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) (Pub. L. 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. This information is obtained in the initial contract application with CMS as well as in enrollment and disenrollment transactions submitted by organizations to CMS.

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. This information is obtained in enrollment and disenrollment applications submitted by beneficiaries.

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 then current Medicare+Choice (M+C) program by replacing it with a new Medicare Advantage (MA) program under Part C of Medicare. These changes included the creation of the Prescription Drug Benefit (Part D), specialized MA Special Needs Plans (SNPs), and made the Medicare Medical Savings Account (MSA) program permanent.

On December 14, 2022 at 4:15 pm (the date and time of public inspection at the Office of the Federal Register), we proposed (CMS-4201-P, RIN 0938-AU96) the following changes: INSERT. See section 15 for details.

- 42 CFR § 422.74, the addition of the burden for notifying a beneficiary of their loss of Special Needs status, submitting the disenrollment transaction, and sending a final notice of disenrollment to the beneficiary.

- 42 CFR § 422.74(b)(2), the addition of the burden for notifying a beneficiary of their mid-year loss of eligibility to remain in their MSA plan and notifying CMS of the disenrollment action.

- 42 CFR §§ 422.566 and 422.629, the addition of burden for MA organizations to utilize a physician or other health care professional with expertise in the field of medicine appropriate to the requested service when reviewing medical necessity decisions.

- 42 CFR § 422.2267(e)(12)(ii), the addition of the burden for MA organizations to update their existing written provider termination notice.

- 42 CFR § 422.101(b)(2) and § 422.101(c), the addition of burden for MA organizations to update coverage requirements for basic benefits and medical necessity determinations.

A. Justification

1. Need and Legal Basis

Section 4001 of the Balanced Budget Act of 1997 (BBA) added sections 1851 through 1859 to the Act to establish the Managed Care program. The Medicare, Medicaid, and SCHIP Benefits Improvement Act and Protection Act of 2000 (Pub. L. 106-554) added requirements to the Managed Care program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. 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 [Publication Date] (87 FR PAGE NUMBER) proposed rule (CMS-4201-P, RIN 0938-AU96) 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. Some of the proposed additions in this collection of information request codify existing CMS policies found in the Medicare Managed Care Manual, Chapter 2, while others establish new policies.

2. Information Users

Users of the collection of information requirement in section 12 of this Supporting Statement include: (1) the MA organizations, (2) CMS, and (3) applicants to MA organizations.

Information is collected from organizations during their initial application to CMS to become a contracted MA organization. Information is also collected from beneficiary applicants to MA organizations in order to enroll or disenroll from an MA plan. 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 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 to CMS is electronic (§§ 422.64, 422.66, and 422.74).
- MA organizations' updating of their provider termination notice template and related systems is electronic (§ 422.2267(e)(12)(ii).

4. Duplication of Similar Information

The information collection requirements that are set out below in section 12 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.

6. Less Frequent Collection

This collection does not set out any daily, weekly, monthly, or annual requirements; rather this information is collected as needed. This information is collected on the least frequent basis necessary to support CMS' administration of the MA program. For example, information from beneficiaries is collected when an enrollment application is filed. If it were to be collected less frequently, CMS would not be able to obtain this data. In another example, MA organization contract non-renewals with CMS are collected on an annual basis, as contracts are year-long and the determination to non-renew an existing contract only needs to occur once to non-renew for the following year. 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: (1) enrollment, (2) disenrollment, (3) marketing, (4) processing of grievances by enrollees, and (5) 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

Serving as the 60-day notice, our proposed rule (CMS-4201-P; RIN 0938-AU96) filed for public inspection at the Office of the Federal Register on December 14, 2022 at 4:15 pm. The rule is scheduled to publish in the Federal Register on December 27, 2022. Comments must be received by 5 p.m. on February 13, 2023.

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 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 that 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: (1) For a beneficiary wishing to join a Religious Fraternal Plan (§ 422.2) and (2) when an MA plan has conscientious objection to covering a procedure on religious grounds (§ 422.206).

12. Information Collection Requirements and Associated Burden Estimates

Subsection 12A sets out burden for collection of information requirements that are subject to the PRA. Subsection 12B lists collection of information requirements that are exempt from the PRA. Subsection 12C lists related collection of information requirements that are approved by OMB under a control number other than 0938-0753 (CMS-R-267).

12A. Information Collection Requirements and Burden Subject to the PRA

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2021 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 BLS' mean hourly wage, our estimated cost of fringe benefits and overhead (calculated at 100 percent of salary), and our adjusted hourly wage.

Occupation Title	Occupation Code	Mean Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Wage ($/hr)
All Occupations	00-0000	28.01	n/a	n/a
Business Operation Specialists, All Other	13-1199	38.10	38.10	76.20
Computer programmer	15-1251	46.46	46.46	92.92
Lawyer	23-1011	71.17	71.17	142.34
Office and Administrative Support Workers, All Other	43-9199	20.47	20.47	40.95
Physician, All Other	29-1229	111.30	111.30	222.60

Software Developers and Programmers	15-1250	54.68	54.68	109.36

Private Sector Wages: As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

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 $28.01/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, 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 $1,566,337.50 (38,250 x $40.95/hr).

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 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 $76.20/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 $10,858,271 (142,497 hr x $76.20/hr) or $59,990 per organization ($10,858,271/181 MA parent organizations).

Information about the MA program (§ 422.64)

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 $76.20/hr (hourly wage of business operation specialist) = $85,801.

