124 hr/2 yr) at a cost of $4,783 ($9,565/2 yr).

In subsequent years (2023 and beyond), we estimate that at most five plans per year will be identified as D-SNP look-alikes under § 422.514(d) due to meeting the enrollment threshold for dually eligible individuals or operating in a state that will begin contracting with D-SNPs or other integrated plans. We believe that these plans would non-renew and transition their membership into another MA-PD plan or a D-SNP. Therefore, the annual burden for the 2023 plan year and subsequent years is estimated at 10 hours (5 plans * 2 hr/plan) at a cost of $771 (10 hr * $77.14/hr) for a business operations specialist to transition enrollees into a new MA-PD plan.

The average annual burden for MA plans over three years is 45 hours ([62 hr+62 hr+10 hr]/3 yr) at a cost of $3,446 ([$4,783 + $4,783 + $771]/3 yr).

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)

Section 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.

In CMS-4185-F (RIN 0938-AT59), we did not calculate the burden for all D-SNPs to assist enrollees with the filing of their grievance or appeal as required in § 422.562(a)(5). Since the provision of such assistance is a usual and customary business practice it is exempt from the PRA under 5 CFR 1320.3(b)(2). We believe that this function would be performed in the absence of federal regulation.

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
- 24,279,575, 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, approximately 176 MA enrollees per MAO,resulting in an annual hourly burden of
- 24,772 hours, with
- An annual aggregate cost 24,772 hours x $77.14 (hourly wage of a business operations specialist) = $1,910,912.

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
- 563, the number of MAOs, resulting in a total annual hourly burden of
- 16,890 hours, resulting in an annual aggregate cost of
- 16,890x $77.14 (hourly wage of a business operations specialist) = $1,302,895.

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
- 242,796, 1% of the number of MA enrollees, the estimated number of enrollees requiring a written notice because of a denial, or 431 MA enrollee per MAO, resulting in an annual hourly burden of
- 242,653 hours, with a consequent annual cost of
- $18,718,252 = 242,653x $77.14 (hourly wage of a business operations specialist).

The total burden associated with § 422.568 is 259,543 hours (16,890 + 242,653) at a cost of $20,021,147 ($1,302,895 + $18,718,252).

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

- 0.1167 hours (7 minutes, the sum of 2 minutes for the organization determination and 5 minutes for the notification), times
- 20% * 24,279,575 or8,625 enrollees requesting organization determinations per MAO, resulting in an annual hourly burden of
- 566,681 hours, with a consequent aggregate annual cost of
- 566,681 x $77.14 (hourly wage of a business operations specialist) = $43,713,772.

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% * 24,279,575 or259, the number of enrollees receiving extension requests per MAO, times, resulting in an annual total burden of
- 12,147 hours, with a consequent annual aggregate cost of
- $937,020 = 12,147 x $77.14 (hourly wage of a business operations specialist).

Thus the total burden of § 422.572 is 578,828 hours (566,681 + 12,147) at a cost of $44,650,792 ($43,713,772+ $937,020).

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
- 563, the number of MAOs, resulting in an annual hourly burden of
- 282 hours, with a consequent aggregate annual cost of
- $21,753 = 282 x $77.14 (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% * 24,279,575 or 431, the number of organization determinations per MAO reaching the reconsideration stage, resulting in an annual burden of
- 970,612 hours, resulting in an aggregate annual cost of
- $74,873,010 = 970,612x $77.14(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% * 431 =108, the number of reconsideration cases per MAO with a decision adverse to the enrollee, resulting in an annual hourly burden of
- 121,608 hours, resulting in an annual aggregate cost of
- $9,380,841 = 121,608 x $77.14 (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 1,092,220 hours (970,612+ 121,608) at an annual cost of $84,253,851 ($74,873,010 + $9,380,841).

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% * 24,279,575 48,559, the number of enrollees admitted to inpatient hospitals who are expected to request reviews, resulting in an annual hourly burden of
- 4,045 hours, with a consequent annual aggregate cost of
- $104,037 = 4,045 x $25.72 (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% * 24,279,575 or 86, the number of enrollees per MAO 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

- 72,627 hours, resulting in an annual aggregate cost of
- 72,627x $77.14 (hourly wage of a business operations specialist) = $5,602,447.

Thus the total annual burden of § 422.622 is 72,627 hours at an annual cost of $5,602,447 for plans and total annual burden of 4,033 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% * 24,279,575 or 3,316, the number of enrollees per MAO experiencing terminations of SNF, HHA or CORF services, resulting in an annual hourly burden of
- 155,564 hours, with a consequent annual aggregate cost of
- $11,996,273 = 155,564 hours x $77.14 (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% * 24,279,575 or 66, the number of enrollees per MAO experiencing terminations of SNF, HHA or CORF services who appeal to the IRE, resulting in an annual hourly burden of
- 55,737 hours (66 enrollee x 563 MAOs x 1.5 hours), with a consequent aggregate annual cost of
- $4,299,552 = 55,737 hours x $77.14(hourly wage of a business operations specialist)

General requirements for applicable integrated plans (§ 422.629)

Under § 422.629(g), applicable integrated plans must send a notice of acknowledgment for all integrated grievances and integrated reconsiderations. A beneficiary's integrated grievance and the subsequent information collection activities necessitated by that grievance are exempt from the requirements of the PRA since the grievance would be submitted in response to an administrative action against a specific individual (5 CFR 1320.4).

