Billing Code 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422, 423, 438, and 498

[CMS-4185-P]

RIN 0938-AT59

Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare Advantage (MA) program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations to implement certain provisions of the Bipartisan Budget Act of 2018; improve quality and accessibility; clarify certain program integrity policies; reduce burden on providers, MA plans, and Part D sponsors through providing additional policy clarification; and implement other technical changes regarding quality improvement. This proposed rule would also revise the appeals and grievances requirements for Medicaid managed care and MA special needs plans for dually eligible individuals to implement certain provisions of the Bipartisan Budget Act of 2018.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [insert date 60 days from date of publication in the Federal Register].

ADDRESSES: In commenting, please refer to file code CMS-4185-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **http://www.regulations.gov.** Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-4185-P,

P.O. Box 8013,

Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-4185-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT:

Theresa Wachter, (410) 786-1157, or Cali Diehl, (410) 786-4053, MA/Part C Issues.

Elizabeth Goldstein, (410) 786-6665, Parts C and D Quality Ratings Issues.

Mark Smith, (410) 786-8015, Prescription Drug Plan Access to Parts A and B Data Issues.

Vanessa Duran, (410) 786-8697, D-SNP Issues.

Frank Whelan, (410) 786-1302, Preclusion List Issues.

Jonathan Smith (410) 786-4671, or Joanne Davis, (410) 786-5127, MA RADV Issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Executive Summary

A. Purpose

The primary purposes of this proposed rule are to: make revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D) regulations based on our continued experience in the administration of the Part C and Part D programs and to implement certain provisions of the Bipartisan Budget Act of 2018. The proposed changes are necessary to—

- Implement the Bipartisan Budget Act of 2018 provisions;
- Improve program quality and accessibility;
- Clarify program integrity policies; and
- Implement other changes.

This proposed rule would meet the Administration's priorities to reduce burden across the Medicare program by reducing unnecessary regulatory complexity, and improve the regulatory framework to facilitate development of Part C and Part D products that better meet the individual beneficiary's healthcare needs. Because the Bipartisan Budget Act of 2018 requires the Secretary to establish procedures, to the extent feasible, for integration and unification of the appeals and grievance processes for dually eligible beneficiaries who are enrolled in Medicaid and in MA special needs plans for dually eligible individuals, this proposed rule also includes proposals to revise the appeals and grievances requirements for Medicaid managed care and MA special needs plans for dually eligible individuals. We note CMS plans to release a proposed Medicare rule in the near future to further the President's agenda of reducing drug costs.

B. Summary of the Major Provisions

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

Section 50323 of the Bipartisan Budget Act of 2018 (Public Law 115-123) created a new section 1852(m) of the Social Security Act (the Act), which allows MA plans to provide "additional telehealth benefits" to enrollees starting in plan year 2020 and treat them as basic benefits for purposes of bid submission and payment by CMS. The statute limits these authorized additional telehealth benefits to services for which benefits are available under Medicare Part B, but that are not payable under section 1834(m) of the Act and have been identified for the applicable year as clinically appropriate to furnish through electronic information and telecommunications technology (section 1852(m)(2)(A)(i) of the Act). Under this proposal, MA plans would be permitted to offer – as part of the basic benefit package – additional telehealth benefits beyond what is currently allowable under the original Medicare telehealth benefit. In addition, we propose to continue authority for MA plans to offer supplemental benefits (that is, benefits not covered by original Medicare) via remote access technologies and/or telemonitoring for those services that do not meet the requirements for additional telehealth benefits.

Section 1852(m)(4) of the Act mandates that enrollee choice is a priority. If an MA plan covers a Part B service as an additional telehealth benefit, then the MA plan must also provide access to such service through an in-person visit and not only as an additional telehealth benefit. The enrollee must have the option whether to receive such service through an in-person visit or as an additional telehealth benefit. In addition, section 1852(m)(2)(A)(ii) of the Act excludes

from additional telehealth benefits any capital and infrastructure costs and investments relating to such benefits. These statutory provisions have guided our proposal.

We propose to establish regulatory requirements that would allow MA plans to cover Part B benefits furnished through electronic exchange as "additional telehealth benefits" – and as part of the basic benefits defined in § 422.101 – instead of separate supplemental benefits. We believe additional telehealth benefits would increase access to patient-centered care by giving enrollees more control to determine when, where, and how they access benefits. We are soliciting comments from stakeholders on various aspects of our proposal, which would help inform CMS's next steps related to implementing the additional telehealth benefits.

2. Dual Eligible Special Needs Plans Provisions (§§ 422.2, 422.60, 422.102, 422.107, 422.111, 422.560 through 422.562, 422.566, 422.629 through 422.634, 422.752, 438.210, 438.400, and 438.402)

Section 50311(b) of the Bipartisan Budget Act of 2018 amends section 1859 of the Act to require integration of the Medicare and Medicaid benefits provided to enrollees in Dual Eligible Special Needs Plans (D-SNPs). In particular, the statute requires: (1) development of unified grievance and appeals processes for D-SNPs; and (2) establishment of new standards for integration of Medicare and Medicaid benefits for D-SNPs.

The statute specifies a number of key elements for unified D-SNP grievance and appeals processes and grants the Secretary discretion to determine the extent to which unification of these processes is feasible. In particular, the unified processes must adopt the provisions from section 1852(f) and (g) of the Act (MA grievances and appeals) and sections 1902(a)(3) and (5), and 1932(b)(4) of the Act (Medicaid grievances and appeals, including managed care) that are most protective to the enrollee, take into account differences in state Medicaid plans to the extent

necessary, be easily navigable by an enrollee, include a single written notification of all applicable grievance and appeal rights, provide a single pathway for resolution of a grievance or appeal, provide clear notices, employ unified timeframes for grievances and appeals, establish requirements for how the plan must process, track, and resolve grievances and appeals, and with respect to benefits covered under Medicare Parts A and B and Medicaid, incorporate existing law that provides continuation of benefits pending appeal for items and services covered under Medicare and Medicaid. The statute requires the Secretary to establish unified grievance and appeals procedures by April 1, 2020 and requires D-SNP contracts with state Medicaid agencies to use the unified procedures for 2021 and subsequent years.

With respect to the establishment of new standards for integration of Medicare and Medicaid benefits, the statute requires that all D-SNPs meet certain new minimum criteria for such integration for 2021 and subsequent years, either by covering Medicaid benefits through a capitated payment from a state Medicaid agency or meeting a minimum set of requirements as determined by the Secretary. The law also stipulates that for the years 2021 through 2025, if the Secretary determines that a D-SNP failed to meet one of these integration standards, the Secretary may impose an enrollment sanction, which would prevent the D-SNP from enrolling new members. In describing the "additional minimum set of requirements" established by the Secretary, the statute directs the Federally Coordinated Health Care Office in CMS to base such standards on "input from stakeholders." We intend to use this rulemaking to solicit input from stakeholders on the implementation of these new statutory provisions as well as to clarify definitions and operating requirements for D-SNPs.

3. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i)(1) and 423.186(i)(1))

In the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Final Rule (hereafter referred to as the April 2018 final rule), CMS codified at §§ 422.160, 422.162, 422.164, and 422.166 (83 FR 16725 through 16731) and §§ 423.180, 423.182, 423.184, and 423.186 (83 FR 16743 through 16749) the methodology for the Star Ratings system for the MA and Part D programs, respectively. This was part of the Administration's effort to increase transparency and advance notice regarding enhancements to the Part C and D Star Ratings program. That final rule included mechanisms for the removal of measures for specific reasons (low statistical reliability and when the clinical guidelines associated with the specifications of measures change such that the specifications are no longer believed to align with positive health outcomes) but, generally, removal of a measure for other reasons would also occur through rulemaking.

At this time, we are proposing enhancements to the cut point methodology for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures. We are also proposing substantive updates to the specifications for a few measures for the 2022 and 2023 Star Ratings, and rules for calculating Star Ratings in the case of extreme and uncontrollable circumstances. Unless otherwise stated, data would be collected and performance measured using these proposed rules and regulations for the 2020 measurement period and the 2022 Star Ratings.

4. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6))

In the April 2018 final rule, CMS removed several requirements pertaining to MA and Part D provider and prescriber enrollment that were to become effective on January 1, 2019. We stated in that final rule our belief that the best means of reducing the burden of the MA and Part D provider and prescriber enrollment requirements without compromising our payment safeguard objectives would be to focus on providers and prescribers that pose an elevated risk to Medicare beneficiaries and the Trust Funds. That is, rather than require the enrollment of MA providers and Part D prescribers regardless of the level of risk they might pose, we would prevent payment for MA items or services and Part D drugs that are, as applicable, furnished or prescribed by demonstrably problematic providers and prescribers. Therefore, we established in the April 2018 final rule a policy under which: (1) such problematic parties would be placed on a "preclusion list"; and (2) payment for MA services and items and Part D drugs furnished or prescribed by these individuals and entities would be rejected or denied, as applicable. The MA and Part D enrollment requirements, in short, were replaced with the payment-oriented approach of the preclusion list.

This proposed rule would make several revisions and additions to the preclusion list provisions we finalized in the April 2018 final rule. We believe these changes would help clarify for stakeholders CMS' expectations with respect to the preclusion list.

5. Medicare Advantage Risk Adjustment Data Validation (RADV) Provisions (§§ 422.300, 422.310(e), and 422.311(a))

The Medicare Advantage Risk Adjustment Data Validation (RADV) program was implemented as the primary corrective action to reduce the Part C improper payment rate in

compliance with the Improper Payments Information Act (IPIA) of 2002, as amended by the Improper Payments Elimination and Recovery Act (IPERA) of 2010 and updated by the Improper Payments Elimination and Recovery Improvement Act (IPERIA) of 2012. In this proposed rule, we would, based on longstanding case law and best practices from HHS and other federal agencies, establish that extrapolation may be utilized as a valid part of audit authority in Part C, as it has been historically a normal part of auditing practice throughout the Medicare program.

Accordingly, we are proposing the following:

• To establish that CMS would use extrapolation in RADV contract-level audits and that the extrapolation authority would apply to the payment year 2011 contract-level audits and all subsequent audits.

• Not to apply a fee-for-service (FFS) Adjuster to audit findings.

C. Summary of Costs and Benefits

Provision	Description	Impact
Requirements for MA Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)	Consistent with section 50323 of the Bipartisan Budget Act of 2018, we propose to allow MA plans to provide "additional telehealth benefits" to enrollees starting in plan year 2020 and treat them as basic benefits for purposes of bid submission and payment by CMS.	Additional telehealth benefits have the potential for significant savings and costs. Significant savings could arise from additional telehealth benefits being used for follow-up and monitoring to prevent future illness or from reduced travel time by enrollees to providers. However, additional telehealth benefits also could lead to an increase in provider visits in situations where face-to-face visits were not otherwise expected to occur. The quantification of these impacts are discussed under various assumptions in this proposed rule.
Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)	Consistent with section 50311(b) of the Bipartisan Budget Act of 2018, we propose to establish, effective 2021, Medicare and Medicaid integration standards for MA organizations seeking to offer D-SNPs. Effective 2021 through 2025, we also propose to require the imposition of an intermediate sanction of prohibiting new enrollment into a D-SNP if CMS determines that the D-SNP is failing to comply with these integration standards. Finally, we propose to create new and modify existing regulatory definitions that relate to D-SNPs.	There would be a $3.4 million cost in the initial year to transition to the new requirements. After that, impact would be negligible.

Provision	Description	Impact
Unified Grievances and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560 – 562, 422.566, 422.629 – 422.634, 438.210, 438.400, and 438.402)	Consistent with section 50311(b) of the Bipartisan Budget Act of 2018, we propose to unify Medicare and Medicaid grievance and appeals procedures for certain D-SNPs that enroll individuals who receive Medicare and Medicaid benefits from the D-SNP and a Medicaid managed care organization offered by the D-SNP's MA organization, the parent organization, or subsidiary owned by the parent organization. Medicare and Medicaid grievance and appeals processes differ in several key ways, which in effect creates unnecessary administrative complexity for health issuers participating across product lines. This proposal would allow enrollees to follow one resolution pathway at the plan level when filing a complaint or contesting an adverse coverage determination with their plan regardless of whether the matter involves a Medicare or Medicaid covered service.	The estimated cost impact in 2021 and subsequent years is $0.2 million.
MA and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), 422.166(a) and 423.186(a), 422.164 and 423.184, and 422.166(i)(1) and 423.186(i)(1))	We are proposing several measure specification updates, adjustments for extreme and uncontrollable circumstances, and an enhanced cut point methodology. The measure changes are routine and do not have a significant impact on the ratings of contracts. The proposed policy for disasters would hold contracts harmless when there are extreme and uncontrollable circumstances affecting them. The proposed methodology to set Star Ratings cut points would help increase the stability and predictability of cut points from year to year.	Negligible impact.
Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6))	We are proposing to make several revisions to the MA and Part D preclusion list policies that we finalized in the April 2018 final rule.	Negligible impact.

Provision	Description	Impact
MA Risk Adjustment Data Validation Provisions (§§ 422.300, 422.310(e), and 422.311(a))	We are proposing to establish that CMS would use extrapolation in RADV contract-level audits and that the extrapolation authority would apply to the payment year 2011 contract-level audits and all subsequent audits, and not to apply a FFS Adjuster to audit findings.	The estimated savings is $1 billion in 2020 to the Trust Fund, due to collections from industry of money improperly paid. In subsequent years the provision would save the Trust Fund at least $381 million each year. The savings result from the Trust Fund not making improper payments. Extrapolating audit findings does not increase the cost burden on the plan. The cost to the plan of complying with a RADV audit is neither the subject of nor affected by this provision. This provision addresses recovering extrapolated or non-extrapolated audit findings. While extrapolation does increase the level of the audit recovery, because returning improper payments is not a cost, the decision to extrapolate does not impact the cost to the plan.

II. Provisions of the Proposed Regulations

A. Implementing the Bipartisan Budget Act of 2018 Provisions

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

Technologies that enable healthcare providers to deliver care to patients in locations remote from the providers (hereafter referred to as "telehealth") are increasingly being used to complement face-to-face patient-provider encounters. Telehealth visits among rural Medicare beneficiaries in particular have increased more than 25 percent a year for the past decade.1 In MA, about 81 percent of MA plans offer supplemental telehealth benefits in the form of remote access technologies in 2018, an increase from 77 percent in 2017. These statistics show that the healthcare industry has made significant advances in technology that enable secure, reliable, real-time, interactive communication and data transfer that were not possible in the past. Moreover, the use of telehealth as a care delivery option for MA enrollees may improve access to and timeliness of needed care, increase convenience for patients, increase communication between providers and patients, enhance care coordination, improve quality, and reduce costs related to in-person care.2

MA basic benefits are structured and financed based on what is covered under Parts A and B (paid through the capitation rate by the government) with coverage of additional items and services and more generous cost sharing provisions financed as supplemental benefits (paid using rebate dollars or supplemental premiums paid by enrollees). Traditionally, MA plans have been limited in how they may deliver telehealth services outside of the original Medicare

1 Mehrotra, A., Jena, A., Busch, A., Souza, J., Uscher-Pines, L., Landon, B. (2016). "Utilization of Telemedicine Among Rural Medicare Beneficiaries." *JAMA*, 315(18): 2015-2016.
2 Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Medicare Payment Policy*, March 2018.

telehealth benefit under section 1834(m) of the the Act because of this financing structure; only services covered by original Medicare under Parts A and B, with actuarially equivalent cost sharing, are in the basic benefit bid paid by the capitation rate. Section 1834(m) of the Act and § 410.78 generally limit payment for telehealth services in original Medicare by authorizing payment only for specific services provided using an interactive audio and video telecommunications system that permits real-time communication between a Medicare beneficiary and a physician or certain other practitioner and by specifying where the beneficiary may receive care (eligible originating sites). Originating sites generally are limited by both geography and patient setting. The statute grants the Secretary the authority to add to the list of allowable telehealth services based on an established annual process, but does not generally provide exceptions from the statutory limitations relating to geography or patient setting. Because sections 1852(a), 1853, and 1854 of the Act limit the basic benefits covered by the government's capitation payment to only Parts A and B services covered under original Medicare with actuarially equivalent cost sharing, telehealth benefits offered by MA plans in addition to those covered by original Medicare are currently offered as supplemental benefits and funded through the use of rebate dollars and/or supplemental premiums paid by enrollees.

On February 9, 2018, President Trump signed the Bipartisan Budget Act of 2018 (Pub. L. 115-123) into law. Section 50323 of the Bipartisan Budget Act of 2018 created a new section 1852(m) of the Act, which allows MA plans to provide "additional telehealth benefits" to enrollees starting in plan year 2020 and treat them as basic benefits (also known as "original Medicare benefits" or "benefits under the original Medicare fee-for-service program option") for purposes of bid submission and payment by CMS. The statute limits these authorized "additional telehealth benefits" to services for which benefits are available under Medicare Part

B but that are not payable under section 1834(m) of the Act and have been identified for the applicable year as clinically appropriate to furnish through electronic information and telecommunications technology (hereinafter referred to as "electronic exchange"). While MA plans have always been able to offer more telehealth services than are currently payable under original Medicare through supplemental benefits, this change in how such additional telehealth benefits are financed (that is, accounted for in the capitated payment) makes it more likely that MA plans will offer them and that more enrollees will use the benefit.

We are proposing to add a new regulation at § 422.135 to implement the new section 1852(m) of the Act and to amend existing regulations at §§ 422.100, 422.252, 422.254, and 422.264. Specifically, we propose to add a new regulation, to be codified at § 422.135, to allow MA plans to offer additional telehealth benefits, to establish definitions applicable to this new classification of benefits, and to enact requirements and limitations on them. Further, we are proposing to amend § 422.100(a) and (c)(1) to include additional telehealth benefits in the definition of basic benefits and add a cross-reference to new § 422.135 to reflect how these benefits may be provided as part of basic benefits. Finally, we are proposing to amend the bidding regulations at §§ 422.252, 422.254, and 422.264 to account for additional telehealth benefits in the basic benefit bid.

Under this proposal, MA plans will be permitted to offer – as part of the basic benefit package – additional telehealth benefits beyond what is currently allowable under the original Medicare telehealth benefit. According to § 422.100(a), MA plans are able to offer original Medicare telehealth benefits described in existing authority at section 1834(m) of the Act and § 414.65. We are proposing that in addition to original Medicare telehealth benefits, MA plans would be able (but not required) to offer additional telehealth benefits described in this proposed

rule and at section 1852(m) of the Act. In addition, we propose to continue authority for MA plans to offer supplemental benefits (that is, benefits not covered by original Medicare) via remote access technologies and/or telemonitoring for those services that do not meet the requirements for additional telehealth benefits, such as the requirement of being covered by Part B when provided in-person. For instance, an MA plan may offer a videoconference dental visit to assess dental needs as a supplemental benefit because services primarily provided for the care, treatment, removal, or replacement of teeth or structures directly supporting teeth are not currently covered Part B benefits and thus would not be allowable as additional telehealth benefits.

We propose to establish regulatory requirements that would allow MA plans to cover Part B benefits furnished through electronic exchange as "additional telehealth benefits" – and as part of the basic benefits defined in § 422.101 – instead of separate supplemental benefits. We believe additional telehealth benefits would increase access to patient-centered care by giving enrollees more control to determine when, where, and how they access benefits.

Section 1852(m)(2)(A)(i) of the Act, as added by the Bipartisan Budget Act of 2018, defines additional telehealth benefits as services--(1) for which benefits are available under Part B, including services for which payment is not made under section 1834(m) of the Act due to the conditions for payment under such section; and (2) that are identified for the applicable year as clinically appropriate to furnish using electronic information and telecommunications technology when a physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not at the same location as the plan enrollee (which we refer to as "through electronic exchange"). In addition, section 1852(m)(2)(A)(ii) of the Act excludes from additional telehealth benefits any capital and infrastructure costs and

investments relating to such benefits. This statutory definition of "additional telehealth benefits" has guided our proposal.

We are proposing a new regulation at § 422.135 to authorize and govern the provision of additional telehealth benefits by MA organizations, consistent with our interpretation of the new statutory provision. First, we propose definitions for the terms "additional telehealth benefits" and "electronic exchange" in proposed regulation text at § 422.135(a). We propose to define "additional telehealth benefits" as services that meet the following: (1) are furnished by an MA plan for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act; and (2) have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange. We propose to define "electronic exchange" as "electronic information and telecommunications technology" as this is a concise term for the statutory description of the means used to provide the additional telehealth benefits. We are not proposing specific regulation text that defines or provides examples of electronic information and telecommunications technology because the technology needed and used to provide additional telehealth benefits will vary based on the service being offered. Examples of electronic information and telecommunications technology (or "electronic exchange") may include, but are not limited to, the following: secure messaging, store and forward technologies, telephone, videoconferencing, other internet-enabled technologies, and other evolving technologies as appropriate for non-face-to-face communication. We believe this broad and encompassing approach will allow for technological advances that may develop in the future and avoid tying the authority in the proposed new regulation to specific information formats or technologies that permit non-face-to-face interactions for furnishing clinically appropriate services.

We are not proposing specific regulation text defining "clinically appropriate," rather, we are proposing to implement the statutory requirement for additional telehealth benefits to be provided only when "clinically appropriate" to align with our existing regulations for contract provisions at § 422.504(a)(3)(iii), which requires each MA organization to agree to provide all benefits covered by Medicare "in a manner consistent with professionally recognized standards of health care." We propose to apply the same principle to additional telehealth benefits, as additional telehealth benefits must be treated as if they were benefits under original Medicare per section 1852(m)(5) of the Act.

The statute limits additional telehealth benefits to those services that are identified for the applicable year as clinically appropriate to furnish through electronic exchange. The statute does not specify who or what entity identifies the services for the year. Therefore, we are proposing to interpret this provision broadly by not ourselves specifying the Part B services that an MA plan may offer as additional telehealth benefits for the applicable year, but instead allowing MA plans to independently determine which services each year are clinically appropriate to furnish in this manner. Thus, our proposed definition of additional telehealth benefits at § 422.135(a) provides that it is the MA plan (not CMS) that identifies the appropriate services for the applicable year. We believe that MA plans are in the best position to identify each year whether additional telehealth benefits are clinically appropriate to furnish through electronic exchange. MA plans have a vested interest in and responsibility for staying abreast of the current professionally recognized standards of health care, as these standards are continuously developing with new advancements in modern medicine. As professionally recognized standards of health care change over time and differ from practice area to practice area, our proposal is flexible enough to take those changes and differences into account.

Furthermore, § 422.111(b)(2) requires the MA plan to annually disclose the benefits offered under a plan, including applicable conditions and limitations, premiums and cost sharing (such as copayments, deductibles, and coinsurance) and any other conditions associated with receipt or use of benefits. MA plans satisfy this requirement through the Evidence of Coverage, or EOC, document provided to all enrollees. This disclosure requirement would have to include applicable additional telehealth benefit limitations. That is, any MA plan offering additional telehealth benefits must identify the services that can be covered as additional telehealth benefits when provided through electronic exchange. We believe that it is through this mechanism (the EOC) that the MA plan will identify each year which services are clinically appropriate to furnish through electronic exchange as additional telehealth benefits.

We solicit comment on this proposed implementation of the statute and our reasoning. We considered whether CMS should use the list of Medicare telehealth services payable by original Medicare under section 1834(m) of the Act as the list of services that are clinically appropriate to be provided through electronic exchange for additional telehealth benefits. In that circumstance, services on the list could be considered as clinically appropriate to be provided through electronic exchange for additional telehealth benefits without application of the location limitations of section 1834(m) of the Act. However, we did not believe that is the best means to take full advantage of the flexibility that Congress has authorized for the MA program. The list of Medicare telehealth services for which payment can be made under section 1834(m) of the Act under the original Medicare program includes services specifically identified by section 1834(m) of the Act as well as other services added to the Medicare telehealth list by CMS that meet certain criteria: (1) the services are similar to services currently on the list such that there are similar roles and interactions among the beneficiaries and the distant site physicians or

practitioners furnishing the services; or (2) the services are not similar to services on the current list but are accurately described by the corresponding code when furnished via telehealth and produce demonstrated clinical benefit to patients when furnished using a telecommunications system. We believe these limitations and criteria do not apply to additional telehealth benefits under new section 1852(m) of the Act for MA plans.

The statute requires the Secretary to solicit comment on what types of items and services should be considered to be additional telehealth benefits. Therefore, we are also soliciting comments on whether we should place any limitations on what types of Part B items and services (for example, primary care visits, routine and/or specialty consultations, dermatological examinations, behavior health counseling, etc.) can be additional telehealth benefits provided under this authority.

An enrollee has the right to request additional telehealth benefits through the organization determination process. If an enrollee is dissatisfied with the organization determination, then the enrollee has the right to appeal the decision. We believe these rights help ensure access to medically necessary services, including additional telehealth benefits offered by an MA plan as proposed in this rule. In addition, CMS audits plan performance with respect to timeliness and clinical appropriateness of organization determinations and appeals.

While the MA plan would make the "clinically appropriate" decision in terms of coverage of an additional telehealth benefit, we note that each healthcare provider must also provide services that are clinically appropriate. We acknowledge that not all Part B items and services would be suitable for additional telehealth benefits because a provider must be physically present in order to properly deliver care in some cases (for example, hands-on examination, administering certain medications). Behavioral health, in particular, is a prime

example of a service that could be provided remotely through MA plans' offering of additional telehealth benefits under this proposal. The President's Commission on Combating Drug Addiction and the Opioid Crisis recommends telehealth as useful in the effort to combat the opioid crisis, especially in geographically isolated regions and underserved areas where people with opioid use disorders and other substance use disorders may benefit from remote access to needed treatment.3

We are proposing in paragraph (b) the general rule to govern how an MA plan may offer additional telehealth benefits. Specifically, we propose that if an MA plan chooses to furnish additional telehealth benefits, the MA plan may treat these benefits as basic benefits covered under the original Medicare fee-for-service program as long as the requirements of proposed § 422.135 are met. We also propose in § 422.135(b) that if the MA plan fails to comply with the requirements of § 422.135, then the MA plan may not treat the benefits provided through electronic exchange as additional telehealth benefits, but may treat them as supplemental benefits. For example, a non-Medicare covered service provided through electronic exchange cannot be offered as an additional telehealth benefit because it does not comply with § 422.135, which is limited to furnishing through electronic exchange otherwise covered Part B covered services, but it may be offered it as a supplemental benefit.

Section 1852(m)(4) mandates that enrollee choice is a priority. If an MA plan covers a Part B service as an additional telehealth benefit, then the MA plan must also provide access to such service through an in-person visit and not only as an additional telehealth benefit. We propose to codify this statutory mandate preserving enrollee choice in regulation text at

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3 https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Meeting%20Draft%20of%20Final%20Report%20-%20November%201%2C%202017.pdf

§ 422.135(c)(1), which would require that the enrollee must have the option to receive a service that the MA plan would cover as an additional telehealth benefit either through an in-person visit or through electronic exchange. Section 1852(m)(5) of the Act mandates that additional telehealth benefits shall be treated as if they were benefits under the original Medicare fee-for-service program option. Based on the manner in which CMS currently allows differential cost sharing under MA plans for original Medicare-covered benefits, in proposed regulation text at § 422.135(f), we propose to allow MA plans to maintain different cost sharing for the specified Part B service(s) furnished through an in-person visit and the specified Part B service(s) furnished through electronic exchange. This aligns with how CMS has traditionally interpreted section 1852(a)(1)(B)(i), (iii), (iv), and (v) of the Act to mean that, subject to specific exceptions in the statute and § 422.100(j), basic benefits must be covered at an actuarially equivalent level of cost sharing from a plan level (that is, an aggregate and not enrollee level) perspective.

In proposed regulation text at § 422.135(c)(2), we propose to require MA plans to use their EOC (at a minimum) to advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange. Similarly, as we propose at § 422.135(c)(3), MA plans would have to use their provider directory to identify any providers offering services for additional telehealth benefits and in-person visits or offering services exclusively for additional telehealth benefits. We believe that these notifications in the EOC and the provider directory are important to ensure choice, transparency, and clarity for enrollees who might be interested in taking advantage of additional telehealth benefits. We request comments on what impact, if any, additional telehealth benefits should have on MA network adequacy policies. Specifically, we will look for the degree to which additional telehealth benefit providers should be considered in the assessment of network adequacy

(including for certain provider types and/or services in areas with access concerns) and any potential impact on rural MA plans, providers, and/or enrollees.

Section 1852(m)(3) of the Act requires the Secretary to specify limitations or additional requirements for the provision or furnishing of additional telehealth benefits, including requirements with respect to physician or practitioner qualifications, factors necessary for the coordination of additional telehealth benefits with other items and services (including those furnished in-person), and other areas identified by the Secretary. We recognize the potential for additional telehealth benefits to support coordinated health care and increase access to care in both rural and urban areas. We expect MA plans will use these types of benefits to support an effective, ongoing doctor-patient relationship and the efficient delivery of needed care.

We propose in regulation text at § 422.135(c)(4) to require an MA plan offering additional telehealth benefits to comply with the provider selection and credentialing requirements provided in § 422.204. An MA plan must have written policies and procedures for the selection and evaluation of providers and must follow a documented process with respect to providers and suppliers, as described in § 422.204. Further, we propose that the MA plan, when providing additional telehealth benefits, must ensure through its contract with the provider that the provider meet and comply with applicable state licensing requirements and other applicable laws for the state in which the enrollee is located and receiving the service. We recognize, however, that it is possible for a state to have specific provisions regarding the practice of medicine using electronic exchange; our intent is to ensure that MA network providers comply with these laws and that MA organizations ensure compliance with such laws and only cover additional telehealth benefits provided in compliance with such laws. We solicit comment on

whether to impose additional requirements for qualifications of providers of additional telehealth benefits, and if so, what those requirements should be.

In order to monitor the impact of the additional telehealth benefits on MA plans, providers, enrollees, and the MA program as a whole, we also propose to require MA plans to make information about coverage of additional telehealth benefits available to CMS upon request, per our proposed regulation text at § 422.135(c)(5). We propose that this information may include, but is not limited to, statistics on use or cost of additional telehealth benefits, manner(s) or method(s) of electronic exchange, evaluations of effectiveness, and demonstration of compliance with the requirements in proposed regulation text at § 422.135. The purpose of requiring MA plans to make such information available to CMS upon request is to determine whether CMS should make improvements to the regulation and/or guidance regarding additional telehealth benefits.

In proposed regulation text at § 422.135(d), we propose to require that MA plans furnishing additional telehealth benefits may only do so using contracted providers. We believe limiting service delivery of additional telehealth benefits to contracted providers offers MA enrollees access to these covered services in a manner more consistent with the statute because plans would have more control over how and when they are furnished. Additionally, MA plans' must have written policies and procedures for the selection and evaluation of providers. These policies must conform with MA credentialing requirements described in § 422.204. These policies would also provide additional oversight of providers' performance, increasing plans' ability to provide covered services such as additional telehealth benefits. We also propose to specify that if an MA plan covers benefits furnished by a non-contracted provider through electronic exchange, then those benefits may only be covered as a supplemental benefit, not an

additional telehealth benefit (that is, not covered as a basic benefit). We request comment on whether the contracted providers' restriction should be placed on all MA plan types or limited only to certain plan types, such as local/regional preferred provider organization (PPO) plans, medical savings account (MSA) plans, and/or private fee-for-service (PFFS) plans. Currently, pursuant to § 422.4(a)(1)(v), PPO plans must provide reimbursement for all plan-covered medically necessary services received from non-contracted providers without prior authorization requirements. Without an opportunity to review the qualifications of the non-contracted provider and to impose limits on how only clinically appropriate services are provided as additional telehealth benefits, PPO plans will not be able to meet the requirements in this proposed rule. Therefore, we are soliciting comment on whether to require just PPOs (and/or MSA plans, PFFS plans, etc.), instead of all MA plan types, to use only contracted providers for additional telehealth benefits.

Per section 1852(m)(2)(A)(ii) of the Act, the term "additional telehealth benefits" does not include capital and infrastructure costs and investments relating to such benefits. We propose to codify this requirement in § 422.254(b)(3)(i) as a restriction on how MA organizations include additional telehealth benefits in their bid submission. We believe that the statutory limit is tied only to the cost to the government of permitting coverage of these additional telehealth benefits as part of the bid for basic benefits. We are not proposing specific definitions of capital and infrastructure costs or investments related to such benefits at this time because the costs and investments needed and used to provide additional telehealth benefits will vary based on the individual MA plan's approach to furnishing the benefits and the MA plan's contracts with providers. Some examples of capital and infrastructure costs include, but are not limited to, high-speed internet installation and service, communication platforms and software,

and video conferencing equipment. We are soliciting comments on what other types of capital and infrastructure costs and investments should be excluded from the bid and how CMS should operationalize this statutory requirement in the annual bid process. We propose to provide a more detailed list of examples in the final rule, based on feedback received from stakeholders.

In § 422.254(b)(3)(i), we propose that MA plans must exclude any capital and infrastructure costs and investments relating to additional telehealth benefits from their bid submission, for both additional telehealth services offered directly by the plan sponsor and services rendered by a third party provider. Accordingly, the projected expenditures in the MA bid for services provided via additional telehealth benefits must not include the corresponding capital and infrastructure costs. Any items provided to the enrollee in the administration of additional telehealth benefits must be directly related to the care and treatment of the enrollee for the Part B benefit. For example, MA plans may not provide enrollees with items such as internet service or permanently install telecommunication systems in an enrollee's home as part of administration of additional telehealth benefits.

In addition to our proposal at § 422.135, we also propose to amend paragraphs (a) and (c)(1) of § 422.100 to explicitly address how additional telehealth benefits may be offered by an MA plan. Section 1852(a)(1)(A) of the Act requires that each MA plan shall provide enrollees benefits under the original Medicare fee-for-service program option. As amended by the Bipartisan Budget Act of 2018, section 1852(a)(1)(B) of the Act defines "benefits under the original Medicare fee-for-service program option" to mean—subject to subsection (m) (regarding provision of additional telehealth benefits)—those items and services (other than hospice care or coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B to individuals entitled to benefits under Part A and enrolled under

Part B. Since this definition is subject to the statutory provision for additional telehealth benefits, this means that all of the same coverage and access requirements that apply with respect to basic benefits also apply to any additional telehealth benefits an MA plan may choose to offer. Therefore, we propose to amend § 422.100(c)(1) to include additional telehealth benefits in the definition of basic benefits and to cross-reference the proposed regulation at § 422.135 that provides the rules governing additional telehealth benefits. We also propose to further clarify the regulation text in § 422.100(c)(1) to track the statutory language described earlier more closely in addressing both kidney acquisition and hospice in the definition of basic benefits. Finally, we propose to make corresponding technical revisions to § 422.100(a) to reference the new paragraph (c)(1) for basic benefits (clarifying that additional telehealth benefits are voluntary benefits for MA plans to offer—not required) and paragraph (c)(2) for supplemental benefits (instead of § 422.102 because supplemental benefits are listed as a benefit type in (c)(2)). We also propose a small technical correction in the last sentence of § 422.100(a) to replace the reference to § 422.100(g) with "this section" because there are a number of provisions in § 422.100—not just paragraph (g)—that are applicable to the benefits CMS reviews.