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 $76.20/hr (hourly wage of business operations specialist) = $287,426.

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 $/hr76.20 (hourly wage of a business operations specialist) = $287,426.

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 $40.95/hr (hourly wage of an administrative and support worker) = $772,399.

The total annual burden of § 422.66 is estimated at 26,406 hours (3,772+ 3,772 + 18,862) at an annual cost of $1,347,251 ($287,426 + $287,426 + $772,399) for plans.

Disenrollment by the MA organization (§ 422.74)

Paragraph (d)(1) states that 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 $76.20/hr (hourly wage of business operations specialist) = $208,102.

Paragraph (d)(7) states that an 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.

PROPOSED *Required Notices for Involuntary Disenrollment for Loss of Special Needs Status (§ 422.74)*

MA organizations that offer special needs plans are currently effectuating involuntary disenrollments for loss of special needs status as part of existing disenrollment processes, including the member notifications outlined in our proposal; therefore, no additional burden is anticipated from this proposal. However, because a burden estimate for these member notifications has not previously been submitted to OMB, due to inadvertent oversight, we are seeking OMB approval under the aforementioned OMB control number.

We are proposing to codify current policy on MA plan notices prior to a member disenrollment for loss of special needs status. MA organizations would be required to provide the member a minimum of 30 days advance notice of disenrollment regardless of the date of the loss of special needs status. Additionally, the organization would be required to provide the member a final notice of involuntary disenrollment, sent within 3 business days following the last day of the period of deemed continued eligibility and before the disenrollment transaction is submitted to CMS.

Where an individual is involuntarily disenrolled from an MA plan for any reason other than death, loss of entitlement to Part A or Part B, the MA organization must give the individual a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual, pursuant to § 422.74(c). The notice requirement in § 422.74(c) is currently covered under the aforementioned control number.

To estimate the number of notices required due to involuntary disenrollments for loss of special needs status, we determined the average number of annual disenrollments due to loss of special needs status. Between 2017 and 2021, there were an average of 55,127 involuntary disenrollments per year due to loss of special needs status.

We estimate that it will take each MA organization 1 minute (0.017 hr) to assemble and disseminate the advance notice, 5 minutes (0.083 hr) to submit the required transaction to CMS for each disenrollment, and 0.017 hr to assemble and disseminate the final notice for each disenrollment. Therefore, the total annual time for each MA organization is 0.1170 hours (0.017 hr +0.083 hr + 0.017 hr) at a cost of $8.92 (0.117 hr * $76.20/hr, the hourly wage of a business operations specialist).

We estimate the aggregate annual burden for all MA organizations to process these disenrollments to be 6,450 hours (55,127 disenrollments *0.117 hr) at a cost of $491,490 (6,450 hr * $76.20/hr).

PROPOSED Involuntary Disenrollment for Individuals Enrolled in an MA Medical Savings Account (MSA) Plan (§ 422.74(b)(2))

The requirement proposed at § 422.74(b)(2)(vii) to establish a process for involuntary disenrollment for an individual who loses eligibility mid-year to be enrolled in an MA MSA plan, and more specifically, the requirement for the MA organization to give the individual a written notice of the disenrollment at § 422.74(c) with an explanation of why the MA organization is planning to disenroll the individual, will be submitted to OMB for approval under control number 0938-0753 (CMS-R-267).

The annual burden associated with this requirement are the burdens of notifying the individual and notifying CMS. Based on CMS-R-267, we estimate that each disenrollment will require 1 minute (0.017 hr.) for the MA MSA plan to notify CMS and 5 minutes (0.083 hr.) for the MA MSA plan to notify the individual. Thus, the total burden per disenrollment is estimated at 6 minutes (0.1 hr) (1 minute to assemble and disseminate the notice to CMS and 5 minutes to assemble and disseminate the notice to the individual) at a cost of $7.62 (0.1 hr x $76.20/hr for a business operations specialist to perform the work).

To obtain aggregate burden we used data from 2019 and 2021 in which there were an average of 4 MSA contracts. We used an average since the data had no visible trend but hovered around a central value. There was an average of 8,624 enrollees during 2019 – 2021 and the average disenrollment was 124. Thus, we estimate:

- An aggregate burden for all MSA contracts of 12 hours (124 disenrollments * 0.1 hr. per disenrollment) at an aggregate cost of $914 (12 hours * $76.20;/hr).

- The average burden per MSA contract is therefore 3 hr. (12 divided by 4) at an average burden of $305 (914 divided by 4). The average number of disenrollments per contract is 31 (124 divided by 4).

SUBPART C, BENEFITS AND BENEFICIARY PROTECTIONS

Requirements relating to basic benefits (§ 422.101)

Section 422.101(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.

PROPOSED Requirements relating to basic benefits (§ 422.101(b)(2), §422.101(b)(6), and § 422.101(c))

At the proposed requirements at 42 CFR § 422.101(b)(2) and § 422.101(c), MA organizations must comply with national coverage determinations (NCD), local coverage determinations (LCD), and general coverage and benefit conditions included in Traditional Medicare statutes and regulations when making medical necessity determinations and must follow Traditional Medicare coverage criteria as specified in NCDs, LCD, or Medicare laws (that is, in Medicare statutes and regulations).

At the proposed requirements at 42 CFR § 422.101(b)(6), in the absence of coverage criteria in an applicable Medicare statute or regulation, NCD or LCD, MA organizations may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature and that this evidence must be made publicly available. Additionally, MA organizations must provide a publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations, a list of the sources of such evidence, and include an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination.