We believe the provision § 422.629(k)(2) results in a reduction in the number of grievance reviews conducted by applicable integrated plans due to the elimination of duplicative grievance reviews for Medicare and Medicaid overlap issues. We do not estimate this burden reduction as this information collection activity is exempt under 5 CFR 1320.4 from the requirements of the PRA since it occurs as part of an administrative action.

Although we do not estimate burden for applicable integrated plans related to information collection activities involved in unifying grievances associated with our provisions at § 422.629, the individual provisions at § 422.629(h) necessitates operational and systems changes on the part of applicable integrated plans. The following sets out our burden estimates related to updates to and recordkeeping and storage.

D-SNPs, like other MA plans, are currently required to maintain records for grievances (§ 422.504(d)). However, § 422.629(h) requires the maintenance of specific data elements consisting of: a general description of the reason for the integrated grievance; the date of receipt; the date of each review or, if applicable, the review meeting; the resolution at each level of the integrated grievance, if applicable; the date of resolution at each level, if applicable; and the name of the enrollee for whom the integrated grievance was filed.

We estimate a one-time burden for applicable integrated plans to revise their systems for recordkeeping related to integrated grievances. We anticipate this task takes a software developer/programmer 3 hours at $102.88/hr. Three hours is consistent with the per-response time estimated in the May 2016 Medicaid Managed Care final rule (81 FR 27498). In aggregate, we estimate a one-time burden of 171 hours (3 hr x 57 contracts) at a cost of $17,592(171 hr x $102.88/hr). Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 57 hours (171 hr x 1/3) at a cost of $5,864 ($17,592x 1/3). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

We do not expect the cost of storage to change under § 422.629(h)(3) since D-SNPs are currently required to store records under § 422.504(d), and the provision will not impose any new or revised storage requirements or burden.

Burden for updates to policies and procedures related to this provision will be calculated under § 422.630.

Integrated grievances (§ 422.630)

Under § 422.630(b), applicable integrated plans are required to accept grievances filed at any time consistent with the Medicaid standard at § 438.402(c)(2)(i). This change has the net effect

of permitting enrollees to file a grievance for a Medicare-covered service outside of the 60-day timely filing standard, as measured from the date of the event or incident that precipitated the grievance. The provision effectively eliminates the timely filing period for Medicare-related grievances. We do not expect this requirement to increase the volume of grievances that an applicable integrated plan is 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.

Under § 422.630(c), enrollees of applicable integrated plans may 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 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 an increase in the volume of grievances that either states or applicable plans are responsible for handling.

Section 422.630(d) permits 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 has a negligible impact on information collection activities because applicable integrated plans already has 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) has no impact on the volume of grievances.

Section 422.630(e)(1) requires that an applicable integrated plan resolve a standard (non-expedited) grievance within 30 days consistent with the MA standard (§ 422.564(e)); under Medicaid (§ 438.408(b)), 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 has 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) requires an 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 has more than a negligible impact on plans since it adopts existing MA requirements for how an applicable integrated plan must notify an enrollee of an extension and the existing Medicaid managed care requirement for the timeliness standard. Thus, applicable integrated plans already has business processes in place to comply with these requirements.

Although we do not estimate burden for applicable integrated plans related to information collection activities involved in unifying grievances associated with our provisions at §§ 422.629 and 422.630, some of the individual provisions in §§ 422.629 (general requirements), 422.630 (integrated grievances), and 422.631 (integrated organization determinations) will necessitate operational and systems changes on the part of applicable integrated plans. The following sections set out our burden estimates related to updates to policies and procedures.

We estimate a one-time burden for each applicable integrated plan to update its policies and procedures to reflect the new integrated organization determination and grievance procedures under §§422.629, 422.630 and 422.631. We anticipate this task will take a business operation specialist 8 hours at $77.14/hr. In aggregate, we estimate a one-time burden of 456 hours (8 hr x 57 contracts) at a cost of $35,176 (456 hr x $77.14/hr). Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 152 hours (456 hr x 1/3) at a cost of $11,725 ($35,176 x 1/3). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

Integrated organization determinations (§ 422.631)

Section 422.631 requires that each applicable integrated plan issue one integrated organization determination, so that all requests for benefits from and appeals of denials of coverage by applicable integrated plans are subject to the same integrated organization determination process. Section 422.631(d)(1) requires that an applicable integrated plan send an integrated notice when the integrated organization determination is adverse to the enrollee. The notice must include information about the determination, as well as information about the enrollee's appeal rights for both Medicare and Medicaid covered benefits. Though integrating information on Medicare and Medicaid appeal rights will be a new requirement, we note that the requirement for a notice and the content of the notice largely align with current requirements in Medicaid (§ 438.404(b)) and MA (§ 422.572(e)). We believe that the provision has minimal impact on plans based on our understanding of how plans that will meet the definition of an applicable integrated plan under the final rule currently handle coverage determinations for full-benefit dual eligible individuals receiving Medicare and Medicaid services through the plan. Currently, if such a plan were to deny or only partially cover a Medicaid service never covered by Medicare (like a personal care attendant or a clear request for Medicaid coverage), it only issues a Medicaid denial (one notice). Under the final rule, it does the same (that is, issue one notice). On the other hand, if the plan denied a service that is covered under either Medicare or Medicaid, such as home health services, we believe that the plan covering both Medicare and Medicaid benefits in most, if not all, states issues an integrated determination notice that includes information about the application of Medicare and Medicaid coverage criteria to the requested service and how to appeal under both Medicare and Medicaid (one notice). The final rule codified this practice for applicable integrated plans.