Additionally, we propose amendments to the bidding regulations at §§ 422.252, 422.254, and 422.264 to account for additional telehealth benefits and correct the inconsistent phrasing of references to basic benefits (for example, these regulations variously use the terms "original Medicare benefits," "benefits under the original Medicare program," "benefits under the original Medicare FFS program option," etc.). In order to make the additional telehealth benefits part of the basic benefit bid and included in the "monthly aggregate bid amount" as part of the original Medicare benefits that are the scope of the basic benefit bid, we propose to update these various phrases to consistently use the phrase "basic benefits as defined in § 422.100(c)(1)." We also

propose a few minor technical corrections to the bidding regulations. Finally, we propose a paragraph (e) in new § 422.135 to state that an MA plan that fully complies with § 422.135 may include additional telehealth benefits in its bid for basic benefits in accordance with § 422.254. This provision means that inclusion in the bid is subject to the bidding regulations we are also proposing to amend here.

In offering additional telehealth benefits, MA plans must comply with existing MA rules, including, but not limited to: access to services at § 422.112; enrollee recordkeeping at § 422.118 (for example, confidentiality, accuracy, timeliness); standards for communications and marketing at § 422.2268 (for example, inducement prohibition); and non-discrimination at §§ 422.100(f)(2) and 422.110(a). Further, in addition to §§ 422.112, 422.118, 422.2268, 422.100(f)(2), and 422.110(a), MA plans must also ensure compliance with other federal non-discrimination laws, such as Title VI of the Civil Rights Act, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act. We are not proposing specific reference to these existing requirements in new § 422.135 because we do not believe that to be necessary. Compliance with these existing laws is already required; we merely note, as an aide to MA organizations, how provision of additional telehealth benefits must be consistent with these regulations. We solicit comment on this policy choice, specifically whether there are other existing regulations that CMS should revise to address their application in the context of additional telehealth benefits.

Finally, section 1852(m)(2)(B) of the Act instructs the Secretary to solicit comments on the implementation of these additional telehealth benefits by November 30, 2018; in addition to proposing regulations to implement section 1852(m) of the Act, we are using this notice of proposed rulemaking and the associated comment period to satisfy this statutory requirement.

We thank commenters in advance for their input to help inform CMS's next steps related to implementing the additional telehealth benefits.

2. Dual Eligible Special Needs Plans

Special needs plans (SNPs) are MA plans created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) that are specifically designed to provide targeted care and limit enrollment to special needs individuals. Under the law, SNPs are able to restrict enrollment to: (1) institutionalized individuals, who are defined in § 422.2 as those residing or expecting to reside for 90 days or longer in a long term care facility; (2) individuals entitled to medical assistance under a state plan under Title XIX; or (3) other individuals with certain severe or disabling chronic conditions who would benefit from enrollment in a SNP. As of June 2018, the CMS website listed 297 SNP contracts with 641 SNP plans that have at least 11 members. These figures included 190 Dual Eligible SNP contracts (D-SNPs) with 412 D-SNP plans with at least 11 members, 49 Institutional SNP contracts (I-SNPs) with 97 I-SNP plans with at least 11 members, and 58 Chronic or Disabling Condition SNP contracts (C-SNPs) with 132 C-SNP plans with at least 11 members. This proposed rule would implement the provisions of the Bipartisan Budget Act of 2018 that establish new requirements for D-SNPs for the integration of Medicare and Medicaid benefits and unification of Medicare and Medicaid grievance and appeals procedures that would be effective in 2021. This proposed rule would also clarify definitions and operating requirements for D-SNPs that would take effect on the effective date of the final rule.

a. Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)

Beneficiaries who are dually eligible for both Medicare and Medicaid can face significant challenges in navigating the two programs, which include separate or overlapping benefits and administrative processes. Fragmentation between the two programs can result in a lack of coordination for care delivery, potentially resulting in-- (1) missed opportunities to provide appropriate, high-quality care and improve health outcomes, and (2) ineffective care, such as avoidable hospitalizations and a poor beneficiary experience of care. Advancing policies and programs that integrate care for dual eligible individuals is one way in which we seek to address such fragmentation. Under plans that offer integrated care, dually eligible beneficiaries receive the full array of Medicaid and Medicare benefits through a single delivery system, thereby improving care coordination, quality of care, beneficiary satisfaction, and reducing administrative burden. Some studies have shown that highly integrated managed care programs perform well on quality of care indicators and enrollee satisfaction.4

D-SNPs are a type of MA plan that is intended to integrate or coordinate care for this population more effectively than standard M A plans or Original Medicare by focusing enrollment and care management on dually eligible individuals. As of June 2018, approximately 2.3 million dually eligible beneficiaries (one 1 of every 6 dually eligible beneficiaries) were enrolled in 412 D-SNPs. About 170,000 dually eligible beneficiaries are enrolled in fully

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4 *See:* Kim, H., Charlesworth, C.J., McConnell, K.J., Valentine, J.B., and Grabowski, D.C. (2017, November 15). *Comparing Care for Dual-Eligibles Across Coverage Models: Empirical Evidence From Oregon*. Retrieved from http://journals.sagepub.com/doi/abs/10.1177/1077558717740206; Anderson, W.L., Feng, Z., & Long, S.K. (2016, March 31). *Minnesota Managed Care Longitudinal Data Analysis*, prepared for the U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE). Retrieved from https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis; Health Management Associates (2015, July 21). *Value Assessment of the Senior Care Options (SCO) Program*. Retrieved from http://www.mahp.com/wp-content/uploads/2017/04/SCO-White-Paper-HMA-2015_07_20-Final.pdf; and Medicare Payment Advisory Committee (2012, June 16). "*Care coordination programs for dual-eligible beneficiaries*." In June 2012 Report to Congress: Medicare and Health Care Delivery System. Retrieved from http://www.medpac.gov/docs/default-source/reports/chapter-3-appendixes-care-coordination-programs-for-dual-eligible-beneficiaries-june-2012-report-.pdf?sfvrsn=0.

integrated dual eligible special needs plans, or FIDE SNPs (that is, where the same organization receives capitation to cover both Medicare and Medicaid services).[5] Several states, including Arizona, Idaho, Hawaii, Massachusetts, Minnesota, New Jersey, New Mexico, New York, Pennsylvania, Tennessee, Texas, Virginia, and Wisconsin, operate Medicaid managed care programs for dually eligible individuals in which the state requires that the Medicaid managed care organizations serving dual eligible individuals offer a companion D-SNP product.

Since the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) first authorized D-SNPs' creation, subsequent legislation has been enacted that has extended their authority to operate and set forth additional programmatic requirements.

• Sections 164 and 165 of the Medicare Improvements for Patients and Providers Act (MIPPA) (Pub..L. 110–275) amended sections 1859 and 1852(a) of the Act to require D-SNPs to--

- Provide each prospective enrollee, prior to enrollment, with a comprehensive written statement that describes the benefits and cost-sharing protections to which the beneficiary is entitled under Medicaid and which are covered by the plan;
- Contract with the state Medicaid agency to provide benefits, or arrange for the provision of Medicaid benefits, which may include long-term care services consistent with state policy, to which such individual is entitled. Notwithstanding this requirement, section 164(c)(4) of MIPPA stipulated that a state is in no way obligated to contract with a D-SNP; and
- Limit the imposition of cost-sharing on full-benefit dual eligible individuals and Qualified Medicare Beneficiaries.

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5 Centers for Medicare & Medicaid Services (2018, June). *SNP Comprehensive Report*. Retrieved from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.

● Section 3205 of the Patient Protection and Affordable Care Act (Pub. L. 111-148) revised section 1853(a)(1)(B) of the Act to permit the Secretary to apply a frailty payment under PACE payment rules to certain D-SNPs that are fully integrated with capitated contracts with states for Medicaid benefits, including long-term care, and that have similar average levels of frailty (as determined by the Secretary) as the PACE program.

Regulations promulgated following the enactment of these laws established provisions that:

• Define at § 422.2 a fully integrated special needs plan (FIDE SNP);

• Require at § 422.107 all MA organizations seeking to offer a D-SNP to enter into a contract containing a minimum set of terms and conditions with the state Medicaid agency;

• Require at § 422.111(b)(2)(iii) D-SNPs to furnish, prior to enrollment, certain benefit and cost-sharing information to dually eligible enrollees; and

• Permit at § 422.308(c)(4) the application of a frailty payment adjustment to FIDE SNPs that have a similar average level of frailty (as determined by the Secretary) as the PACE program.[6]

Because the current regulations establish only minimum requirements, state Medicaid agencies may exercise authority to establish requirements that surpass the minimum, and to that end, we have seen states leverage their contracts with D-SNPs to limit D-SNP enrollment to individuals who also receive Medicaid benefits through the same organization, collect certain data from the D-SNP, and integrate beneficiary communication materials and care management processes to provide dual eligible enrollees a more seamless, coordinated experience of care.7

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6 *See* 73 FR 54226 (September 18, 2008) and 76 FR 21432 (April 15, 2011)

7 Verdier, J, Kruse, A., Sweetland Lester, R., Philip, A.M., & Chelminsky, D. (2016, November). "State Contracting with Medicare Advantage Dual Eligible Special Needs Plans: Issues and Options." Retrieved from

CMS supports states that have an interest in pursuing integrated care models for dual eligible individuals, including through the use of their contracts with MA organizations offering D-SNPs, and currently provides technical assistance to states seeking to develop solutions tailored to their local market conditions, beneficiary characteristics, and policy environment.

Through this proposed rule, we are establishing new requirements in accordance with section 50311(b) of the Bipartisan Budget Act of 2018, which amended section 1859 of the Act to require that all D-SNPs meet certain new minimum criteria for Medicare and Medicaid integration for 2021 and subsequent years. Beyond the newly enacted amendments to the Act, we are also using this rulemaking to add requirements and clarifications to existing regulations to codify guidance and policy since D-SNPs were established nearly 15 years ago and to update certain aspects of the regulations. Under the newly enacted section 1859(f)(8)(D)(i) of the Act, the statute calls for D-SNPs, for 2021 and subsequent years, to meet one or more of three specified requirements, to the extent permitted under state law, for integration of benefits:

• A D-SNP must, in addition to meeting the existing requirement of contracting with the state Medicaid agency under section 1859(f)(3)(D) of the Act, coordinate long-term services and supports (LTSS), behavioral health services, or both, by meeting an additional minimum set of requirements for integration established by the Secretary based on input from stakeholders. Such requirements for integration could include: (1) notifying the state in a timely manner of hospitalizations, emergency room visits, and hospital or nursing home discharges of enrollees; (2) assigning one primary care provider for each enrollee; or (3) data sharing that benefits the coordination of items and services under Medicare and Medicaid.

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http://www.integratedcareresourcecenter.com/PDFs/ICRC_DSNP_Issues__Options.pdf.

• A D-SNP must either-- (1) meet the requirements of a fully integrated dual eligible special needs plan described in section 1853(a)(1)(B)(iv)(II) of the Act (other than the requirement that the plan have similar average levels of frailty as the PACE program); or (2) enter into a capitated contract with the state Medicaid agency to provide LTSS, behavioral health services, or both.

• The parent organization of a D-SNP that is also the parent organization of a Medicaid managed care organization providing LTSS or behavioral services must assume "clinical and financial responsibility" for benefits provided to beneficiaries enrolled in both the D-SNP and Medicaid managed care organization.

Section 50311(b) of the Bipartisan Budget Act of 2018 also authorizes the Secretary, in section 1859(f)(8)(D)(ii) of the Act, to impose an enrollment sanction on MA organizations offering a D-SNP that fails to meet at least one of these integration standards in plan years 2021 through 2025. In the event that the Secretary imposes such a sanction, the MA organization must submit to the Secretary a plan describing how it will come into compliance with the integration standards.

(1) Definitions of a "Dual Eligible Special Needs Plan", "Fully Integrated Dual Eligible Special Needs Plan", "Highly Integrated Dual Eligible Special Needs Plan", and "Aligned Enrollment" (§ 422.2)

We are proposing new definitions for the terms "dual eligible special needs plan," "fully integrated dual eligible special needs plan," "highly integrated dual eligible special needs plan," and "aligned enrollment," for purposes of part 422 (that is, the rules applicable to the MA program) and this proposed rule.

Through this notice of proposed rulemaking, we propose to consolidate statutory and regulatory references to a D-SNP and, in so doing, clearly state in § 422.2 the minimum requirements for a D-SNP. Currently, D-SNPs are described in various sections of 42 CFR part 422, including provisions governing the definition of specialized MA plans for special needs individuals in § 422.2, the supplemental benefit authority for D-SNPs that meet a high standard of integration and minimum performance and quality-based standards in § 422.102(e), state Medicaid agency contracting requirements in § 422.107, and specific benefit disclosure requirements in § 422.111(b)(2)(iii). In our proposed definition at § 422.2, we describe a dual eligible special needs plan as a type of specialized MA plan for individuals who are eligible for Medicaid under Title XIX of the Act that provides, as applicable, and coordinates the delivery of Medicare and Medicaid services, including LTSS and behavioral health services, for individuals who are eligible for such services; has a contract with the state Medicaid agency consistent with § 422.107 that meets the minimum requirements in paragraph (c) of such section; and satisfies at least one of following integration requirements: (1) it meets the additional state Medicaid agency contracting requirement at proposed § 422.107(d) (described in section II.A.2.a.(2)) of this proposed rule that surpasses the minimum requirements in current regulations at § 422.107(c); 2) it is a highly integrated dual eligible special needs plan (HIDE SNP), as described in further detail later in this section; or (3) it is FIDE SNP. In addition, we propose elsewhere in this proposed rule additional performance requirements for D-SNPs that we have not incorporated into the definition; for example, a D-SNP would provide assistance to individuals filing a grievance or appeal for a Medicaid services in accordance with proposed § 422.562(a)(5) (described in section II.A.2.b.(1) of this proposed rule).

While we do not explicitly cite or summarize the integration requirement at section 1859(f)(8)(D)(i)(III) of the Act in this proposed regulatory definition, we interpret the statutory language on assuming clinical and financial responsibility for benefits (as discussed later in this proposed rule) to mean that such a D-SNP would always satisfy the requirement of being a FIDE SNP or HIDE SNP. We believe that this proposed definition identifies the minimum requirements for an MA plan to be a D-SNP under section 1859 of the Act as amended by the Bipartisan Budget Act of 2018, as well as clarifies the applicability of the separate regulatory provisions that establish these minimum standards. We solicit comment whether our proposed definition meets these goals or should be revised to include other regulatory provisions that establish requirements for D-SNPs.

We believe it is important to clarify through this rulemaking the meaning of the requirement in section 1859(f)(3)(D) of the Act, which is currently codified at § 422.107(b), that the MA organization have responsibility under the contract for providing benefits or arranging for benefits to be provided for individuals entitled to Medicaid. We have not interpreted the meaning of this statutory language, "arranging for benefits," in previous rulemaking or in subregulatory guidance. We propose to interpret "arranging for benefits" as requiring a D-SNP, at a minimum, to coordinate the delivery of Medicare and Medicaid benefits. We propose to relocate this requirement to our proposed D-SNP definition. While our interpretation is consistent with the new statutory integration standards, this clarification is based on requirements for D-SNPs that existed prior to the enactment of the Bipartisan Budget Act of 2018 that we believe should be strengthened. We believe coordination would encompass a wide range of activities that a D-SNP may engage in for their dual eligible members. For example, if a D-SNP identifies through an enrollee's health risk assessment and/or individualized care plan, as

required by § 422.101(f), functional limitations or mental health needs, the D-SNP would verify the enrollee's eligibility for LTSS and/or behavioral health services under Medicaid; determine how the enrollee receives such services (through FFS Medicaid or through another Medicaid managed care product); and make arrangements with the applicable Medicaid program (state Medicaid agency or managed care plan) for the provision of such services by the appropriate payer and/or provider. We recognize that not all of a D-SNP's membership will be eligible for the full complement of Medicaid services, particularly those who are partial-benefit dual eligible individuals whose Medicaid eligibility is limited to payment of their Medicare premiums, and if applicable, deductibles and cost-sharing.8 However, for all enrollees who are eligible for Medicaid services, the D-SNP must fulfill its statutory responsibility to arrange for the provision of Medicaid benefits by facilitating a beneficiary's meaningful access to such benefits. We believe it would be insufficient for a D-SNP to limit its coordination activity simply to telling a beneficiary to call or write their Medicaid managed care plan or state agency without giving specific contact information, giving specific coaching on the roles of the Medicaid program (that is, the state agency or Medicaid managed care plan versus the D-SNP), and offering additional support if needed. We solicit comment on whether our proposed definition should be more prescriptive in identifying which plan activities constitute coordination or whether it should remain broadly defined as proposed.

[8] Partial-benefit dual eligible programs are commonly referred to collectively as the "Medicare Savings Program" (MSP). The MSP includes 4 eligibility groups: Qualified Medicare Beneficiary Program without other Medicaid (QMB Only) for whom Medicaid pays their Medicare Part A premiums, if any, Medicare Part B premiums, and to the extent consistent with the Medicaid State plan, Medicare Part A and B deductibles, coinsurance and copays for Medicare services provided by Medicare providers; Specified Low-Income Medicare Beneficiary Program without other Medicaid (SLMB Only) and Qualifying Individual (QI) Program for whom Medicaid pays the Part B premiums; Qualified Disabled and Working Individual (QDWI) Program for whom Medicaid pays the Part A premiums.

We propose revising the definition of fully integrated dual eligible special needs plan at § 422.2 to align with the proposed definition of a D-SNP and to codify current policy. Specifically, we propose the following:

• Striking the reference to a "CMS approved MA-PD" plan in the current FIDE SNP definition and paragraph (1), which refers to the individuals eligible for enrollment in a FIDE SNP, because those provisions duplicate elements of the new proposed definition of a D-SNP at § 422.2;

• Replacing the reference to "dual eligible beneficiaries" with "dual eligible individuals" in newly redesignated paragraph (1) to align with the terminology used in section 1935(c) of the Act;

• Adding to newly redesignated paragraph (2) that a FIDE SNP's capitated contract with a state Medicaid agency may include specified behavioral health services, as well as replacing the term "long-term care" benefits with "long-term services and supports" to better describe the range of such services FIDE SNPs cover in capitated contracts with states. We also propose codifying in paragraph (2) the current policy that the FIDE SNP's capitated contract with the state provide coverage of nursing facility services for at least 180 days during the plan year;9

• Striking references to coordination of covered Medicare and Medicaid "health and long-term care" and referring more broadly to Medicare and Medicaid services in in newly redesignated paragraph (3); and

• Replacing the reference to "member" materials with "beneficiary communication materials," consistent with the definition of "communication materials" at § 422.2260.

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9 Following the April 2, 2012 issuance of the "Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," Chapter 16b of the Medicare Managed Care Manual was revised to include this policy.

We propose to codify a definition of highly integrated dual eligible special needs plan (HIDE SNP) at § 422.2. Under the proposed definition, a HIDE SNP would be a type of D-SNP offered by an MA organization that has – or whose parent organization or another entity that is owned and controlled by its parent organization has – a capitated contract with the Medicaid agency in the state in which the D-SNP operates that includes coverage of LTSS, behavioral health services, or both, consistent with state policy.

We note that all the requirements of a D-SNP would also apply to a HIDE SNP, such as the obligation to provide, as applicable, and coordinate Medicare and Medicaid benefits. In contrast to a FIDE SNP, a D-SNP could satisfy the requirements of a HIDE SNP if its parent organization offered a companion Medicaid product that covered only LTSS or behavioral health services, or both, under a capitated contract. Because a FIDE SNP covers comprehensive Medicaid benefits including LTSS and behavioral health services, any FIDE SNP would also be a HIDE SNP, but not all HIDE SNPs would qualify to be FIDE SNPs. In defining a HIDE SNP, we chose to adopt the phrase "consistent with state policy" to align with the FIDE SNP definition. We interpret this phrase, both for FIDE SNPs and HIDE SNPs, as an important acknowledgement of variation in how states elect to provide coverage of LTSS or behavioral health services under their capitated contracts with D-SNPs and Medicaid managed care plans (for example, MCOs in the case of FIDE SNPs, and MCOs, PIHPs, and PAHPs in the case of HIDE SNPs). For example, one state may include all Medicaid behavioral health services in its capitated contracts, while another state may carve out a particular service from its capitated contracts with a Medicaid managed care plan covering behavioral health services. We interpret the phrase "consistent with state policy" as allowing CMS to permit certain carve-outs where consistent with or necessary to accommodate state policy, except for where specifically

prohibited (such as for nursing facility services in the FIDE SNP definition). As such, among the states that have capitated contracts with D-SNPs or the D-SNPs' parent organizations, CMS can still determine that D-SNPs meet the FIDE SNP or HIDE SNP definition despite these types of variations allowed under this proposal. We solicit comment on this proposed definition, including on whether additional requirements for HIDE SNPs should be addressed in the definition.

We also propose to establish at § 422.2 a definition for the term aligned enrollment, as many of the other D-SNP proposals in this proposed rule are based on this concept. Under our proposal, aligned enrollment occurs when a full-benefit dual eligible individual is a member of a D-SNP and receives coverage of Medicaid benefits from the D-SNP or from a Medicaid managed care organization, as defined in section 1903(m) of the Act, that is: (1) the same organization as the MA organization offering the D-SNP; (2) its parent organization; or (3) another entity that is owned and controlled by the D-SNP's parent organization. Aligned enrollment, as we propose to define it, would not arise where the MA organization or its parent organization has a contract with the applicable state to offer a prepaid inpatient health plan (PIHP) or prepaid ambulatory health plan (PAHP) in the state's Medicaid program. Unlike a Medicaid MCO, these other Medicaid managed care plans cover only specific and non-comprehensive set of services. In the event that it is the policy of the state Medicaid agency to limit a D-SNP's membership to individuals with aligned enrollment, we would describe this practice as "exclusively aligned enrollment," which is embedded in the definition of "aligned enrollment." For example, some states limit D-SNP enrollment to full-benefit dual eligible individuals who also choose to receive Medicaid benefits through the D-SNP or a Medicaid MCO operated by the same entity (that is, by the MA organization) or by the MA organization's

parent organization. Such a limitation would be included in the state Medicaid agency contract with the D-SNP. Exclusively aligned enrollment is relevant to how we propose to apply the integrated grievance and appeals requirements described in section II.A.2.b. of this proposed rule. We solicit comment on how we propose to define aligned enrollment given its relevance to the category of D-SNPs to which the integrated grievance and appeals procedures apply. We also solicit comment on whether we should consider other types of Medicaid managed care arrangements beyond companion Medicaid MCOs, as defined in section 1903(m) of the Act and codified at § 438.2, operated by a HIDE SNP's parent organization.

Finally, we propose in our definition of a D-SNP at § 422.2 to codify that an MA organization seeking to offer a D-SNP must satisfy any one (or more) of the three integration requirements in section 1859(f)(3)(D)(i) of the Act. We note that the statutory language requires that plans meet one or more statutorily identified integration requirements to the extent permitted under state law. We interpret this phrase as acknowledging and respecting the flexibility provided to states under the Medicaid program while imposing on D-SNPs integration requirements that Congress has deemed necessary. In approximately 20 states, state law does not permit enrollment of dual eligible individuals in managed care for Medicaid services, which would effectively preclude a D-SNP in such a state from being a HIDE SNP (paragraph 2) or FIDE SNP (paragraph 3). Similarly, in other states, certain Medicaid benefits, such as LTSS and behavioral health services, are carved out of Medicaid managed care, which could similarly preclude a D-SNP from meeting paragraphs (2) or (3) of our proposed definition of a D-SNP. As we discuss in the context of our definitions of a FIDE SNP and HIDE SNP, a carve-out by the state of a minimal scope of services is permissible so long as comprehensive services are covered under the capitated Medicaid contract. For these reasons, we propose to interpret this statutory

provision in a way that provides multiple avenues for a MA plan to qualify as a D-SNP. However, we considered other interpretations of this particular provision. For example, we considered whether this phrase should mean that in states that have Medicaid managed care programs for dual eligible individuals, all MA organizations seeking to offer a D-SNP could do so only if they were under contract with the state to offer a companion Medicaid managed care plan in that state, on the grounds that such an opportunity is permitted under state law. We solicit comments on our proposed interpretation as well as alternatives. We also request comment on whether and how our proposed definition could or should be revised consistent with the interpretation we take of the statute.

These proposed definitions serve to describe different types of D-SNPs based on the degree to which they integrate Medicaid benefits at the plan level. FIDE SNPs that limit enrollment to full-benefit dual eligible individuals and require (or have) exclusively aligned enrollment across Medicare and Medicaid constitute the most extensive level of integration, with the greatest potential for holistic and person-centered care coordination, integrated appeals and grievances, comprehensive beneficiary communication materials, and quality improvement. HIDE SNPs with exclusively aligned enrollment are plans that share much of this potential but integrate a narrower set of Medicaid benefits than FIDE SNPs. We believe that an entity can only truly hold "clinical and financial responsibility" for the provision of Medicare and Medicaid benefits, as described at section 1859(f)(8)(D)(i)(III) of the Act, in the scenarios of exclusively aligned enrollment. Therefore, the plans that meet this criterion would be FIDE SNPs and HIDE SNPs that have exclusively aligned enrollment, as these terms are defined under our proposal. By virtue of these exclusively aligned plans' status as a FIDE SNP or HIDE SNP, they would

also satisfy the integration requirement at section 1859(f)(8)(D)(i)(II) of the Act, which we codified in paragraphs (2) and (3) of the definition of a D-SNP at § 422.2.

FIDE SNPs and HIDE SNPs where aligned enrollment is possible – but not required – under the state contract with the D-SNP and the state's administration of its Medicaid managed care program would constitute another form of integration, albeit to a lesser degree. In such a D-SNP, it is likely that some share of the D-SNP's enrollment is aligned enrollment but not exclusively aligned enrollment. Some dual eligible individuals enrolled in that plan may: (1) enroll in a Medicaid managed care plan operated by a different parent organization; or (2) receive their Medicaid benefits through Medicaid fee-for-service. These other choices may be a result of individual choice even when a Medicaid managed care plan offered by the same entity (or parent organization) as the MA D-SNP is available or may be the result of the applicable state's decisions in administering its Medicaid program.

Under section 1859(f)(8)(D)(i) of the Act, those D-SNPs that are neither FIDE SNPs nor HIDE SNPs must meet an additional state Medicaid contracting requirement beginning in 2021. Our proposed definition of a D-SNP addresses this in paragraph (1), cross-referencing the proposed new requirement in paragraph (d) of § 422.107. This new requirement, which involves the provision of notice when an individual who belongs to a group of high-risk dual eligible individuals has a hospital and skilled nursing facility admission, is discussed in section II.A.2.b.(2) of the proposed rule in greater detail. We solicit comments on this proposal and, in particular, on alternative approaches to classifying D-SNPs consistent with requirements of section 1859(f)(8)(D)(i) of the Act.

(2) Dual Eligible Special Needs Plans and Contracts with States (§ 422.107)

In § 422.107, we propose changes to more clearly articulate the requirements of the contract between the D-SNP and the state Medicaid agency, while also incorporating the changes

required by the Bipartisan Budget Act of 2018. In summary, we propose to make the following changes:

• Delete language in paragraph (b) that is extraneous and duplicative of the proposed definition of a D-SNP in § 422.2;

• Make clarifying edits in paragraphs (c)(1) through (c)(3), which govern the minimum requirements of the contract between the D-SNP and the state Medicaid agency;

• Redesignate paragraph (d) as paragraph (e), which relates to compliance dates; and

• Establish a revised paragraph (d) that describes the new minimum contracting requirement under the Bipartisan Budget Act of 2018 that the newly designated paragraph (e)(2) would make effective January 1, 2021.

Section 50311(b) of the Bipartisan Budget Act of 2018 amended section 1859(f) of the Act by creating a new paragraph (8)(D)(i)(I) to require that the Secretary establish additional requirements for D-SNPs' contracts with state Medicaid agencies. We address in our preamble discussion about our proposed definition of D-SNP how this provision requires a D-SNP to have a state Medicaid agency contract that includes additional coordination requirements (subsection (f)(8)(D)(i)(I) of the Act); be a FIDE SNP or HIDE SNP (subsection (f)(8)(D)(i)(II) of the Act); or have exclusively aligned enrollment and have its parent organization accept full clinical and financial responsibility for all Medicare and Medicaid covered services (subsection (f)(8)(D)(i)(III) of the Act), depending on the state's election.

We are proposing to implement subsection (f)(8)(D)(i)(I) of the Act itself by establishing at § 422.107(d) that any D-SNP that is not a FIDE SNP or HIDE SNP is subject to an additional contracting requirement. Under this proposed new contract requirement, the D-SNP would be required to notify the state Medicaid agency, or individuals or entities designated by the state

Medicaid agency, of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full-benefit dual eligible individuals, as determined by the state Medicaid agency. Our proposal would also permit the D-SNP to authorize another entity or entities (such as a D-SNP's network providers) to notify the state Medicaid agency and/or individuals or entities designated by the state Medicaid agency on its behalf, with the understanding that the D-SNP ultimately would retain responsibility for complying with this requirement. Our intent in proposing this notification requirement is to promote the integration of Medicare and Medicaid benefits by establishing a minimum contracting requirement that has the effect of increasing D-SNPs' care coordination activity around care transitions. In such care transitions, there is a clear need to share information among parties concerned with the beneficiary's care and there is a risk of potential harm to the beneficiary when effective communication and coordination do not occur. In our experience, there are known gaps when a beneficiary migrates from one setting where services are covered under Medicare, such as an inpatient or SNF stays, to another setting where services such as LTSS, including home and community based services (HCBS), that are covered under Medicaid.[10] This proposed provision is intended to promote successful transitions of care into a setting of the beneficiary's choice, and increase coordination among those involved in furnishing and paying for primary care, acute care, LTSS, and behavioral health services. The proposed requirement for notification is just one facet of successful, holistic care transitions, but we believe it is an essential catalyst for the process.

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[10] "Improving Care Transitions," Health Affairs Health Policy Brief, September 13, 2012. DOI: 10.1377/hpb20120913.327236. Retrieved from https://www.healthaffairs.org/do/10.1377/hpb20120913.327236/full/; and Segal, M., Rollins, E., Hodges, K., and Roozeboom, M. "Medicare-Medicaid Eligible Beneficiaries and Potentially Avoidable Hospitalizations." *Medicare & Medicaid Research Review*, 2014: 4 (1), p. E1-E10. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4053188/pdf/mmrr2014-004-01-b01.pdf.

In permitting a state Medicaid agency to specify which subpopulations of high-risk full-benefit dual eligible individuals the D-SNP must focus on through this effort, we are seeking to give states flexibility to begin on the path toward greater integration on a smaller scale and, in collaboration with the D-SNPs in their markets, test different approaches. As processes and infrastructure mature, a state Medicaid agency may choose through its contracts with D-SNPs to scale up this notification to include additional data, additional subpopulations of full-benefit dual eligible individuals, or both. High-risk beneficiaries could include those who are receiving HCBS or participating in a Medicaid health home program in accordance with section 1945 of the Act. Alternatively, or in addition, the state Medicaid agency could use claims or encounter data to target particular groups, such as those who have a history of hospital readmissions or who are high utilizers of acute care services, LTSS, or behavioral health services. Under this proposal, we would give the state Medicaid agency broad latitude to establish notification procedures and protocols, including the recipients of the admission notifications, timeframes by which a D-SNP must furnish this information directly or indirectly, and how such notification would occur. We are proposing to defer to state Medicaid agencies on the manner in which notification occurs, that is, whether it involves an automated or manual process. For example, in markets where there is existing infrastructure to leverage, such as a state health information exchange, a state may elect an approach that requires data sharing across a common platform using industry standards, including those adopted by the Office of the National Coordinator for Health IT in accordance with 45 CFR part 170, subpart B. Regardless of process, the expectation is that notifications occur timely in order to ensure prompt care coordination and effective care transitions. To that end, we strongly encourage states to use the most efficient notification mechanisms available, which may include the state's health information exchange. However, we

appreciate that not every state is similarly positioned and, therefore, if a state elected to implement this requirement on a smaller scale, targeting a small subset of beneficiaries, a solution that does not initially require automation may be more appropriate and pragmatic. We support state Medicaid agencies in their efforts to adopt the policies and procedures for this notification requirement that work best for them and D-SNPs participating in their markets. Regardless of what approach a state chooses to take under this proposal, our aim is to have actionable information that enables providers and payers to facilitate seamless care transitions for high-risk populations, that is, those full-benefit dual eligible individuals who are among the most ill and medically complex or who are most likely to benefit from effective interventions (such as through the provision of LTSS and behavioral health services) that enable them to live independently in the setting of their choice and in a way that values their own needs and preferences.

We believe that our proposal to establish a notification requirement for D-SNPs for high-risk individuals' hospital and skilled nursing facility admissions is consistent with the criteria we used to evaluate various options for the minimum contracting requirements. We considered whether a proposal would--

- Meaningfully improve care coordination and care transitions, thereby improving health outcomes for dually eligible beneficiaries;
- Minimize burden on plans and states relative to the improvements in care coordination and transitions;
- Provide flexibility to state Medicaid agencies;
- Enable CMS to assess compliance with minimal burden on CMS, plans, and providers; and

• Be consistent with the statutory amendments made by the Bipartisan Budget Act of 2018.

We solicit comment on whether our proposal satisfies these criteria to a greater extent than the more prescriptive or alternative proposals we considered as described in further detail in this section of this proposed rule; whether our reasoning for why our proposal is preferable to the more prescriptive or alternative proposals is sound; whether there are other minimum contacting requirements that we did not consider that are superior to our proposal; and whether our proposal provides sufficient incentives for plans and states to pursue greater levels of integration. For example, we considered the following:

• We considered proposing that notice requirements apply for all full-benefit dual eligible individuals' hospital and SNF admissions. We believe our proposal is preferable because it limits the administrative burdens for states and MA organizations and focuses efforts on high-risk beneficiaries for whom there is likely to be some Medicaid care coordination infrastructure.

• We considered proposing a minimum size for the state-selected high-risk population. In contrast, our proposal for new § 422.107(d) gives state Medicaid agencies the discretion to decide what it means that a group of beneficiaries is at high risk and how large or small the group(s) may be.