We expect that each plan annually will have new policies that they create. We believe that the public posting of the summary of evidence used to develop a plan's internal coverage criteria would require minimal time. We estimate that over the course of a year 2 business days or 16 hours would be an adequate estimate of time needed for a business operations specialist to make all postings. Thus, the per contract burden is 16 hours at a cost of $1,219 (16 * $76.20) and the aggregate burden over 697 contracts is 11,152 hours (697 contracts * 16 hours/contract) at a cost of $849,782 (11,152 hr * $76.20/hr).

Special rules for point of service option (§ 422.105)

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)(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).

Special Needs Plans and dual-eligibles: Contract with state Medicaid agency (§ 422.107)

(a) – This section described the burden associated with a contract between a dual-eligible special needs plan (D-SNP) and a State Medicaid agency. This is 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.

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 $76.20/hr (hourly wage of a business operations specialist)= $802,386.

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 $142.34/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 $75,156 (1,056 hr x $142.34/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 $25,052 ($75,156 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 $192,982 [((2,080 hr x $109.36/hr) + (2,080 hr x $76.20/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 $64,327 ($192,982x 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 $142.34/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 $315,425, (2,216 hr x $142.34/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 $105,142, ($315,425 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 $5,241,699 [(28,248 hr x $109.36/hr) + (28,248 hr x $76.20/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 $1,747,233 ($5,241,699 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)

The MA organization must make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date 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 be notified.

PROPOSED Enrollee Notification Requirements for MA Provider Contract Terminations (§ 422.111(e))

We are proposing to revise § 422.111(e) by establishing specific enrollee notification requirements for no-cause and for-cause provider contract terminations and adding specific and more stringent enrollee notification requirements when primary care and behavioral health

provider contract terminations occur.

This proposal to amend §§ 422.111(e) would impact MA organizations in terms of the burden required to identify those enrollees who must be notified of provider contract terminations per CMS requirements, to develop and send the required written notices, to develop the scripts for the required telephonic notices, and to make the required enrollee telephone calls and any necessary follow-up calls. However, CMS does not currently collect data regarding the widely variable number of provider contract terminations an MA organization undergoes in a given contract year, nor the number of enrollees affected by each termination. Therefore, we do not have information to estimate the extent of MA provider contract terminations, how many enrollees are affected and need to be notified per § 422.111(e), or how the MA program would be impacted as we see the effects of the proposed regulation. The actual direct burden of this provision arises from MA organization staff hours spent, resources purchased, and enrollee notifications provided. MA organizations may also differ in how their spending for the proposed requirements evolves over time as they test strategies and redevelop their approaches to complying with the regulation.

We are unable to estimate the burden for the proposed telephonic notice requirement at proposed § 422.111(e)(1)(i) because the number of primary care and behavioral health provider contract terminations an MA organization undergoes in a given contract year is unknown, as are the number of affected enrollees per termination.

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 $76.20/hr = $1,430,502.6.

SUBPART D, QUALITY IMPROVEMENT PROGRAM

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 control number 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 $76.20/hr (hourly wage for business operations specialist) = $48,768.

SUBPART E, RELATIONS WITH PROVIDERS

Participation procedures (§ 422.202)

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 $76.20/hr (hourly wage of a business operations specialist) = $357,607.

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.

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 $76.20/hr (hourly wage of a business operations specialist) = $21,488.

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

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 $76.20/hr (hourly wage of a business operations specialist) = $2,210 dollars.

SUBPART G, PAYMENTS TO MEDICARE ADVANTAGE ORGANIZATIONS

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

- 1/20th 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 $76.20/hr (hourly wage of a business operations specialist) = $157,353.

SUBPART K, APPLICATION PROCEDURES AND CONTRACTS FOR MEDICARE ADVANTAGE ORGANIZATIONS

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 $76.20/hr (hourly wage of a business operations specialist) = $386,105.

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 $76.20/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 $9,449 (124 hr * $76.20/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 $4,725 ($9,449/2 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 $762 (10 hr * $76.20/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 $3,404 ([$4,725 + 4,725 + $762]/3 yr).

SUBPART M, GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

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 $76.20/hr (hourly wage of a business operations specialist) = $1,887,626.

Organization Determinations and General Requirements for Applicable Integrated Plans (§§ 422.566 and 422.629)

Under the existing requirements related to organization determinations and integrated organization determinations, if a plan expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. We are proposing that additionally, the reviewing physician or health care professional must have expertise in the field appropriate to the requested

service. We do not believe this proposal will impose additional staffing burden on plans, but the burden related to the medical necessity review function has not previously been identified as a separate and distinct line item in this PRA package because it is inherent in the overall processing of organization determinations that is accounted for in this package (e.g., estimates for 422.568 related to standard organization determinations). In light of existing review requirements applicable to organization determinations and integrated organization determinations, coupled with the requirements at § 422.152 for MA plans (including AIPs) to engage in ongoing quality improvement (including in processing requests for initial or continued authorization of services) and the contract requirement provisions at § 422.504, we believe plans already have the requisite expertise in staffing to satisfy the proposed requirement. Therefore, the proposed requirement that the physician or other appropriate health care professional have expertise in the field appropriate to the requested service may at most result in plans reallocating staff resources in certain cases to ensure that someone with appropriate expertise is reviewing the request; however, we don't believe that this proposal will require additional staffing for MA organizations and AIPs. If this proposal is finalized, MA organizations and AIPs would maintain the flexibility to utilize a physician or other health care professional, so long as they have expertise in the field of medicine that is appropriate for the services at issue. Under this proposed approach, an appropriate physician or other health care professional with expertise appropriate to the requested service would be reviewing the coverage request at a lower level of review.