Also under § 422.568(d), if the plan covers a service such as durable medical equipment or home health services under Medicaid, but denies the same service under Medicare's rules, it must issue a Medicare denial even though the service was actually covered by the plan based on its Medicaid contract. Under the final rule, a plan covering both Medicare and Medicaid benefits no longer needs to issue a notice in this situation. We do not have data to estimate the number of instances in which D-SNPs currently issue denial notices related to overlap services; therefore, we are unable to reliably estimate the reduction in plan burden resulting from our unified appeals requirements.

We developed a model integrated denial notice form for use by applicable integrated plans. The model form, form instructions, and associated requirements and burden have been submitted to OMB for approval. The 60-day notice published in the Federal Register on October 18, 2019 (84 FR 55966). The 30-day notice was published on April 15, 2020 (85 FR 20914). The collection of

information documents are currently on our PRA website. Additionally, changes to the procedures for applicable integrated plans are reflected in the current Notice of Denial of Medical Coverage form and instructions (OMB control number 0938-0892; CMS-10003).

Although we do not estimate burden for applicable integrated plans related to information collection activities involved in unifying grievances associated with our provisions at § 422.631, some of the individual provisions in § 422.631 will necessitate operational and systems changes on the part of applicable integrated plans. Burden for these provisions is calculated under § 422.630.

Integrated reconsideration (§ 422.633)

A beneficiary's appeal of an adverse integrated coverage determination and the subsequent information collection activities necessitated by that appeal are exempt from the requirements of the PRA since the appeal would be submitted in response to an administrative action against a specific individual (5 CFR 1320.4). This exemption covers any information collection activities undertaken after the adverse integrated organization determination by an applicable integrated plan, including: acknowledgement of integrated reconsiderations under § 422.629(g), recordkeeping related to integrated appeals at § 422.629(h), and notification of the applicable integrated plan's integrated reconsideration determination at § 422.633(f)(4).

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 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 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 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 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 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 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 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 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, during 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.

Table 1 summarizes the annual burden for all provisions scored in this information collection request.

Table 1: Summary of annual burden estimates.

Regulatory Citation	Annual Frequency	Number of respondents	Number of responses per respondent	Total Responses	Time (Hours per Response)	Total Time (Hours)[1]	Wages ($/hr)	Total Labor Cost[2]
§ 422.52	As occurs	236 MAOs	1	153,000	0.25	38,250	$36.82	$1,408,365
§ 422.62	As occurs	563 MAOs	9,451	1,710,650	0.0833	142,497	$77.14	$10,992,219
§ 422.64	Annually	563 MAOs	1	563	2	1,126	$77.14	$86,860
§ 422.66(b)(3)(i)	As occurs	563 MAOs	1	226,339	0.0167	3,772	$77.14	$291,589
§ 422.66(b)(3)(iii)	As occurs	563 MAOs	1	226,339	0.0167	3,772	$77.14	$291,589
§ 422.66(b)(3)(iv)	As occurs	563 MAOs	1	226,339	0.0833	18,862	$36.82	$694,204
§ 422.74	As occurs	563 MAOs	1	27,313	0.1	2,731	$77.14	$210,669
§ 422.107	One time	277 MAOs	1	277	8	739	$139.72	$103,253
§ 422.107	One time	176 MAOs	1	176	107	18832	$90.01*	$1,695,068
§ 422.107	Annually	277 MAOs	*Varies*	351	30	10,530	$77.14	812,284
§ 422.132	Annually	563 MAOs	1	563	40	22,520	$77.14	$1,737,193
§ 422.158	Annually	10 deeming	1	10	64	640	$77.14	$49,370