• We considered requiring a notification for every emergency department visit, as mentioned in section 1859(f)(8)(D)(i)(I) of the Act. We believe our proposal is preferable because it focuses on hospital and SNF admissions where CMS believes there is the greatest opportunity to target interventions and improve outcomes, and during which there is more time to initiate discharge planning than during an emergency department visit. However, we note that a state Medicaid agency could choose to require a notification for full-benefit dual eligible

individuals who are high utilizers of emergency departments, where there may be opportunities to address barriers to accessing primary care and unmet health care needs.

• We considered proposing that the notification occur not later than 48 hours after the D-SNP learns of the admission or discharge. We opted instead to defer to the state Medicaid agency on such matters. We believe that states may choose to use this information for their own purposes, including program oversight; alternatively, or in addition, a state Medicaid agency may opt to require a direct notification between the D-SNP and Medicaid managed care organization (MCO) or a specified Medicaid provider to allow for the timeliest action following a care transition or other significant event.

• We considered focusing on better coordination of individual health needs assessments and mechanisms to reduce assessment burden for enrollees. We continue to hear of scenarios where a D-SNP enrollee is assessed separately by the D-SNP and then again by their Medicaid MCO, even though there may be a high degree of overlap in what each organization is assessing and ultimately what each organization is asking of the enrollee. Because we are unclear on the scope of the problem, we solicit comment on how pervasive this issue is and the extent of overlap in the assessment instruments and degree of burden on providers and beneficiaries. We welcome feedback for our consideration in the final rule, specifically on the extent to which the requirements that we propose do not accomplish enough or should be modified to address this issue. For example, we seek comment on whether a coordination obligation for D-SNPs should be adopted that could require, for example, each D-SNP to take affirmative steps to schedule its assessments at the same time as similar outreach is conducted by the Medicaid managed care plan, to use a combined or aligned assessment instrument, or take other steps that would minimize the burden on enrollees or providers.

• We considered requiring D-SNPs to identify any enrollees who are in need of LTSS and behavioral health services and transmitting such information to the state Medicaid agency. However, D-SNPs are already required, at § 422.101(f), to develop individualized care plans and perform health risk assessments that identify the physical, psychosocial, and functional needs of each SNP enrollee. We do not wish to duplicate an existing requirement, but to the extent the current regulation text is insufficient to accomplish this or additional regulatory standards for identifying and sharing information are necessary, we welcome comment on that topic.

• We considered requiring D-SNPs to train plan staff and their network providers on the availability of LTSS and behavioral health services covered by Medicaid. While we believe that such awareness, understanding, and training are vitally important to delivering appropriate care to full-benefit dual eligible individuals, we also believe that it is an intrinsic administrative function of a D-SNP in fulfilling its responsibility to coordinate the delivery of Medicare and Medicaid benefits and therefore potentially duplicative of existing requirements, including the requirement to train plan staff and network providers on the D-SNP model of care.

• We considered requiring D-SNPs to solicit state input on the plan's model of care (which is currently required and submitted to CMS pursuant to § 422.101(f)), health risk assessment instrument, and beneficiary communication materials. However, we were disinclined to impose such a requirement on D-SNPs that do not have exclusively aligned enrollment. Further, in states without capitated arrangements with D-SNPs for the provision of Medicaid services, Medicaid agencies may not see a role for themselves in reviewing such documents, and we did not want such a requirement to create additional burden for states. State Medicaid Agencies, however, can choose to require that a D-SNP provide such documents for state input through their contracts with D-SNPs. We seek comment on whether our assumptions about state

burden are correct and whether there are compelling reasons why additional contracting requirements in this area may be necessary.

• Finally, we considered the merits of requiring D-SNPs to share data with state Medicaid agencies or entities designated by State Medicaid Agencies that would benefit the coordination of Medicare and Medicaid items and services, as described in section 1859(f)(8)(D)(i)(I) of the Act, as an example for implementing that provision. However, we ultimately decided against proposing such a requirement here so we can further assess the operational and technical hurdles and costs for both state Medicaid agencies and D-SNPs. Instead, we are proposing to focus initially on establishing the notification requirement for hospital and SNF admissions, which we believe will lead to more immediate improvements in the care transitions process. However, we solicit comment on whether there should be additional regulatory requirements around data sharing.

We seek feedback on our notification proposal at § 422.107(d), including the ways that State Medicaid Agencies and plans would fulfill this requirement, and the additional contracting requirements we considered, as summarized in this section.

In addition to the new requirement for contracts between the State and MA organization at proposed § 422.107(d) for D-SNPs that are not FIDE SNPs or HIDE SNPs, we are proposing to include additional specifications in the regulations governing D-SNP contracts with State Medicaid Agencies at § 422.107 by amending paragraph (b) and several provisions in paragraph (c). We do not believe that these specifications materially alter these agreements; however, we are proposing them in response to questions raised since the State Medicaid agency contracting requirements were promulgated in the September 2008 interim final rule (73 FR 54226). We also

believe that these changes align with the integration requirements for D-SNPs in the Bipartisan Budget Act of 2018.

We are proposing to modify the general rule for contracts with D-SNPs at § 422.107(b) to strike "The MA organization retains responsibility under the contract for providing benefits, or arranging for benefits to be provided, for individuals entitled to receive medical assistance under Title XIX. Such benefits may include long-term care services consistent with state policy." We believe that these sentences would no longer be necessary to describe the mandatory content of the contract. Our proposed definition at §422.2 of "D-SNP" requires the plan to provide, as applicable, and coordinate the delivery of Medicare and Medicaid services; we believe this is sufficient for D-SNPs to be aware of the requirement and for CMS to enforce it.

We propose to revise the contracting requirement at § 422.107(c)(1), which currently requires the contract to document the MA organization's responsibility, including financial obligations, to provide or arrange for Medicaid benefits to specify instead that the contract must document the MA organization's responsibility to provide, as applicable, and coordinate the delivery of Medicaid benefits, including LTSS and behavioral health services, for individuals who are eligible for such services. This proposed revision would clarify that in some cases, the D-SNP may cover (that is, provide directly or pay health care providers for providing) Medicaid benefits under a capitated contract with the State Medicaid agency, but in all cases, it must coordinate the delivery of Medicaid benefits. In addition to being codified in our proposed revisions to § 422.107(c)(1), this is consistent with our proposed definition of "dual eligible special needs plan," which indicates that each D-SNP "coordinates the delivery of Medicare and Medicaid services." Current regulations use the phrase "providing benefits, or arranging for benefits to be provided" but do not describe what it means for D-SNPs to provide or arrange for

Medicaid benefits; we believe this proposed amendment to impose an affirmative duty to provide benefits, as applicable, and otherwise coordinate the delivery of benefits clarifies that D-SNPs must play an active role in helping beneficiaries access such services as necessary. We further believe that "coordination" more aptly describes the activity in which D-SNPs are engaged with respect to a beneficiary's Medicaid benefits. We solicit comment on whether our proposed amendments to this section fully communicate what we intend to require of D-SNPs or whether there are additional revisions we ought to consider to express our intent more clearly for D-SNPs, State Medicaid Agencies, and other stakeholders.

In §422.107(c)(2), we propose to revise the current requirement that the contract between the D-SNP and the State Medicaid Agency document the categories of dual eligible individuals who are eligible to enroll in the D-SNP. This provision currently requires the contract to specify whether the D-SNP can enroll categories of partial-benefit dual eligible individuals or whether enrollment is limited to full-benefit dual eligible individuals. We are proposing to revise this requirement to specify not only the categories of eligibility but also any additional criteria of eligibility to account for such conditions of eligibility under Medicaid as nursing home level of care and age. These criteria could also include a requirement for D-SNP enrollees to enroll in a companion Medicaid plan to receive their Medicaid services.

Finally, at §422.107(c)(3), we propose that the contract between the D-SNP and the State Medicaid Agency document the Medicaid services the D-SNP is responsible for covering in accordance with a capitated contract with the D-SNP directly or through a risk contract, defined at § 438.2, with the companion Medicaid managed care organization operated by the D-SNP's parent organization. We believe that this change, if finalized as proposed, would reduce burden on D-SNPs to identify and document in the contract every Medicaid-covered service. D-SNPs

often submit to CMS a list of all Medicaid services in their State Medicaid Agency contracts, even those for which the D-SNP is not under a capitated contract and for which the D-SNP bears no risk. Even with this change, we continue to expect D-SNPs, for purposes of coordinating their enrollees' Medicaid benefits as required in the proposed definition of a D-SNP in § 422.2, to know and understand all services covered in each state's approved state plan, including any services that may be carved out and covered separately from the D-SNP. This clarifying change would enable us to identify the particular Medicaid services that are covered under a capitated contract for FIDE SNPs and HIDE SNPs, and we seek comment on whether the regulatory change fully communicates what we wish to require. We intend to issue sub-regulatory guidance to address any changes made under this rulemaking that impact D-SNPs contracts with State Medicaid Agencies.

(3) Conforming and Technical Changes (§§ 422.60(g), 422.102(e), 422.107(b), and 422.111(b)(2)(iii))

We are also proposing to make conforming changes to several sections of Part 422 that address D-SNPs by adopting consistent terminology with respect to dual eligible individuals and creating cross-references to the newly proposed definitions. First, at § 422.60(g), which addresses CMS authority to implement passive enrollment, we propose to use the term "highly integrated dual eligible special needs plan" in place of text referring to D-SNPs that meet a high level of integration. This is consistent with our new proposed definition in § 422.2. This technical change would not materially change the plan types that are eligible for passive enrollment; the existing rule simply refers to them as D-SNPs that meet a high standard of integration under the supplemental benefit authority at §422.102(e). Second, we also propose clarifying at § 422.102(e) that not only HIDE SNPs meeting minimum quality and performance

standards are eligible to offer supplemental benefits, but FIDE SNPs that similarly meet minimum quality and performance standards may do so as well. While this amendment does not change what has occurred in practice, we believe it clarifies the types of plans that are eligible to offer enhanced supplemental benefits. Third, in the general rule at § 422.107(b), we are proposing to substitute a "special needs plan serving beneficiaries eligible for both Medicare and Medicaid (dual-eligible)" with "dual eligible special needs plan." Already explicit in the proposed definition of a D-SNP is that such plans exclusively serve individuals who are eligible for Medicaid under Title XIX of the Act, and we believe that the language in the current regulations is extraneous. Finally, at § 422.111(b)(2)(iii), which requires D-SNPs to provide written information to dual eligible enrollees about their eligibility for cost-sharing protections and Medicaid benefits, we propose to use the term "dual eligible special needs plan" consistent with the proposed definition.

(4) Eligibility of Partial-Benefit Dual Eligible Individuals for Dual Eligible Special Needs Plans

We considered proposing limits on the enrollment of partial-benefit dual eligible individuals in D-SNPs, since there are no Medicaid services that the D-SNP is integrating or coordinating on their behalf. We continue to question the benefit that partial-benefit dual eligible individuals derive from their enrollment in a D-SNP relative to the challenges associated with allowing such enrollment. For example, allowing D-SNPs to enroll both partial- and full-benefit dual eligible individuals significantly limits the ability of plans, CMS, and states to simplify beneficiary communications materials. We ultimately decided against proposing any such limits on enrollment at this time but continue to consider this issue. We invite comments on this topic.

(5) Suspension of Enrollment for Non-Compliance with D-SNP Integration Standards (§ 422.752)

Section 50311(b) of the Bipartisan Budget Act of 2018 amended section 1859(f) of the Act by creating a new paragraph (8)(D)(ii) to permit the Secretary, for plan years 2021 through 2025, to impose an intermediate sanction of stopping all new enrollment into a D-SNP if the Secretary determines that the D-SNP is failing to comply with the integration requirements set forth in section 1859(f)(8)(D)(i) of the Act. By establishing statutory requirements that established a minimum level of integration of D-SNPs in section 50311 of the Bipartisan Budget Act of 2018, we believe the goal was for all dual eligible beneficiaries enrolled in D-SNPs to receive a greater level of integration of Medicare and Medicaid benefits than is the case under current regulations. Because the Bipartisan Budget Act of 2018 limited the applicability of the Secretary's authority to impose an intermediate sanction on plans that do not comply with the integration requirements to plan years 2021 through 2025, we believe that the intent of this provision is to offer an alternative to outright contract or plan termination for D-SNPs that fail to meet the new integration requirements during the period of 2021 through 2025. We believe the enrollment sanction authority is a lesser penalty than a contract or plan termination to provide time for D-SNPs to transition to the new integration requirements without creating potentially significant disruption to current D-SNP enrollees as a result of outright termination. In addition to authorizing this lesser sanction, the statute requires a corrective action plan, which we believe strengthens our interpretation, as it illustrates a preference for ultimate compliance by D-SNPs with the integration requirements. As provided in section 1859(f)(8)(D)(i) of the Act, in the event that such a sanction is imposed, the plan must submit to the Secretary (at a time, and in a form and manner, specified by the Secretary) information describing how the plan will come into compliance with the integration requirements.

The statute authorizes this lesser sanction but does not require that it be used, leaving it to our discretion whether an enrollment sanction combined with a corrective action plan is sufficient to achieve the goals of the statute. We believe that it would be appropriate to impose the enrollment sanction for non-compliant D-SNPs before initiating any contract termination or other sanction or enforcement action. Therefore, we propose to amend § 422.752 by adding a new paragraph (d) that would require CMS to impose an enrollment suspension when CMS finds that the plan is non-compliant with the integration requirements during plan years 2021 through 2025, rather than initiating outright termination. While the statute grants the Secretary discretion to sanction plans that fail to meet the new integration requirements, starting in 2021, by stopping all new enrollment into such plans, our proposal would establish predictability for states, beneficiaries, and MA organizations by requiring its imposition for non-compliant plans in lieu of termination or other actions. However, we stress that we interpret this proposal as leaving discretion for CMS, if the D-SNP does not submit an acceptable corrective action plan or fails to abide by the correction action plan, to determine that contract termination or other action is still possible. In addition, in the event that any harm to enrollees is imminent, we retain authority to immediately terminate the contract. We also propose in § 422.752(d) that the suspension of enrollment would continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. The procedures, remedies, and appeal rights available to plans subject to intermediate sanctions provided in § 422.756 would apply to D-SNPs that are sanctioned under this new authority.

b. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560 – 562, 422.566, 422.629 – 634, 438.210, 438.400, and 438.402)

Section 1859(f)(8)(B) of the Act, as added by the Bipartisan Budget Act of 2018, directs the Secretary to establish new procedures that unify, to the extent feasible, Medicare and Medicaid grievance and appeals procedures for D-SNPs. This new authority provides an important opportunity to address an area of longstanding misalignment between the Medicare and Medicaid programs. Medicare and Medicaid grievance and appeal processes have developed independently and operate entirely separately. Medicare's fee-for-service appeals processes (authorized primarily under section 1869 of the Act for Part A and B claims appeals), and MA's processes (authorized under sections 1852(f) and 1852(g) of the Act for grievance and appeal processes) are subject only to federal regulation and oversight as part of the federally-administered Medicare program. Medicaid grievances and appeals are authorized under sections 1902(a)(3) and 1902(a)(5) of the Act for Medicaid programs more generally and section 1932(b)(4) of the Act for Medicaid managed care plans. Unlike Medicare and MA, Medicaid appeals and grievance procedures are subject to both federal and state regulation and are primarily subject to state oversight and administration as part of a joint federal-state financed program. Medicare Part D grievances and appeals are authorized under sections 1860D-4(f) and (g) of the Act and are outside the scope of our authority to unify grievances and appeals under new section 1859(f)(8)(B) of the Act; we note, however, that D-SNPs are all required to provide Part D prescription drug coverage pursuant to § 422.2.

Both the Medicare and Medicaid grievance and appeals systems include regulations establishing procedures for the fee-for-service programs as well as regulations governing managed care plans, including processes at the plan and post-plan levels for adjudicating appeals. Medicare rules are found at 42 CFR part 405 subpart I (general) and part 422 subpart M (Medicare Advantage); Medicaid rules are at 42 CFR part 431 subpart E (general) and part 438

subpart F (managed care). Regulations for the Medicare and Medicaid programs take broadly similar approaches to managed care appeals in that both programs establish a process for resolving a dispute at the plan level initially, followed by an opportunity for post-plan review. However, these appeals systems operate independently with sometimes subtle but important differences related to notices, adjudication timeframes, availability of benefits continuing while the appeal is pending, and levels of review. Similarly, regulations for the Medicare and Medicaid programs take different approaches with respect to some processes for grievances, including filing and adjudication timeframes and the availability of an expedited grievance process.

Although comparatively few beneficiaries file grievances or appeals,[11] these processes are vital safeguards to ensure that beneficiaries' concerns and needs are met promptly. Because of Medicare and Medicaid's misalignments in this area, beneficiaries who are dually eligible for Medicare and Medicaid can face a confusing array of choices when they seek to file a grievance or appeal. They may not know whether their complaint is tied to Medicare or Medicaid, and thus may not know where to direct their grievance. They may be uncertain if the item or service they seek is covered by Medicare, by Medicaid, or potentially by both programs, and thus may not know when or where to file an appeal following the denial of a service. The issue is particularly complicated for items and services such as home health and certain durable medical equipment that are sometimes covered by both programs but under different circumstances.

This confusion for beneficiaries and for those assisting them can result in costly and inefficient duplication of effort, as beneficiaries may file grievances and appeals under both programs when only one was necessary. Health plans and federal and state agencies may incur

11 For example, in 2016, Medicare Part C plans reported 2.93 complaints (grievances) per 1,000 enrollees per month and 19.3 reconsideration requests (appeals) per 1,000 enrollees per month. See Analysis of Calendar Year 2016 Medicare Part C Reporting Requirements Data, available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html.

additional burdens and costs from having to administer parallel appeals systems. Finally, these misalignments may lead to unintended harms in the form of delayed or denied access to needed services as beneficiaries expend time and energy pursuing ultimately fruitless appeals in one program when they should have been pursuing them in the other.

We have made previous efforts to better align Medicare and Medicaid grievances and appeals for dual eligible individuals. The success of these prior efforts suggests to us that further alignment in this area is feasible. Under § 460.122, the Programs of All-inclusive Care for the Elderly (PACE) include an integrated appeals system that handles all initial appeals at the organization level. The Medicaid managed care May 2016 final rule (81 FR 27478) took several steps to bring Medicaid managed care grievance and appeals rules into closer alignment with both Medicare and the private insurance market. Notable changes for Medicaid managed care enrollees in that final rule included requiring one single level of plan review prior to the state fair hearing as well as aligning many timeframes for resolving grievances and appeals.

The operation of Medicare-Medicaid Plans (MMPs) in the CMS' Financial Alignment Initiative capitated model demonstrations has provided us with the most extensive experience integrating grievances and appeals for dually eligible enrollees in the managed care setting. MMPs are responsible for covering the full range of Medicare and Medicaid benefits and operating integrated grievance and appeals systems. We have developed these systems in collaboration with participating State Medicaid Agencies, using waiver authority under section 1115A of the Act and, in some cases, section 1115 of the Act. Development of these systems has required in-depth examination of various aspects of Medicare and Medicaid grievance and appeals rules to determine where misalignments exist and to decide how to resolve these misalignments in a way that is maximally protective of beneficiaries' rights. Our experience with

MMPs suggests that, although implementing a new system can be challenging, once in operation integrated grievance and appeals systems can be simpler for beneficiaries to navigate than separate systems for Medicare and Medicaid.

Under the newly enacted amendments to section 1859(f)(8)(B) of the Act, the Secretary is required to establish, not later than April 2020 and for inclusion in contracts for D-SNPs for 2021 and subsequent years, procedures unifying grievances and appeals procedures consistent with several principles:

• Under paragraph (8)(B)(ii), the new unified procedures must include provisions that are most protective for the enrollee and, to the extent feasible as determined by the Secretary, are compatible with unified timeframes and consolidated access to external review. The statute requires that the procedures take into account differences under state Medicaid plans, and be easily navigable by enrollees.

• Additionally, under paragraph (8)(B)(iii), the integrated processes implemented are required to include a single written notice that includes all relevant grievance and appeal rights; a single pathway for resolution of covered items and services; notices written in plain English and available in languages and formats that are accessible to enrollees (including in non-English languages that are prevalent in the service area of the specialized MA plan); unified timelines for processes such as filing, acknowledging, and resolving the appeal or grievance; and requirements for plans to process, track, and resolve the grievances and appeals to ensure enrollees are notified timely of decisions and can track the status of their grievance or appeal.

• Finally, under paragraph (8)(B)(iv), new grievance and appeals procedures shall, with respect to all benefits under Medicare Parts A and B and Medicaid subject to appeal under such procedures, incorporate provisions under current law and implementing regulations that provide

continuation of benefits pending appeal under Title XVIII and Title XIX. We address this statutory provision in section II.A.2.b.(7).

Using this statutory framework, we developed the following goals to guide development of proposals to implement the unified grievance and appeals provisions:

- Adopt provisions that are most protective of the enrollee;
- Reduce burden on beneficiaries (and those assisting them), plans, states, and providers; and
- Maintain state flexibility and minimize disruption by building on existing rules and policies.

These policy goals also reflect our belief that timely, efficient, accessible, and well-functioning grievance and appeals systems are critical to ensuring that beneficiaries have access to needed items and services. Such systems are especially vital for dually eligible beneficiaries who typically lack financial resources that might enable other beneficiaries to pay out-of-pocket for needed items or services while a dispute is pending. We welcome comments regarding these policy goals and the extent to which the proposed regulations are consistent with them.

Our policy goal of minimizing disruption is informed by statutory language directing the Secretary to establish unified provisions to the extent feasible (section 1859(f)(8)(B)(i) of the Act). Consistent with this statutory standard, we are primarily proposing incremental changes that are currently feasible, conform to other current law, and build upon existing systems. As we gain further experience with unified grievances and appeals, we may consider additional changes in the future, consistent with our authority.

Our proposals under this notice of proposed rulemaking can be divided into two substantively different types in addition to technical amendments proposed. We propose to

incorporate these changes into and conform existing regulations in parts 422 and 438. First, we are proposing to establish requirements for all D-SNPs, relative to the role they play in assisting full-benefit dual eligible individuals, to assist with Medicaid-related coverage issues and grievances (§ 422.562(a)). Second, we are also proposing new requirements in accordance with section 1859(f)(8)(B) of the Act to create integrated grievance and appeals systems for a limited subset of D-SNPs ("applicable integrated plans"), identified using terms and concepts we propose to define in amendments to § 422.561, with the integrated processes established by proposed new regulations (§§ 422.629-422.634). Finally, we propose a number of changes of a technical and conforming nature to existing provisions in parts 422 and 438 (§§ 422.560, 422.562, 422.566, 438.210, 438.400, and 438.402).

Section 1859(f)(8)(B)(i) of the Act requires the Secretary to establish unified grievance and appeals procedures for D-SNPs not later than April 2020, and section 1859(f)(8)(C) of the Act requires the use of these unified procedures in D-SNP contracts for 2021 and subsequent years. The statute does not, however, explicitly rule out the possibility of implementing such unified processes prior to 2021. We interpret the statute as permitting a state to adopt unified grievance and appeals processes for integrated D-SNPs and Medicaid plans in that state consistent with our final regulations on this topic starting as soon as the regulations establishing such procedures are final. Such a state could require establishment of unified appeals and grievance procedures consistent with CMS' regulations in its Medicaid agency contract required under § 422.107. We solicit comments on this interpretation of the statutory implementation date requirements and our proposal to make unified procedures available to states in this way before 2021.

(1) Assisting with Medicaid coverage issues and grievances (§422.562(a)(5))

As an incremental step towards improving all D-SNP enrollees' experiences with accessing Medicaid benefits, and pursuing grievances and appeals, we propose new regulation text to require all D-SNPs to assist beneficiaries with Medicaid coverage issues and grievances, including authorizations for or appeals related to Medicaid-related services at § 422.562 by adding a new paragraph (a)(5). These new requirements are consistent with our existing guidance and expectations for D-SNPs, but we are proposing regulations to define their scope and set mandatory standards to which we can hold D-SNPs accountable. Consistent with the statutory requirement at section 1859(f)(3)(D) of the Act that D-SNPs arrange for their enrollee's Medicaid benefits, we believe that all D-SNPs should assist enrollees with resolving Medicaid coverage problems, including assistance with filing grievances, requesting coverage, and requesting appeals. Such assistance is consistent with the standard we are proposing as part of the definition of a D-SNP in section II.A.2.a of this proposed rule, which states that all D-SNPs provide a minimum level of coordination across Medicare and Medicaid. Under our proposal, D-SNPs have a responsibility to coordinate the delivery of Medicaid services for enrollees whether or not the D-SNP itself contracts with the state to provide Medicaid services. We clarify here that the requirements at 422.562(a)(5) are additional requirements for D-SNPs, specifically related to assisting with access to benefits, appeals and grievances. At § 422.562(a)(5), we propose to supplement the obligation to provide, as applicable, and coordinate Medicaid benefits by adding a requirement that when a D-SNP receives an enrollee's request for services, appeal, or grievance related to Medicaid-covered services (regardless of whether such coverage is in Medicaid fee-for-service or a Medicaid managed care plan, such as a Medicaid MCO, PIHP, or PAHP as defined in § 438.2), the D-SNP must provide a certain level of assistance to the enrollee. This proposal, which we hope would result in a more seamless process for enrollees in

accessing Medicaid benefits and pursuing grievance and appeals for D-SNP enrollees, complements how we believe section 1859(8)(f)(B) of the Act directs us to unify D-SNP and Medicaid appeal and grievance procedures to the extent feasible.

In new paragraph (a)(5)(i), we propose to describe the types of assistance we would require all D-SNPs to provide to their enrollees regarding Medicaid-related coverage issues and grievances, including authorization of services, and appeals. We propose in paragraph (a)(5)(i) to include assistance for all D-SNP enrollees, regardless of the type of Medicaid coverage in which they are enrolled. While we specifically list Medicaid fee-for-service and Medicaid managed care plans, it is not our intention to exclude any type of Medicaid delivery system. However, we request comment on whether there are other systems that should be noted specifically, or if there are specific circumstances where providing the assistance contemplated in this section is ill-advised or infeasible.

Our proposed regulation at §422.562(a)(5)(i) includes a list of illustrative examples, at paragraphs (5)(i)(A) through (5)(i)(C), which we do not intend to be an exhaustive list of how a D-SNP would be required to comply with the assistance obligation in § 422.562(a)(5)(i). In paragraph (a)(5)(i)(A), we address explaining to a D-SNP enrollee how to request Medicaid authorization and file an appeal. Our proposed text includes examples of the type of assistance we expect D-SNPs to provide to their enrollees when the enrollees need information and explanations about obtaining Medicaid services. We recognize that state Medicaid systems vary substantially, and that the specific forms of assistance will also vary from market to market. We do not seek to be overly prescriptive in the types of assistance a D-SNP must provide, and our examples are not intended to be exhaustive. We propose, in paragraphs (5)(i)(A)(1) through (5)(i)(A)(3), examples of the types of assistance that a D-SNP must offer, and upon acceptance

or request, provide its enrollees, such as specific instructions on how to contact the entity that may cover the service (for example, the Medicaid managed care plan or a contact in the fee-for-service system), and assistance in obtaining and filling out forms necessary for the next steps in the process.

In paragraph (a)(5)(i)(B), we propose that D-SNPs provide assistance in the actual filing of grievances and appeals. Not all enrollees would need such assistance; for many enrollees, simply receiving information under paragraph (a)(5)(i) would be sufficient. When a D-SNP enrollee needs assistance with the act of filing a Medicaid grievance or appeal, their D-SNP should provide that help. However, the D-SNP is not obligated to represent the enrollee in Medicaid appeals. We welcome comments regarding this proposal; in particular, we ask for comments regarding how D-SNPs that do not have aligned enrollment would comply with this requirement when such entities might have financial and clinical responsibility for the disputed services, potentially presenting a conflict of interest.

In paragraph (a)(5)(i)(C),we propose that the D-SNP assist the enrollee in obtaining documentation in support of a request for authorization or appeal. Obtaining documents such as medical records can be a challenge for any beneficiary, especially for those with limited resources who may lack broadband access to receive large documents electronically, may have unreliable mail service, may not be able to afford printing costs, and may not have easy access to transportation to pick up documents in person. We believe that D-SNP care coordinators are a logical choice to help an enrollee assemble medical documentation and may be particularly well-positioned to assist in compiling records, as they would have insight into the types of documentation enrollees need to support similar requests made to the D-SNP.

The examples listed in proposed paragraph (a)(5)(i)(A) through (C) are not intended to be an exhaustive list, but rather are to provide some leading examples of the assistance we believe any D-SNP should provide. Accordingly, it would not be acceptable for a D-SNP to tell an enrollee simply to contact "Medicaid" in general when the enrollee encounters a problem with his or her Medicaid coverage or is obviously in need of assistance in figuring out how to file an appeal of a denial of Medicaid-covered benefits. We invite comments on this proposal, specifically whether the regulation text is clear enough that the examples are not an exhaustive list of methods of assistance that the D-SNP must offer its enrollees, as well as suggestions for other examples of assistance that we should include in regulation or address in subsequent subregulatory guidance.

In proposing these amendments to § 422.562(a)(5), we recognize that offering and providing useful, effective assistance — and therefore compliance with this proposed requirement — may appear challenging. For example, some D-SNPs today may have difficulty determining what type of Medicaid coverage a member has (for example, fee-for-service vs. managed care; which specific managed care plan the enrollees is in; which services are carved out). Without accurate and timely information on the enrollee's Medicaid coverage, it is difficult to effectively help the enrollee navigate, for example, which entity to contact, and what forms are necessary, to pursue coverage or an appeal. Full compliance with our proposal requires that D-SNPs and states maintain data sharing that allows D-SNPs to determine the type and source of Medicaid coverage of their enrollees. However, we believe it is reasonable to expect that D-SNPs, as plans focused on serving dually eligible beneficiaries, take steps to access such information to provide effective care coordination for dual eligible enrollees and to implement more seamless (even if not unified) grievance and appeals systems. Moreover, providing such assistance may further be in a

D-SNP's interest, if the enrollee's access to Medicaid-covered services like personal care services and other HCBS prevents an otherwise avoidable hospitalization, for example. We welcome comments on this proposal, suggestions for additional examples of assistance, as well as comments on challenges D-SNPs and others envision in implementing the provisions of proposed paragraph (a)(5).

We also propose language related to enrollees accepting the offer of assistance in proposed paragraph (a)(5)(i). We do not expect or want D-SNPs to implement any processes that might act as barriers to enrollees in accessing assistance nor do we want to create barriers to D-SNPs providing such assistance; if an enrollee does not want the D-SNP's help in resolving an issue, then the D-SNP would not be obligated under our proposal to provide assistance against the enrollee's wishes. At the same time, we do not intend to create any affirmative obligation on the D-SNP to assist enrollees if they decline the offer of assistance. Enrollees are free to decide for themselves how to navigate their Medicaid coverage. In our proposal, the only obligation on D-SNPs is to offer assistance, and when a request is made or an offer of assistance is accepted, to provide it. We welcome comments on whether the regulation text, as we have proposed it, is the best way to achieve this goal.

In paragraph (a)(5)(ii), we propose to specify that the D-SNP's obligation to offer assistance arises whenever the D-SNP becomes aware of an enrollee's need for a Medicaid-covered service. Our proposal includes text explicitly clarifying that enrollees do not need to make a specific request to their D-SNP for assistance. We expect that D-SNPs, as plans with expertise in serving dually eligible beneficiaries, should be able to identify a potential Medicaid coverage issue as part of their regular assessments and care management processes. For example, a D-SNP may become aware that an enrollee is unsatisfied with the personal care services she is

receiving based on the work of a care coordinator or from a call or email from the enrollee or enrollee's family. Our proposed regulation text does not explicitly require a D-SNP to use its care coordination or case management programs to identify this type of issue. However, if the issue comes to the attention of the D-SNP, we would expect the plan to offer to assist the enrollee in resolving the coverage issue(s) or grievance given the D-SNP's responsibility, consistent with our proposed definition of a D-SNP at § 422.2, that such a D-SNP provide, as applicable, and coordinate the delivery of Medicare and Medicaid services for its enrollees. We request comments on whether we should include such explicit direction to D-SNPs in the regulation to identify issues that an enrollee is having, or whether our proposed regulation text is sufficiently clear that D-SNPs will understand and meet our goal of providing assistance to an enrollee such that the enrollee can access benefits regardless of whether the benefit is covered by Medicare or Medicaid. We are not proposing any new requirements related to assistance with Medicare covered services. We are also not proposing any new requirements related to services for partial-benefit dual eligible enrollees. Partial-benefit dual eligible enrollees do not qualify for the full range of Medicaid services, and therefore, we do not believe the proposed rule creates any new obligation for D-SNPs to offer assistance for such enrollees. We welcome comments regarding the provisions at proposed § 422.562(a)(5)(ii) and the need for any further clarification limiting the scope of § 422.562(a)(5) to full-benefit dual eligible individuals.

In paragraph (a)(5)(iii), we propose to provide further detail on the methods of assistance required by proposed paragraph (a)(5)(i). The methods we propose in the regulation are intended to be examples of what a D-SNP will be required to offer and provide to enrollees and will depend, to some extent, on the needs and preferences of the enrollee. In paragraph (a)(5)(iii)(A), we note that a D-SNP may provide coaching to the enrollee to promote self-advocacy. Some

dually eligible enrollees are highly adept at advocating for themselves, and may require only modest assistance – for example, a phone number or direction to an appropriate website – or help with technical terms in explaining why they need a specific piece of equipment. We welcome comments on the methods of assistance and whether further detail is needed. In paragraph (a)(5)(iii)(B) we propose to make explicit a requirement that a D-SNP provide whatever reasonable assistance an enrollee needs in navigating the Medicaid grievance and appeals systems, such as assistance completing forms. We note that existing regulations (for example, §§ 422.111(h)(1)(iii) and 438.406(a)) address the provision of interpretation services. In the context of grievances and appeals, Medicaid requirements also currently require auxiliary aids and services for enrollees who have limited English proficiency or disabilities that require accommodation (§ 438.406(a)).[12] The language in this section is very similar to obligations already required of Medicaid managed care organizations at § 438.406(a). Medicare plans also have existing obligations under Title VI of the Civil Rights Act of 1964 to take reasonable steps to ensure meaningful access by individuals with limited English proficiency and under section 504 of the Rehabilitation Act to take appropriate steps to ensure effective communication with individuals with disabilities, including the provision of auxiliary aids and services. We have opted not to specify the preferred technical forms of assistance that would be required under this proposal, as the evolution of technology and the increases in integration over time may change the analysis of what methods of assistance are reasonable for a D-SNP to be required to provide to its enrollees. However, because D-SNPs are already required to provide similar assistance to their enrollees in other circumstances, we do not anticipate that compliance with this provision

12 In addition, the Medicaid managed care regulation at § 438.10(d) addresses the requirement to provide translation and assistance in a broader context.

should be burdensome to plans. We welcome comments on this matter, including whether and how our goals might be met with more specific regulation text.