According to 2020 MA plan reported data, 1,786,733 (5.7 percent of all 31,346,194 Medicare pre-service organization determination decisions) are unfavorable coverage decisions (the decision is fully or partially unfavorable to the enrollee). If this proposal is implemented, we estimate that 2.85 percent (one-half of the current rate of 5.7 percent), or 893,367 (0.0285 * 31,346,194 pre-service organization determinations) of the organization determinations will be unfavorable and reviewed by a physician or other appropriate health care professional with expertise in the requested service. We estimate that a physician, at the rate of $222.60 per hour (hourly wage of "Physician, all others"), spends 30 minutes reviewing an organization determination request for medical necessity for a total estimated burden of $99,431,858 (446,684 hours * $222.60) to conduct medical necessity reviews on 893,367 unfavorable organization determinations.

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
- 16,890 x $76.20/hr (hourly wage of a business operations specialist) = $1,287,018.

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
- $18,490,159 = 242,653 x $76.20/hr (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 $19,777,177 ($1,287,018+ $18,490,159).

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 $76.20/hr (hourly wage of a business operations specialist) = $43,181,092.

Paragraph (b) requires that, when the MA organization extends the deadline, it notifies 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
- $925,601 = 12,147 x $76.20/hr (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 $44,106,693 ($43,181,092+ $925,601).

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
- $21,488 = 282 x $76.20/hr (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
- $73,960,634 = 970,612 x $76.20/hr (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
- $9,266,530 = 121,608 x $76.20/hr (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 $83,227,164 ($73,960,634 + $9,266,530).

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.

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
- $113,300 = 4,045 x $28.01/hr (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
- 72,627 x $76.20/hr (hourly wage of a business operations specialist) = $5,534,177.

Thus the total annual burden of § 422.622 is 72,627 hours at an annual cost of $5,534,177for plans and total annual burden of 4,045 hours at an annual cost of $113,300 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
- $11,853,977 = 155,564 hours x $76.20/hr (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
- $4,247,159 = 55,737 hours x $76.20/hr (hourly wage of a business operations specialist)

General requirements for applicable integrated plans (§ 422.629)

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 $109.36/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 $18,701(171 hr x $109.36/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 $6,234 ($18,701x 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 $76.20/hr. In aggregate, we estimate a one-time burden of 456 hours (8 hr x 57 contracts) at a cost of $34,747 (456 hr x $76.20/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 $11,582 ($34,747 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. For integrating information on Medicare and Medicaid appeal rights, 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.

SUBPART V, MEDICARE ADVANTAGE COMMUNICATION REQUIREMENTS

Required materials and content (§ 422.2267)

PROPOSED Enrollee Notification Requirements for MA Provider Contract Terminations (§ 422.2267(e)(12)(ii))

We are proposing to revise: § 422.2267(e)(12) to specify the requirements for the content of the notification to enrollees about a provider contract termination.

We are able to estimate the one-time burden on MA organizations to update their existing written provider termination notice in compliance with the new required notice content that we are proposing at § 422.2267(e)(12)(ii). We expect MA organizations to engage in some routine software development to update their notice template and related systems to incorporate the new proposed requirements, which we are proposing will be delineated in an MA Provider Termination Notice model document developed by CMS staff (thus not incurring COI burden). This proposed model is being posted for public review and comment in conjunction with this PRA package. We estimate that one or two software developers working at a wage of $92.92/hr will spend a total of 8 hours updating an MA organization's existing provider termination notice template and related systems based on CMS's model. With approximately 697 MA organizations impacted by this proposed change, this results in a total of 5,576 hours (697 MA organizations * 8 hours), at an aggregate cost across all MA organizations of $518,122 (5,576 hours * $92.92/hr). We are unable to estimate the burden for the proposed telephonic notice requirement at proposed § 422.2267(e)(12)(iii) because the number of primary care and behavioral health provider contract terminations an MA organization undergoes in a given contract year is unknown, as are the number of affected enrollees per termination.

Summary of Collection of Information Requirements and Associated Burden Estimates

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	$40.95	$1,566,338
§ 422.62	As occurs	563 MAOs	9,451	1,710,650	0.0833	142,497	$76.20	$10,858,271
§ 422.64	Annually	563 MAOs	1	563	2	1,126	$76.20	$85,801
§ 422.66(b)(3)(i)	As occurs	563 MAOs	1	226,339	0.0167	3,772	$76.20	$287,426
§ 422.66(b)(3)(iii)	As occurs	563 MAOs	1	226,339	0.0167	3,772	$76.20	$287,426
§ 422.66(b)(3)(iv)	As occurs	563 MAOs	1	226,339	0.0833	18,862	$40.95	$772,399