Regulatory Citation	Annual Frequency	Number of respondents	Number of responses per respondent	Total Responses	Time (Hours per Response)	Total Time (Hours)[1]	Wages ($/hr)	Total Labor Cost[2]
		organizations						
§ 422.202	Weekly	563 MAOs	50	28,150	0.1667	4,693	$77.14	$362,018
§ 422.206	As occurs	563 MAOs	1	563	0.5	282	$77.14	$21,753
§ 422.216	As occurs	5 MAOs	70	350	0.0833	29	$77.14	$2,237
§ 422.320	As occurs	563 MAOs	22	12,386	0.1667	2,065	$77.14	$159,294
§ 422.506	Annually	563 MAOs	1	563	9	5,067	$77.14	$390,868
§ 422.514	Annually	22 MAOs	1	22	2	45	$77.14	$3,446
§ 422.564	As occurs	563 MAOs	176	99,088	0.25	24,772	$77.14	$1,910,912
§ 422.568(b)	As occurs	563 MAOs	1	563	30	16,890	$77.14	$1,302,895
§ 422.568(d)	As occurs	563 MAOs	431	242,653	1	242,653	$77.14	$18,718,252
§ 422.572	As occurs	563 MAOs	8,625	4,855,875	0.1167	566,681	$77.14	$43,713,772
§ 422.572	As occurs	563 MAOs	259	145,817	0.0833	12,147	$77.14	$937,020
§ 422.584	As occurs	563 MAOs	1	563	0.5	282	$77.14	$21,753
§ 422.590	As occurs	563 MAOs	431	242,653	4	970,612	$77.14	$74,873,010
§ 422.590	As occurs	563 MAOs	108	60,804	2	121,608	$77.14	$9,380,841
§ 422.622(e)	As occurs	563 MAOs	86	48,418	1.5	72,627	$77.14	$5,602,447
§ 422.624	As occurs	563 MAOs	3,316	1,866,908	0.0833	155,513	$77.14	$11,996,273
§ 422.626	As occurs	563 MAOs	66	37,158	1.5	55,737	$77.14	$4,299,552
§§ 422.629-.631	One time	57 MAOs	1	57	8	152	$77.14	$11,725
§ 422.629	One time	57 MAOs	1	57	3	57	$102.88	$5,864
§ 422.2440	As occurs	8 MAOs	346	2,765	0.0167	46	$77.14	$3,548
§ 422.2440	As occurs	8 MAOs	346	2,765	0.0167	46	$77.14	$3,548
§ 422.2440	As occurs	8 MAOs	346	2,765	0.0833	230	$36.82	$8,481
§ 422.38	As occurs	53 MAOs	35,236	1,867,519	0.0833	155,564	$77.14	$12,000,207
Subtotal (Private Sector)	*Varies*	*563*	*Varies*	*12,090,382*	*Varies*	*2,672,069*	*Varies*	*$204,102,379*
§ 422.107	One time	44	1	44	24	352	$139.72	$24,591
§ 422.107	One time	13	1	13	160	1,387	$90.01*	$62,422
Subtotal (State)	*Varies*	*44*	*1*	*57*	*Varies*	*1,739*	*Varies*	*$87,013*
§ 422.622(b)	As occurs	48,559	1	48,559	0.0833	4,045	$25.72	$104,037
Subtotal (Beneficiaries)	*As occurs*	*48,559*	*1*	*48,559*	*Varies*	*4,045*	*$25.72*	*$104,037*
TOTAL	***Varies***	***49,176***	***Varies***	***12,138,998***	***Varies***	***2,677,853***	***Varies***	***$204,293,429***

Notes:

1. Reflects division by 3 to annualize a one-time update over 3 years.
2. For state burdens, reflects 50 percent reduction to Federal Matching program.

3. Average of $77.14 and $102.88, the wages of a business operations specialist and programmer working simultaneously on this task.

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. 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. 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 Final Rule CMS-4185-F (RIN: 0938-AT59)

Integration

Starting in 2021, section 50311(b) of the Bipartisan Budget Act of 2018 establishes new Medicare and Medicaid integration standards for MA organizations seeking to offer D-SNPs.

The impacts of these standards were presented in section III.B.2. of the final rule and in Section 12 of this PRA package. However, the impact estimates in Section 12 reduced the cost to state Medicaid agencies by 50 percent, reflecting a 50 percent Federal Financial Participation (FFP) rate; consequently, we must now present this 50 percent reduction as a cost to the Federal Government. Table III includes transfers to the Federal Government.

As detailed in Table III, the total first year cost is $4.5 million ($4.0 million to plans + $0.25 million to State Medicaid Agencies and $0.25 million to the federal government). The $ 3.9 million represents a true cost since it pays for the services of lawyers, software developers and programmers, and business operation specialists. Of this $4.5 million, $4.0 million is a cost to plans, while $0.5 million is a cost to the state Medicaid agencies which transfers $0.25 million to the federal government.

TABLE III: FIRST YEAR COSTS OF D-SNP INTEGRATION REQUIREMENTS

Item	Number of Respondents	Hours per Respondent	Total Hours	Cost per Hour ($)	Cost to D-SNPs ($)	Cost to State Medicaid Agencies ($)	Transfers to Federal Government ($)
Initial update by state Medicaid agency of its contracts with D-SNPs	44 (states)	24	1,056	136.44	n/a	72,040	72,040
Initial establishment of system for notification of hospital and SNF admissions by state Medicaid agency	13	160	2,080	100.41	n/a	104,426	104,426
	13	160	2,080	77.14	n/a	73,882	73,882
Initial update by D-SNPs of their contracts with state Medicaid agency	208 (D-SNPs)	8	1,664	136.44	227,036	n/a	n/a
Initial notification of hospital and SNF admissions by D-SNPs to state Medicaid agency	136	160	21,760	100.41	2,184,922	n/a	n/a
	136	160	21,760	77.14	1,545,830	n/a	n/a
Total by Stakeholder	252	Varies	50,400	Varies	3,957,788	250,348	250,348

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

Unified Grievances and appeals

There are three areas where this provision will have an impact, listed here and discussed in further detail later in this section.

a. Updating plan grievance policies and procedures and consolidation of plan grievance notifications and reviews;
b. Updating applicable integrated plan appeals policies and procedures; and
c. Sending appeal files to enrollees who request them.