In paragraph (a)(5)(iv), we propose to require that a D-SNP provide documentation to CMS upon request that demonstrates how the D-SNP is providing the assistance proposed under paragraph (a)(5)(i).

In paragraph (a)(5)(v), we propose to clarify that D-SNPs are not required to represent enrollees in Medicaid appeals. We welcome comments regarding whether any further clarification is needed on this issue.

(2) Statutory Basis and Scope for Unifying Grievances and Appeals (§ 422.560)

In § 422.560, we propose to add new paragraphs (a)(4) and (b)(5) to address the statutory basis and scope of our proposal to establish unified grievance and appeals processes for a subset of D-SNPs. Specifically, we are proposing a new paragraph (a)(4) to cite section 1859(f)(8) of the Act and provide that the procedures under that section apply in place of otherwise applicable grievance and appeals procedures with respect to items and services provided by certain D-SNPs. We are also proposing to add new paragraph (b)(5) to identify the scope of the new proposed regulations – that is, requirements for applicable integrated plans with regard to unified appeals and grievance procedures. The substance of these proposals is addressed in sections II.A.2.a.(3) through (11) of this proposed rule.

(3) Definitions of "Applicable Integrated Plan", "Integrated Appeal", "Integrated Grievance", "Integrated Organization Determination", and "Integrated Reconsideration," and General Requirements for Applicable Integrated Plans (§§ 422.561 and 422.629)

A central challenge to implementing unified grievance and appeals systems for D-SNPs and the Medicaid managed care organization operated by such plan's parent organization is the

variety of enrollment scenarios across states. There are only a limited number of D-SNPs in which aligned enrollment, as defined in proposed § 422.2, is possible – that is, a situation when a full-benefit dual eligible individual is enrolled in a D-SNP and receives coverage of Medicaid benefits from the D-SNP or from a Medicaid managed care organization, as defined in section 1903(m) of the Act, operated by the D-SNP's parent organization or by another entity that is owned and controlled by the D-SNP's parent organization. Even fewer D-SNPs operate in states where that State Medicaid Agency mandates such aligned enrollment. With exclusively aligned enrollment, all of the enrollees of the D-SNP also receive Medicaid services through the D-SNP or an affiliated Medicaid managed care organization operated by such plan's parent organization. We believe it is most feasible to unify grievance and appeals systems under exclusively aligned enrollment because one organization is responsible for both Medicare and Medicaid coverage, albeit through separate contracts.

The bulk of D-SNP enrollment, however, is not exclusively aligned. In most states, the majority of D-SNP enrollees have Medicaid coverage either through a different organization's Medicaid MCO, in a prepaid ambulatory or inpatient health plan (PAHP or PIHP), or through a state's Medicaid fee-for-service system. In these circumstances, the D-SNP has no control over the Medicaid grievance and appeals processes. Even a D-SNP that has a Medicaid managed care organization operated by such plan's parent organization available to its enrollees, but whose members may instead enroll in other Medicaid plans, can only unify the procedures for Medicaid appeals and grievances of those enrollees who are also simultaneously enrolled in the Medicaid managed care organization operated by such plan's parent organization. We do not believe it is feasible at this time to implement fully unified grievance and appeals systems for D-SNPs and

Medicaid managed care plans that do not have the same enrollees or where the organizations offering the D-SNPs and Medicaid plans are unaffiliated or even competitors.

We propose to add definitions for new terms used in this notice of proposed rulemaking to govern the integrated grievance and appeals processes. In § 422.561 we propose new definitions for "applicable integrated plan," which is the specific type of D-SNP and affiliated Medicaid plan that would be governed by the new integrated grievance and appeals regulations. In our definition of applicable integrated plan, we propose to include only a subset of D-SNPs, that is, only FIDE SNPs and HIDE SNPs with exclusively aligned enrollment, terms that are defined at proposed § 422.2 and described in section II.A.2.a.(1) of this proposed rule. We propose that the affiliated Medicaid plan be a Medicaid managed care organization, as defined in section 1903(m) of the Act, that is offered by-- (1) the D-SNP with exclusively aligned enrollment; (2) the parent organization of such D-SNP; or (3) another entity that is owned and controlled by the parent organization of such D-SNP. Thus, our proposal for unified grievance and appeals procedures would apply only to the enrollees of the subset of D-SNPs that are FIDE SNPs or HIDE SNPs with exclusively aligned enrollment and the affiliated Medicaid managed care organizations through which such enrollees receive their Medicaid services. As we note in our discussion of the proposed definition of aligned enrollment in section II.A.2.a of this proposed rule, we would not consider a D-SNP's companion Medicaid plan to be an applicable integrated plan where it is a prepaid inpatient health plan (PIHP) or prepaid ambulatory health plan (PAHP) in the state's Medicaid program. We solicit comments on our proposed definition of an applicable integrated plan and how it reflects which plans and entities would have to use the unified grievance and appeals procedures we propose in this rule. We also seek comment on

whether limiting our proposed policies to MCOs, rather than including PIHPs and PAHPs, is appropriate in light of the statute and our policy goals.

The requirements for non-fully integrated D-SNPs would remain unchanged. This means that there would be different sets of requirements for different types of D-SNPs, and we are proposing these new defined terms to make these separate requirements distinct. We estimate that, currently, this subset of plans comprises a small share of the overall D-SNP market: 37 plans in 8 states, covering approximately 150,000 enrollees nationwide. We believe that these are the plans for which integrated grievance and appeals processes as we propose here are most suitable. We seek comment on our belief that exclusively aligned enrollment provides the most feasible context for unifying grievance and appeals systems and – recognizing that states can organize managed care enrollment policy in a variety of ways – whether our use of the term "exclusively aligned enrollment" captures the optimal universe of managed care arrangements for such unification.

For the purpose of differentiating the terminology and procedures within this framework, we propose to establish definitions for "integrated organization determination," "integrated appeal," "integrated reconsideration," and "integrated grievance" and apply them exclusively to applicable integrated plans.

Integrated organization determinations would encompass both Medicare organization determinations, as described in § 422.566, and adverse benefit determinations, as defined in § 438.400(b); however, these determinations would be made by applicable integrated plans and would therefore be subject to the integrated organization determination procedures in proposed §§ 422.629, 422.631, and 422.634. These would be the first decisions made by the applicable integrated plan regarding coverage, approval, or payment for a covered service. We propose to

define this term by referencing Medicare organization determinations as described in § 422.566, actions as defined in §431.200, and adverse benefit determinations as defined in § 438.400(b) to parallel the scope of the MA, Medicaid, and Medicaid managed care regulations, rather than by using a specific list of decisions or actions to ensure that the applicable regulations using this term truly unify and integrate the applicable concepts from both the Medicare and Medicaid programs.

Similarly, integrated reconsiderations would be the appeal of the adverse integrated organization determinations by an applicable integrated plan with respect to the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service. Under our proposal, an integrated reconsideration would be the same as an MA plan's reconsideration (in § 422.580) of an organization determination (defined in § 422.566) and the appeal (defined in § 438.400(b)) of an adverse benefit determination. Integrated reconsiderations would encompass both Medicare reconsiderations, as described in §§ 422.578, 422.580, 422.582, and 422.584, and appeals, as defined for the Medicaid managed care context in § 438.400(b). However, these determinations would be made by applicable integrated plans and therefore subject to the integrated reconsideration procedures in proposed § 422.629 and 422.632 through 422.634.

We propose defining integrated appeals to encompass integrated reconsiderations, and any additional post-plan level unified appeal processes that may be implemented in the future. Our proposed definition is similar to the definition of appeal in MA, at § 422.561, which encompasses both the reconsideration level of the appeal process, as well as additional stages of

the appeals process such as review by an independent entity, hearings before ALJs, review by the Medicare Appeals Council and judicial review.

Additionally, we propose to define an integrated grievance as a dispute or complaint that would be defined and covered, for grievances filed by an enrollee in non-applicable integrated plans, under § 422.564 or §§ 438.400 through 438.416. Integrated grievances would not include appeals procedures or QIO complaints, as described in § 422.564(b) and (c), respectively. An integrated grievance made by an enrollee in an applicable integrated plan would be subject to the integrated grievance procedures in §§ 422.629 and 422.630. This means that an integrated grievance would include a Medicare or Medicaid complaint or dispute about the applicable integrated plan or the enrollee's providers that is not a complaint or dispute about such plan's coverage determination (referred to as an integrated organization determination in this proposed rule).

Our proposed definitions for integrated grievance, integrated organization determination, and integrated reconsideration are intended to replicate the scope and meaning of the parallel terms in parts 422 subpart M and part 438 subpart E regarding the appeals and grievance procedures required of, respectively, MA organizations and Medicaid managed care plans because we are proposing that the regulations and procedures proposed here take the place of those part 422 and part 438 procedures for applicable integrated plans. We solicit comment whether our proposal adequately accomplishes this.

We propose at § 422.629 to establish general requirements for applicable integrated plans, as defined in § 422.561. In paragraphs (a) and (b), we propose language that sets forth the scope of the requirements and general process that applicable integrated plans must implement. In paragraph (a)(1), we propose to specify that the proposed rules apply in lieu of the general

requirements for MA organizations at §§ 422.564, 422.566(c) and (d) and 422.568 – 422.596, and Medicaid managed care plans at §§ 438.404 – 438.424, and encompass integrated grievances, integrated organization determinations, and integrated reconsiderations. In paragraph (b), we set forth the general requirement that applicable integrated plans create integrated processes to administer these grievance and appeals requirements.

In proposed paragraph (c), we address an overarching question about whether a state may establish requirements that are different for the applicable integrated plan(s) using the state Medicaid agency contract required under § 422.107. Specifically, we propose to apply the flexibility offered to states under Medicaid regulations, which establish a floor for enrollee protections, while also offering states flexibility to impose more stringent requirements for timeframes and notices so long as they are more protective of beneficiaries. States may already have laws in effect that take advantage of this flexibility. For example, under § 438.408(b)(2), a Medicaid managed care plan must resolve a standard appeal within a timeframe established by the state, but not to exceed 30 calendar days. The maximum timeframe for an MA organization to decide a standard reconsideration is also no later than 30 calendar days (§ 422.590(a)(1)). Ohio Medicaid, however, sets this timeframe for its Medicaid managed care plans at 15 days unless an extension is granted.[13] If an integrated appeals process under this proposal were to be implemented in Ohio, we would allow adoption of that 15-day standard for all standard integrated appeals. We believe that by preserving state flexibility in adopting more stringent, beneficiary-protective requirements, we are adhering to the direction set forth in sections 1859(f)(8)(B)(ii)(I) and (II) of the Act for us to take into account differences in state plans under Title XIX. Finally, in paragraph (c), we propose to codify the opportunity for states to establish

13 See Ohio Administrative Code 5160-58-08.4(D)(6), available at http://codes.ohio.gov/oac/5160-58-08.4.

standards that differ from the standards set forth in these regulations in its State Medicaid Agency contract, per § 422.107, with the applicable integrated plans. We are soliciting comments on our proposed approach, and specifically how we propose to allow state flexibilities to be incorporated into the unified procedures for an applicable integrated plan.

In paragraph (d), we propose that the applicable integrated plan provide the enrollee who is requesting the integrated reconsideration a reasonable opportunity, in writing and in person, to present evidence and testimony and make legal and factual arguments in support of their appeal. On this topic, both the MA standard at § 422.586 and the Medicaid standard at § 438.406(b)(4) are similar in granting this right to the enrollee for the plan-level appeal; however, under Medicaid regulation, this right extends to grievances, whereas in MA, it does not. We also propose to require that applicable integrated plans inform enrollees of the limited time available for these opportunities in cases were the timeframe is expedited, similar to § 422.586 and § 438.406(b)(4).

In paragraph (e), we propose to require applicable integrated plans to provide reasonable assistance to the enrollee with respect completing and submitting their integrated appeals and integrated grievances, as well as on navigating this process. This proposal would impose on applicable integrated plans a similar standard as applies to Medicaid managed care plans pursuant to § 438.406(a). As discussed earlier, plans have existing obligations under Title VI of the Civil Rights Act of 1964 and section 504 of the Rehabilitation Act, so we do not believe that incorporating this beneficiary protection to this context would create an unreasonable burden. Here, as also discussed earlier in this preamble related to proposed § 422.562(b)(3)(ii), we opted not to specify the preferred technical forms of assistance, as preferred standards can change as technology evolves.

We propose at paragraph (f) a general rule, using cross-references to the requirements in §§ 422.560, 422.561, 422.562, 422.566, and 422.592 through 422.626, to specify the regulations that apply to the applicable integrated plan for grievance and appeals processes unless otherwise noted.

We propose at paragraph (g) to require applicable integrated plans to send the enrollee an acknowledgement of receipt in writing for all integrated grievances and integrated reconsiderations. Currently, the Medicaid regulation at § 438.406(b) requires acknowledgement of grievances and appeals, and MA guidance explains the need for written acknowledgement of oral requests for reconsideration (see Medicare Managed Care Manual Chapter 13, section 70.2). Section 1859(f)(8)(B)(iii)(IV) of the Act, as added by section 50311(b) of the Bipartisan Budget Act of 2018, specifically calls for unified timelines and procedures for acknowledgement of appeals and grievances We propose to adopt the standard currently in § 438.406(b) for applicable integrated plans, and we propose to clarify that the acknowledgement should be in written form. We believe that this requirement is both beneficial to enrollees and assists them in determining the status of the grievance or appeal, and thus is in alignment with the standard in section 1859(f)(8)(B) of the Act for the unified procedures.

In paragraph (h), we propose to adopt Medicaid's grievance and appeals recordkeeping requirements, as required for Medicaid managed care plans at § 438.416, to require applicable integrated plans to maintain records of integrated appeals and grievances and review them as part of their ongoing monitoring procedures. The requirements that we propose also align with relevant MA requirements for grievance recordkeeping (see § 422.564(g)) and are consistent with the MA requirements for general recordkeeping (see § 422.504(d)).

We propose in paragraphs (i) and (j) to incorporate similar provisions as are imposed on Medicaid managed care plans pursuant to §§ 438.410(b) and 438.414 regarding relationships between the plan and its contracted network providers. Specifically, in paragraph (i), we propose to prohibit an applicable integrated plan from taking any punitive action against a provider for requesting an integrated organization determination or integrated reconsideration, similar to the provisions in §§ 422.570(f) and 438.410(b). We believe that these standards would establish beneficiary protections in the context of applicable integrated plans because the threat of punitive action might otherwise discourage a provider from pursuing, on the enrollee's behalf, or supporting an enrollee in pursuing, an integrated appeal for a needed item or service. We also propose requiring, in paragraph (j), such a plan to disclose information about its appeals and grievances procedures at the time it enters into a contract with a provider or subcontractor. We propose to include specific topics which must be covered in this information to providers, and these specific topics are the same as in existing Medicaid regulations (see § 438.414, which cites to § 438.10(g)(2)(xi) for this purpose). Although there are no specific MA regulations that impose the same requirements on D-SNPs, Medicare regulations require that MA organizations communicate information on medical policy and medical management procedures (see § 422.202(b)). We believe this proposed requirement aligns with the goals of the statute in educating providers to help ensure an easily navigable system for enrollees, where providers understand the system and their role in it.

In paragraph (k), we propose regulatory standards controlling who must review an integrated organization determination. The part 422 and part 438 regulations each impose standards of this type but they are not identical. In developing our proposal, we sought to combine the MA and Medicaid managed care requirements for who must review an organization

determination. This new requirement would apply to grievances, as is currently the case § 438.406 but not in the applicable MA regulations. In paragraph (k)(1), we propose to include the requirement from Medicaid (§ 438.406(2)(iii)) that any individual who reviews an integrated appeal or grievance must consider all information submitted by the enrollee, regardless of whether the information was previously made available to the plan. In paragraph (k)(2), we propose to include the requirements for reviews of Medicaid grievances (from § 438.406(2)) for who can review a grievance to integrated grievances. There are no requirements in Medicare for who can review a grievance; however, we believe that ensuring that the individual who reviews a grievance has appropriate expertise for the circumstances is an important enrollee protection that should be applied to integrated grievances.

In paragraph (k)(3), we propose to include the existing requirements from MA (§ 422.566) for who can review an organization determination. There are no requirements in Medicaid for who can review a service authorization request; however, we believe that ensuring that the individual who reviews an integrated organization determination has appropriate expertise for the circumstances is an important enrollee protection that should be applied to integrated organization determination. We also propose language that, in accordance with current MA regulations (§ 422.566(d)) requires that physicians or other health care professionals who review integrated organization determinations have an unrestricted license and be acting within the scope of that license.

In paragraph (k)(4) we propose to combine existing MA and Medicaid requirements for who can review a reconsideration or adverse benefit determination since both sets of existing regulations have relevant requirements. MA and Medicaid requirements are largely similar for individuals who review appeals be someone who was not involved in a previous level of review,

and, in cases involving medical necessity, someone who has appropriate clinical expertise (§§ 422.590 and 438.406(b)(2)). These existing requirements are reflected in our proposed requirements.

(4) Authorization for Filing Appeals (§ 422.629(l))

We propose at § 422.629(l) to combine the MA and Medicaid requirements, such that a treating provider or authorized representative can file an appeal on behalf of an enrollee. Medicaid managed care rules at § 438.402(c)(1)(ii) require written authorization from the enrollee where a physician or other authorized representative files an appeal involving a benefit to which the enrollee may be entitled. MA rules at § 422.566(c), however, allow a treating provider to file an appeal on behalf of an enrollee without written authorization from the enrollee, although the provider is required to provide notice to the beneficiary. We believe the MA requirement is generally more beneficial to beneficiaries, as it imposes fewer procedural requirements to filing an appeal for the enrollee, for example, if an enrollee has factors that make signing an authorization difficult. The Medicaid requirements, on the other hand, may serve to mitigate the risk that a provider would file an appeal against an enrollee's interest and without an enrollee's consent, particularly to take advantage of the Medicaid provisions that allow a benefit to continue while the appeal is pending, an issue we discuss in more detail in section II.A.1.b.(7) of this preamble for proposed § 422.632. We believe our proposal reduces barriers for enrollees to have appeals filed, while also accounting for risk to enrollees by requiring the enrollee's written consent only when there is a request for continuation of benefits. However, we invite comments as to whether an approach closer to Medicaid's, in which written authorization would be required in all cases when a provider files an appeal on behalf of a beneficiary, would be preferable.

(5) Integrated Grievances (§ 422.630)

At § 422.630, we propose to largely parallel Medicare and Medicaid requirements where these requirements are the same with regard to the treatment of integrated grievances. Where MA includes a requirement that Medicaid does not, or vice versa, or where the MA and Medicaid regulations conflict, we propose applying the requirement that best aligns with the principles and statutory requirements discussed in section II.A.1.b. of this preamble. For integrated grievances, we specifically propose:

• At paragraph (a), to establish the general purpose of the regulation, similar to § 438.402(a) and § 422.564(a), by requiring that an applicable integrated plan provide meaningful procedures for timely hearing and resolving integrated grievances filed by an enrollee. We propose to define the scope of the required procedures as being applicable to any grievances between the enrollee and the plan or any entity or individual through which the applicable integrated plan covers health care services. We propose this requirement for the applicable integrated plan to be responsible for ensuring timely and appropriate resolution of a grievance even if the grievance pertains to an act or decision by one of the applicable integrated plan's contracted providers or vendors. Our proposed regulation text mirrors the Medicare Advantage language at § 422.564(a) for this requirement. We believe that clearly ensuring that an applicable integrated plan is ultimately responsible for resolving all grievances related to services that it is responsible for providing is an important enrollee protection and provides enrollees with an easily navigable, single pathway for resolution of grievances, consistent with sections 1859(f)(8)(B)(ii)(I) and (III) and (iii)(II) of the Act.

• At paragraph (b), to provide that an enrollee may file a grievance at any time. The relevant Medicaid regulation (§ 438.402(c)(2)(i)) allows a grievance to be filed at any time,

while the MA regulation (§ 422.564(d)(a)) limits grievance filing to within 60 days of the event at issue. We propose to impose the standard that is more protective of enrollees on applicable integrated plans.

• At paragraph (c), to allow grievances orally or in writing, in alignment with Medicare and Medicaid requirements, while allowing for integrated grievances related to Medicaid benefits to be filed with the state, in states that have processes in place in accordance with § 438.402(c)(3). We propose to include current state processes, where they exist, for enrollees to file grievances with the state that relate to Medicaid benefits. The option for a state to accept grievances currently exists in the Medicaid regulations (see § 438.402(c)(3)). We believe that this is an important protection for enrollees and, in proposing requirements that are most protective to the enrollee and take into account differences in state plans, we are proposing to leave this option for filing grievances open to enrollees, if it is otherwise an option in the state's Medicaid program.

• At paragraph (d), we propose to largely parallel the Medicare Advantage requirements (at § 422.564(f)) for when an enrollee can file an expedited grievance because we find them a protection for beneficiaries. Medicare Advantage regulations require that plans provide for expedited grievances in cases when: 1) a plan extends the timeframe for resolving an organization determination or reconsideration, or 2) the grievance involves a refusal to grant an enrollee's request for an expedited organization determination or reconsideration (§ 422.564(f)). The Medicaid managed care regulations do not include a federal provision for expedited grievances.

• At paragraph (e)(1), to parallel Medicare Advantage's 30-day timeframe for resolving the grievance and Medicare Advantage's requirements for how the applicable integrated plan

must respond to grievances, depending on how the grievance is received and the basis upon which the enrollee filed the grievance; again we find the Medicare Advantage provision to be more protective of enrollees. Medicaid requires plans to resolve grievances within 90 days (§ 438.408(b)(1)), while Medicare Advantage regulations require that plans resolve them within 30 days (§ 422.564(e)). Medicare Advantage regulations address the issue of how a managed care plan must respond to grievances depending on how the grievance was received and the issue in dispute (§ 422.564(e)(3)). Medicaid leaves requirements for responding to grievances to the state to determine, provided that the requirements set by the state meet, at a minimum, the requirements described at § 438.10 (§ 438.408(d)(1)).

• At paragraph (e)(2), to include a provision permitting the applicable integrated plan to extend the time period in which a determination on an integrated grievance must be issued to the enrollee. We propose this provision to parallel Medicare Advantage (§ 422.564(e)(2)) and Medicaid managed care (§ 438.408(c)(1)) requirements that extend the grievance resolution timeframe by up to 14 days. We also propose to adopt a combination of the Medicare Advantage and Medicaid managed care requirements for how an applicable integrated plan must notify an enrollee of an extension. MA regulations require that the MA plan immediately notify the enrollee in writing of the reason for the delay (§ 422.564(e)(2)), while Medicaid managed care requires notice within 2 calendar days (§ 438.408(c)(2)). We have combined those requirements in our proposal here, such that applicable integrated plans must notify enrollees immediately, but no later than within 2 calendar days, which we believe to be in line with the principles identified in section 1859(f)(8)(B)(iii) of the Act for timely, clear notification for enrollees.

We invite comments on these topics, specifically whether the proposed regulation text accurately incorporates the standards from the underlying part 422 or part 438 regulation that are more beneficial to the enrollee.

For each of these issues, we propose to adopt the requirement that is most protective for enrollees and that ensures timely, clear, and understandable resolution and notification. We propose to give enrollees the most flexibility in filing a grievance by not putting any limits on when it can be filed and providing clear guidance to ensure enrollees can support their cases with relevant information. We also propose timeframes that ensure plans resolve the grievance quickly and provide clear notice to enrollees of the resolution. We solicit comment on whether we have adequately captured all relevant enrollee protections here.

(6) Integrated Organization Determinations (§ 422.631)

In proposed § 422.631, we describe the procedures applicable integrated plans would follow in making an integrated organization determinations. In paragraph (a), we propose that, as part of a unified process, all requests for benefits covered by applicable integrated plans must be subject to the same integrated organization determination process.

In paragraph (b), we propose to adopt the MA provisions at § 422.568(a) allowing an enrollee to request an integrated organization determination either orally in writing, but requiring requests for payment to be made in writing. The Medicaid managed care regulations do not include specific rules in this area.

In paragraph (c), we propose to articulate the standard for making an expedited organization determination. Both MA (at § 422.570(c)) and Medicaid (at § 438.210(d)(2)) have similar standards for an expedited organization determination, and we propose to reflect the standards of both programs. This proposed provision tracks existing MA regulation language

more closely than the Medicaid language with respect to who can make the request (proposed paragraph (c)(1)), and how it should be considered and decided (proposed paragraph (c)(3)), though we believe the MA and Medicaid requirements are functionally the same. At paragraph (c)(2), we propose to include the more specific language from the MA regulations at § 422.570(b)(1) that the request to expedite the appeal can be made orally or in writing. We invite comments regarding alternative phrasing.

In paragraph (d), we propose rules regarding timeframes and notices when resolving integrated coverage determinations. In paragraph (d)(1), we propose to require that an applicable integrated plan send a written integrated notice when the organization determination (standard or expedited) is adverse to the enrollee. We propose to include text specifically identifying as adverse determinations requiring a notice any decision to authorize a service or item in an amount, duration, or scope that is less than the amount requested or previously requested or authorized for an ongoing course of treatment. We also propose to include text specifying, consistent with Medicaid managed care requirements (§ 438.404(c)(5)), that the applicable integrated plan must send an integrated determination notice when it fails to make a timely decision, since such a failure constitutes an adverse decision, and that the enrollee may then request an integrated reconsideration. The proposed notice would include information about the determination, as well as information about the enrollee's appeal rights for both Medicare and Medicaid covered benefits. Though integrating information on Medicare and Medicaid appeal rights would be a new requirement if this proposed requirement is finalized, we propose content requirements for the notice that generally largely align with current requirements in Medicaid (§ 438.404(b)) and MA (§ 422.572(e)). We also propose that the notice be written in plain language

and available in a language and format that is accessible to the enrollee consistent with 1859(f)((8)(B)(iii)(III) of the Act.

In paragraph (d)(2), we propose timelines for sending this notice that largely align with both existing Medicare and Medicaid requirements. We propose, in paragraph (d)(2)(i)(A), to require that applicable integrated plans send a notice of an integrated organization determination at least 10 days before the date of action if a previously authorized benefit is being reduced, suspended or terminated, as is currently required for Medicaid managed care plans under § 438.404(c), with some exceptions in accordance with §§ 431.213 and 431.214. Exceptions under § 431.213 include circumstances where the enrollee cannot, or does not wish to, be reached – for example, there exists factual information confirming the enrollee's death or the enrollee is no longer eligible for services, or if the State Medicaid Agency determines that the beneficiary has been accepted for Medicaid services in another jurisdiction. Exceptions under § 431.214 allow for less advance notice to the enrollee in cases of probable fraud. This standard for the timing of these notices (within 10 days subject to specific exceptions) is adopted from Medicaid and aligns with the timing for enrollees to request (under § 438.420) continuation of a previously authorized benefit while the integrated reconsideration is pending because it gives the enrollee enough time, upon receiving the notice, to request that the benefit continue without a potential gap in the benefit. We propose, in paragraph (d)(2)(i)(B), to require that applicable integrated plans send the notice as expeditiously as the enrollee's health condition requires but no later than 14 calendar days from receipt of the request for a standard integrated organization determination, and propose to permit extensions, in proposed paragraph (d)(2)(ii), in circumstances that largely parallel those that exist in Medicare and Medicaid currently. In paragraph (d)(2)(iii), we propose requirements for notice in cases of extension which largely

parallel current MA and Medicaid requirements at § 422.572(b)(2) and § 438.404(c)(4)(i), respectively. Both MA and Medicaid currently require that the health plan notify the enrollee of the delay and the right to file a grievance. Section 422.631(d)(2)(iii)(A) as proposed largely parallels § 422.572(b)(2), which provides more specific direction on timing of the notice. We are proposing to apply the MA requirement that the enrollee be notified of the right to file an expedited grievance in these instances. We also propose in paragraph (d)(2)(iii)(B) regulatory text controlling when the notice of the determination must be sent in cases where the applicable integrated plan takes an extension.

In paragraph (d)(2)(iv)(A), we propose the deadline for issuing notice of expedited integrated organization determinations. Both MA and Medicaid require expedited organization determinations (or adverse actions) within 72 hours of the request, with the possibility of extending that timeframe by 14 calendar days. We propose, at paragraph (d)(2)(iv)(B), to mirror the MA requirements (§ 422.570(d)), with required procedures when an applicable integrated plan denies a request for expediting an organization determination. In paragraph (d)(2)(iv)(C) we propose to include requirements, which parallel MA requirements (§ 422.572(d)), for applicable integrated plans when obtaining necessary information from noncontract providers. These requirements specify that the applicable integrated plan must reach out to a noncontract provider within 24 hours of the initial request for an expedited integrated organization determination. Though Medicaid managed care regulations to not contain a similar requirement, Medicaid managed care plans currently must resolve expedited appeals under the same timeframes and, therefore, should already be reaching out to providers for information necessary to process expedited appeals in a similarly timely manner.

(7) Continuation of Benefits Pending Appeal (§ 422.632)

Section 50311(b) of the Bipartisan Budget Act of 2018 amended section 1859(f) of the Act by creating a new paragraph (8)(B)(iv) requiring that the unified appeals procedures we develop with respect to all benefits under Medicare Parts A and B and Title XIX that are subject to appeal under such unified procedures incorporate provisions under current law and implementing regulations that provide continuation of benefits pending appeal under Titles XVIII and XIX. We interpret this provision as requiring CMS to apply continuation of benefits to all Medicare Parts A and B and Medicaid benefits under our proposed unified appeals processes. The statutory language "with respect to all benefits under parts A and B and title XIX subject to appeal under such procedures" modifies the verb "incorporate." Therefore, we interpret the provision as requiring CMS to incorporate statutory and regulatory provisions for continuation of benefits into the unified appeal procedures for all Parts A and B benefits, and not only those benefits that are already permitted to be continued under current law (Medicaid benefits and limited Medicare benefits, as described in more detail later in this section of the proposed rule).

We considered current laws and implementing regulations related to continuation of benefits under Medicare and Medicaid and found that Medicare's continuation of benefits provisions are of limited relevance, but that there are significant Medicaid provisions that must be incorporated in our integrated standards. Continuation of benefits exists in very limited circumstances in Medicare currently. A Medicare beneficiary can receive an extension of inpatient hospital stays when the beneficiary appeals a notice of discharge to the Quality Improvement Organization (QIO) under §§ 405.1205 through 405.1208 and §§ 422.620 and 422.622. We do not propose any changes to the existing QIO process, as its specialized nature does not lend itself readily to expansion to other services such as those covered by Medicaid.

Medicaid's continuation of benefits provisions are considerably more comprehensive, and we propose to incorporate them into this unified appeals process. These Medicaid rules, found in §§ 431.230 and 431.231 (general) and § 438.420 (managed care), are grounded in constitutional due process principles articulated in Goldberg v. Kelly, 397 U.S. 254 (1970), that recognize the importance of allowing people with limited financial resources to challenge a decision prior to the decision taking effect. Under § 438.420, a Medicaid managed care plan is required, upon request of the enrollee, to cover certain Medicaid benefits while an appeal is pending, provided that: (1) The enrollee files the request for an appeal timely in accordance with §438.402(c)(1)(ii) and (c)(2)(ii); (2) the appeal involves the termination, suspension, or reduction of previously authorized services; (3) the services were ordered by an authorized provider; (4) the period covered by the original authorization has not expired; and (5) the enrollee timely files for continuation of benefits.

We also note that continuation of benefits has been included as part of the integrated appeals process in the Financial Alignment Initiative demonstrations, under processes that largely parallel what we are proposing in these regulations. We request comment on our interpretation of the statutory requirements related to continuation of benefits pending appeal.

Accordingly, we propose that the existing standards for continuation of benefits at § 438.420 apply to applicable integrated plans for Medicare benefits under Parts A and B and Medicaid benefits in our proposed integrated appeals requirements at § 422.632. Under our proposal, as is applicable to Medicaid managed care plans currently, if an applicable integrated plan decides to stop (as a termination or suspension) or reduce a benefit that the enrollee is currently authorized to receive, the enrollee could request that the benefit continue to be provided at the currently authorized level while the enrollee's appeal is pending through the

integrated reconsideration. The enrollee would be required to make a timely request for the continuation, as further detailed below.

We anticipate that this provision will simplify the appeals process for both plans and beneficiaries, as it will be unnecessary to determine which ongoing benefits are subject to continuation pending appeal. This has been our experience in the Financial Alignment Initiative demonstrations. In addition, as we note in the Regulatory Impact Analysis, relatively few Medicare benefits are continuing in nature, and we therefore do not anticipate a significant financial cost related to the implementation of this provision by applicable integrated plans.

We propose, at paragraph (a), a definition for "timely files." This definition would mirror the definition at § 438.420(a), with minor revisions to make the text applicable to applicable integrated plans instead Medicaid managed care plans.

We propose, at paragraph (b), to require a previously authorized service covered under Medicaid or Medicare Part A or Part B, excluding supplemental benefits as defined at §422.103, to be continued pending an appeal of a termination of those services. We propose to require that the continuation of these services as a covered benefit would be conditioned on the same five criteria listed in § 438.420 being met.

We propose, at paragraph (c), to require that an applicable integrated plan continue such services pending issuance of the integrated reconsideration. We note that for Medicaid managed care plans that are not applicable integrated plans, continuation of these services after the integrated reconsideration and pending resolution of the state fair hearing is controlled by §438.420(c). Our proposal for continuation of services pending appeal would provide a unified, consistent rule for Medicaid and Medicare Part A and Part B benefits, excluding supplemental benefits defined in § 422.103, for the duration of the unified appeals process proposed here for

all plan level appeals. Proposed § 422.632(c)(2) therefore provides that continuation of services ends when the applicable integrated plan issues an adverse integrated reconsideration. If the applicable integrated plan finds in favor of the enrollee, benefits would continue in accordance with the favorable integrated reconsideration. In proposed § 422.632(c)(3), we propose requirements for Medicaid-covered benefits to continue after the applicable integrated plan issues an adverse integrated reconsideration, mirroring the requirements currently in Medicaid managed care regulations (see § 438.420(c)(2)). The enrollee must make the request and file for a state fair hearing within 10 calendar days after the applicable integrated plan sends the notice of the integrated reconsideration. We also propose to mirror requirements from § 438.420 for how long Medicaid-covered benefits must continue by requiring that the benefits continue until the enrollee withdraws the request for the state fair hearing or until the state fair hearing decision is issued.

We considered alternative approaches to implementing benefits pending appeal, and we believe integrating through the plan-level reconsideration stage of the appeal process is the most feasible approach at this time. The right for a Medicaid beneficiary to have Medicaid benefits continue through a state fair hearing, which is the second level of appeal for an enrollee, would not be impacted by this proposal. The process that we propose for an enrollee's benefits to continue during the state fair hearing process mirrors the current process under Medicaid regulations at § 438.420.