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]
§ 422.74(d)(1)	As occurs	563 MAOs	1	27,313	0.1	2,731	$76.20	$208,102
§ 422.107	One time	277 MAOs	1	277	8	739	$142.34	$105,189
§ 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	$76.20	$802,386
§ 422.132	Annually	563 MAOs	1	563	40	22,520	$76.20	$1,716,024
§ 422.158	Annually	10 deeming organizations	1	10	64	640	$76.20	$48,768
§ 422.202	Weekly	563 MAOs	50	28,150	0.1667	4,693	$76.20	$357,607
§ 422.206	As occurs	563 MAOs	1	563	0.5	282	$76.20	$21,488
§ 422.216	As occurs	5 MAOs	70	350	0.0833	29	$76.20	$2,210
§ 422.320	As occurs	563 MAOs	22	12,386	0.1667	2,065	$76.20	$157,353
§ 422.506	Annually	563 MAOs	1	563	9	5,067	$76.20	$386,105
§ 422.514	Annually	22 MAOs	1	22	2	45	$76.20	$3,429
§ 422.564	As occurs	563 MAOs	176	99,088	0.25	24,772	$76.20	$1,887,626
§ 422.568(b)	As occurs	563 MAOs	1	563	30	16,890	$76.20	$1,287,018
§ 422.568(d)	As occurs	563 MAOs	431	242,653	1	242,653	$76.20	$18,490,159
§ 422.572	As occurs	563 MAOs	8,625	4,855,875	0.1167	566,681	$76.20	$43,181,092
§ 422.572	As occurs	563 MAOs	259	145,817	0.0833	12,147	$76.20	$925,601
§ 422.584	As occurs	563 MAOs	1	563	0.5	282	$76.20	$21,488
§ 422.590	As occurs	563 MAOs	431	242,653	4	970,612	$76.20	$73,960,634
§ 422.590	As occurs	563 MAOs	108	60,804	2	121,608	$76.20	$9,266,530
§ 422.622(e)	As occurs	563 MAOs	86	48,418	1.5	72,627	$76.20	$5,534,177
§ 422.624	As occurs	563 MAOs	3,316	1,866,908	0.0833	155,513	$76.20	$11,850,091
§ 422.626	As occurs	563 MAOs	66	37,158	1.5	55,737	$76.20	$4,247,159
§§ 422.629-.631	One time	57 MAOs	1	57	8	152	$76.20	$11,582
§ 422.629	One time	57 MAOs	1	57	3	57	$109.36	$6,234
§ 422.2440	As occurs	8 MAOs	346	2,765	0.0167	46	$76.20	$3,505
§ 422.2440	As occurs	8 MAOs	346	2,765	0.0167	46	$76.20	$3,505

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]
§ 422.2440	As occurs	8 MAOs	346	2,765	0.0833	230	$40.95	$9,419
§ 422.38	As occurs	53 MAOs	35,236	1,867,519	0.0833	155,564	$76.20	$11,853,977
Subtotal (Private Sector)	*Varies*	*563*	*Varies*	*12,090,382*	*Varies*	*2,672,069*	*Varies*	*$201,901,190*
§ 422.107	One time	44	1	44	24	352	$142.34	$25,052
§ 422.107	One time	13	1	13	160	1,387	$90.01*	$62,422
Subtotal (State)	*Varies*	*44*	*1*	*57*	*Varies*	*1,739*	*Varies*	*$87,474*
§ 422.622(b)	As occurs	48,559	1	48,559	0.0833	4,045	$28.01	$113,300
Subtotal (Beneficiaries)	*As occurs*	*48,559*	*1*	*48,559*	*Varies*	*4,045*	*$28.01*	*$113,300*
TOTAL	***Varies***	***49,176***	***Varies***	***12,138,998***	***Varies***	***2,677,853***	***Varies***	***$202,101,964***

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 $76.20/hr and $109.36/hr, the wages of a business operations specialist and programmer working simultaneously on this task.

Collection of Information Instruments and Instruction/Guidance Documents

There is one information instrument or instruction/guidance document associated with proposed Enrollee Notification Requirements for MA Provider Contract Terminations (§§ 422.111 and 422.2267), which is the MA Provider Termination Notice model document. All other requirements are set out in the CFR and in the respective rulemaking documents.

12B. Information Collection Requests Exempt From the Paperwork Reduction Act

This section lists collection of information requirements that are exempt from the PRA. It includes exemptions pertaining to administrative actions, exemptions pertaining to nine or fewer respondents, and exemptions pertaining to usual and customary business practices.

Exemptions Pertaining to Administrative Actions

The following CFR sections set out information collection requirements are associated with an administrative action (5 CFR 1320.4(a)(2) and (c)). In that regard the requirements and burden are exempt from the requirements of the PRA.

Access to services (§ 422.112)
Right to a hearing (§ 422.600)
Request for an ALJ hearing (§ 422.602)
Medicare Appeals Council (MAC) review (§ 422.608)
Judicial Review (§ 422.612)
Notifying Enrollees of hospital discharge appeal rights (§ 422.620)
General requirements for applicable integrated plans (§ 422.629)
Integrated reconsideration (§ 422.633)
Request for reconsideration (§ 422.650)
Request for hearing (§ 422.662)
Disqualification of hearing officer (§ 422.668)
Time and place of hearing (§ 422.670)
Record of hearing (§ 422.686)
Notice and effect of hearing decision (§ 422.690)
Effect of revised determination (§ 422.698)

Exemptions Pertaining to Nine or Fewer Respondents

The following CFR sections set out set out information collection requirements where we estimate fewer than ten respondents. Consequently, the information collection requirements and burden are exempt (5 CFR 1320.3(c)) from the requirements of the PRA.