Following are details on these three areas of impact.

a. Updating Plan Grievance Policies and Procedures and Consolidation of Plan Grievance Notifications and Reviews

In addition to the costs estimated for § 422.630 in burden estimate section of this supporting statement, we estimate the impact of sending a notice of acknowledgement under § 422.629(g). Applicable integrated plans must send a notice of acknowledgment for all grievances, both those submitted orally and in writing. Medicaid managed care organizations are currently required to send this notice under § 438.406(b)(1), whereas MA plans are not currently required to send this notice. Under the final rule, applicable integrated plans must now send this notice for all grievances, not only those pertaining to Medicaid issues. In the absence of data on the types of grievances submitted, we assume half the grievances currently made to an applicable integrated plan are related to Medicare issues and half are related to Medicaid issues. The estimated aggregate annual burden across all plans from this provision is 32 hours (1,892 grievances x 1/60 hr) at a cost of $2,297 (1,892 grievances x 1/60 hr x $72.84/hr).

b. Updating Applicable Integrated Plan Appeals Policies and Procedures
Applicable integrated plans' internal appeals policies and procedures must be updated to comply with the unified appeals requirements. In terms of updates, we see no reason to differentiate between the work required for grievances and appeals. Therefore, as indicated in the impact estimate for 422.630 in Section 12 of this PRA package, we estimate a one-time cost of $29,864 ($19,812 for updating policies and procedures + $10,051 for recordkeeping) for updating applicable integrated plans' appeals policies and procedures.

c. Sending Appeal Files to Enrollees Who Request Them

Medicaid managed care regulations under § 438.406(b)(5) currently require plans to send, for free, appeal case files to enrollees who appeal while, in contrast, the Parts C & D Enrollee Grievance, Organization/Coverage Determinations, and Appeals Guidance, § 50.5.2, requires MA plans to send such files at a reasonable cost.[1] Our final rule requires the applicable integrated plans to send such files for free. To estimate this cost, we must first estimate the cost of sending such a file.

Livanta, a Quality Improvement Organization, estimates the cost per case file as $40-$100.[2] This can be justified independently with a stricter range as follows: Assuming a typical case file has 100 pages, it would weigh about 1 pound at 6 pages per ounce. The cost of mailing a 1-pound case file by FedEx (to assure security) is $10. The cost of photocopying 100 pages at a minimum rate of $0.05 per page is $5. The $0.05 per page is likely to be an overestimate for plans that own their own photocopying equipment. Thus, the total cost of photocopying and mailing would be about $15. We assume a correspondence clerk, BLS occupation code 43-4021,[3] would take 1 hour of work, at $36.64 per hour (including 100 percent for overtime and fringe benefits) to retrieve the file, photocopy it, and prepare it for mailing. Thus we estimate the total cost at $36.64 + $10 + $5 = $51.64.

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[1] See https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.

[216] See https://bfccqioarea1.com/recordrequests.html

[3] https://www.bls.gov/oes/current/oes_nat.htm

We need further estimates to complete the calculation. We assume 43.5 total appeals (favorable and unfavorable) per 1000.[4] Based on our experience, we assume that 10 percent of all appeals would require a file sent. Finally, as indicated in the impact to 422.630 in Section 12 of this PRA package as well as Table IV of this PRA package, there are 37 applicable integrated plans in 34 contracts with 150,000 enrollees in 2018 projected to grow to 172,000 enrollees in 2021. Thus we estimate the total annual cost of mailing files to enrollees as $38,637 (that is, 172,000 enrollees * 4.35 percent appeals * 10 percent requesting files * $51.64 cost).

The aggregate impact of unified grievances and appeals is a cost $0.07 million the first year and $0.04 million for the next 9 years. The total cost is $0.4 million. $0.07 million.

Total Federal Burden

We estimate an annual Federal burden of $12.65 million.

15. Program/Burden Changes

This information collection request incorporates the new minimum criteria for dual eligible special needs plans (D-SNPs) to integrate Medicare and Medicaid benefits detailed in section 50311(b) of the Bipartisan Budget Act of 2018 and set forth in final rule (CMS-4185-F, RIN 0938-AT59) for CY2020 and 2021. The integration requirements improve care coordination, quality of care, and beneficiary satisfaction while reducing administrative burden. We have also revised Section 12 by removing burden estimates and cost calculations for the standard ("long") model enrollment form to elect an MA plan established at 42 CFR 422.50 and 422.60. The burden for this form has been extracted into its own stand-alone package (CMS-10718). In addition, we have updated all cost calculations within this PRA package to align with the most current BLS data and have not changed any other requirements.

This request updates the burden to reflect revisions that are set out under our CMS-4190-Final rule. The revisions account for the addition of burden for:

- 42 CFR 422.62, the addition of the burden for determining an applicant's eligibility for an election period that was inadvertently omitted from previous burden collections.
- 42 CFR 422.514, the addition of a contract requirement limiting CMS contracts to MA plans consisting of 80 percent or more dually eligible enrollees if such plans are non-special needs plans (SNPs)
- 42 CFR 422.2440, accounting for certain costs associated with anticipated enrollment changes attributable to the addition of a deductible-based adjustment to the medical loss ratio (MLR) for MA MSA contracts with relatively low enrollment.