In proposed paragraph (d), we address whether an applicable integrated plan can seek recovery for the costs of services provided while an appeal is pending. Medicaid regulations allow states to determine whether or not a plan, or the state, can seek recovery for the costs of services provided pending appeal (§ 431.230(b)). If a state permits such recovery under managed

care, plans must inform enrollees of this possibility (§ 438.420(d)). As noted in the preamble to the 2016 final Medicaid managed care rule, such notices can have the effect of deterring enrollees from exercising the right to appeal.14 Moreover, Medicare's provision allowing benefits to continue is limited, as noted earlier, to an extension of inpatient hospital stays when the beneficiary appeals a notice of discharge to the Quality Improvement Organization (QIO) under §§ 405.1205 through 405.1208, and 422.620 and 422.622.[15] Finally, in a number of our Financial Alignment Initiative demonstrations, we and our state partners have explicitly declined to allow MMPs to recover of the costs of services provided pending appeal. Neither MMPs nor states have noted any adverse impact on the costs of services provided pending appeal. Therefore, in paragraph (d), we propose to prohibit recovery of the costs of services provided pending the integrated reconsideration and, for Medicaid-covered benefits, any state fair hearing, to the extent that services were continued solely under § 422.632, for all applicable integrated plans and state agencies.

We considered several alternatives to this approach. We considered proposing to use the same rule as § 438.420(d) and applying it to all services provided pending appeal by applicable integrated plans. Under this alternative, a state's Medicaid recoupment policy would also apply to Medicare benefits provided by an applicable integrated plan pending appeal. However, there is no recoupment provision under Medicare that parallels the recoupment process under Medicaid managed care. As we noted earlier, continuation of services without imposing financial liability

[14] 81 FR 27512 (May 6, 2016).

[15] We note that while regulations at 42 CFR 405.1200 through 405.1204 and 422.624 and 422.626 address appeal rights for Medicare beneficiaries related to terminations of certain facility services and potential continuation of services pending those appeals, those regulations generally require the beneficiary to pay for services received after the date and time designated on the termination notice him or herself unless the beneficiary prevails on the appeal. As an individual always has the right to choose to receive non-covered services when bearing financial responsibility for those services, we believe these scenarios are not truly continuations of benefits pending appeal as the services might not be covered.

on the enrollee in Medicare exists in the narrow circumstances related to extension of inpatient hospital stays when the beneficiary appeals a notice of discharge to the Quality Improvement Organization (QIO). If an enrollee files a timely request for QIO review of the discharge, the enrollee is not responsible for the costs of the hospital services during the QIO review, even if the QIO ultimately finds that the hospital stay should not be continued (§ 422.422(f)). Developing a recoupment policy in Medicare, and communicating it to enrollees, could become administratively complex while offering little benefit to enrollees or plans, considering the limited financial resources of dually eligible enrollees.

We also considered adopting the Medicaid rule at § 438.420(d) only for services provided under Title XIX – that is, Medicaid-covered services. This approach would preserve state flexibility, but it would risk creating administrative complexity for plans and confusion for enrollees, as it would necessitate differentiating between services for which financial recovery was possible and those for which it was not. We invite comments on our proposed approach to prohibit the recovery of the costs of services provided pending appeal, our considered alternatives, and any other possible approaches.

(8) Integrated Reconsiderations (§ 422.633)

In proposed § 422.633, we lay out our proposed provisions for an integrated reconsideration process for applicable integrated plans. As with other provisions, we compared relevant Medicare and Medicaid provisions, and where they differ, we chose to adopt the policy that is most protective of the beneficiary.

In paragraph (a), we propose that applicable integrated plans may only have one plan level of appeal. This provision is consistent with § 438.402(b), which prohibits more than one

plan level of appeals, and § 422.590, which permits only one internal reconsideration before an adverse decision is subject to review by the independent review entity.

In paragraph (b), we propose to adopt a rule similar to § 438.402(c)(1)(i)(B) regarding the permissibility of external medical reviews: Medicaid managed care plan enrollees may be offered an opportunity to elect external medical review under a state external review process. Under our proposal, the ability to elect external medical review would apply only to Medicaid covered services that are the subject of an adverse integrated reconsideration issued by an applicable integrated plan because D-SNPs, like all MA plans, are not subject to state external review procedures.16

In paragraph (c), we propose a right for each enrollee, and their representatives, to review the medical records in the enrollee's case file, consistent with the protection for Medicaid enrollees under § 438.406(b)(5). We believe that this protection for Medicaid enrollees in a managed care plan is appropriate for dually eligible enrollees and should apply to applicable integrated plans. In particular, we propose adopting Medicaid's provision prohibiting plans from charging for copies of records, as we believe the policy applicable for MA plans, which permits plans to charge beneficiaries reasonable copying fees, is inappropriate and less protective of dual eligible individuals, who typically have limited income. We invite comments on this proposal.

In paragraph (d)(1), we propose timelines for filing for a standard integrated reconsideration that, consistent with both MA (at § 422.582(b)) and Medicaid managed care (at § 438.402(c)(2)(ii)) regulations, would require that an integrated reconsideration be filed within 60 days of the date of the denial notice. We propose, in paragraph (d)(2), that oral inquiries seeking to make an integrated reconsideration be treated as integrated reconsiderations; this is generally

[16] Section 1856(b)(3) of the Act preempts state regulation of Medicare Advantage plans.

consistent with § 438.406(b)(3), which we find to be the more protective of enrollees than the MA provision at §422.582(a) which gives MA plans discretion in deciding to accept oral requests for reconsideration. We believe that applying the Medicaid rule to applicable integrated plans is appropriate because initiating an integrated reconsideration orally may be the easiest way for enrollees to start the integrated reconsideration process quickly, and timely filing can be especially important to ensure aid continues pending the integrated reconsideration resolution under proposed § 422.632. We are not proposing to include the language in § 438.406(b)(3) requiring beneficiaries to provide written confirmation of oral requests because such a requirement would be inconsistent with MA policy that directs plans that do accept oral requests for reconsideration to provide written confirmation to the beneficiary (see Medicare Managed Care Manual Chapter 13, section 70.2). We propose, in paragraph (d)(3), to include current requirements from MA (at § 422.582(c)) that allow for extending the timeframe for an enrollee, or a physician acting on behalf of an enrollee, to file a late reconsideration. As in MA, we propose to allow late filing when a party to the integrated organization determination or a physician acting on behalf of the enrollee can show good cause for the extension and makes the request in writing. We find that this is an important beneficiary protection that should be applied to our proposed integrated process.

In paragraph (e), we propose to address procedures for filing expedited integrated reconsiderations. Both MA (at § 422.584) and Medicaid (at § 438.408(b)(3)) regulations permit filing of expedited appeals. The MA regulation provides greater detail regarding how plans are to consider requests for expedited reconsiderations. The proposed language in paragraphs (e)(1), and (e)(2) aligns with § 422.584 in permitting the enrollee or health care provider to file a written or oral request for an expedited reconsideration. The proposed language in paragraph (e)(3)

aligns with § 422.584 in setting the standard that the applicable integrated plan must use in deciding whether to expedite the integrated reconsideration. We invite comments regarding whether additional specificity or harmonizing between Medicare and Medicaid's requirements is needed in this area.

In paragraph (e)(4), we propose notice requirements related to requests for expedited integrated reconsiderations. We propose requirements that parallel Medicaid managed care requirements for notice to the enrollee when the request for an expedited integrated reconsideration is denied (§ 438.410(c)(2)) – specifically, that the plan must give prompt oral notice and written notice within 2 calendar days and transfer the matter to the standard timeframe for making an integrated reconsideration (that is, the timeframe specified in paragraph (f)(1)). The MA requirements for notice, when an enrollee's request for an expedited integrated reconsideration is denied, are for the plan to provide prompt oral notice and, subsequently, written notice within 3 calendar days (§ 422.584(d)(2)). We find that the Medicaid managed care requirements are more protective for enrollees by requiring faster notification when the request to expedite is denied. We propose to apply the MA requirements for what applicable integrated plans must include in the written notice to enrollees when the request to expedite the integrated reconsideration is denied (§ 422.584(d)(2)). The MA requirements for the contents of this notice are more extensive than the Medicaid managed care requirements (§ 438.410(c)(2)). We find the additional content requirements to be more protective of enrollees by providing them more information on options, and also helping to make the process more navigable for enrollees.

In paragraph (e)(5) we propose to include requirements, which mirror MA requirements (§ 422.590(d)(3)), for applicable integrated plans when obtaining necessary information from noncontract providers. These requirements specify that the applicable integrated plan must reach

out to a noncontract provider within 24 hours of the initial request for an expedited integrated reconsideration. Though Medicaid managed care regulations do not contain a similar requirement, Medicaid managed care plans currently must resolve expedited appeals under the same timeframes and, therefore, should already be reaching out to providers for information necessary to process expedited appeals in a similarly timely manner.

In paragraph (f), we propose timelines and procedures for resolving an integrated reconsideration request. We propose specific requirements for applicable integrated plans. Both MA (at § 422.590(a)) and Medicaid (at § 438.408(b)(2)) require resolution of pre-service standard appeal requests within 30 calendar days. We propose the same rule in paragraph (f)(1), with the addition of a provision mirroring § 422.590(a)(2), that the integrated reconsideration decision be issued as expeditiously as the enrollee's health requires but no later than 30 calendar days from the date the applicable integrated plan receives the request for the integrated reconsideration.

However, MA and Medicaid managed care differ in the timeframes within which plans must resolve post-service appeals (that is, appeals related to payment requests). Medicaid regulations at § 438.408(b)(2) do not distinguish between pre-service and post-service appeals – all appeals must be resolved within 30 calendar days. In contrast, while MA regulations require that plans resolve standard reconsiderations within 30 calendar days for pre-service appeals, plans have 60 days to resolve post-service denials of payment. Although we do not believe the volume of appeals for payment is high for individuals dually eligible for Medicare and Medicaid, it is more protective for enrollees to have all integrated reconsiderations resolved in 30 calendar days, particularly given what may be significant financial needs for the individual. Similarly, we are not proposing to incorporate into the unified appeals process MA's regulation that expedited

organization determinations are not required in post-service payment cases. Again, we do not believe the volume of post-service cases that otherwise qualify under the requirements for an expedited integrated organization determination would be high, so we do not expect this to be a burden to D-SNPs that would be required to comply with unified appeals requirements we propose here. There may be circumstances in which an enrollee's financial need is particularly pressing. Accordingly, in § 422.633(f)(1), we propose to require that all integrated reconsiderations be resolved within 30 calendar days of receipt similar to the Medicaid managed care regulations. We considered applying the approach taken in the MA regulations that gives MA plans more time to resolve post-service payment cases so that plans can prioritize cases where an enrollee is waiting for a service to start or an item to be provided. However, given the financial circumstances of enrollees in applicable integrated plans, we propose requiring the same resolution timeframe for all integrated reconsideration to ensure prompt repayment. We invite comments on this proposal – both on the overall 30 calendar day period and on permitting expedited post-service integrated reconsideration – as we recognize this would constitute a change to current D-SNP operations.

In paragraph (f)(2), we propose to establish the timeframes for expedited reconsiderations. Both MA (at § 422.590(d)(1)) and Medicaid (at § 438.408(b)(3)) allow 72 hours for resolution of an expedited reconsideration or appeal. We propose to adopt the same rule for integrated reconsiderations. We also propose to apply the Medicaid managed care requirement (at § 438.408(d)(2)(ii)) by requiring that applicable integrated plans make reasonable efforts to give enrollees oral notice of the resolution in expedited cases, in addition to sending the written notice within 72 hours of receipt of the request.

In paragraph (f)(3)(i), we propose criteria for an applicable integrated plan to extend the timeframe for resolving either a standard or expedited reconsideration. MA (at § 422.590(e)) and Medicaid (at § 438.408(c)) have similar rules, both allowing 14-day extensions upon request of the enrollee (or the enrollee's representative) and when the plan can demonstrate an extension is in the enrollee's interest. We propose to adopt a similar standard here, generally using the standard in § 438.408(c) that the plan must show that the extension is in the enrollee's interest and that the information is necessary. We also propose to use the MA standard that the timeframe may be extended if there is a need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request, as this standard is more protective of the enrollee. Using this standard, an applicable integrated plan would be prohibited from extending the deadline for its integrated reconsideration in order to gather information to justify continuing its original denial of coverage. We request comments regarding whether additional specificity is needed.

In paragraph (f)(3)(ii), we propose requirements for the notice that applicable integrated plans must send to enrollees when the plan extends the timeframe for making its determination, in accordance with the requirements in this paragraph. We propose to require that the applicable integrated plan make reasonable efforts to give the enrollee prompt oral notice and give the enrollee written notice within 2 calendar days. These requirements align with current Medicaid managed care regulations at § 438.408(c)(2). The MA regulation requires that the plan notify the enrollee in writing as expeditiously as the enrollee's health condition requires, but no later than the expiration of the extension period (§ 422.590(e)(2)). We find the Medicaid managed care requirements to be more protective to enrollees since they are likely to provide faster notice to the enrollee of the determination. We also propose that the notice of the extension include the

reason for the delay and inform the enrollee of the right to file an expedited grievance if the enrollee disagrees with the decision to extend the timeframe. Both Medicaid managed care and MA require similar information. However, only MA requires information on an expedited grievance process, since only MA includes an expedited grievance process. Since we are proposing to include an expedited grievance process, we are proposing to require information about that process in this notice.

In paragraph (f)(4), we propose requirements for providing appellants with notices regarding the resolution of reconsiderations. We propose to require that applicable integrated plans send notices within the resolution timeframes established in this section for all integrated reconsideration determinations. Medicaid managed care regulations require notices of all determinations. MA regulations will no longer, effective for the 2019 plan year, require MA plans to send written determinations in cases where the determination is fully or partially unfavorable to the enrollee because MA enrollees will still receive a notice from the independent entity once the MA plan forwards the case for fully or partially unfavorable determinations (see 83 FR 16634 through 16635). We believe that requiring applicable integrated plans to send notices for all integrated reconsideration determinations is in line with the principles identified in section 1859(f)(8)(B) of the Act for a unified process, and timely, clear notification for enrollees. We also propose to include language requiring that the notice be written in plain language and available in a language and format that is accessible to the enrollee consistent with section 1859(8)(B)(iii)(III) of the Act. We also propose, in paragraphs (f)(4)(i) and (ii), to adopt the standards similar to those governing the content of a notice found in § 438.408(e) – namely, that the plan must provide a notice of the integrated reconsideration for an adverse decision that includes the reason for the decision and the date of completion. We propose in paragraph

(f)(4)(ii)(A) that, for integrated notices not resolved wholly in the enrollee's favor, the notice include an explanation of the next level of appeal under both Medicare and Medicaid, and what steps the enrollee must take to further pursue the appeal. Our expectation is that the integrated notice will enable the enrollee to understand which program covers the benefit at issue. We also propose in paragraph (f)(4)(ii)(B) that the notice include specific information about the ability to request continuation of Medicaid-covered benefits pending appeal.

(9) Effect (§ 422.634)

We propose, at § 422.634(a), to use the same standard as in existing MA and Medicaid regulations related to a plan's failure to made a timely determination. If an applicable integrated plan fails to make a timely determination at any point in the appeals process (for an integrated organizational determination or an integrated reconsideration), that failure would constitute an adverse determination, such that the enrollee could move forward with the next level of appeal procedures (see §§ 438.400(b)((b), 438.402(c)(1)(i)(A), 438.408(c)(3), 422.568(f), and 422.572(f)).

We propose, at § 422.634(b), to establish the next steps in the appeals process if the enrollee receives an adverse decision from the applicable integrated plan on the integrated reconsideration. For cases involving Medicare benefits, we propose, for applicable integrated plans at § 422.634(b)(1)(i), the same processes as currently exist in MA at § 422.590(a)(2) and (d)(4) for forwarding the case file and timing. In § 422.634(b)(1)(ii) and (iii), we propose to mirror the MA regulations (§ 422.590(a)(2) and (d)(3)) with requirements for applicable integrated plans to forward the case file to the independent entity.

At § 422.634(b)(2), we propose that for cases involving Medicaid benefits, the enrollee may initiate a state fair hearing no later than 120 calendar days from the date of the applicable

integrated plan's notice of resolution. This proposal would, in effect, impose the same process on appeals from integrated reconsiderations related to Medicaid coverage as applies under § 438.408(f)(2) and (3). We also propose to include the requirement that a provider who has not already obtained the written consent of an enrollee must do so before filing a request for a state fair hearing, in accordance with existing Medicaid requirements, since our proposed regulations would only apply new processes and requirements through the integrated reconsideration.

We also propose to parallel, at proposed § 422.634(c), MA regulation language at § 422.576 clarifying that determinations are binding on all parties unless the case is appealed to the next applicable level of appeal. We also propose to specify that this means that, in the event that an enrollee pursues an appeal in multiple forums simultaneously (for example, files for an external state medical review and an integrated reconsideration with the applicable integrated plan, and the integrated reconsideration decision is not in the enrollee's favor but the external state medical review decision is), an applicable integrated plan would be bound by, and must implement, decisions favorable to the enrollee from state fair hearings, external medical reviews, and independent review entities (IRE).

We propose, at § 422.634(d), to parallel Medicaid requirements, from § 438.424(a), detailing how quickly services must be put in to place for an enrollee after he or she receives a favorable decision on an integrated reconsideration or state fair hearing. We propose to include the current Medicaid managed care requirement that, if a decision is favorable to the enrollee, the applicable integrated plan must authorize or provide the disputed benefit as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. MA's rule for effectuation of a standard organization determination at § 422.618(a) also requires effectuation as expeditiously as the enrollee's health requires, but

allows a maximum of 30 days. We believe the shorter, 72-hour maximum is more protective of the needs of dually eligible beneficiaries. We also note that a 72-hour effectuation period is the same as Medicare's timeframe for an expedited determination at § 422.619(a), so that plans should be accustomed to effectuating decisions under this timeframe. Finally, we also propose in this paragraph to maintain the same effectuation timelines for reversals by the Medicare independent review entity as apply to other MA plans.

We propose, at § 422.634(e), for Medicaid-covered benefits, to parallel Medicaid requirements from § 438.424(b) governing how services that were continued during the appeal must be paid for, if the final determination in the case is a decision to deny authorization of the services. For Medicare-covered services, we propose that the applicable integrated plan will cover the cost of the benefit.

(10) Unifying Medicare and Medicaid Appeals Subsequent to Integrated Reconsideration

The new section 1859(f)(8)(B)(ii) of the Act directs us to include, to the extent we determine feasible, consolidated access to external review under an integrated process. We interpret "external review" in this statutory provision as meaning review outside the plan, including by a government agency or its designee. For MA, this includes the independent review entity (IRE) and ALJ review described in §§ 422.592 through 422.602. For Medicaid, this includes the state fair hearing process described in Part 431 Subpart E, as well as any additional external review offered under state law.

A unified and integrated appeals process subsequent to a plan decision could be significantly simpler for beneficiaries to navigate, as they would not have to determine whether they should be pursuing a Medicare appeal, a Medicaid appeal, or both. Such a process could reduce burden for plans, states, and the federal government by reducing the number of

duplicative appeals. However, unifying D-SNP and Medicaid appeals subsequent to the reconsideration level also presents considerable challenges. Currently, once a D-SNP or Medicaid managed care plan makes a final decision on an appeal, the federally-administered Medicare and state-administered Medicaid appeals processes are entirely separate. Although they have some common principles, such as ensuring access to an independent administrative hearing, they differ in many respects. Specific differences include:

• Reconsideration by an independent entity: Section 1852(g)(4) of the Act, which is implemented in MA rules at §§ 422.592 through 422.596, requires that all adverse plan appeal decisions be reviewed by an independent entity. Under the regulations, this review is on the record and happens automatically for Part C claims, as the MA plan is required to forward any adverse reconsideration to the IRE. This IRE review takes place before a beneficiary can request an administrative hearing before an administrative law judge but, because each adverse reconsidered determination is automatically forwarded to the IRE, the enrollee is not required to initiate these reviews. In the Medicaid managed care context, there is no federal regulation or statute that similarly requires a review by an external entity before access to a governmental review; pursuant to §§ 438.402(c)(1)(i)(B) and 438.408(f)(1)(ii), a state may make a voluntary external medical review process available to enrollees in a Medicaid managed care plan so long as the process does not interfere with enrollees' right to proceed to a state fair hearing.

• Immediate access to an administrative hearing: The applicable Medicaid managed care program regulations (§§ 438.402(c)(1)(i)(B) and 438.408(f)) specify that any external review cannot be required before allowing a beneficiary to proceed to the state fair hearing, so that the state fair hearing process is available immediately following the Medicaid managed care plan's appeal determination if the enrollee elects.

• Amount in controversy: Section 1852(g)(5) of the Act requires that an amount in controversy be met for a hearing before the Secretary on appeal and for judicial review. In 2018, those thresholds are $160 for an Administrative Law Judge hearing and $1,600 for judicial review.[17] Medicaid has no similar provision.

• Reviewing agency and subsequent review: Medicaid program rules at Part 431 Subpart E (which are not limited to Medicaid managed care plans but also control appeals in the Medicaid fee-for-service context) require that beneficiaries always have the right to request a hearing before the state agency for a review of a denial of service (§ 431.205(b)(1)) or for a reduction, termination, or reason described at § 431.220(a). Medicaid hearings are held by the state Medicaid agency or, in limited circumstances, its designee. Subsequent review procedures vary based on state law. Section 1852(g)(5) of the Act provides that a MA enrollee is entitled, if the amount in controversy threshold is met, to a hearing before the Secretary to the same extent as is provided in section 205(b) of the Act. The MA regulations (at §§ 422.562(b)(4)(iv) – (vi) and (d), and §§ 422.600 through 422.616) implement this requirement by providing for appeals to be made to the Office of Medicare Hearings and Appeals and Medicare Appeals Council using substantially the same procedures and processes used for appeals of claims denials under Part A and Part B of Medicare.

• Timelines and procedural rules: Medicaid's procedural rules on matters such as timelines and location of a hearing vary by state and may differ from the rules applicable to MA. For example, Medicaid rules at § 431.224 allow for expedited fair hearing hearings under certain circumstances, whereas there is no equivalent expedited hearing process at the Medicare ALJ level for Part C/MA appeals.

[17] 82 FR 45592 (September 29, 2017).

In addition, our authority to unify appeals procedures under Medicare and Medicaid and to provide consolidated access to external review under section 1859(f)(8)(B) of the Act cannot be used to diminish any appeal rights under Medicare or Medicaid. In the context of establishing the unified procedures for appeals and grievances, the statute provides authority to waive only section 1852(g)(1)(B) of the Act (which imposes certain notice requirements for MA organizations) and directs unification – rather than amendment or elimination – of procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) of the Act. In many ways, those statutory provisions do not direct specific procedures but provide some measure of discretion in effectuating appeal rights. But where those statutory provisions are specific, we generally do not have authority under section 1859(f)(8)(B) of the Act to waive the specific requirements in establishing unified procedures and processes. In addition to the statutory differences we have already outlined earlier, section 1852(g)(5) of the Act providing Medicare beneficiaries with an opportunity for a hearing before the Secretary, and the analogous provision at section 1902(a)(3) of the Act providing Medicaid beneficiaries with a hearing before the state Medicaid agency, are rights that must be met and present challenges in establishing a consolidated, unified, post-plan appeals process. We believe that a state-level unified appeals process to adjudicate both Medicare and Medicaid claims would satisfy section 1902(a)(3) of the Act in providing Medicaid beneficiaries with access to a state fair hearing. However, to comply with section 1852(g)(5) of the Act, such a system would need to include a pathway for a federal review of Medicare claims, in a manner that provides a hearing before the Secretary. Conversely, a federal-level unified appeals process would satisfy section 1852(g)(5) of the Act but would need to include a pathway for an enrollee to elect additional state agency review of Medicaid claims. Finally, we believe as a practical matter that any entity adjudicating cases in a unified

process outside its traditional jurisdiction (that is, a state entity reviewing Medicare claims or a federal entity reviewing Medicaid claims) should be subject to some additional review to ensure that its decisions were consistent with the applicable law (that is, federal Medicare and state Medicaid criteria for benefits coverage).

Based on these complexities, we believe it is not feasible to propose a unified post-plan appeals process (that is, adjudication of appeal subsequent to an applicable integrated plan's integrated reconsideration of an initial adverse determination) at this time. Instead we ask for comments on viable paths forward given the constraints presented by the statutory mandates for the MA and Medicaid appeals processes and our experience gained through demonstrations. We hope to propose the establishment of a unified post-plan appeals process in a future rulemaking, based on comments from this request for information and additional experience. We discuss our experiences and key areas for comment below.

Our sole experience with a unified appeals process subsequent to the plan's final reconsideration of an initial benefit denial operates under demonstration authority at the state level through a partnership between CMS and the state of New York as part of the Financial Alignment Initiative capitated model demonstrations. The New York Financial Alignment Initiative demonstration, called Fully Integrated Duals Advantage (FIDA), includes a fully integrated appeals process for appeals from Medicare-Medicaid Plans (MMPs) authorized under section 1115A waiver authority.[18] We note that this model was established under demonstration authority prior to enactment of section 1859(f)(B)(8) of the Act, and some aspects of the model may not be fully consistent with the provisions of Titles XVIII and XIX as they would operate

[18] Section 2.13 of the FIDA contract, available at https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/NYFIDAContract01012018.pdf.

under a unified process implemented under the new statute. In the FIDA integrated process, all adverse decisions by FIDA MMPs, regardless of amount in controversy, are automatically forwarded to a specialized unit of the New York administrative hearing agency that conducts state Medicaid fair hearings. This specialized unit has staff trained in both Medicare and Medicaid coverage rules, schedules each denial for a hearing, and applies both Medicare and Medicaid coverage criteria in reviewing the decision. Decisions affirming an MMP's denial may be appealed to the federal Departmental Appeals Board's Medicare Appeals Council, thereby ensuring an opportunity for federal review of Medicare claims.

Our experience with the New York FIDA unified appeals process suggests that any procedures we establish for a unified post-plan appeals process should be available as an option for states to implement in partnership with CMS, rather than a nationwide requirement. The New York FIDA experience has taught us that operating a unified process requires considerable commitment, planning, and coordination by both CMS and the state Medicaid agency, as well as from other agencies that are part of the administrative hearing and review process for Medicare and Medicaid (in this case, the New York state hearing agency and the federal Departmental Appeals Board (DAB)). Although models other than the New York FIDA model are feasible, any unified adjudication entity for D-SNP appeals subsequent to the plan's reconsideration would need to administer its own procedures and be familiar with the substance of both Medicare and state-specific Medicaid coverage rules. Given the resources and commitment needed, we anticipate that only a limited number of states would wish to pursue a unified system with CMS for appeals processes following the decisions by applicable integrated plans. In addition, based on our experience with the Financial Alignment Initiative demonstrations in other states, we believe an appeals system that is integrated at the plan level but which diverges

subsequently can also be effective at ensuring appropriate review of plan decisions. Therefore, we believe that mandating a unified process subsequent to reconsideration for all states would be unwise and likely infeasible.

We also believe that any post-plan appeals process should be limited to appeals of decisions made by applicable integrated plans as we propose to define them in § 422.561. We believe the integrated organization determination and integrated reconsideration processes we propose in §§ 422.631 and 422.633 lend themselves to an integrated post-plan appeals process much more than a system that attempts to integrate appeals made by separate MA and Medicaid managed care plans.

Any regulation to establish a post-plan unified appeals process would need to address the following misalignments in particular:

• *Harmonizing the Medicare Advantage requirement for an external independent review with Medicaid's prohibition on additional levels of administrative review between a plan decision and a state fair hearing:* The approaches to post-plan review do not align neatly across Medicare Advantage and Medicaid managed care. Section 1852(g)(4) of the Act (governing Medicare Advantage appeals processes) requires that CMS contract with an independent external entity to conduct an external review of all adverse reconsiderations. CMS has implemented this provision at § 422.592 by requiring an automatic referral of adverse plan reconsiderations to the IRE for an administrative review. In the appeals structure for Medicaid managed care plans, a plan's adverse action is not reviewed automatically, but beneficiaries may request a fair hearing before the state Medicaid agency (or, in limited cases, its designee) immediately following a plan's decision, under procedures described in Part 431 Subpart E. Requiring an additional level of external review for all integrated appeals prior to allowing a state fair hearing would be

inconsistent with Medicaid policy, as we have only permitted establishment of external medical reviews for Medicaid managed care plans if such reviews do not impede access to a state fair hearing (see, for example, § 438.408(f)(1)(ii) and discussion at 81 FR 27518 (May 6, 2016)). We are concerned that having a requirement for external review of all adverse integrated reconsiderations before access to the state fair hearing would impede dually eligible beneficiaries' timely access to a fair hearing. However, allowing beneficiaries to proceed directly to a governmental hearing to address Medicare-related issues without prior external review could be inconsistent with the MA statutory requirement for independent, external review. Furthermore, if the review, be it external or by state fair hearing, were not automatic, then an adverse reconsideration might not be reviewed at all, which would be inconsistent with protection provided by the automatic referral in § 422.592. We do not believe either a purely Medicare-based or Medicaid-based procedure is desirable in a unified post-plan appeals process.

We have considered one approach that could accommodate these constraints. Under this potential approach, a state entity with expertise in both Medicare and Medicaid coverage rules would review all adverse integrated reconsiderations issued by the plan. This entity would conduct its review in the form of an automatic state fair hearing consistent with Medicaid hearing procedures (such as the opportunity to present evidence), as is done in the New York FIDA demonstration. The automatic fair hearing would also constitute the independent external review required by section 1852(g)(4) of the Act. In order to comply with the statute, CMS and the state entity would have to enter into a contract to perform the independent review. Following this state fair hearing, appeals regarding Medicare-related issues would be subject to additional appeal rights, but as we discuss below, operationalizing those rights presents challenges as well.

We invite comments on the feasibility and desirability of this approach. We are particularly interested in whether there are instructive analogous examples of state-federal contracting that successfully demonstrate states performing a task subject to federal oversight. We also seek input regarding any advantages and disadvantages to providing the automatic review in the form of a state fair hearing. Finally, we welcome suggestions for alternative models that could harmonize the MA and Medicaid managed care requirements while maintaining compliance with all statutory provisions.

- *Preserving the right to hearing before the Secretary:* Section 1852(g)(5) of the Act requires the opportunity for Medicare beneficiaries to have a hearing before the Secretary when an amount in controversy threshold is met. In order to preserve that right, a unified process would need to allow a beneficiary whose appeal is unsuccessful at the independent review level to request a hearing before the Secretary (presumably through the Office of Medicare Hearings and Appeals (OMHA)) when an appeal involves a Medicare item or service (meaning a Part A benefit, Part B benefit, or supplemental benefit offered under the Medicare Advantage contract) meeting the amount in controversy threshold. But this appeal level would not be available for appeals of Medicaid-based cases or for Medicare cases not meeting the amount in controversy. In effect, this would mean beneficiaries would need to split their cases into separate Medicare and Medicaid pathways if they wished to seek a hearing before the Secretary for their Medicare claims meeting the amount in controversy. In addition, it would essentially create the possibility for two hearings: first an automatic integrated independent review and fair hearing at a state-level integrated entity, followed by an optional Medicare-only hearing at OMHA for Medicare matters meeting the amount in controversy threshold. Although such a process could be operationalized, we believe it might also be confusing to beneficiaries and inconsistent with the

goal of a simpler unified appeals process. We therefore seek comments how best to preserve beneficiaries' rights under section 1852(g)(5) of the Act and simultaneously establish a unified process.

• *Pathways for subsequent review:* We seek input on the related question of how to structure other forms of subsequent review for a unified post-plan appeal. Any unified procedure must preserve both state-specific avenues for further review of Medicaid-related fair hearing decisions (for example, additional administrative review and state court review) and ensure that Medicare-related decisions are reviewable consistent with section 1852(g)(5) of the Act (for example, review by the Medicare Appeals Council and federal judicial review under certain circumstances). We believe that maintaining all these routes of appeal would mean that a unified case would eventually have to be separated into Medicaid and Medicare components, which could be difficult for beneficiaries and plans to navigate. We invite comments regarding how to approach this problem. We are considering providing state Medicaid agencies with the authority to delegate review of a state fair hearing decision to a federal entity (at state option and only with the federal entity's consent) in order to keep the unified appeal together. This is the approach in the New York FIDA demonstration, where the Medicare Appeals Council can review Medicaid aspects of a FIDA decision. Such an approach may be technically feasible, but we seek input regarding the advantages and disadvantages of such a delegation.

• *Specificity of rulemaking:* Depending on the resolution of these issues in developing a unified post-plan appeals process, additional federal rulemaking is likely to be necessary to amend or create exceptions to the current MA requirements for IRE review and the governmental administrative appeals process (see §§ 422.592 through 422.619). In addition to statutory requirements for rulemaking (for example, the Administrative Procedure Act and

section 1871 of the Act), it would also be necessary to ensure that all stakeholders have an opportunity to review and comment on the proposal. However, establishing a specific process in federal regulation constrains our ability to accommodate state-specific flexibility. Some flexibility is possible: for example, timelines for review by an independent entity are not established by Medicare regulation. Timelines for a unified independent review and fair hearing could therefore also vary by state to reflect state-specific fair hearing rules. But any substantial variation that affected appeal rights for MA (specifically D-SNP) enrollees might be subject to additional federal rulemaking. For example, a model that would limit unified post-plan appeals to only certain benefits (for example, services like home health and durable medical equipment where Medicare and Medicaid have differing coverage rules), would be subject to additional rulemaking. We seek comment regarding what aspects of a unified post-plan appeals process would necessitate state-specific flexibility, including discussion of whether any of those aspects would implicate rights under MA statute or would otherwise necessitate additional federal rulemaking.

In summary, we believe that establishment of a unified post-plan appeals process may be feasible in the future if we can address these issues, and we believe that such a process could offer benefits to beneficiaries, plans, states, and the federal government. We welcome feedback from all stakeholders on the issues raised earlier, as well as any others pertaining to a post-plan appeals process.

(11) Conforming Changes to Medicare Managed Care Regulations and Medicaid Fair Hearing Regulations (§ 422.562, § 422.566, § 438.210, § 438.400, and § 438.402)

We propose a number of changes to Medicaid managed care, Medicaid fair hearing, and Medicaid single state agency regulations to conform with our proposed unified grievance and appeals provisions. Following is a summary of these proposed changes.

• In § 422.562(a)(1)(i) and (b), we propose to add cross references to the proposed integrated grievance and appeals regulations along with new text describing how the provisions proposed in this rule for applicable integrated plans would apply in place of existing regulations.

• In § 422.566, we propose to add additional language to paragraph (a) to establish that the procedures we propose in this rule governing integrated organization determinations and integrated reconsiderations at proposed § 422.629 through § 422.634 apply to applicable integrated plans in lieu of the procedures at §§ 422.568, 422.570, and 422.572.