Election process (§ 422.60(g))
Disenrollment by the MA organization (§ 422.74(d)(2–3))
Coordination of benefits with employer or union group health plans and Medicaid. (§ 422.106(c)(1) and (d)(1))
Disclosure requirements (§ 422.111)
Access to services (§ 422.112)
Special rules for MA private fee-for-service plans (§ 422.216)
Submission of bids (§ 422.254(e))
Incorrect collections of premiums and cost sharing (§ 422.270)
Monthly Payments (§ 422.304)
Special rules for beneficiaries enrolled in MA MSA plans (§ 422.314)
Modification or termination of contract by mutual consent (§ 422.508)
Termination of contract by CMS (§ 422.510)
Termination of contract by the MA organization (§ 422.512)

Exemptions Pertaining to Usual and Customary Business Practices

The time, effort, and financial resources necessary to comply with the following collection of information requirements would be incurred by persons during the normal course of their activities and, therefore, should be considered usual and customary business practices. Consequently, the information collection requirements and burden are exempt (5 CFR 1320.3(b)(2)) from the requirements of the PRA.

Special rules for point of service option (§ 422.105)
Disclosure requirements (§ 422.111)
Access to services (§ 422.112)
Confidentiality and accuracy of enrollee records (§ 422.118)
Participation procedures (§ 422.202)
Provider selection and credentialing (§ 422.204)
Provider antidiscrimination rules (§ 422.205)
General provisions (§ 422.562)
Licensing of marketing representatives and confirmation of marketing resources (§ 422.2272)
Broker and agent commissions and training of sales agents (§ 422.2274)

12C. Information Collection Requests Approved by OMB Under a Different Control Number

This section lists related collection of information requirements that are approved by OMB under a control number other than 0938-0753 (CMS-R-267).

Election process (§ 422.60(a–f)) The burden associated with the reporting provision is approved by OMB under control number 0938-0935 (CMS-10237).

Information about the MA program (§ 422.64) The burden associated with the PBP submission is approved by OMB under control number 0938-0763 (CMS-R-262).

Disenrollment by the MA organization (§ 422.74) This requirement is approved by OMB under control number 0938-0763 (CMS-R-262).

Requirements relating to basic benefits (§ 422.101) The burden with producing and delivering the ANOC and EOC and for notifying members when the deductible (if any) has been reached is approved by OMB under control number 0938-1051 (CMS-10260).

Benefits under an MA MSA plan (§ 422.103) The burden associated with production and dissemination of the ANOC and EOC is approved by OMB under control number 0938-0935 (CMS-10237).

Special rules for point of service option (§ 422.105) The burden associated with production and dissemination of the ANOC and EOC is approved by OMB under control number 0938-0935 (CMS-10237).

Disclosure requirements (§ 422.111) The burden associated with production and dissemination of the ANOC and EOC is approved by OMB under control number 0938-0935 (CMS-10237).

Access to services (§ 422.112) The burden of the application process is approved by OMB under control number 0938-0935 (CMS-10237).

Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services (§ 422.113) The burden of the application process is approved by OMB under control number 0938-0935 (CMS-10237).

Information on advance directives (§ 422.128) These requirements are identical to the requirements currently approved under OMB control number 0938-0610 (CMS-R-10). The burden of creating and disseminating the ANOC and EOC is approved by OMB under control number 0938-1051 (CMS-10260).

Quality improvement program (§ 422.152) The burden associated with all quality requirements is approved by OMB under control numbers 0938-1023 (CMS-10209) and 0938-1141 (CMS-10379).

Special rules for MA private fee-for-service plans (§ 422.216) The burden for submitting such EOMB statements for all MA plans is approved by OMB under control number 0938-1228 (CMS-10453). The burden for submitting a bid is approved by OMB under control number 0938-0263 (CMS-R-262).

Risk adjustment data (§ 422.310) The burden is approved by OMB under control number 0938-0878 (CMS-10062).

State licensure requirement (§ 422.400) The burden is approved by OMB under control number 0938-0935 (CMS-10237).

Application requirements (§ 422.501) The burden is approved by OMB under control number 0938-0935 (CMS-10237).

General provisions (§ 422.503)/Contract provisions (§ 422.504) The burden associated with this requirement is approved by OMB under control number 0938-0935 (CMS-10237).

General provisions (§ 422.550) The National Data Reporting Requirements burden is approved by OMB under control number 0938-0469 (CMS-906).

General provisions (§ 422.562) The burden for production and dissemination of the ANOC and EOC is approved by OMB under control number 0938-1051 (CMS-10260).

Definitions (§ 422.2260) The burden associated with production and dissemination of Marketing materials is approved by OMB under control number 0938-0935 (CMS-10237).

Review and distribution of marketing materials (§ 422.2262) The burden for producing and disseminating these documents is approved by OMB under control number 0938-1051 (CMS-10260). The burden associated with production and dissemination of Marketing materials is approved by OMB under control number 0938-0935 (CMS-10237).

Guidelines for CMS review and notification (§ 422.2264) The burden associated with production and dissemination of Marketing materials is approved by OMB under control number 0938-0935 (CMS-10237).

Standards for MA organization marketing (§ 422.2268) The burden associated with production and dissemination of Marketing materials is approved by OMB under control number 0938-0935 (CMS-10237).

Broker and agent commissions and training of sales agents (§ 422.2274) The burden for producing and disseminating these documents is approved by OMB under control number 0938-1051 (CMS-10260).