Lastly, this request updates the burden for existing estimates based on the most recent Part C enrollment numbers.

[4] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html

Summary of Changes

The following table summarizes the additions to CMS-R-267 associated with CMS-4185-F and CMS-4190-F.

Regulatory Reference	Respondents	Total Number of Responses	Hours Per Response	Total Hours[1]	Wages ($/hr)	Total Cost ($)
§ 422.107 (Initial update of States of their Contracts with D SNPs)	44	44	24	352	139.72	24,591
§ 422.107 (Initial notification systems for State Medicaid Agencies)	13	13	160	1,387	90.01[3,]	62,422
Subtotal (States)	*44*	*57*	*Varies*	*1,739*	*Varies*	87,013
§ 422.62 (Part C Election Period: Determine eligibility)	181	1,710,650	0.0833	142,197	77.14	10,992,219
§ 422.107 (Initial updates of D-SNPs of their Contracts with the State)	277	277	8	739	139.72	103,253
§ 422.107 (Initial notification of D-SNPs to Medicaid Agencies)	176	176	107	18,832	90.01[3,]	1,695,068
§ 422.514 (D-SNP Look-Alikes transitions)	67	67	2	45	77.14	3,446
§§ 422.629, 422.630, and 422.631 (Updates to D-SNP policies and procedures)	57	57	8	152	77.14	11,725
§ 422.629(g) (Recordkeeping)	57	57	3	57	102.88	5,864
§ 422.2440 (MLR: Notify enrollees)	8	2,765	0.0167	46	77.14	3,548
§ 422.2440 (MLR: Submit to CMS)	8	2,765	0.0167	46	77.14	3,548
§ 422.2440 (MLR: Archive)	8	2,765	0.0833	230	36.82	8,481
§ 423.38 (Part D Election Period: Determine eligibility)	53	1,867,519	0.0833	155,564	77.14	12,000,207
Subtotal (Private Sector)	*563*	*3,587,098*	*Varies*	*317,908*	*Varies*	*24,827,359*
TOTAL	**607**	**3,587,155**	**Varies**	**319,647**	**Varies**	***24,914,372***

Notes:
1. Reflects division by 3 to annualize a one-time update over 3 years.
2. For state burdens, reflects 50 percent reduction to Federal Matching program.
3. Average of $77.14 and $102.88, the wages of a business operations specialist and programmer working simultaneously on this task.

The follow table summarizes the burden removed from CMS-R-267 and established in CMS-10718.

Regulatory Reference	Respondents	Total Number of Responses	Hours Per Response	Total Hours	Wages ($/hr)	Total Cost ($)
§ 422.60 (Beneficiaries completing and submitting enrollment form)	7,995,563	7,995,563	0.333	2,662,522	25.72	68,480,066

Regulatory Reference	Respondents	Total Number of Responses	Hours Per Response	Total Hours	Wages ($/hr)	Total Cost ($)
§ 422.60 (MAO determining an enrollee's eligibility for enrollment)	181	7,995,563	0.0833	666,297	77.14	51,398,151
§ 422.60 (MAO submitting an enrollment transaction to CMS)	181	7,995,563	0.0167	133,259	77.14	10,279,599
§ 422.60 (MAO noticing enrollee of acceptance or denial of enrollment)	181	7,995,563	0.0167	133,259	77.14	10,279,599
§ 422.60 (MAO filing and retaining enrollment form)	181	7,995,563	0.0833	666,297	36.82	24,533,056
TOTAL	**7,995,744**	**39,977,815**	**Varies**	**4,261,634**	**Varies**	***164,970,471***

Our June 2, 2020 final rule (CMS-4190-F, RIN 0938-AT97) finalized the following information collection requirement (ICR) changes:

ICRs Regarding Contracting Standards for Dual Eligible Special Needs Plan (D-SNP) Look-Alikes (§ 422.514)

As described in Section 12, we estimate each plan will take a one-time amount of 2 hours at $77.14/hr for a business operations specialist to submit all enrollment changes to CMS necessary to complete the transition process. The burden for MA organizations to transition enrollees to other MA-PD plans during the 2021 and 2022 plan years is 124 hours (62 D-SNP look-alikes * 2 hr/plan) at a cost of $9,565 (124 hr * $77.14/hr). We averaged this burden for the 62 plans over the 2021 and 2022 plan years, resulting in an annual burden of 62 hours (124 hr/2 yr) at a cost of $4,783 ($9,565/2 yr). In subsequent years (2023 and beyond), we estimate that at most five plans per year will be identified as D-SNP look-alikes under § 422.514(d). We believe that these plans would non-renew and transition their membership into another MA-PD plan or a D-SNP. Therefore, the annual burden for the 2023 plan year and subsequent years is estimated at 10 hours (5 plans * 2 hr/plan) at a cost of $771 (10 hr * $77.14/hr) for a business operations specialist to transition enrollees into a new MA-PD plan. The average annual burden for MA plans over three years is 45 hours ([62 hr+62 hr+10 hr]/3 yr) at a cost of $3,446 ([$4,783 + $4,783 +$771]/3 yr). The impact is summarized in the table below.