• In § 438.210(c) and (d), we propose to add cross references to the proposed integrated grievance and appeals regulations along with new text describing how the provisions proposed in this rule for applicable integrated plans would apply in place of existing regulations to determinations affecting dually eligible individuals who are also enrolled in a D-SNP with exclusively aligned enrollment, as those terms are defined in § 422.2. In § 438.210(f), we propose to make these Medicaid changes applicable to applicable integrated plans no later than January 1, 2021, but, consistent with our discussion earlier on the effective dates of our proposed unified appeals and grievance procedures overall, we would not preclude states from applying them sooner.

• In § 438.400, we propose adding a new paragraph (a)(4) to include the statutory basis for the proposed integration regulations (section 1859(f)(8) of the Act). We also propose to amend § 438.400(c) to clarify that these Medicaid changes apply to applicable integrated plans

no later than January 1, 2021, but, consistent with our discussion earlier on the effective dates of this rule overall, we would not preclude states from applying them sooner.

• In §438.402, we propose amending paragraph (a) to allow a Medicaid managed care plan operating as part of an applicable integrated plan to the grievance and appeal requirements laid out in §§ 422.629 through 422.634 in lieu of the normally applicable Medicaid managed care requirements.

3. Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§ 423.153)

a. Background

This proposed rule sets forth the manner in which CMS proposes to implement section 50354 of the Bipartisan Budget Act of 2018 (BBA), Pub. L. 115-123, enacted on February 9, 2018. Section 50354 amends section 1860D-4(c) of the Social Security Act by adding a new paragraph (6) entitled *"Providing Prescription Drug Plans with Parts A and B Claims Data to Promote the Appropriate Use of Medications and Improve Health Outcomes"*. Specifically, section 1860D–4(c)(6)(A), as added by section 50354 of the BBA, provides that the Secretary shall establish a process under which the sponsor of a Prescription Drug Plan (PDP) that provides prescription drug benefits under Medicare Part D may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format standardized extracts of Medicare claims data about its plan enrollees. Such extracts would contain a subset of Medicare Parts A and B claims data as determined by the Secretary. In defining the specific data elements and time frames for the Parts A and B claims data included in such extracts, hereinafter referred to as "Medicare claims data," the Secretary is instructed, at section 1860D-(4)(c)(6)(D) of the Social Security Act, to include data "as current as practicable."

Section 1860D-4(c)(6)(B), as added by section 50354 of the BBA, further specifies that PDP sponsors receiving such Medicare claims data for their corresponding PDP plan enrollees may use the data for: (i) optimizing therapeutic outcomes through improved medication use; (ii) improving care coordination so as to prevent adverse healthcare outcomes, such as preventable emergency department visits and hospital readmissions; and (iii) for any other purposes determined appropriate by the Secretary. Finally, section 1860D-4(c)(6)(C) states that the PDP sponsor may not use the data: (i) to inform coverage determinations under Part D; (ii) to conduct retroactive reviews of medically accepted conditions; (iii) to facilitate enrollment changes to a different PDP or a MA-PD plan offered by the same parent organization; (iv) to inform marketing of benefits; and (v) for any other purpose the Secretary determines is necessary to include in order to protect the identity of individuals entitled to or enrolled in Medicare, and to protect the security of personal health information.

b. Provisions of the Proposed Rule

To implement the new statutory provision at section 1860D-4(c)(6), as added by section 50354 of the BBA, we propose to add a new paragraph (g) at § 423.153. Throughout this discussion of our proposed approach, we identify options and alternatives to the policies we propose. We strongly encourage comments on our proposed approach, as well as any alternatives.

c. Purposes and Limitations on the Use of Data

Section 1860D-4(c)(6)(B) of the Act expressly permits the use of Medicare claims data for two specified purposes: (1) to optimize therapeutic outcomes through improved medication use and (2) to improve care coordination so as to prevent adverse health outcomes. In addition,

section 1860D-4(c)(6)(B)(iii) provides that the Secretary can determine if there are other appropriate purposes for which the data may be used.

Therefore, consistent with the statute, we propose at §423.153(g)(3), that PDP sponsors would be permitted to use Medicare claims data to optimize therapeutic outcomes through improved medication use, and to improve care coordination so as to prevent adverse health outcomes. In addition, we propose to permit PDP sponsors to use Medicare claims data for the purposes described in the first or second paragraph of "health care operations" under 45 CFR 164.501, or that qualify as "fraud and abuse detection or compliance activities" under 45 CFR 164.506(c)(4). We also propose to permit disclosures that qualify as a "required by law" disclosure as defined at 45 CFR 164.103. We believe these uses should encompass the full range of activities for which the PDP sponsors will need Medicare claims data. However, we request comments on whether there are any additional purposes for which PDP sponsors should be permitted to use Medicare claims data provided under this subsection.

Section 1860D-4(c)(6)(C) of the Act places specific limitations on how Medicare claims data provided to the PDP sponsors may be used and also permits the Secretary to determine if any additional limitations should be imposed to protect the identity of individuals entitled to, or enrolled for, benefits under Medicare and to protect the security of personal health information. Therefore, consistent with these statutory limitations, at §423.153(g)(4), we propose that PDP sponsors must not use Medicare claims data provided by CMS under this subsection for any of the following purposes: (i) To inform coverage determinations under Part D; (ii) To conduct retroactive reviews of medically accepted indications determinations; (iii) To facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization; and/or (iv) to inform marketing of benefits.

Section 1860D-4(c)(6)(C)(v) of the Act provides that the Secretary may place additional limitations on the use of Medicare claims data as necessary to protect the identity of individuals entitled to, or enrolled for, benefits under Part D, and to protect the security of personal health information. CMS is committed to ensuring beneficiary-level data is protected by strict privacy and security requirements. Therefore, at §423.153(g)(4)(v), we also propose to require that the PDP sponsor contractually bind its Contractors that it anticipates giving access to Medicare claims data, and any other potential downstream data recipients, to the terms and conditions imposed on the PDP Sponsor under the proposed provision at § 423.153(g). In addition, we propose at §423.153(g)(4)(vi) that CMS may refuse to make future releases of Medicare claims data to the PDP sponsor if it makes a determination or has a reasonable belief that unauthorized uses, reuses, or disclosures have taken place.

We believe that PDP sponsors are business associates receiving Medicare claims data on behalf of the PDP, a health plan and HIPAA covered entity. We also believe that Medicare claims data provided to PDP sponsors under § 423.153(g) is protected health information (PHI). As a business associate, the PDP sponsor is required to comply with the HIPAA Rules, including Privacy, Security and Breach Notification requirements for PHI. Therefore, we do not propose any additional limitations on the PDP sponsors' use of the Medicare claims data. However, we request comments on whether there are any additional limitations that should be placed on Medicare claims data provided under §423.153(g). To ensure that the PDP sponsors understand the purposes for which the Medicare claims data may be used and the limitations on its use, we propose at §423.153(g)(5)) to require that, as a condition of receiving the requested data, the PDP sponsor must attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data in paragraphs (3) and (4) of § 423.153(g). We propose to require this

attestation as a means of ensuring an understanding of, and compliance with, the terms and conditions of data access. We believe that our proposal to require PDP sponsors to attest that they will comply with these requirements is necessary to ensure the protection of the identities of Medicare beneficiaries and the security of the Medicare claims data. We request comments on our proposal to require PDP sponsors to submit an attestation and on the specific requirements that should be included in that attestation.

d. Data Request

Section 1860D-4(c)(6)(A) of the Act provides that the Secretary shall establish a process under which a PDP sponsor of a prescription drug plan may submit a request for the Secretary to provide the sponsor with standardized extracts of Medicare claims data for its enrollees. Therefore, we propose at §423.153(g)(1) to establish a process by which a PDP sponsor may submit a request to CMS to receive standardized extracts of Medicare claims data for its enrollees. We propose to accept data requests on an ongoing basis beginning January 1, 2020. We propose to require that such data requests must be submitted in a form and manner specified by CMS. Consistent with the discretion accorded to the Secretary under section 1860D-4(c)(6)(D) of the Act, we propose not to allow PDP sponsors to request data for subsets of their enrolled beneficiary populations. We propose allowing requests to be submitted without an end date, such that the request, once reviewed for completeness and approved, will remain in effect until one or more of the following occur: the PDP sponsor notifies CMS that it no longer wants to receive Medicare claims data, CMS cancels access to Medicare claims data when a PDP sponsor leaves the Part D program, or CMS concludes or has a reasonable belief, at its sole discretion, that the PDP sponsor has used, reused or disclosed the Medicare claims data in a manner that violates the requirements of section 1860D-4(c)(6) and § 425.153(g) of the Act.

Upon receipt of the request from the PDP sponsor and the PDP's execution of an attestation discussed earlier, and review for completeness and approval of the application by CMS or its contractor, we propose that the PDP sponsor would be provided access to Medicare claims data.. We note that access to Medicare claims data will be further subject to all other applicable laws, including, but not limited to, the part 2 regulations governing access to certain substance abuse records (42 CFR part 2).

d. Data Extract Content

To develop a proposed data set to include in the standardized extracts of Medicare claims data, we first considered what Medicare claims data PDP sponsors might require if they were to undertake the activities expressly permitted by section 1860D-4(c)(6)(B) of the Act. In doing so, we attempted to limit the data set to the minimum data that we believe PDP sponsors would need to carry out those statutory activities and the additional activities we are proposing to permit under § 423.153(g)(3). That is, we sought to establish data access limits that would comport with the HIPAA Privacy Rule's minimum necessary concept at 45 CFR 164.502(b) and 164.514(d), and CMS' policy-driven data release policies.

We believe that data from all seven claim types, including inpatient, outpatient, carrier, durable medical equipment, hospice, home health, and skilled nursing facility data, would be required to carry out the permitted uses of the data under section 1860D-4(c)(6)(B) and the proposed provision at § 423.153(g)(3). We believe that information on all Parts A and B services provided to a patient, as well as the dates on which those services were furnished, would provide a more complete picture of a patient's health care services and support care coordination and quality improvement activities. In addition, this claims information would provide insight into the services or procedures that resulted in a patient receiving a certain prescription drug, and the

particular care setting in which the drug was prescribed, which will assist PDP sponsors in promoting the appropriate use of medication and improving health outcomes for their enrollees.

We also considered the types of data elements that other entities request when they ask for data to conduct care coordination and quality improvement work. For example, we looked at the data elements requested by entities participating in the CMS Oncology Care Model (OCM). OCM aims to provide higher quality, more highly coordinated oncology care at the same or lower cost to Medicare. Because Section 1860D-4(c)(6) focuses on providing Medicare claims data to promote the appropriate use of medications and improve health outcomes, we propose to initially include the following Medicare Parts A and B claims data elements (fields) in the standardized extract: an enrollee identifier, diagnosis and procedure codes (for example, ICD-10 diagnosis and Healthcare Common Procedure Coding System (HCPCS) codes); dates of service; place of service; provider numbers (for example, NPI); and claim processing and linking identifiers/codes (for example, claim ID, and claim type code). CMS will continue to evaluate the data elements provided to PDP sponsors to determine if data elements should be added or removed based on the information needed to carry out the permitted uses of the data. In making decisions about adding data elements to the standardized extracts, CMS will consider whether the additional data elements support the purposes for which the data can be used. Any proposed changes would be established through rulemaking.

We next considered the beneficiary population for which we should draw the identified data elements, and what time span of data would best serve PDP sponsors while honoring the requirement at section 1860D-4(c)(6)(D) of the Act that the data should be as current as practicable. Taking into account the purpose for which Medicare claims data is being provided, namely to support the appropriate use of medications and improve health outcomes, we believe

that only the most current data is relevant. Therefore, because only the most timely data is needed for care coordination purposes, we propose at §423.153(g)(2) to draw the standardized extracts of Medicare claims data for items and services furnished under Medicare Parts A and B to beneficiaries who are enrolled in a Part D plan offered by the Part D sponsor at the time of the disclosure. We anticipate that Medicare claims data would be provided at least quarterly with approximately a 3 month lag from the last day of the last month of the prior quarter. In addition, we anticipate it can take up to two months to process and ship the data extracts from the date the quarterly data is available. Therefore, we propose that the first standardized data extract would be available to PDP sponsors no earlier than August 15, 2020, which would include, at a minimum, data for the period beginning January 1, 2020, and ending on March 1, 2020. In addition, given the permitted uses of the data, we propose to use a standard format to deliver the resulting data to each PDP sponsor with standard format extracts, meaning that CMS would not customize the extracts for a PDP sponsor. We propose to make these standardized data extracts available to eligible PDP sponsors at least quarterly, as described earlier, but only on a specified release date that would be applicable to all eligible PDP Sponsors. That is, we propose that newly eligible PDP sponsors would not have an opportunity to request standardized data extracts generated retroactively after the passing of the release date for a given release. Therefore, if a PDP sponsor submits a request, is approved to receive data, and executes its attestation after the release of a set of data extracts (for example, after the release date for Quarter 1 2020), we anticipate that the newly eligible PDP Sponsor would not receive data until the next standardized data extract is available (for example, the release date for Quarter 2 of 2020).

We believe that these standardized data extracts would provide PDP sponsors with the minimum data necessary to carry out the permitted uses specified in section 1860D-4(c)(6)(B) of

the Act and as proposed at §423.153 (g)(3). We seek comments about the proposed frequency and contents of the standardized data extracts.

B. Improving Program Quality and Accessibility

1. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i)(1) and 423.186(i)(1))

a. Introduction

Earlier this year, in the April 2018 final rule, CMS codified at §§ 422.160, 422.162, 422.164, and 422.166 (83 FR 16725 through 83 FR 16731) and §§ 423.180, 423.182, 423.184, and 423.186 (83 FR 16743 through 83 FR 16749) the methodology for the Star Ratings system for the MA and Part D programs, respectively. This was part of the Administration's effort to increase transparency and advance notice regarding enhancements to the Part C and D Star Ratings program. Going forward CMS must propose through rulemaking any changes to the methodology for calculating the ratings, the addition of new measures, and substantive measure changes. The April 2018 final rule included mechanisms for the removal of measures for specific reasons (low statistical reliability and when the clinical guidelines associated with the specifications of measures change such that the specifications are no longer believed to align with positive health outcomes) but, generally, removal of a measure for other reasons would also occur through rulemaking.

Commenters to last year's Notice of Proposed Rulemaking (NPRM) expressed overall support for the use of the hierarchical clustering algorithm which is the methodology used for determining the non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measure-specific cut points. The cut points are used to separate a measure-specific distribution of scores into distinct, non-overlapping groups, or star categories. However, the

majority of commenters also recommended some enhancements be made to the proposed clustering methodology to capture the attributes that they consider important. Commenters expressed a strong preference for cut points that are stable, predictable, and free from undue influence of outliers. Further, some commenters expressed a preference for caps to limit the amount of movement in cut points from year to year. CMS did not finalize any changes in last year's rule to the clustering algorithm for the determination of the non-CAHPS cut points for the conversion of measure scores to measure-level Star Ratings to allow the necessary time to simulate and examine the feasibility and impact of the suggestions provided in response to the proposed rule. In addition, CMS evaluated the degree to which the simulations captured the desired attributes identified by the commenters.

At this time, we are proposing enhancements to the cut point methodology for non-CAHPS measures. We are also proposing substantive updates to the specifications for 2 measures for the 2022 Star Ratings and substantive updates to the specifications for 1 measure for the 2023 Star Ratings. We are also proposing rules for calculating Star Ratings in the case of extreme and uncontrollable circumstances. Unless otherwise stated, data would be collected and performance would be measured as described in these proposed rules and regulations for the 2020 measurement period; the associated quality Star Ratings would be released prior to the annual election period held in late 2021 for the 2022 contract year and would be used to assign Quality Bonus Payment ratings for the 2023 payment year. Because of the timing of the release and use in conjunction with the annual coordinated election period, these would be the "2022 Star Ratings."

b. Definitions

We propose to add the following definitions for the respective subparts in part 422 and part 423, in paragraph (a) of §§ 422.162 and 423.182, respectively. These proposed new definitions are relevant for our proposed policies and are used in that context.

- *Absolute percentage cap* is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.

- *Cut point cap* is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut point. A cut point cap can restrict upward movement, downward movement, or both.

- *Guardrail* is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.

- *Mean resampling* refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchical clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.

By leaving out one of the 10 groups for each run, 9 of the 10 groups which is 90 percent of the applicable measure scores are used for each run of the clustering algorithm.

- *Restricted range* is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outer fence outliers (first quartile - 3*Interquartile Range (IQR) and third quartile + 3*IQR).19

We propose to specify in the definition the criteria used to identify the values that correspond to the outer fences which are used to identify extreme outliers in the data. Outer fence outliers use established statistical criteria for the determination of the boundary values that correspond to the outer fences. The outer fences are the boundary values for an outer fence outlier such that any measure score that either exceeds the value of the upper outer fence (third quartile + 3*IQR) or that is less than the lower outer fence (first quartile - 3*IQR) is classified as an outer fence outlier and excluded from the determination of the value of the restricted range cap.

- *Restricted range cap* is a cap applied to non-CAHPS measures that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated using the prior year's measure score distribution.

We welcome comments on these definitions.

c. Measure-Level Star Ratings (§§ 422.166(a), 423.186(a))

At §§ 422.166(a) and 423.186(a) we codified the methodology for calculating Star Ratings at the measure level. The methodology for non-CAHPS measures employs a hierarchical clustering algorithm to identify the gaps that exist within the distribution of the measure-specific scores to create groups (clusters) that are then used to identify the cut points. The Star Ratings categories are designed such that the scores in the same Star

19 The first quartile is median of the lower half of the data, or in other words the value in the data once arranged in numerical order that divides the lower half into two equal parts. The third quartile is the median of the upper half of the data.

Ratings category are as similar as possible and the scores in different Star Ratings categories are as different as possible. The current methodology uses only data that correspond to the measurement period of the data used for the current Star Ratings program. The cut points, as implemented now, are responsive to changes in performances from one year to the next. Changes in the measure-level specific cut points across a Star Ratings year reflect lower or higher measure performance than the prior year, as well as shifts in the distribution of the scores.

In the April 2018 final rule, CMS detailed the goals of the Star Ratings program. The overarching goals of the Star Ratings program and the specific sub-goals of setting cut points serve as the rationale for any proposed changes.

The Star Ratings display quality information on Medicare Plan Finder to help beneficiaries, families, and caregivers make informed choices by being able to consider a plan's quality, cost, and coverage; to provide information for public accountability; to incentivize quality improvement; to provide information to oversee and monitor quality; and to accurately measure and calculate scores and stars to reflect true performance. In addition, pursuant to section 1853(o) of the Act and the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes Final Rule (76 FR 21485 through 21489), the Star Ratings are also used to assign Quality Bonus Payments as provided in §422.558(d).

To separate a distribution of measure scores into distinct groups or star categories, a set of values must be identified to separate one group from another group. The set of values that break the distribution of the scores into non-overlapping groups is referred to as a set of cut points. The primary goal of any cut point methodology is to disaggregate the distribution of scores into discrete categories such that each grouping accurately reflects true performance.

The current MA Star Ratings methodology converts measure-specific scores to measure-level Star Ratings so as to categorize the most similar scores within the same measure-level Star Rating while maximizing the differences across measure-level Star Ratings. To best serve their purpose, the Star Ratings categories must capture meaningful differences in quality across the Star Ratings scale and minimize the risk of misclassification. For example, it would be considered a misclassification if a "true" 4-star contract were scored as a 3-star contract, or vice versa, or if nearly-identical contracts in different measure-level star categories were mistakenly identified. CMS currently employs hierarchical clustering to identify the cut points for non-CAHPS measures to ensure that the measure-level Star Ratings accurately reflect true performance and provide a signal of quality and performance on Medicare Plan Finder to empower beneficiaries, families, and caregivers to make informed choices about plans that would best align with their priorities.

We solicited comments regarding the approach to convert non-CAHPS measure scores to measure-level Star Ratings (82 FR 56397 through 56399). We requested stakeholders to provide input on the desirable attributes of cut points and recommendations to achieve the suggested characteristics. In addition, we requested that commenters either suggest alternative cut point methodologies or provide feedback on several options detailed in the regulation such as setting the cut points by using a moving average, using the mean of the 2 or 3 most recent years of data, or restricting the size of the change in the cut points from 1 year to the next.

The commenters identified several desirable attributes for the cut points that included stability, predictability, attenuation of the influence of outliers, restricted movement of the cut points from 1 year to the next, and either pre-announced cut points before the plan preview

period or pre-determined cut points before the start of the measurement period. In the April 2018 final rule (83 FR 16567), we expressed appreciation for our stakeholders' feedback and stated our intent to use it to guide the development of an enhanced methodology. So as not to implement a methodology that may inordinately increase the risk of misclassification, CMS has analyzed and simulated alternative options to assess the impact of any enhancements on the Star Ratings program and assess the degree to which the alternative methodology captures the desirable attributes that were identified by stakeholders. While CMS balances the request of stakeholders to increase predictability and stability of the cut points from year to year, the goals of the Star Ratings program, the integrity of the methodology, and the intent of the cut point methodology remain the same. The intent of the cut point methodology is still to accurately measure true performance. We intend our proposal to serve these goals and solicit comment on whether we have met our objective in this respect.

A Technical Expert Panel (TEP), comprised of representatives across various stakeholder groups, convened on May 31, 2018 to provide feedback to CMS's Star Ratings contractor (currently RAND Corporation) on the Star Ratings framework, topic areas, methodology, and operational measures. Information about the current members of the TEP can be found at https://www.rand.org/content/dam/rand/pubs/conf_proceedings/CF300/CF391/RAND_CF391.members.pdf. One topic discussed was possible enhancements to the clustering methodology used to convert non-CAHPS measure scores to measure-level Star Ratings. The TEP provided input on the importance of the cut point attributes of predictability and stability. To increase the level of predictability, several TEP members discussed the use of caps. Further, the TEP suggested that the influence of outliers should be addressed in the methodology. While some TEP members spoke to the utility of pre-announced thresholds to allow contracts to make decisions,

other TEP members stated that there are real risks in doing so. After reviewing the data that would need to be employed for pre-announced cut points along with the measure score and cut point trends, TEP members were concerned about using older data to predict cut points. For example, high performers may stop their focus on particular measures if they knew in advance that they would receive a 5-star rating. Likewise, contracts whose measure performance would not reach high Star Ratings may stop working on achieving a goal perceived to be unattainable. Some of the TEP members requested that CMS, in addition to addressing outliers, establish guardrails so cut points do not fluctuate too much from year to year. Additional information about the TEP can be found at http://www.rand.org/star-ratings-analyses.

CMS has examined numerous alternative methodologies to minimize the influence of outliers, to restrict the upward or downward movement of cut points from one year to the next, and to simulate prediction models to allow either limited advance notice or full advance notice of cut points prior to the measurement period. As part of our analyses, we have analyzed trends in performance across the Star Ratings measures. The ability to announce cut points before (full advance notice) or during (partial advance notice) the measurement period requires the use of modeling and older data to project the cut points, as well as the need for an alternative methodology for new measures introduced to the Star Ratings program. Modeling is challenging given differences in the performance trends over time across the Star Ratings measures, thus a single approach for predicting all future performance does not accurately reflect performance for all measures.

Using prediction models to establish future cut points may have unintended consequences and misalign with the underlying goals of the Star Ratings program and sub-goals of setting cut points. Predicting future cut points using older data can lead to both over or under-estimations of

performance which results in a distorted signal of the Star Ratings. Over projections in the cut points will result in higher cut points and lower measure-level Star Ratings. Conversely, under projections can lead to lower cut points and higher measure-level Star Ratings. The risk of misclassification is heightened when the accuracy of the projected cut points is diminished. The use of older data for setting cut points does not allow the Star Ratings to be responsive to changes in performance in the current year. Furthermore, setting cut points in advance of the measurement year may lead to MA organizations and Part D sponsors not focusing on certain areas once they achieve a set threshold, eliminating incentives for improvement.

For example, CMS provided incentives for eligible providers to adopt certified Electronic Health Records (EHRs) and report quality measures under the Meaningful Use (MU) initiative. There were large gains in performance for a subset of Star Ratings measures that were enabled through the EHR, a structural change among health care providers in the delivery of care. Further, an examination of performance over time of EHR-enabled measures indicates a decrease in variability of measure scores with contract performance converging toward greater uniformity. Modeling future performance using past performance would fail to capture the large gains in performance in the EHR-enabled measures, which would have resulted in cut points that were artificially low and measure-level Star Ratings that were higher than true performance.

Pre-announced cut points for other subsets of measures in the Star Ratings would present different challenges as compared to EHR-enabled measures. Performance on new measures typically has more room to improve, and large year-to-year gains are possible and desirable from a quality improvement perspective. Projecting cut points using older data from periods of rapid improvement would artificially inflate future cut points which would cause artificially low measure-level Star Ratings. Measures that demonstrate very slow, consistent growth over time

could have projected cut points that are artificially high. The further the projection is in advance of the measurement period, the larger the potential for unintended consequences. In addition, there exists the possibility of external factors, other than structural, that are unanticipated and unforeseen that could impact the distribution of scores for which modeling would not capture.

Some of the challenges of full or partial advance notice include all of the following:

- Older data often do not accurately reflect current performance.
- The trend in average performance is not always linear.
- External or structural factors may occur that can lead to substantial changes from period to period rather than steady slow year-over-year improvement.
- Larger gains in performance year to year exist for relatively new measures, compared to more established measures.
- The rate of change is less likely to be linear at lower threshold levels where contracts have greater opportunities for improvement.
- Decreasing variation in measure scores reflects greater improvements in performance for lower versus higher-performing contracts – contract performance is converging over time toward greater uniformity.

These challenges are critical to consider because if we modify the current methodology to predict (or set) cut points using older data and a single model across all measures, we risk causing unintended consequences such as significantly diminishing incentives for improvement or having the Star Ratings misaligned with changes in performance that may be due to external or structural factors.

Based on stakeholder feedback and analyses of the data, we propose two enhancements to the current hierarchical clustering methodology that is used to set cut points for non-CAHPS

measure stars in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i). The first proposed enhancement is mean resampling. With mean resampling, measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchical clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values. Mean resampling reduces the sensitivity of the clustering algorithm to outliers and reduces the random variation that contributes to fluctuations in cut points and, therefore, improves the stability of the cut points over time. Mean resampling uses the most recent year's data for the determination of the cut points; thus, it does not require assumptions for predicting cut points over time and it continues to provide incentives for improvement in measure scores. The drawback of mean resampling alone is that it does not restrict the movement of the cut points, so the attribute of predictability is not fully captured with this methodology.

To increase the predictability of the cut points, we also propose a second enhancement to the clustering algorithm: a guardrail for measures that have been in the Part C and D Star Ratings program for more than 3 years. The proposed guardrail of 5 percent would be a bi-directional cap that restricts movement both above and below the prior year's cut points. A 5 percent cap restricts the movement of a cut point by imposing a rule for the maximum allowable movement per measure threshold; thus, it allows a degree of predictability. The trade-off for the predictability provided by bi-directional caps is the inability to fully keep pace with changes in performance across the industry. While cut points that change less than the cap would be unbiased and keep pace with changes in the measure score trends, changes in overall performance that are greater than the cap would not be reflected in the new cut points. A cap on

upward movement may inflate the measure-level Star Ratings if true gains in performance improvements cannot be fully incorporated in the current year's ratings. Conversely, a cap on downward movement may decrease the measure-level Star Ratings since the ratings would not be adjusted fully for downward shifts in performance.

A measure-threshold-specific cap can be set multiple ways and the methodology may differ based on whether the measure is scored on a 0 to 100 scale or an alternative scale. For measures on a 0 to 100 scale, the cap can restrict the movement of the measure cut points from one year to the next by a fixed percentage, such as an absolute 5 percentage point cap. For measures not on a 0 to 100 scale, the cap can be determined for each measure by using a percentage of the measure's score distribution or a subset of the distribution, such as 5 percent of the range of the prior year scores without outer fence outliers, referred to as a restricted range cap. Alternatively, a restricted range cap can be used for all measures, regardless of scale, using a cap based on the range of the prior year scores without outliers. We propose an absolute 5 percentage point cap for all measures scored on a 0 to 100 scale and 5 percent of the restricted range for all measures not on a 0 to 100 scale, but we are also considering alternatives to the 5 percent cap, such as using 3 percent; we believe that any cap larger than 5 percent would not provide the predictability requested by stakeholders that we are trying to incorporate. While smaller caps provide more predictability, it is more likely that the cut points will not keep pace with changes in measure scores in the industry as the cap size gets smaller, and may require future larger one-time adjustments to reset the measure cut points. Therefore, we are not sure that a smaller cap, even at a 3 percent threshold, would meet our programmatic needs and goals of providing accurate pictures of the underlying performance of each contract and its comparison to other contracts. We are proposing 5 percent because the use of the cap allows predictability of

the cut points from year to year, but also balances the desire to continue to create incentives for contracts to focus on the quality of care of their enrollees and strive to improve performance. If the cut points are not keeping pace with the changes in the scores over time, CMS may need to propose in the future how to periodically adjust the cut points to account for significant changes in industry performance.

In summary, we propose to modify §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to add mean resampling to the current clustering algorithm to attenuate the effect of outliers, and measure-specific caps in both directions to provide guardrails so that the measure-threshold-specific cut points do not increase or decrease more than the cap from one year to the next. We propose a 5 percentage point absolute cap for measures on a 0 to 100 scale and a 5 percent restricted range cap ((0.05) * (maximum value – minimum value), where the maximum and minimum values are calculated using the prior year's measure score distributions excluding outer fence outliers). For any new measures that have been in the Part C and D Star Rating program for 3 years or less, we propose to use the hierarchal clustering methodology with mean resampling for the first 3 years in the program in order to not cap the initial increases in performance that are seen for new measures. We welcome comments on this proposal, including comments on the percentage used for the cap, whether the cap should be an absolute percentage difference for measures on a 0 to 100 scale, whether the cap should be a percent of the range of prior year scores without outliers for all measures or for the subset of measures not on a 0 to 100 scale, whether the cap should be in both the upward and downward directions, and alternative methods to account for outliers.

d. Updating Measures (§§ 422.164, 423.184)

In the April 2018 final rule (83 FR 16537), CMS stated that due to the regular updates and revisions made to measures, CMS would not codify a list of measures and specifications in regulation text; CMS adopted a final list of measures for the contract year 2019 measurement period and indicated how changes to that list – additions, updates, removals – would be done in the future, using the Advance Notice and Rate Announcement under section 1853(b) of the Act or rulemaking. The regulations at §§ 422.164 and 423.184 specify the criteria and procedure for adding, updating, and removing measures for the Star Ratings program. CMS lists the measures used for the Star Ratings each year in the Technical Notes or similar guidance document with publication of the Star Ratings. In this rule, CMS is proposing measure changes to the Star Ratings program for performance periods beginning on or after January 1, 2020 and performance periods beginning on or after January 1, 2021. For new measures and substantive updates to existing measures, as described at §§ 422.164(c) and (d)(2), and §§ 423.184(c) and (d)(2), CMS will initially announce and solicit comment through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act and subsequently propose these measures through rulemaking to be added to the Star Ratings program. Proposals here for substantive updates have been discussed in prior Call Letters (contract years 2018 and 2019). We will continue the process of announcing our intent with regard to measure updates in future Call Letters. Any measures with substantive updates must be on the display page for at least 2 years before use in the Star Ratings program. For new measures and measures with substantive updates, as described at §§ 422.166 (e)(2) and 423.186 (e)(2), the measure will receive a weight of 1 for the first year in the Star Ratings program. In the subsequent years, the measure will be assigned the weight associated with its category.

(1) Proposed Measure Updates

(a) Controlling High Blood Pressure (Part C)

Due to the release of new hypertension treatment guidelines from the American College of Cardiology and American Heart Association20, NCQA has implemented updates to the Controlling High Blood Pressure measure for HEDIS 2019. NCQA has revised the blood pressure target to <140/90 mmHg. NCQA has also made some structural changes to the measure that included allowing two outpatient encounters to identify the denominator and removing the medical record confirmation for hypertension, allowing the use of telehealth services for one of the outpatient encounters in the denominator, adding an administrative approach that utilizes CPT category II codes for the numerator, and allowing remote monitoring device readings for the numerator. Given the change to the blood pressure target and our rules for moving measures with substantive changes to the display page, this measure will be moved to the display page for the 2020 and 2021 Star Ratings. We propose to return this measure as a measure with substantive updates by the measure steward (NCQA) to the 2022 Star Ratings using data from the 2020 measurement year with, as required by § 422.164(d)(2) and § 422.166 (e)(2), a weight of 1 for the first year and a weight of 3 thereafter.

(b) MPF Price Accuracy (Part D)

Continued evaluation of sponsors' pricing data used by beneficiaries is important; therefore, we propose to make enhancements to the MPF Price Accuracy measure to better measure the reliability of a contract's MPF advertised prices. In accordance with

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20 See Whelton P.K., Carey R.M., Aronow W.S., et al. (2018). Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Journal of the American College of Cardiology. 71(19): e127-e248. Available at http://www.onlinejacc.org/content/71/19/e127?_ga=2.143510773.1362500146.1536262802-126396490.1536262802.

§ 423.184(d)(2), the substantively updated measure would be a display measure for 2020 and 2021 and we are proposing to use it in the 2022 Star Ratings in place of the existing MPF Price Accuracy measure, which will remain in the Star Ratings until that replacement under § 423.184(d)(2). The proposed update would measure the magnitude of difference, as well as the frequency of price differences. We propose to implement the following changes for this measure:

- Factor both how much and how often prescription drug event (PDE) prices exceeded the prices reflected on the MPF by calculating a contract's measure score as the mean of the contract's Price Accuracy and Claim Percentage scores, based on the indexes in this rule:

++ The Price Accuracy index compares point-of-sale PDE prices to plan-reported MPF prices and determines the magnitude of differences found. Using each PDE's date of service, the price displayed on MPF is compared to the PDE price. The Price Accuracy index is computed as: (Total amount that PDE is higher than MPF + Total PDE cost) / (Total PDE cost)

++ The Claim Percentage index measures the percentage of all PDEs that meet the inclusion criteria with a total PDE cost higher than total MPF cost to determine the frequency of differences found. The Claim Percentage index is computed as:
(Total number of claims where PDE is higher than MPF) / (Total number of claims)

++ The best possible Price Accuracy index is 1 and the best possible Claim Percentage index is 0. This indicates that a plan did not have PDE prices greater than MPF prices.

++ A contract's measure score is computed as:

--- Price Accuracy Score = 100 – ((Price Accuracy Index - 1) * 100)

--- Claim Percentage Score = (1 – Claim Percentage Index) * 100

--- Measure Score = (0.5 * Price Accuracy Score) + (0.5 * Claim Percentage Score)

- Increase the claims included in the measure:

++ Expand the days' supply of claims included from 30 days to include claims with fills of 28-34, 60-62, or 90-100 days.