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
Initial establishment of system for notification of hospital and SNF admissions by state Medicaid agency	13	160	2,080	76.20	n/a	79,248	779,248
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
Initial notification of hospital and SNF admissions by D-SNPs to state Medicaid agency	136	160	21,760	76.20	1,658,112	n/a	n/a
Total by Stakeholder	252	Varies	50,400	Varies	4,070,070	255,714	255,714

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.

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).

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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.

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

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

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

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

On December 14, 2022 at 4:15 pm (the date and time of public inspection at the Office of the Federal Register), we proposed (CMS-4201-P, RIN 0938-AU96) the following changes.

1. ICRs Applying D-SNP Look-Alike Requirements to Plan Benefit Package Segments (§ 422.514)

We propose adding a new paragraph at § 422.514(g) to clarify that the D-SNP look-alike contracting limitations at § 422.514(d) through (f) apply to segments of the MA plan.

Based on January 2022 Monthly Membership Report data, we estimate that the proposed change would result in three MA plan segments being identified as D-SNP look-alikes, and these D-SNP look-alikes would likely transition the approximately 3,000 current 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) using the transition process described in § 422.514(e). Based on our analysis of proposed D-SNP look-alike transitions for contract year 2023, two D-SNP look-alikes in contract year 2022 are proposing to transition a combined total of approximately 7,000 D-SNP look-alike enrollees into two new non-SNP MA plan segments, which could create two new D-SNP look-alikes for contract year 2023.

In June 2020 final rule (85 FR 33877 through 33880), we estimated each D-SNP look-alike would take a one-time effort of 2 hours for a business operations specialist to submit all enrollment changes to CMS necessary to complete the transition process. We also stated that, after the prohibition on D-SNP look-alikes was implemented, at most five plans per year would 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. These estimates were submitted to OMB for approval under control numbers 0938-0753 (CMS-R-267). The requirement and burden estimates (5 respondents, 5 total responses, and 10 total hours) were approved by OMB under control number 0938-0753 (CMS-R-267).

Our proposed clarification at § 422.514(g) does not change the transition process nor our burden estimates. Additionally, the proposed addition of non-SNP MA plan segments to the contracting limitations at § 422.514 does not change our estimates that at most five plans (including PBP segments) per year would be identified as D-SNP look-alikes; therefore, the estimated number of respondents and burden estimates in control numbers 0938-0753 (CMS-R-267) would not change.

2. Required Notices for Involuntary Disenrollment for Loss of Special Needs Status (§ 422.74)

MA organizations that offer special needs plans are currently effectuating involuntary disenrollments for loss of special needs status as part of existing disenrollment processes, including the member notifications outlined in our proposal; therefore, no additional burden is anticipated from this proposal. However, because a burden estimate for these member notifications has not previously been submitted to OMB, due to inadvertent oversight, we are seeking OMB approval under the aforementioned OMB control number.

We are proposing to codify current policy on MA plan notices prior to a member disenrollment for loss of special needs status. MA organizations would be required to provide the member a minimum of 30 days advance notice of disenrollment regardless of the date of the loss of special needs status. Additionally, the organization would be required to provide the member a final notice of involuntary disenrollment, sent within 3 business days following the last day of the period of deemed continued eligibility and before the disenrollment transaction is submitted to CMS.

Where an individual is involuntarily disenrolled from an MA plan for any reason other than death, loss of entitlement to Part A or Part B, the MA organization must give the individual a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual, pursuant to § 422.74(c). The notice requirement in § 422.74(c) is currently covered under the aforementioned control number.

To estimate the number of notices required due to involuntary disenrollments for loss of special needs status, we determined the average number of annual disenrollments due to loss of special needs status. Between 2017 and 2021, there were an average of 55,127 involuntary disenrollments per year due to loss of special needs status.

We estimate that it will take each MA organization 1 minute (0.017 hr) to assemble and disseminate the advance notice, 5 minutes (0.083 hr) to submit the required transaction to CMS for each disenrollment, and 0.017 hr to assemble and disseminate the final notice for each disenrollment. Therefore, the total annual time for each MA organization is 0.1170 hours (0.017 hr +0.083 hr + 0.017 hr) at a cost of $8.92 (0.117 hr * $76.20/hr, the hourly wage of a business operations specialist).

We estimate the aggregate annual burden for all MA organizations to process these disenrollments to be 6,450 hours (55,127 disenrollments *0.117 hr) at a cost of $491,490 (6,450 hr * $76.20/hr).

3. ICRs Regarding Involuntary Disenrollment for Individuals Enrolled in an MA Medical Savings Account (MSA) Plan (§ 422.74(b)(2))

The requirement proposed at § 422.74(b)(2)(vii) to establish a process for involuntary disenrollment for an individual who loses eligibility mid-year to be enrolled in an MA MSA plan, and more specifically, the requirement for the MA organization to give the individual a written notice of the disenrollment at § 422.74(c) with an explanation of why the MA organization is planning to disenroll the individual, will be submitted to OMB for approval under control number 0938-0753 (CMS-R-267).

The annual burden associated with this requirement are the burdens of notifying the individual and notifying CMS. Based on CMS-R-267, we estimate that each disenrollment will require 1 minute (0.017 hr.) for the MA MSA plan to notify CMS and 5 minutes (0.083 hr.) for the MA MSA plan to notify the individual. Thus, the total burden per disenrollment is estimated at 6 minutes (0.1 hr) (1 minute to assemble and disseminate the notice to CMS and 5 minutes to assemble and disseminate the notice to the individual) at a cost of $7.62 (0.1 hr x $76.20/hr for a business operations specialist to perform the work).