SUMMARY OF PLAN BURDEN ESTIMATES FOR CONTRACT REQUIREMENTS AT § 422.514

Respondents	Subject	OMB Control No. (CMS ID No.)	2021	2022	2023	3-year average
MA organization	Transition enrollees (§ 422.514(e))	0938-0753 (CMS-R-267)	$4,783 (62 hr)	$4,783 (62 hr)	$771 (10 hr)	$3,446 (45 hr)

ICRs Regarding Medical Loss Ratio (MLR) Deductible Factor for MA Medical Savings Account (MSA) Contracts (§ 422.2440)

Our June 2, 2020 (85 FR 33796) final rule (CMS-4190-F, RIN 0938-AT97) amends § 422.2440 to provide for the application of a deductible-based adjustment ("deductible factor") to the MLR calculation for MA MSA contracts that receive a credibility adjustment. The deductible factor serves as a multiplier on the credibility factor. The application of the deductible factor will increase the MLRs of MSA contracts that receive this adjustment. We believe that the change to the MLR calculation for MSAs could potentially cause the number of enrollees in MSA plans to increase relative to enrollment projections because we expect more MA organizations to offer MA MSA plans based on this change in the MLR calculation.

Our burden estimate assumes the following:

- For the first year that the deductible factor is in effect (excluding 2021 as the MSA deductible factor was not finalized until after the deadline for MA organizations to submit applications to offer MA plans for coverage effective in 2021), the number of MA MSA contracts will double from 4 to 8.
- Over the first three years (excluding 2021), enrollment in MSAs will double relative to previous enrollment projections. We assume that, relative to projections in the baseline, MSA enrollment will be 33.33 percent higher in contract year 2022 (increasing from 7,812 to 10,416), 66.67 percent higher in 2023 (increasing from 8,179 to 13,632), and 100 percent higher in contract year 2024 (increasing from 8,531 to 17,062) to contract year 2030 (increasing from 10,354 to 20,708).
- Half of the new enrollees in MA MSA plans would otherwise have been enrolled in other types of MA plans, and half would otherwise have been enrolled in FFS Medicare. We did not have a basis for assuming whether migration to MSAs would predominantly be from FFS Medicare or from non-MSA MA plans. The process for enrolling in an MA plan is the same regardless of whether that plan is an MSA or a non-MSA. Therefore, we assume that the burden to enroll in an MSA plan and a non-MSA plan is the same.

An MA organization must give a 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 minute per application processed. We estimate that it will take 1 minute at $77.14/hr for a business operations specialist to electronically generate and submit a notice to convey the enrollment or disenrollment decision for each beneficiary. As noted previously, we anticipate that half of the new enrollees in MSAs will already be enrolled in other MA plans, meaning the current burden estimate for their enrollment is already accounted for in the currently approved collection.

For 2022, the burden to complete the notices for the other half of new MSA enrollees (that is, the new enrollees who would otherwise enroll in FFS Medicare) is approximately 22 hours (2,604/2 notices * 1 min/60) at a cost of $1,697 (22 hr * $77.14/hr) or $1.30 per notice ($1,697/1,302 notices) or $212 per organization ($1,697/8 MA organizations). For 2023, the burden to complete the notices for the half of new MSA enrollees who would otherwise enroll in

FFS Medicare is approximately 45 hours (5,453/2 notices * 1 min/60) at a cost of $3,471 (45 hr * $77.14/hr) or $1.28 per notice ($3,471/2,727 notices) or $434 per organization ($3,471/8 MA organizations). For 2024, the burden is approximately 71 hours (8,531/2 notices * 1 min/60) at a cost of $5,477 (71 hr * $77.14/hr) or $1.34 per notice ($5,477/4,090 notices) or $685 per organization ($5,477/8 MA organizations).

The average burden per year is 46 hours ([22 hr + 45 hr + 71 hr]/3) at an average cost of $3,548 ([$1,697 + $3,471 + $5,477]/3).

The burden associated with electronic submission of enrollment information to CMS is estimated at 1 minute at $77.14/hr for a business operations specialist to submit the enrollment information to CMS during the open enrollment period. For 2022, the burden to complete the notices for the other half of new MSA enrollees (that is, the new enrollees who would otherwise enroll in FFS Medicare) is approximately 22 hours (2,604/2 notices * 1 min/60) at a cost of $1,697 (22 hr * $77.14/hr) or $1.30 per notice ($1,697/1,302 notices) or $212 per organization ($1,697/8 MA organizations). For 2023, the burden to complete the notices for the half of new MSA enrollees who would otherwise enroll in FFS Medicare is approximately 45 hours (5,453/2 notices * 1 min/60) at a cost of $3,471 (45 hr * $77.14/hr) or $1.28 per notice ($3,471/2,727 notices) or $434 per organization ($3,471/8 MA organizations). For 2024, the burden is approximately 71 hours (8,531/2 notices * 1 min/60) at a cost of $5,477 (71 hr * $77.14/hr) or $1.34 per notice ($5,477/4,090 notices) or $685 per organization ($5,477/8 MA organizations).