++ Identify additional retail claims using the PDE-reported Pharmacy Service Type code. Claims for pharmacies that are listed as retail in the MPF Pharmacy Cost file and also have a pharmacy service type on the PDE of either Community/Retail or Managed Care Organization (MCO) will be included.

- Round a drug's MPF cost to 2 decimal places for comparison to its PDE cost. Post-rounding, the PDE cost must exceed the MPF cost by at least one cent ($0.01) in order to be counted towards the accuracy score (previously, a PDE cost which exceeded the MPF cost by $0.005 was counted). A contract may submit an MPF unit cost up to 5 digits, but PDE cost is always specified to 2 decimal places.

Under our proposed update, PDEs priced lower than the MPF display pricing will continue to be ignored and will not have an impact on the measure score or rating. Only price increases are counted in the numerator for this measure. We propose to add this updated measure to the 2022 Star Ratings based on the 2020 measurement year with a weight of 1.

(3) Plan All-Cause Readmissions (Part C)

NCQA is modifying the Plan All-Cause Readmissions measure for HEDIS 2020 (measurement year 2019). The measure assesses the percentage of hospital discharges resulting in unplanned readmissions within 30 days of discharge. The changes made by NCQA are: adding observation stays as hospital discharges and readmissions in the denominator and the numerator; and removing individuals with high frequency hospitalizations. These changes were implemented by the measure steward (NCQA) based on the rise in observation stays to ensure

the measure better reflects patient discharge and readmission volumes. Removing individuals with high frequency hospitalizations from the measure calculation allows the readmissions rates not to be skewed by this population. To date, CMS has only included the 65+ age group in the Plan All-Cause Readmissions measure. CMS is proposing to combine the 18-64 and 65+ age groups as the updated measure specifications are adopted and to use NCQA's new recommendation of 150 as the minimum denominator. Given the substantive nature of the proposed updates for this measure, it would be moved to display for the 2021 and 2022 Star Ratings under our proposal and § 422.164(d)(2). We propose to return this measure as a measure with substantive updates by the measure steward (NCQA) to the 2023 Star Ratings using data from the 2021 measurement year with, as required by § 422.164(d)(2) and § 422.166(e)(2), a weight of 1 for the first year and a weight of 3 thereafter.

(4) Improvement Measures (Parts C and D)

The process for identifying eligible measures to be included in the improvement measure scores is specified as a series of steps at §§ 422.164(f)(1) and 423.184(f)(1). As part of the first step, the measures eligible to be included in the Part C and D improvement measures are identified. Only measures that have a numeric score for each of the 2 years examined are included. We propose to add an additional rule at §§ 422.164(f)(1)(iv) and 423.184(f)(1)(iv) that would exclude any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s). The proposed new standard would ensure that the numeric scores for each of the 2 years are unbiased. If a measure's measure-level Star Rating receives a reduction for data integrity concerns in either of the 2 years, the measure would not be eligible to be included in the improvement measure(s) for that contract.

TABLE 1: PROPOSED ADDITIONS AND UPDATES TO INDIVIDUAL STAR RATING MEASURES

The measure descriptions listed in the tables are high-level summaries. The Star Ratings measure specifications supporting document, *Medicare Part C & D Star Ratings Technical Notes*, provides detailed specifications for each measure. Detailed specifications include, where appropriate, the identification of a measure's: 1) numerator, 2) denominator, 3) calculation, 4) time frame, 5) case-mix adjustment, and 6) exclusions. The Technical Notes document is updated annually. In addition, where appropriate, the Data Source descriptions listed in this table reference the technical manuals of the measure stewards. The annual Star Ratings are produced in the fall of the prior year to assist beneficiaries in choosing their health and drug plan during the annual open enrollment. For example, Star Ratings for the year 2022 are produced in the fall of 2021.

1. If a measurement period is listed as 'the calendar year 2 years prior to the Star Ratings year' and the Star Ratings year is 2022, the measurement period is referencing the January 1, 2020 to December 31, 2020 period.
2. For CAHPS, HOS, and HEDIS/HOS measures, the measurement period is listed as 'most recent data submitted for the survey of enrollees.' See measure stewards' technical manuals, as referenced in Data Source column, for the specific measurement periods of the most recent data submitted.

TABLE 1A: PROPOSED UDATES TO INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2020

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Ratings	Reporting Requirements (Contract Type)
Part C Measure								
Controlling Blood Pressure (CBP)	Percent of plan members 18-85 years of age who had a diagnosis of hypertension (HTN) and whose blood pressure was adequately controlled (<140/90).	Managing Chronic (Long Term) Conditions	Intermediate Outcome Measure Weight of 3	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0018	Clustering	MA-PD and MA-only
Part D Measure								
MPF Price Accuracy	A score comparing the prices members actually pay for their drugs to the drug prices the plan provided for the Medicare Plan Finder website.	Drug Safety and Accuracy of Drug Pricing	Process Measure Weight of 1	PDE data, MPF Pricing Files	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP

* NCQA HEDIS Technical Specifications, Volume 2

TABLE 1B: PROPOSED UPDATES TO INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2021

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Ratings	Reporting Requirements (Contract Type)
Part C Measure								
Plan All-Cause Readmissions (PCR)	Percent of acute inpatient stays that were followed by an unplanned acute readmission or an observation stay for any diagnosis within 30 days, for members ages 18 and over. Rates are risk-adjusted.	Managing Chronic (Long Term) Conditions	Intermediate Outcome Measure Weight of 3	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#1768	Clustering	MA-PD and MA-only, except for 1876 Cost Plans

* NCQA HEDIS Technical Specifications, Volume 2

(5) Data Integrity

At §§ 422.164(g)(1)(iii) and 423.184(g)(1)(ii), CMS codified a policy to make scaled reductions to the Star Ratings for a contract's Part C or Part D appeals measures because the relevant Independent Review Entity (IRE) data are not complete based on the Timeliness Monitoring Project (TMP) or audit information. The reduction is applied to the measure-level Star Ratings for the applicable appeals measures. We propose adding an additional regulatory provision at §§ 422.164(g)(1)(iii)(O) and 423.184(g)(1)(ii)(M) that would assign a 1-star rating to the applicable appeals measure(s) if a contract fails to submit TMP data for CMS's review to ensure the completeness of their IRE data. We believe it is appropriate to assume that there is an issue related to the performance when the MA organization or Part D plan sponsor has refused to provide information for the purposes of our oversight of the compliance with the appeals requirements. Our proposal to modify measure-specific ratings due to data integrity issues is separate from any CMS compliance or enforcement actions related to a sponsor's deficiencies; these rating reductions are necessary to avoid falsely assigning a high star to a contract, especially when the MA organization or Part D sponsor has refused to submit data for us to evaluate performance in this area and to ensure that the data submitted to the IRE are complete.

(6) Review of Sponsors' Data

At §§ 422.164(h)(1) and 423.184(h)(1), CMS proposes to codify a policy regarding the deadlines for an MA organization or Part D plan sponsor to request CMS or the IRE to review a contract's appeals or CMS to review a contract's Complaints Tracking Module (CTM) data. For example, information regarding the Part C and Part D appeals process is available to MA organizations and is updated daily on the IRE website. Additionally, sponsors can access the Part D Appeals Reports under the Performance Metrics pages in HPMS. To allow enough time for

the IRE to make any necessary changes to ensure the accuracy of a contract's measure score, we are proposing that requests for CMS or the IRE to review contract data must be received no later than June 30 of the following year in order to have time to use accurate information in the Star Ratings calculations (for example, changes to contract year 2018 appeals data must be made by June 30, 2019 for the 2020 Star Ratings). Reopenings are not taken into account under this proposed deadline for corrections to the IRE data. When the decision is evaluated for purposes of the appeals measures, if a reopening occurs and is decided prior to May 1, the revised determination is used in place of the original reconsidered determination. If the revised determination occurs on or after May 1, the original reconsidered determination is used.

Similarly, we propose that any requests for adjustments following CMS's CTM Standard Operating Procedures for the complaints measures be made by June 30 of the following year in order for the changes to be reflected in a contract's Star Ratings data (for example, changes to contract year 2018 complaints data must be made by June 30, 2019 for the 2020 Star Ratings).

e. Extreme and Uncontrollable Circumstances

Extreme and uncontrollable circumstances such as natural disasters can directly affect Medicare beneficiaries and providers, as well as the Parts C and D organizations that provide them with important medical care and prescription drug coverage. These circumstances may negatively affect the underlying operational and clinical systems that CMS relies on for accurate performance measurement in the Star Ratings program, all without fault on the part of the MA organization or Part D plan sponsor. We propose to adjust the Star Ratings to take into account the effects of extreme and uncontrollable circumstances that occurred during the performance or measurement period. CMS is also concerned that certain natural disasters and emergencies may interfere in plans' abilities to provide services for their enrollees. In this rule, we describe

proposed policies for identifying affected contracts and adjusting the Star Ratings measures. These policies are largely the same as those described in the 2019 final Call Letter, with the substantive exception of eliminating the difference-in-differences adjustment for survey data. The difference-in-differences adjustment showed no consistent, negative impact of extreme and uncontrollable circumstances on the 2019 Star Ratings; therefore, we are eliminating this adjustment to simplify the methodology for calculating Star Ratings in cases of extreme and uncontrollable circumstances. We propose to codify a series of special rules for calculation of the Star Ratings of certain contracts in certain extreme and uncontrollable circumstances in paragraph (i) of §§ 422.166 and 423.186.

We propose that the adjustments be tailored to the specific areas experiencing the extreme and uncontrollable circumstance in order to avoid over-adjustment or adjustments that are unnecessary. Health and drug plans can serve enrollees across large geographic areas, and thus they may not be impacted in the same manner as healthcare providers such as hospitals or medical centers in specific physical locations. To ensure that the Star Ratings adjustments focus on the specific geographic areas that experienced the greatest adverse effects from the extreme and uncontrollable circumstance and are not applied to areas sustaining little or no adverse effects, our proposal is to target the adjustments to specific contracts and to further specify and limit the adjustments.

(1) Identification of Affected Contracts

In paragraph (i)(1) of §§ 422.166 and 423.186, we propose to identify MA and Part D contracts affected by extreme and uncontrollable circumstances during the performance or measurement period that may have affected their performance on Star Ratings measures or their ability to collect the necessary measure-level data. These "affected contracts" would be the

contracts eligible for the adjustments specified in this proposed rule to take into account the effects of the extreme and uncontrollable circumstances. For an MA or Part D contract to be considered an affected contract under our proposal, the contract would need to meet all of the following criteria:

- The contract's service area is within an "emergency area" during an "emergency period" as defined in Section 1135(g) of the Act.
- The contract's service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).
- A certain minimum percentage (25 percent for measure star adjustments or 60 percent for exclusion from cut point and Reward Factor calculations) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

We propose to identify an area as having experienced extreme and uncontrollable circumstances if it is within an "emergency area" and "emergency period" as defined in section 1135(g) of the Act, and also is within a county, parish, U.S. territory or tribal government designated in a major disaster declaration under the Stafford Act, and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s) (https://www.phe.gov/emergency/news/healthactions/section1135/Pages/default.aspx). Major disaster areas are identified and can be located on FEMA's website at https://www.fema.gov/disasters. To ensure the policy is applied to those contracts most likely to have experienced the greatest adverse effects, we propose to narrow it to apply to contracts with a certain minimum percentage of enrollees residing in an area declared as an Individual

Assistance area because of the disaster declaration. Individual Assistance includes assistance to individuals and households, crisis counseling, disaster case management, disaster unemployment assistance, disaster legal services, and the disaster Supplemental Nutrition Assistance Program. We focus on enrollees residing in counties eligible for Individual Assistance because of a major disaster, because most Star Ratings measures are based on services provided directly to beneficiaries in their local area. Health and drug plans can serve enrollees across large geographic areas, and thus they may not be impacted in the same manner as healthcare providers such as hospitals or medical centers in specific physical locations. Therefore, we believe adjustments to the Star Ratings are most appropriately targeted to contracts serving beneficiaries who were eligible for individual and household assistance because of the disaster declaration.

For adjustments, at least 25 percent or 60 percent of the enrollees under the contract must reside in Individual Assistance areas identified because of the extreme and uncontrollable circumstances. This ensures that the adjustments are limited to contracts that we believe may have experienced a real impact from the extreme and uncontrollable circumstance in terms of operations or ability to serve enrollees. In calculations for the 2019 Star Ratings, we observed that contracts tend to have either very few enrollees impacted or most of their enrollees impacted due to the nature of contracts either covering a broad region or a localized area. If 1 out of 4 enrollees was impacted during the period of the year when the disaster hit, we believe there is a small chance that scores may have been impacted. The selection of the exclusion of numeric measures scores from contracts with 60 percent or more enrollees impacted from the determination of the cut points is conservative in case scores are impacted in contracts where a clear majority or all of the enrollees are impacted. Using the Individual Assistance major disaster declaration as a requirement for the extreme and uncontrollable event policy also ensures that the

policy applies only when the event is extreme, meriting the use of special adjustments to the Star Ratings.

We propose that contracts that do not meet the definition of an "affected contract" would not be eligible for any adjustments based on the occurrence of the extreme and uncontrollable circumstances. However, meeting the criteria to be an affected contract is not sufficient for all the adjustments we propose.

(2) CAHPS Adjustments

For CAHPS, we propose two different types of special rules for affected contracts: exemption from having to administer the CAHPS survey or adjustments to the Star Ratings on the CAHPS measures if the affected contract must administer the CAHPS survey. CAHPS measures are based on a survey conducted early in the year in which the Star Ratings are released that is, the year before the year to which the Star Ratings are applicable. For example, the CAHPS survey in early 2019 will be used for the 2020 Star Ratings, which are released in late 2019, before the annual coordinated election period for 2020.

We propose at §§ 422.166(i)(2)(i) and 423.186(i)(2)(i), that an MA and Prescription Drug Plan contract, even if it is an affected contract, must administer the CAHPS survey unless the contract demonstrates to CMS that the required sample for the CAHPS survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to a FEMA-designated disaster in the prior calendar year and requests and receives a CMS approved exception. We believe that displacement of a substantial number of the contract's enrollees would make it practically impossible to contact the required sample for the CAHPS survey. For an affected contract that receives the exemption from administering the CAHPS survey, we

propose at 422.166(i)(2)(iii) and 423.186(i)(2)(iii) that the affected contract would receive the prior year's CAHPS measure stars (and corresponding measure scores).

For other affected contracts, we propose an adjustment to the CAHPS scores and Star Ratings based on the administered survey and the percentage of enrollees in the affected contract that reside in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance. We propose that affected contracts with at least 25 percent of enrollees residing in Individual Assistance areas at the time of the extreme and uncontrollable circumstance would receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure (including the annual flu vaccine measure). For example, for the 2022 Star Ratings for affected contracts, we would take the higher of the 2021 Star Ratings or the 2022 Star Ratings for each CAHPS measure. The affected contract would receive the CAHPS measure score for the corresponding Star Rating year chosen. We propose the 25 percent threshold to avoid including contracts with very few enrollees impacted. The measure-level scores for contracts with very few enrollees impacted should not be adversely affected by these extreme and uncontrollable circumstances. If a small percentage of enrollees were impacted by an extreme and uncontrollable circumstance, it should not have a significant impact on measure scores.

(3) HOS Adjustments

For the HOS survey, we propose to follow similar procedures as CAHPS but due to the follow-up component of HOS, the adjustment would be to the Star Ratings for the year after the completion of the follow-up HOS survey that is administered 2 years after the baseline HOS survey. For example, the 2022 Star Ratings are based on data collected from April through June 2020 and reflect experiences over the past 12 months. The data collected in 2021 will be used

for the 2023 Star Ratings, so responses may reflect the impact of 2020 extreme and uncontrollable circumstances and thus, those circumstances may have an impact on the 2023 Star Ratings.

As described at proposed § 422.166(i)(3)(i), an MA contract, even if it is an affected contract, must administer the HOS surveys the year after the extreme and uncontrollable circumstance unless the contract demonstrates to CMS that the required sample cannot be contacted because a substantial number of the contract's enrollees are displaced due to a FEMA-designated disaster during the measurement period and requests and receives a CMS approved exception. For an affected contract that receives the exemption from administering the HOS survey, we propose at paragraph (i)(3)(iii) that the affected contract would receive the prior year's HOS and HEDIS-HOS measure stars (and corresponding measure scores).

We propose at § 422.166(i)(3)(iv) that the affected contracts with at least 25 percent of enrollees residing in Individual Assistance areas at the time of the extreme and uncontrollable circumstance would receive the higher of the previous year's Star Rating or current year's Star Rating for each HOS and HEDIS-HOS measure (and corresponding measure score) for the Star Ratings 3 years after the eligible extreme and uncontrollable circumstance. As an example, for the 2023 Star Ratings for contracts affected by an extreme and uncontrollable circumstance in 2020, we would take the higher of the 2022 or 2023 Star Ratings and corresponding measure score for each HOS and HEDIS-HOS measure.

(4) HEDIS Adjustments

For HEDIS, we propose that an MA contract, even if an affected contract, would be required to report HEDIS data to CMS unless the contract demonstrates to CMS an inability to obtain both administrative and medical record data required for HEDIS measures due to a

FEMA-designated disaster in the prior calendar year and requests and receives a CMS approved exception. All contracts in FEMA-designated disaster areas can work with NCQA to request modifications to the samples for measures that require medical record review. For affected contracts that have service areas with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, we propose to take the higher of the previous year's Star Rating or current year's Star Rating (and corresponding measure score) for each HEDIS measure. For example, for the 2022 Star Ratings for affected contracts we would take the higher of the 2021 or 2022 Star Ratings for each HEDIS measure.

(5) New Measure Adjustments

At proposed §§ 422.166(i)(5) and 423.186(i)(3), we propose to implement a hold harmless provision for *new* Star Ratings measures if the inclusion of all applicable new measure(s) brings down the summary and/or overall rating. That is, for affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, all the new measures would be excluded from the calculation of the summary and/or overall rating if their inclusion brings a contract's summary (or in the case of MA-PD contracts, the overall) rating down.

(6) Other Star Ratings Measure Adjustments

For all other measures for affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance (that occurs during the measurement or performance period), we propose to take the higher of the previous or current year's measure Star Rating (and then use the corresponding measure score), as described at proposed §§ 422.166(i)(6) and 423.186(i)(4). For example, for

the 2022 Star Ratings for affected contracts, we would take the higher of the 2021 or 2022 Star Ratings. We propose to exclude from this adjustment policy the Part C Call Center – Foreign Language Interpreter and TTY Availability and Part D Call Center – Foreign Language Interpreter and TTY Availability measures, except for extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study. These measures and the underlying performance are completely in the plan's control; we believe therefore that there should generally be no impact from the declaration of an extreme and uncontrollable circumstance on plan performance in these areas.

(7) Exclusion from Improvement Measures

Contracts must have data for at least half of the measures[21] used to calculate the Part C or Part D improvement measures to be eligible to receive a rating in each improvement measure. For affected contracts that revert back to the data underlying the previous year's Star Rating for a particular measure, we propose that measure would be excluded from both the count of measures (for the determination of whether the contract has at least half of the measures needed to calculate the relevant improvement measure) and the applicable improvement measures for the current and next year's Star Ratings as stated at proposed §§ 422.166(i)(7) and 423.186(i)(5). That is, we would follow our usual rule where to receive a Star Rating in the improvement measures, a contract must have measure scores for both years in at least half of the required measures used to calculate the Part C improvement or Part D improvement measures. The use of the data from the previous year's Star Ratings means that there is no measure score from the current year's Star Ratings, so the usual rule would eliminate the measure from consideration.

21 See §§ 422.164(f) and 423.184(f) for more information on Part C and Part D improvement measures.

As an example, for affected contracts that revert back to the 2021 Star Ratings data for a particular measure for the 2022 Star Ratings, we would exclude that measure from the count of measures and applicable improvement measures for the 2022 and 2023 Star Ratings.

(8) Missing Data

Except in cases where an exception was granted as described earlier, we propose that for all measures eligible for the extreme and uncontrollable circumstance adjustment, if an affected contract has missing data in either the current or previous year (for example, because of a biased rate or the contract is too new or too small), the final measure rating would come from the current year as described at proposed §§ 422.166(i)(8) and 423.186(i)(6). For example, if a contract affected by an eligible 2020 extreme and uncontrollable circumstance was not granted an exception for data collection and does not have sufficient data to receive a measure-level 2022 Star Rating, it would not receive a numeric rating for that measure for the 2022 Star Ratings regardless of whether it received a numeric rating in the previous year. Similarly, if an affected contract has missing measure data in the previous year but received a numeric rating in the current year, it would receive the current year's rating for its final measure rating. In both cases, the measure would be excluded from the contract's improvement score(s) following our usual rules.

(9) Cut Points for Non-CAHPS Measures

Currently, the Star Rating for each non-CAHPS measure is determined by applying a clustering algorithm to the measures' numeric value scores from all contracts required to submit the measure. The cut points are derived from this clustering algorithm. At proposed §§ 422.166(i)(9) and 423.186(i)(7), we propose to exclude from this clustering algorithm the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-

designated Individual Assistance area at the time of the extreme and uncontrollable circumstance. These contracts would be excluded to ensure that any impact of the extreme and uncontrollable circumstance on their measure-level scores would not have an impact on the cut points for other contracts. However, these cut points calculated for all other non-affected contracts would be used to assess these affected contracts' measure Star Ratings. We would compare the affected contract's previous year's measure Star Ratings to the current year's measure Star Ratings to determine which is higher, and therefore used for the affected contract's Star Ratings calculations, as previously discussed. For example, for the 2022 Star Ratings we would compare the 2021 and 2022 measure Star Ratings for affected contracts.

Reward Factor. Similarly, at proposed §§ 422.166(i)(10) and 423.186(i)(8), we propose that affected contracts with 60 percent or more of their enrollees impacted would also be excluded from the determination of the performance summary and variance thresholds for the Reward Factor. However, these contracts would still be eligible for the Reward Factor based on the mean and variance calculations of other contracts.

In conclusion, we are proposing a new set of rules regarding adjusting the calculation of Star Ratings for the Parts C and D organizations who are impacted by extreme and uncontrollable circumstances to be codified at paragraphs §§ 422.166(i) and 423.186(i).

2. Improving Clarity of the Exceptions Timeframes for Part D Drugs (§§ 423.568, 423.570, and 423.572)

In this proposed rule we are proposing a change to Part D adjudication timeframes related to exception requests in cases where a prescribing physician's or other prescriber's supporting statement has not been received by the plan sponsor. We are proposing to limit the amount of time an exception request can be held open in a pending status while the Part D plan sponsor

attempts to obtain the prescribing physician's or other prescriber's supporting statement. Section 1860D-4(g)(2) of the Act prescribes that in the case of a drug plan that provides for tiered cost-sharing for drugs on a formulary and provides for lower cost-sharing for preferred drugs on a formulary, a Part D enrollee may request an exception to the tiered cost-sharing. Under such an exception, a non-preferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the enrollee or would have adverse effects or both. Part D plan sponsors are required to have an exceptions process consistent with guidelines established by the Secretary. These guidelines are set forth at § 423.578 and permit an enrollee to request an exception to a plan's tiered cost-sharing, an exception for an off-formulary drug, and an exception to a utilization management requirement. Given the language in section 1860D-4(g)(2) of the Act referencing the determination of the prescribing physician that the preferred drug for treating the enrollee's condition would not be as effective, would have adverse effects, or both, the prescriber's supporting statement is a key component to the regulations governing the exceptions process. A plan sponsor's exceptions criteria must include a description of the criteria the plan sponsor uses to evaluate the prescribing physician's or other prescriber's statement. Due to the importance of the prescriber's supporting statement in the exceptions process, the adjudication timeframes for a coverage determination that involves an exception request do not begin until the prescribing physician's or other prescriber's supporting statement is received by the Part D plan. For example, § 423.568(b) states the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exception request, the physician's or

other prescriber's supporting statement. Under current guidance, plans are instructed not to keep an exception request open indefinitely and are instructed to apply a reasonableness standard for holding the request open pending receipt of the prescriber's supporting statement. Chapter 18 of the Medicare Prescription Drug Manual instructs that if the plan does not receive the physician's or other prescriber's supporting statement within a reasonable period of time, the plan should make its determination based on whatever evidence exists.

We have received feedback from plan sponsors and other stakeholders that there should be more certainty in the timeframe applied to the exceptions process. We are seeking to balance the importance of the plan receiving the prescriber's supporting statement so that a thorough decision may be made on the request and having a standard maximum time for notifying an enrollee of an exception request decision. We believe greater certainty in the exceptions process will be beneficial to enrollees and plans. Establishing a fixed period in which the plan must render a decision on an exception request may also have the effect of more timely submission of supporting statements by prescribers once they become familiar with the fixed timeframe in which plans must issue a decision on an exception request. To that end, we are proposing to amend §§ 423.568(b), 423.570(d)(1) and 423.572(a) to state that, for an exception request, the plan must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 72 hours (or 24 hours in the case of an expedited decision) of receipt of the prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first. Consistent with existing regulations, the plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision on an exception request no later than 72 hours (or 24 hours in the case of an expedited decision) after receiving the prescriber's supporting statement. We are not proposing a

change to the existing timeframes for issuing decisions, except that we are proposing an outside limit to the timeframe to address instances in which a prescriber's supporting statement is not timely received. The proposed change limits the timeframe for notifying the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of the decision to no later than 14 calendar days following receipt of the request. In other words, in cases where the plan does not receive a prescriber supporting statement (or does not receive it timely) it must notify the enrollee (and prescriber, as appropriate) of its decision no later than 14 calendar days from the receipt of the request. For example, if the plan sponsor receives the prescriber's supporting statement late in the adjudication time period (for example, on the 12th day), the plan sponsor would still be required to notify the enrollee of its decision no later than 14 calendar days from the receipt of the request. We understand that a supporting statement that is received late in the adjudication time period may mean the plan sponsor has less time to conduct its review, but we believe this circumstance is mitigated by the value in having greater certainty in the process by establishing a maximum timeframe for notifying the enrollee of the plan sponsor's decision. If the plan sponsor does not have clinical support to approve the exception request, the plan will issue the standardized denial notice and explain in specificity the reason for the denial, the documentation needed to approve coverage of the requested drug, and the enrollee's right to request an appeal. We believe this proposed approach affords the plan sponsor a reasonable period of time to obtain the prescriber's supporting statement while establishing greater certainty in the time period in which the enrollee will receive a decision on an exception request. If the enrollee is dissatisfied with the decision, the enrollee has the right to request an appeal. We invite comments on this proposal.

C. Clarifying Program Integrity Policies

1. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE

a. Background

In the April 2018 final rule, we removed several requirements pertaining to MA and Part D provider and prescriber enrollment. One requirement, outlined in § 423.120(c)(6), stated that for a prescription to be eligible for coverage under the Medicare Part D program, the prescriber must have: (1) an approved enrollment record in the Medicare fee-for-service program; or (2) a valid opt-out affidavit on file with a Part A/Part B Medicare Administrative Contractor (A/B MAC). A second requirement, outlined in § 422.222, stated that providers that furnish health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization must be enrolled in Medicare and be in an approved status no later than January 1, 2019. (The removal of these requirements had been proposed in a proposed rule that appeared in the **Federal Register** on November 28, 2017, titled "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program" (82 FR 56336) (hereafter referred to as the November 2017 proposed rule)).

The overall purpose of Medicare provider enrollment is to prevent fraud, waste, and abuse, and to protect Medicare beneficiaries, by allowing CMS to carefully screen all providers and suppliers (especially those that potentially pose an elevated risk to Medicare) to confirm that they are qualified to furnish, order, certify, refer, or prescribe Medicare items, services, or drugs. The previously mentioned Part D and MA enrollment provisions would have supplemented our

longstanding requirements, outlined in 42 CFR part 424, subpart P that all providers and suppliers that furnish Part A or B Medicare items or services enroll in Medicare.

During our preparations to implement the Part D and MA enrollment provisions by the January 1, 2019 effective date, several provider organizations expressed concerns about our forthcoming requirements. Regarding Part D, stakeholders expressed concerns that (1) most prescribers pose no risk to the Medicare program, (2) certain types of physicians and eligible professionals prescribe Part D drugs only very infrequently, and (3) the burden to the prescriber community would outweigh the program integrity benefits of the Part D enrollment requirement. Regarding MA, some stakeholders were concerned about the burden of having to enroll in Medicare, particularly considering that health care providers in MA organization networks that would have to enroll in Medicare must also undergo credentialing by their respective health plans. While enrolling such prescribers and providers gives Medicare a greater degree of scrutiny in determining a prescriber's or provider's qualifications, we noted in the April 2018 final rule that the perceived burden associated with this process could cause some prescribers and providers not to enroll in Medicare, thus possibly leading to access to care issues if such providers left MA networks as a result. As of early 2018, approximately 420,000 Part D prescribers and 120,000 MA providers remained unenrolled in Medicare.

Given these concerns, we stated in the April 2018 final rule our belief that the best means of reducing the burden of the Part D and MA enrollment requirements without compromising our payment safeguard objectives would be to focus on prescribers and providers that pose an elevated risk to Medicare beneficiaries and the Trust Funds. That is, rather than require the enrollment of Part D prescribers and MA providers regardless of the level of risk they might pose, we would prohibit payment for Part D drugs and MA items or services that are, as

applicable, prescribed or furnished by demonstrably problematic prescribers and providers. Therefore, we established in the April 2018 final rule a policy under which: (1) such problematic parties would be placed on a "preclusion list"; and (2) payment for Part D drugs and MA services and items prescribed or furnished by these individuals and entities would be rejected or denied, as applicable.

For purposes of this proposed rule, the most pertinent policies we finalized in the April 16, 2018 rule included the following:

• In § 423.100 (for Part D) and § 422.2 (for MA), we stated that the term "preclusion list" means a CMS-compiled list of, as applicable, prescribers and providers that:

++ Meet all of the following requirements:

++ The individual or entity is currently revoked from the Medicare program under § 424.535.

++ The individual or entity is currently under a reenrollment bar under § 424.535(c).

++ CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:

-- The seriousness of the conduct underlying the individual's or entity's revocation.

-- The degree to which the individual's or entity's conduct could affect the integrity of the Part D or MA program.

-- Any other evidence that CMS deems relevant to its determination; or

++ Meet both of the following requirements:

++ The individual or entity has engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare.

++ CMS determines that underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:

-- The seriousness of the conduct underlying the individual's or entity's revocation.

-- The degree to which the individual's or entity's conduct could affect the integrity of the Part D or MA program.

-- Any other evidence that CMS deems relevant to its determination.

• We revised and added various provisions in 42 CFR part 498, subpart A, that permitted individuals and entities to appeal their inclusion on the preclusion list. Specifically:

++ We added a new paragraph (20) to § 498.3(b) stating that a CMS determination to include an individual or entity on the preclusion list constitutes an initial determination.

++ In § 498.5, we added a new paragraph (n) containing the following provisions:

-- In paragraph (n)(1), we stated that any individual or entity dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list may request a reconsideration in accordance with § 498.22(a).

-- In paragraph (n)(2), we stated that if CMS or the individual or entity under paragraph (n)(1) is dissatisfied with a reconsidered determination under paragraph (n)(1), or a revised reconsidered determination under § 498.30, CMS or the individual or entity is entitled to a hearing before an administrative law judge (ALJ).

-- In paragraph (n)(3), we stated that if CMS or the individual or entity under paragraph (n)(2) is dissatisfied with a hearing decision as described in paragraph (n)(2), CMS or the individual or entity may request review by the Departmental Appeals Board (DAB) and the individual or entity may seek judicial review of the DAB's decision.

• In § 423.120(c)(6)(v) (for Part D) and § 422.222(a)(2) (for MA), we stated that CMS would send written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice would contain the reason for said inclusion and would inform the individual or entity of their appeal rights. We further stated that the affected party could appeal their inclusion on the preclusion list in accordance with Part 498.

• We stated in § 423.120(c)(6)(iv)(A) that a Part D sponsor or its Pharmacy Benefit Manager (PBM) must not reject a pharmacy claim or request for reimbursement for a Part D drug unless the sponsor has provided the written notice to the beneficiary described in § 423.120(c)(6)(iv)(B). Under paragraph (iv)(B), the Part D sponsor or its PBM must:

++ Provide an advance written notice to any beneficiary who has received a prescription from a prescriber on the preclusion list as soon as possible but to ensure that the beneficiary receives the notice no later than 30 days after the publication of the most recent preclusion list; and

++ Ensure that reasonable efforts are made to notify the prescriber of a beneficiary who was sent a notice under paragraph (iv)(B).

• We stated in the preamble to the April 2018 final rule that individuals and entities would only be placed on the preclusion list upon exhausting their first level of appeal.

• In the preamble to the previously mentioned November 2017 proposed rule (82 FR 56446), we stated that if a beneficiary's access to a service, item, or drug is denied because of the application of the preclusion list to his or her prescriber or provider, the beneficiary would be permitted to appeal alleged errors in applying the preclusion list. However, in the April 2018 final rule (83 FR 16660), we stated that if payment is denied because the prescriber or provider is on the preclusion list, the beneficiary would not have the right to appeal.

• We stated in April 2018 final rule (83 FR 16642) that an unenrolled individual or entity would remain on the preclusion list for the same length of time as the reenrollment bar that we could have imposed on the individual or entity had they been enrolled in Medicare and then revoked.

In addition, we stated that the preclusion list provisions in the April 2018 final rule (83 FR 16440) were to become effective on January 1, 2019.

b. Proposed Changes

For reasons stated in this section III.C.1.b. of this proposed rule, we propose to make changes to several of the preclusion list policies outlined in the April 2018 final rule.

(1) Appeals Process for Individuals and Entities on the Preclusion List

Similar to individuals and entities that are placed on the preclusion list, providers and suppliers whose Medicare enrollment is revoked for one or more of the revocation reasons described in § 424.535 (for example, the provider submitted false information to Medicare, has engaged in abusive prescribing of Part D drugs, or is excluded by the Office of Inspector General (OIG)) may appeal such revocation under § 498.5(l). Under § 498.22(b)(3), the provider or supplier has 60 days from receipt of the notice of revocation from CMS or its contractor to request a reconsideration, which is considered the first level of appeal. CMS has 90 days to render its reconsideration decision and to notify the provider or supplier thereof.