To obtain aggregate burden we used data from 2019 and 2021 in which there were an average of 4 MSA contracts. We used an average since the data had no visible trend but hovered around a central value. There was an average of 8,624 enrollees during 2019 – 2021 and the average disenrollment was 124. Thus, we estimate:

• An aggregate burden for all MSA contracts of 12 hours (124 disenrollments * 0.1 hr. per disenrollment) at an aggregate cost of $914 (12 hours * $76.20;/hr).

• The average burden per MSA contract is therefore 3 hr. (12 divided by 4) at an average burden of $305 (914 divided by 4). The average number of disenrollments per contract is 31 (124 divided by 4).

4. ICRs Regarding Enrollee Notification Requirements for MA Provider Contract Terminations (§§ 422.111 and 422.2267)

We are proposing to revise: (1) § 422.111(e) by establishing specific enrollee notification requirements for no-cause and for-cause provider contract terminations and adding specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur; and (2) § 422.2267(e)(12) to specify the requirements for the content of the notification to enrollees about a provider contract termination.

This proposal to amend §§ 422.111(e) and 422.2267(e)(12) would impact MA organizations in terms of the burden required to identify those enrollees who must be notified of provider contract terminations per CMS requirements, to develop and send the required written notices, to develop the scripts for the required telephonic notices, and to make the required enrollee telephone calls and any necessary follow-up calls. However, CMS does not currently collect data regarding the widely variable number of provider contract terminations an MA organization undergoes in a given contract year, nor the number of enrollees affected by each termination. Therefore, we do not have information to estimate the extent of MA provider contract terminations, how many enrollees are affected and need to be notified per § 422.111(e), or how the MA program would be impacted as we see the effects of the proposed regulation. The actual direct burden of this provision arises from MA organization staff hours spent, resources purchased, and enrollee notifications provided. MA organizations may also differ in how their spending for the proposed requirements evolves over time as they test strategies and redevelop their approaches to complying with the regulation.

Despite our inability to quantify certain burden for this proposal, we are able to estimate the one-time burden on MA organizations to update their existing written provider termination notice in

compliance with the new required notice content that we are proposing at § 422.2267(e)(12)(ii). We expect MA organizations to engage in some routine software development to update their notice template and related systems to incorporate the new proposed requirements, which we are proposing will be delineated in an MA Provider Termination Notice model document developed by CMS staff (thus not incurring COI burden). This proposed model is being posted for public review and comment in conjunction with this PRA package. We estimate that one or two software developers working at a wage of $92.92/hr will spend a total of 8 hours updating an MA organization's existing provider termination notice template and related systems based on CMS's model. With approximately 697 MA organizations impacted by this proposed change, this results in a total of 5,576 hours (697 MA organizations * 8 hours), at an aggregate cost across all MA organizations of $518,122 (5,576 hours * $92.92/hr). We are unable to estimate the burden for the proposed telephonic notice requirement at proposed §§ 422.111(e)(1)(i) and 422.2267(e)(12)(iii) because the number of primary care and behavioral health provider contract terminations an MA organization undergoes in a given contract year is unknown, as are the number of affected enrollees per termination.

5. ICRs Regarding Clarifications of Coverage Criteria for Basic Benefits (§422.101)

We are proposing that MA plans must comply with national coverage determinations (NCD), local coverage determinations (LCD), and general coverage and benefit conditions included in Traditional Medicare statutes and regulations when making medical necessity determinations. This rule proposes that MA plans must follow Traditional Medicare coverage criteria as specified in NCDs, LCD, or Medicare laws (that is, in Medicare statutes and regulations).

This proposal further proposes that in the absence of coverage criteria in an applicable Medicare statute or regulation, NCD or LCD, an MA plan may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature and that this evidence must be made publicly available.

This proposal also adds a new requirement that in creating these internal policies, MA organizations must provide a publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations, a list of the sources of such evidence, and include an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. We expect that each plan annually will have new policies that they create.

We believe that the public posting of the summary of evidence used to develop a plan's internal coverage criteria would require minimal time. We estimate that over the course of a year 2 business days or 16 hours would be an adequate estimate of time needed for a business operations specialist to make all postings. Thus the per contract burden is 16 hours at a cost of $1,219 (16 * $76.20) and the aggregate burden over 697 contracts is 11,152 hours (697 contracts * 16 hours/contract) at a cost of $849,782 (11,152 hr * $76.20/hr).

Summary of Changes

Regulation Section	Item	Respondents	Number of Responses	Time per Response (hr)	Total Annual Time (hr)	Hourly Labor Cost ($/hr)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
§ 422.74	Involuntary Disenrollment: Loss of Special Needs Status	181	55,127	0.117	6,450	76.20	491,490	491,490
§ 422.74(b)(2)	MSA Involuntary Disenrollment	4	124	0.1	12	76.20	914	914
§ 422.101	Clarifications of Coverage Criteria for Basic Benefits	697	697	16	11,152	76.20	849,782	849,782
§ 422.2267(e)(12)(ii)	MA Provider Termination Notices	697	697	8	5,576	92.92	518,122	518,122
TOTAL	-	882	55,948	varies	12,038	varies	1,010,526	1,860,308,

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/medicare/eligibility-and-enrollment/medicaremangcareeligenrol

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.