The average burden per year is 46 hours ([22 hr + 45 hr + 71 hr]/3) at an average cost of $3,548 ([$1,697 + $3,471 + $5,477]/3).

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 $36.82/hr for an office and administrative support worker to perform record retention for the additional MA MSA enrollees. In aggregate, we estimate an annual burden for 2022 of 109 hours (2,604/2 beneficiaries * 5 min/60) at a cost of approximately $4,013 (109 hr * $36.82/hr) or $502 per organization ($4,013/8 MA organizations). For 2023, we estimate an aggregated annual burden of 227 hours (5,453/2 beneficiaries * 5 min/60) at a cost of approximately $8,358 (227 hr * $36.82/hr) or $1,634 per organization ($7,821/8 MA organizations). For 2024, we estimate an aggregated annual burden of 355 hours (8,531/2 beneficiaries * 5 min/60) at a cost of approximately $13,071 (355 hr *$36.82/hr) or $1,634 per organization ($13,071/8 MA organizations).

The average burden per year is 230 hours ([109 hr + 227 hr + 355 hr]/3) at an average cost of $8,481 ([$4,013 + $8,358 + $13,071]/3).

For 2022, we estimate a total burden for all MA organizations resulting from this provision to be 153 hours (22 hr + 22 hr + 109 hr) at a cost of $7,407 ($1,697 + $1,697 + $4,013). Per organization, we estimate an annual burden of 19.1 hours (153 hr/8 MA organizations) at a cost of $926 ($7,407/8 organizations). For 2023, we estimate a total burden for all MA organizations resulting from this provision to be 317 hours (45 hr + 45 hr + 227 hr) at a cost of $15,300 ($3,471 + $3,471 + $8,358). Per organization, we estimate an annual burden of approximately 40 hours (317 hr/8 MA organizations) at a cost of $1,912.50 ($15,300/8 organizations).

For 2024, we estimate a total burden for all MA organizations resulting from this provision to be 497 hours (71 hr + 71 hr + 355 hr) at a cost of $24,025 ($5,477 + $5,477 + $13,071). Per organization, we estimate an annual burden of approximately 62 hours (497 hr/8 MA organizations) at a cost of $3,003 ($24,025/8 organizations).

Note: The burden to beneficiaries in submitting the MSA enrollment request has been included in the PRA package CMS-10718; the control number is pending at OMB (ICR Reference Number: 202003-0938-002).

Impact of MSA/MLR by Subject

Respondents	Subject	2021	2022	2023	3-year average
MA organizations	Notice to beneficiaries	$1,697 (22 hours)	$3,471 (45 hours)	$5,477 (71 hours)	$3,548 (46 hours)
MA organizations	Submission to CMS	$1,697 (22 hours)	$3,471 (45 hours)	$5,477 (71 hours)	$3,548 (46 hours)
MA organizations	Record retention	$4,013 (109 hours)	$8,358 (227 hours)	$13,071 (355 hours)	$8,481 (230 hours)
MA organizations total		*$7,407 153 hr*	*$15,300 317 hr*	*$24,025 497 hr*	*$14,528 322 hr*

ICRs Regarding Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)

We are proposing to codify certain Part C (at § 422.62(b)(4) through (b)(25)) and Part D (at § 423.38(c)(11) through (c)(32)) SEPs for exceptional circumstances currently set out in sub-regulatory guidance that MA organizations and Part D plan sponsors have implemented and are currently following. We are also proposing to establish two new additional SEPs for exceptional circumstances: the SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer.

We do not believe the proposed changes will adversely impact individuals requesting enrollment in Medicare health or drug plans, the plans themselves, or their current enrollees. Similarly, we do not believe the proposed changes would have any impact on the Medicare Trust Fund.

Our proposal represents the codification of existing policy on SEPs for exceptional circumstances that has been specified in sub-regulatory guidance for quite some time, as well as the addition of the two aforementioned new SEPs for exceptional circumstances. MA organizations and Part D plan sponsors are currently assessing applicants' eligibility for election periods as part of existing enrollment processes; therefore, no additional burden is anticipated from this proposal. However, because a burden estimate for determining an applicant's eligibility for an election period has not previously been submitted to OMB, due to inadvertent oversight, we are seeking their approval under this control number.

We estimate it would take approximately 5 minutes (0.0833 hr) at $77.14/hr for a business operations specialist to determine an applicant's eligibility for an election period.

The burden for all MA organizations is estimated at 142,497 hours (1,710,650 beneficiary SEP elections x 0.0833 hr) at a cost of $10,544,778 (142,497.1450 hr x $77.14/hr) or $23,532 per MA organization ($10,544,778/468 MA organizations).

Burden Reconciliation

Burden Type	Total Requested (A)	Change Due to New Statute (B)	Change Due to Program Discretion (C)	Change Due to Program Adjustment (D)	Total Currently Approved (E)
Total Responses	12,138,998	3,587,155		-19,865,497	35,597,180
Total Time	2,677,853	319,647		-6,466,889	9,466,233

16. Publication/Tabulation Dates

Generally there are no publication or tabulation dates. However, as 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

The expiration date is displayed at https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.

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.