As already mentioned, under § 423.100 (for Part D) and § 422.2 (for MA), an individual or entity may be placed on the preclusion list if their Medicare enrollment is revoked, the individual or entity is currently under a reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. Having stated in the April 2018 final rule (83 FR 16662) that individuals and entities

would only be placed on the preclusion list upon exhausting their first level of appeal, we are concerned that there could be a very lengthy delay before the individual or entity is actually placed on said list. This is because the individual or entity, under existing regulations, would be able to first appeal their revocation and, if unsuccessful, could next appeal their placement on the preclusion list because of the revocation. Consider the following example:

- A provider receives a revocation notice on March 1.
- The provider has until April 30 (or 60 days) to file a request for reconsideration.
- CMS has until July 29 (or 90 days) to render its reconsideration decision.
- CMS sends notice of its denial of the provider's reconsideration on July 29, at which point the revoked provider has until September 28 (or 60 days from the date of the notice) to now request a reconsideration of its inclusion on the preclusion list.
- The provider requests a reconsideration of its inclusion on the preclusion list on September 28.
- CMS has until December 27 (or 90 days) to render its reconsideration decision.
- CMS sends notice of its denial of the provider's reconsideration on December 27.
- With the first level of appeal completed, the provider is placed on the preclusion list.

The end result of this process is that it could take up to nearly 9 months before a provider is placed on the preclusion list, meaning that, for instance, a prescriber who was revoked for a felony conviction could continue to prescribe covered Part D drugs for an extended period before placement on the preclusion list results in a prohibition against payment by a Part C plan, Medicare cost plan, Part D plan, or PACE organization to the prescriber (for any health care services furnished) for the prescribed drug. This is inconsistent with the principal goal of the preclusion list, which is to prevent payment for Part D drugs or MA services or items prescribed

or furnished, as applicable, by problematic parties. Such a lengthy delay could place Medicare beneficiaries and the Trust Funds at risk.

We believe that an appropriate balance can be found between preserving a prescriber's or provider's appeal rights and ensuring that problematic parties are placed on the preclusion list as soon as feasible. To facilitate this objective, we propose several regulatory changes that would consolidate the revocation and preclusion list appeals processes so that they run concurrently, rather than consecutively. This means, in effect, that if a prescriber or provider is to be placed on the preclusion list in conjunction with a revocation under § 424.535, no more than 5 months would expire before the preclusion list inclusion occurs. Though we recognize that 5 months is not an inconsiderable length of time, it would be preferable to the previously referenced 9-month period while still ensuring that affected prescribers and providers have an opportunity to be heard.

The specific regulatory revisions we propose regarding this issue are as follows:

• In § 423.120(c)(6)(v), we propose to:

++ Consolidate the existing version of paragraph (v) into a revised § 423.120(c)(6)(v)(A).

++ Establish a new § 423.120(c)(6)(v)(B) stating that in situations where the prescriber's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535:

-- The notice described in paragraph (c)(6)(v)(A) must also include notice of the revocation, the reason(s) for the revocation, and a description of the prescriber's appeal rights concerning the revocation.

-- The appeals of the prescriber's inclusion on the preclusion list and the prescriber's revocation shall be filed jointly by the prescriber and, as applicable, considered jointly by CMS under 42 CFR part 498.

• In § 422.222(a)(2), we propose to do the following:

++ Move the existing version of this paragraph into a new § 422.222(a)(2)(i).

++ Establish a new § 422.222(a)(2)(ii) stating that in situations where the individual's or entity's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535:

-- The notice described in paragraph (a)(2)(i) must also include notice of the revocation, the reason(s) for the revocation, and a description of the individual's or entity's appeal rights concerning the revocation.

-- The appeals of the individual's or entity's inclusion on the preclusion list and the individual's or entity's revocation shall be filed jointly by the individual or entity and, as applicable, considered jointly by CMS under 42 CFR part 498.

• In § 498.5(n)(1), we propose to do the following:

++ Move the existing version of this paragraph to a new § 498.5(n)(1)(i).

++ Establish a new § 498.5(n)(1)(ii)(A) stating that in situations where the individual's or entity's inclusion on the preclusion list is based on a Medicare revocation under § 424.535 and the individual or entity receives contemporaneous notice of both actions, the individual or entity may request a joint reconsideration of both the preclusion list inclusion and the revocation in accordance with § 498.22(a).

++ Establish a new § 498.5(n)(1)(ii)(B) stating that the individual or entity may not submit separate reconsideration requests under paragraph (ii)(A) for inclusion on the preclusion list or a revocation if the individual or entity received contemporaneous notice of both actions.

We believe these changes would clarify our expectations and the program procedures concerning the filing of appeals when a party's placement on the preclusion list is based on a Medicare revocation. We also stress that our proposed appeals consolidation would not affect appeals of OIG exclusions, which are handled through a separate process outlined in the applicable OIG regulations.

(2) Timing of Addition to the Preclusion List

Although, as mentioned previously, we stated in the April 2018 final rule (83 FR 16662) that prescribers and providers would only be placed on the preclusion list upon exhausting their first level of appeal, we did not include this language in the regulatory text. We propose to do so in this proposed rule to reiterate our position on this important issue. We believe that fairness warrants that the affected prescriber or provider have an opportunity to be heard before being included on the preclusion list. Therefore, we propose in new § 423.120(c)(6)(v)(C)(*1*) (for Part D) and new § 422.222(a)(3)(i) (for MA) that, respectively, a prescriber or provider would only be included on the preclusion list after the expiration of either of the following:

• If the prescriber or provider does not file a reconsideration request under § 498.5(n)(1), the prescriber or provider will be added to the preclusion list upon the expiration of the 60-day period in which the prescriber or provider may request a reconsideration.

• If the prescriber or provider files a reconsideration request under § 498.5(n)(1), the prescriber or provider will be added to the preclusion list effective on the date on which CMS, if applicable, denies the prescriber's or provider's reconsideration. [22]

However, we also believe that an exception to these proposed policies is necessary for preclusion list inclusions that are based on an OIG exclusion. This is because section 1862(e) of the Act (42 U.S.C. 1395y(e)) is clear that no federal health care program payment may be made for any items or services furnished by an excluded individual or entity, or directed or prescribed by an excluded physician. We believe that a failure to add an excluded provider or prescriber to the preclusion list until the expiration of the applicable time periods in § 423.120(c)(6)(v)(C)(*1*) (for Part D) and § 422.222(a)(3)(i) (for MA) would be inconsistent with section 1862(e) of the Act. Accordingly, we propose in new § 423.120(c)(6)(v)(C)(*2*) (for Part D) and § 422.222(a)(3)(ii) (for MA) that an excluded prescriber or provider would be added to the preclusion list effective on the date of the exclusion.

(3) Effective Date

We propose that, with one exception, the preclusion list regulatory revisions and additions addressed in this proposed rule would become applicable to MA organizations (and cost plans and PACE organizations by virtue of cross-references in parts 417 and 460 to the MA part 422 regulation) and Part D plans on January 1, 2020. Considering the need to ensure that stakeholders have as much time as possible to prepare for these revisions and additions, we believe that a January 1, 2020 effective date is appropriate. However, we also propose that the effective date of our previously mentioned consolidated appeals provisions in

[22] In the April 2018 final rule, we adopted cross-references in 42 CFR Parts 417 and 460 to Part 422 so that our MA preclusion list provisions in that rule would also apply to, respectively, cost plans (Part 417) and PACE organizations (Part 460). Consistent with said cross-references, our MA preclusion list provisions in this proposed rule would similarly apply to cost plans and PACE organizations.

§§ 423.120(c)(6)(v), 422.222(a)(2), and § 498.5(n)(1) would be 60 days after their publication in a final rule. As discussed in section C.1.b.(1) above, it is important that problematic providers be placed on the preclusion list as soon as possible; for this reason, we believe it would be inconsistent with CMS' program integrity objectives to wait until January 1, 2020 to implement our consolidated appeals provisions. We also solicit public comments on whether some or all of our other proposed preclusion list provisions discussed in this section III.C.1. of this proposed rule should become effective and applicable beginning 60 days after the publication date of this proposed rule.

We note that the January 1, 2019 preclusion list effective date identified in the April 2018 final rule remains in place, and the preclusion list provisions finalized in that rule will continue to be implemented on January 1, 2019.

(4) Claim Denials and Beneficiary Notification

We stated in the April 2018 final rule (83 FR 16440) that, upon CMS' publication of the first preclusion list, once a prescriber or provider is added to such initial list after the completion of their first level of appeal, claims would not be impacted for a 90-day period thereafter (82 FR 16667). We explained that this 90-day period would include -- (1) a 30-day period for the plans and MA organizations to intake the preclusion list data; and (2) a 60-day period in which the plan or MA organization would (a) notify the beneficiary of the prescriber's or provider's preclusion and (b) work to transition the beneficiary to a new prescriber or provider. Once this 90-day period expires, claim denials would commence.

The purpose of this policy was to give Part D plans and MA organizations additional time immediately following the January 1, 2019 effective date to accustom themselves to the preclusion list process and file layout. We also believed that beneficiaries should be given

advance notice that, as applicable, certain Part D drugs and MA services and items they receive as patients of the precluded prescriber or provider would no longer be covered as of the expiration of the 90-day period. However, we emphasized that all subsequent updates to the preclusion list, that is, all updates after the release of the initial preclusion list---would not require the expiration of a 90-day period before claims were denied. There were two reasons for this. First, we did not believe that the plans and MA organizations would need the aforementioned 30-day period any longer, for they would have become better acclimated to the operational aspects of the preclusion list process. Second, since most of the parties included on the initial preclusion list would remain on it in subsequent updates and, accordingly, affected beneficiaries would already have received notice of their prescriber's or provider's appearance on the initial preclusion list, we did not believe that repeated, monthly notices to beneficiaries thereafter would be warranted. As such, for subsequent preclusion list updates, claim denials would begin effective upon the date the prescriber or provider was included on the preclusion list, which, as indicated previously, would be that specified in revised § 423.120(c)(6)(v) and new § 422.222(a)(3).

Upon further consideration, we are concerned that beneficiaries whose prescribers and providers are added to subsequent updates to the preclusion list would not receive any notice of those additions nor of the consequences of placement of such providers and prescribers on the preclusion list. This could greatly impede the ability of enrollees to obtain needed services, items, or drugs for an extended period of time; indeed, by the time a beneficiary learns of his or her prescriber's or provider's inclusion on the preclusion list (through, for instance, receipt of a claim denial) and he or she thereafter manages to find a new prescriber or provider, many months could elapse. We believe that such situations must be avoided and, to that end, that the

previously mentioned notification requirement and delayed denial of claims for the initial preclusion list should apply to each subsequent update as well. Accordingly, we propose that claim denials for preclusion list updates, beginning in 2020, would occur consistent with the following timeframes listed below (although we would recommend that plans implement these timeframes for any updates to the preclusion list posted in 2019 subsequent to the initial preclusion list):

- Upon the posting of the updated preclusion list, the Part D sponsor or MA organization would be required to send notice to the beneficiary that his or her prescriber or provider has been added to preclusion list within 30 days of the posting of the updated preclusion list. We believe a 30-day period is necessary to allow the plans to carefully review the preclusion list updates to identify new or removed prescribers or providers, make any applicable operational adjustments, and send notices to beneficiaries whose prescribers or providers are now on the preclusion list.
- Beginning 60 days after sending the beneficiary notice(s) described in the previous paragraph, the plan sponsor or MA organization would deny the prescriber's or provider's prescriptions or claims. This 60-day period would give beneficiaries time to locate another prescriber or provider from whom they can receive Part D prescriptions or MA services and items.

With these timeframes, therefore, a total period of 60 to 90 days (depending chiefly on when the beneficiary notification is sent) would elapse between the date on which the preclusion list update is posted and the date on which claims denials would begin. We recognize that applying this 60- to 90-day period to subsequent updates (rather than exclusively to the initially posted list) could result in a precluded prescriber or provider being permitted to continue treating Part D and MA beneficiaries for several months without their Part D prescriptions or MA claims

being denied. However, we believe that the prevention of potentially serious dangers to the health and safety of Medicare beneficiaries that could ensue if they are without crucial medications for an extended period must take precedence.

Although, as already mentioned, we discussed the delayed claim denial period in the April 2018 final rule (83 FR 16441), we did not incorporate this policy into the regulatory text. Further, while § 423.120(c)(6) contains certain provisions regarding preclusion list beneficiary notification, there are no such concomitant provisions for MA in § 422.222. Thus, we propose to make the following revisions and additions, as applicable, to § 423.120(c)(6) and § 422.222 in this proposed rule in order to incorporate our beneficiary notification proposals:

• Section 422.222 would be revised as follows:

++ Existing paragraph (a)(1) would be moved to a new paragraph (a)(1)(i) that would state: "Except as provided in paragraph (a)(1)(ii) of this section, an MA organization must not make payment for a health care item or service furnished by an individual or entity that is included on the preclusion list, defined in § 422.2."

++ New paragraph (a)(1)(ii) would state: "With respect to MA providers that have been added to an updated preclusion list, the MA organization must do all of the following:"

++ New paragraph (a)(1)(ii)(A) would state: "No later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received an MA service or item from the individual or entity added to the preclusion list in this update."

++ New paragraph (a)(1)(ii)(B) would state: "Must ensure that reasonable efforts are made to notify the individual or entity described in paragraph (a)(1)(ii) of this section of a beneficiary who was sent a notice under paragraph (a)(1)(ii)(A) of this section; and"

++ New paragraph (a)(1)(ii)(C) would state: "Must not deny payment for a service or item furnished by the newly added individual or entity , solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (a)(1)(ii)(A) of this section."

Under the MA regulation at 42 CFR 422.224, MA organizations are prohibited from paying individuals and entities that are on the CMS preclusion list. We understand that this language includes both contracted and non-contracted parties; therefore, this prohibition against paying precluded individuals and entities would include contracted and non-contracted parties for purposes of the provisions in § 422.222(a)(1), for we believe it is necessary to ensure that the scope of the payment prohibition in the latter section aligns with that already established in § 422.224. Further, we believe that applying this requirement to both contracted and non-contracted parties better safeguards our beneficiaries while also increasing consistency by aligning with the OIG exclusion process, which is also applied to both contracted and non-contracted parties.

Consistent with our proposed changes to § 422.222(a)(1), we propose to delete the existing structure of § 423.120(c)(6)(iv), which we cited previously, and replace it with the following:

++ A new opening paragraph of (c)(6)(iv) would state:

"With respect to Part D prescribers that have been added to an updated preclusion list, the Part D plan sponsor must do all of the following:"

++ Revised paragraph (c)(6)(iv)(A) would state: "Subject to all other Part D rules and plan coverage requirements, and no later than 30 days after the posting of this updated preclusion

list, must provide an advance written notice to any beneficiary who has received a Part D drug prescribed by a prescriber added to the preclusion list in this update."

++ Revised paragraph (c)(6)(iv)(B) would state: "Must ensure that reasonable efforts are made to notify the prescriber described in paragraph (c)(6)(iv) of this section of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(A) of this section; and"

++ New paragraph (c)(6)(iv)(C) would state: "Must not reject a pharmacy claim or deny beneficiary request for reimbursement for a Part D drug prescribed by the prescriber, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (c)(6)(iv)(A) of this section."

For providers and prescribers that are both on the preclusion list and excluded by the OIG, the aforementioned beneficiary notification process would not be intended to replace or supplant any existing OIG processes for notifying beneficiaries of excluded providers or prescribers.

(5) Beneficiary Appeals

We mentioned earlier that in the preamble to the April 2018 final rule, we stated that if payment is denied because the prescriber or provider is on the preclusion list, the affected beneficiary would not have the right to appeal that denial. However, we did not include accompanying regulatory text in the final rule. To remedy this, we propose to add new § 423.120(c)(6)(viii) and § 422.222(a)(4) stating that payment denials based upon, respectively, a prescriber's or provider's inclusion on the preclusion list are not appealable by beneficiaries.

(6) Felony Convictions

We proposed in the November 2017 proposed rule to keep unenrolled prescribers and providers on the preclusion list for the same length of time as the reenrollment bar that we could

have imposed on the prescriber or provider had they been enrolled and then revoked. While this policy was finalized in the April 2018 final rule, it was not included in the regulatory text. Given this, we propose several regulatory revisions.

First, we propose to revise the definitions of "preclusion list" in §§ 423.100 and 422.2. The current definitions contain two general categories of parties that could be included on the preclusion list -- (1) prescribers and providers that are currently revoked from Medicare and are under a reenrollment bar; and (2) prescribers and providers that have engaged in behavior for which CMS could have revoked the prescriber or provider to the extent applicable had they been enrolled in Medicare. Although these two categories encompass felony convictions, we believe that the severity of felonious behavior warrants the establishment of a third category that is specific to felony convictions. Therefore, we propose to remove felony convictions from the scope of the first two categories, with the new third category covering prescribers and providers---regardless of whether they are or were enrolled in Medicare---that have been convicted of a felony under federal or state law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program; we note that this language is consistent with that in the current version of § 424.535(a)(3), which permits CMS to revoke a provider's or supplier's enrollment based on a federal or state felony conviction within the past 10 years. Recognizing, however, that the facts of each case are different and must be judged on their own merits, we propose that CMS would first consider the following factors before determining whether a prescriber's or provider's inclusion on the preclusion list is warranted under our new proposed third category for felony convictions: (1) the severity of the offense; (2) when the offense occurred; and (3) any other information that CMS deems relevant to its determination. We also acknowledge that with the expansion of the number of preclusion list categories from two to

three, we must, and propose to, add an "or" to the regulatory text immediately after the second category in the preclusion list definitions. This would clarify that a prescriber or provider need only come within the purview of one of the three categories to be included on the preclusion list.

Second, we propose to establish new §§ 423.120(c)(6)(vii) and 422.222(a)(5) that would codify, clarify, and expand upon the previously mentioned policy concerning the length of a prescriber's or provider's inclusion on the preclusion list:

• In §§ 423.120(c)(6)(vii)(A) and 422.222(a)(5)(i), we propose that, except as provided in §§ 423.120(c)(6)(vii)(C) and (D) and 422.222(a)(5)(iii) and (iv), revoked prescribers and providers, respectively, would be included on the preclusion list for the same length of time as the prescriber's or provider's reenrollment bar. This would be consistent with our intended, though uncodified, policy in the April 2018 final rule (83 FR 16441).

• In §§ 423.120(c)(6)(vii)(B) and 422.222(a)(5)(ii), we propose that, except as provided in §§ 423.120(c)(6)(vii)(C) and (D) and 422.222(a)(5)(iii) and (iv), unenrolled prescribers and providers, respectively, would be included on the preclusion list for the same length of time as the reenrollment bar that we could have imposed on the prescriber or provider had they been enrolled and then revoked. This would codify the previously mentioned policy concerning the period of time that unenrolled providers and suppliers would remain on the preclusion list.

• In §§ 423.120(c)(6)(vii)(C) and 422.222(a)(5)(iii), we propose that, except as provided in §§ 423.120(c)(6)(vii)(D) and 422.222(a)(5)(iv), prescribers and providers---regardless of whether they are or were enrolled in Medicare---that are included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter time length of time is warranted. Factors that we would consider in making such a determination would be: (1) the

severity of the offense; (2) when the offense occurred; and (3) any other information that CMS deems relevant to its determination.

We believe that the seriousness of certain types of felonious behavior could, in some cases, warrant the prescriber's or provider's inclusion on the preclusion list for a very lengthy period of time. Indeed, we recognized this in a proposed rule published in the **Federal Register** on March 1, 2016 titled "Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process" (81 FR 10720). We proposed in this proposed rule to extend the maximum reenrollment bar under § 424.535(c) from 3 years to 10 years so that the Medicare program, the Medicare Trust Funds, and beneficiaries could be protected from providers that engaged in especially egregious activities, including felonies. To ensure such protections, we believe that a maximum 10-year preclusion list period for felony convictions is justified. Conversely, because certain felonies may not warrant a 10-year inclusion on the preclusion list, we believe that certain factors, as already described, should be weighed in determining the applicable timeframe.

We emphasize that because our proposed preclusion list period for felonious prescribers and providers would begin on the date of the conviction, such parties may be included on the preclusion list for less than 10 years even if CMS imposes the full 10-year period. To illustrate, assume that a physician is convicted of a felony on January 2, 2020. CMS imposes a 10-year preclusion list period, and he is added to the preclusion list on June 2, 2020. Because the 10-year period commences on the date of the conviction (January 2, 2020), the physician would only be on the preclusion list for 9 years and 6 months.

The OIG in many cases excludes providers and prescribers for a period that is longer than the period permitted for a reenrollment bar under § 424.535(c). As discussed previously, section

1862(e) of the Act is clear that no federal health care program payment may be made for any items or services furnished by an excluded individual or entity, or directed or prescribed by an excluded physician. We believe that CMS should keep an excluded provider or prescriber on the preclusion list at least until the provider or prescriber has been reinstated by the OIG in order to be consistent with section 1862(e) of the Act. Consequently, we propose in new § 423.120(c)(6)(vii)(D) and 422.222(a)(5)(iv) that in cases where a prescriber or provider is excluded by the OIG, the prescriber or provider remains on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(7) Beneficiary Liability

During the notice and comment period for the November 2017 proposed rule (82 FR 16664), we received a comment recommending that in CMS' implementation of the preclusion list, the beneficiary should be held harmless unless the beneficiary engaged in fraudulent activity. We interpreted this comment to be, in the context of MA, that the beneficiary should not be held financially liable if the MA provider that furnished to him or her the service or item in question is on the preclusion list. We generally agreed with this, noting in our response to said comment:

• The contract provisions required between the MA plan and a network provider in accordance with § 422.504(g)(1)(iii) are binding on providers. Such agreements specify that Qualified Medicare Beneficiary (QMB) programs must not be charged cost sharing when the state is responsible for paying such amounts under the Medicaid program.

• Section 422.504(g) contains broader beneficiary protection requirements for MA organizations. This includes a requirement that the plan must indemnify the beneficiary from any fees that are the legal obligation of the MA organization for services furnished by providers

that do not contract, or that have not otherwise entered into an agreement, with the MA organization, to provide services to the organization's enrollees.

Section 422.504 outlines provisions that a contract between an MA organization and CMS must contain. Paragraph (g) thereof outlines requirements to which the MA organization must agree; under paragraph (g)(1), each MA organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability (for example, as a result of an organization's insolvency or other financial difficulties) for payment of any fees that are the legal obligation of the MA organization. To implement our overall position as it pertains to the preclusion list, we believe that a specific addition to § 422.504(g)(1) is necessary. Consistent with our existing authority under section 1857(e)(1) of the Act, we thus propose to add a new paragraph (g)(1)(iv) to § 422.504 under which the MA organization agrees that the enrollee must not have any financial liability for services or items furnished to the enrollee by an MA contracted individual or entity on the preclusion list, as defined in § 422.2 and as described in § 422.222. We acknowledge that the effect of this provision would be limited to providers under contract with the MA organization, for we believe this is consistent with the general applicability and scope of § 422.504 and the ability of the MA organization to control or impose requirements on the health care providers that furnish covered services and items to enrollees. Nonetheless, we believe that proposed paragraph (g)(1)(iv) would help financially protect beneficiaries from problematic providers as well as codify the previously mentioned position we expressed in the preamble of the April 2018 final rule (83 FR 16646) but did not address in the regulatory text.

(8) Technical Correction Concerning the Term "Individual" (§ 423.120(c)(6))

We also propose to make technical changes to §423.120(c)(6)(i), (ii), (iii), and (vi). These paragraphs state as follows, respectively:

• Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must reject, or must require its PBM to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the preclusion list, defined in § 423.100.

• Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary if the request pertains to a Part D drug that was prescribed by an individual who is identified by name in the request and who is included on the preclusion list, defined in § 423.100.

• A Part D plan sponsor may not submit a prescription drug event (PDE) record to CMS unless it includes on the PDE record the active and valid individual NPI of the prescriber of the drug, and the prescriber is not included on the preclusion list, defined in § 423.100, for the date of service.

• CMS has the discretion not to include a particular individual on (or if warranted, remove the individual from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to prescriptions.

Because some states permit pharmacies to prescribe medications, we believe that the use of the term "individual" in paragraphs (i), (ii), (iii), and (vi) is too restrictive. We therefore propose in paragraphs (i), (ii), and (vi) to change this term to "prescriber" so as to clarify that the prescriber need not be an individual. In a similar vein, we propose:

• In § 423.120(c)(6)(iii) to change the phrase "individual NPI of the prescriber" to "NPI of the prescriber", and

• In paragraph (2)(i) of the definition of "preclusion list" in § 423.100 (and as reflected in our previously discussed proposal to revise this paragraph (see section II.C.1.b.6. of this proposed rule)) to change the phrase "he or she" to "prescriber."

(9) Proposed Provisions

Given the foregoing, we propose the following changes:

• We would revise the definition of "preclusion list" in § 422.2 as follows:

++ Paragraph (1)(i) of the definition would be changed from "the individual or entity is currently revoked from Medicare under § 424.535" to "the individual or entity is currently revoked from Medicare for a reason other than that stated in § 424.535(a)(3) of this chapter."

++ Paragraph (2)(i) of the definition would be changed from "the individual or entity has engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare" to "the individual or entity has engaged in behavior, other than that described in § 424.535(a)(3) of this chapter, for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare."

++ We would add the word "or" to the end of paragraph (2)(ii)(C) of the definition.

++ New paragraph (3) would read as follows: "The individual or entity, regardless of whether they are or were enrolled in Medicare, has been convicted of a felony under federal or state law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph are: (1) the severity of the offense; (2) when the offense occurred; and (3) any other information that CMS deems relevant to its determination."

• We would revise § 422.222 such that it would read as follows:

++ Existing paragraph (a)(1) would be moved to a new paragraph (a)(1)(i) that would state: "Except as provided in paragraph (a)(1)(ii) of this section, an MA organization must not make payment for a health care item or service furnished by an individual or entity that is included on the preclusion list, defined in § 422.2."

++ New paragraph (a)(1)(ii) would state: "With respect to MA providers that have been added to an updated preclusion list, the MA organization must do all of the following:"

++ New paragraph (a)(1)(ii)(A) would state: "No later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received an MA service or item from the individual or entity added to the preclusion list in this update;"

++ New paragraph (a)(1)(ii)(B) would state: "Must ensure that reasonable efforts are made to notify the individual or entity described in paragraph (a)(1)(ii) of this section of a beneficiary who was sent a notice under paragraph (a)(1)(ii)(A) of this section; and

++ New paragraph (a)(1)(ii)(C) would state: "Must not deny payment for a service or item furnished by the newly added individual or entity, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (a)(1)(ii)(A) of this section."

++ In new § 422.222(a)(2)(i), we propose to incorporate therein the current version of § 422.222(a)(2).

++ New § 422.222(a)(2)(ii) would state: "If the individual's or entity's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:".

++ New § 422.222(a)(2)(ii)(A) would state: "The notice described in paragraph (a)(2)(i) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the individual's or entity's appeal rights concerning the revocation."

++ New § 422.222(a)(2)(ii)(B) would state: "The appeals of the individual's or entity's inclusion on the preclusion list and the individual's or entity's revocation shall be filed jointly by the individual or entity and, as applicable, considered jointly by CMS under 42 CFR part 498 of this chapter.

++ New § 422.222(a)(3)(i) would state: "Except as provided in paragraph (3)(ii), an individual or entity will only be included on the preclusion list after the expiration of either of the following:".

++ New § 422.222(a)(3)(i)(A) would state: "If the individual or entity does not file a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list upon the expiration of the 60-day period in which the individual or entity may request a reconsideration; or".

++ New § 422.222(a)(3)(i)(B) would state: "If the individual or entity files a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list effective on the date on which CMS, if applicable, denies the individual's or entity's reconsideration.."

++ New § 422.222(a)(3)(ii) would state: "An OIG excluded individual or entity is added to the preclusion list effective on the date of the exclusion.

++ New § 422.222(a)(4) would state: "Payment denials based upon an individual's or entity's inclusion on the preclusion list are not appealable by beneficiaries."

++ New § 422.222(a)(5)(i) would state: "Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the individual's or entity's reenrollment bar."

++ New § 422.222(a)(5)(ii) would state: "Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the individual or entity had they been enrolled and then revoked."

++ New § 422.222(a)(5)(iii) would state: "Except as provided in paragraph (a)(5)(iv) of this section, an individual or entity, regardless of whether they are or were enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter time length of time is warranted. Factors that CMS considers in making such a determination are: (A) the severity of the offense; (B) when the offense occurred; and (C) any other information that CMS deems relevant to its determination."

++ New § 422.222(a)(5)(iv) would state: "In cases where an individual or entity is excluded by the OIG, the individual or entity shall remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later. "

• New § 422.504(g)(1)(iv) would state that the MA organization agrees that the enrollee shall not have any financial liability for services or items furnished to the enrollee by an MA contracted individual or entity on the preclusion list, as defined in § 422.2 and as described in § 422.222.

• We would revise the definition of "preclusion list" in § 423.100 as follows:

++ Revised paragraph (1)(i) of the definition would state: "The prescriber is currently revoked from Medicare for a reason other than that stated in § 424.535(a)(3) of this chapter."

++ Revised paragraph (2)(i) of the definition would state: "The prescriber has engaged in behavior, other than that described in § 424.535(a)(3) of this chapter, for which CMS could have revoked the prescriber to the extent applicable had the prescriber been enrolled in Medicare."

++ We would add the word "or" to the end of paragraph (2)(ii)(C) of the definition.

++ New paragraph (3) would state: "The prescriber, regardless of whether the prescriber is or was enrolled in Medicare, has been convicted of a felony under federal or state law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph are: (i) the severity of the offense; (ii) when the offense occurred; and (iii) any other information that CMS deems relevant to its determination."

• We would revise § 423.120(c)(6) as follows:

++ In paragraphs (c)(6)(i), (ii), and (vi), we would change the term "individual" to "prescriber."

++ In paragraph (iii), we would change the phrase "individual NPI of the prescriber" to "NPI of the prescriber".

++ A new opening paragraph of (c)(6)(iv) would state: "With respect to Part D prescribers that have been added to an updated preclusion list, the Part D plan sponsor must do all of the following:"

++ Revised paragraph (c)(6)(iv)(A) would state: "Subject to all other Part D rules and plan coverage requirements, and no later than 30 days after the posting of this updated preclusion

list, must provide an advance written notice to any beneficiary who has received a Part D drug prescribed by a prescriber added to the preclusion list in this update;"

++ Revised paragraph (c)(6)(iv)(B) would state: "Must ensure that reasonable efforts are made to notify the prescriber described in paragraph (c)(6)(iv) of this section of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(A) of this section; and"

++ New paragraph (c)(6)(iv)(C) would state: "Must not reject a pharmacy claim or deny a beneficiary request for reimbursement for a Part D drug prescribed by the prescriber, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (c)(6)(iv)(A) of this section."

++ New § 423.120(c)(6)(v)(A) would state: "CMS sends written notice to the prescriber via letter of their inclusion on the preclusion list. The notice must contain the reason for the inclusion on the preclusion list and inform the prescriber of their appeal rights. A prescriber may appeal their inclusion on the preclusion list under this section in accordance with part 498 of this chapter."

++ New § 423.120(c)(6)(v)(B) would state: "If the prescriber's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:".

++ New § 423.120(c)(6)(v)(B)(*1*) would state: "The notice described in paragraph (c)(6)(v)(A) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the prescriber's appeal rights concerning the revocation."

++ New § 423.120(c)(6)(v)(B)(*2*) would state: "The appeals of the prescriber's inclusion on the preclusion list and the prescriber's revocation shall be filed jointly by the prescriber and, as applicable, considered jointly by CMS under part 498 of this chapter."

++ New § 423.120(c)(6)(v)(C)(*1*) would state: "Except as provided in paragraph (c)(6)(v)(C)(*2*), a prescriber will only be included on the preclusion list after the expiration of either of the following:".

++ New § 423.120(c)(6)(v)(C)(*1)(i)* would state: "If the prescriber does not file a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list upon the expiration of the 60-day period in which the prescriber may request a reconsideration; or".

++ New § 423.120(c)(6)(v)(C)(*1)(ii)* would state: "If the prescriber files a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list effective on the date on which CMS, if applicable, denies the prescriber's reconsideration.

++ New § 423.120(c)(6)(v)(C)(*2)* would state: "An OIG excluded prescriber is added to the preclusion list effective on the date of the exclusion."

++ New § 423.120(c)(6)(vii)(A) would state: "Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the prescriber's reenrollment bar."

++ New § 423.120(c)(6)(vii)(B) would state: "Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the prescriber had the prescriber been enrolled and then revoked."

++ Section 423.120(c)(6)(vii)(C) would state: "Except as provided in paragraph (c)(6)(vii)(D) of this section, a prescriber, regardless of whether the prescriber is or was enrolled

in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are: (1) the severity of the offense; (2) when the offense occurred; and (3) any other information that CMS deems relevant to its determination."

++ Section 423.120(c)(6)(vii)(D) would state: "In cases where a prescriber is excluded by the OIG, the prescriber shall remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

++ New paragraph (c)(6)(viii) would state: "Payment denials under paragraph (c)(6) that are based upon the prescriber's inclusion on the preclusion list are not appealable by beneficiaries."

• We propose to revise 42 CFR part 498 as follows:

++ New § 498.5(n)(1)(i) would state: "Any individual or entity that is dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list (as defined in § 422.2 or § 423.100 of this chapter) may request a reconsideration in accordance with § 498.22(a)."

++ New § 498.5(n)(1)(ii)(A) would state: "If the individual's or entity's inclusion on the preclusion list is based on a Medicare revocation under § 424.535 of this chapter and the individual or entity receives contemporaneous notice of both actions, the individual or entity may request a joint reconsideration of both the preclusion list inclusion and the revocation in accordance with § 498.22(a)."

++ New § 498.5(n)(1)(ii)(B) would state: "The individual or entity may not submit separate reconsideration requests under paragraph (n)(1)(ii)(A) of this section for inclusion on

the preclusion list or a revocation if the individual or entity received contemporaneous notice of both actions."

2. Medicare Advantage Risk Adjustment Data Validation Provisions (§§ 422.300, 422.310(e), and 422.311(a))

a. Background

Subpart G of the MA regulations at part 422 describes how payment is made to MA organizations. These payment principles are based on sections 1853, 1854, and 1858 of the Act. Subpart G also sets forth the requirements for making payments to MA organizations offering local and regional MA plans, including calculation of MA capitation rates.

Section 1853(a)(3) of the Act requires that we risk adjust our payments to MA organizations. Risk adjustment strengthens the Medicare program by ensuring that accurate payments are made to MA organizations based on the health status plus demographic characteristics of their enrolled beneficiaries and ensures that MA organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees expected to incur lower health care costs and more for less healthy enrollees expected to incur higher health care costs). Accurate payments to MA organizations also help ensure that providers are paid appropriately for the services they provide to MA beneficiaries. In general, the current risk adjustment methodology relies on enrollee diagnoses and encounters, as specified by the International Classification of Disease, currently the Tenth Revision Clinical Modification guidelines (ICD-10-CM), to prospectively adjust capitation payments for a given enrollee based on the health status of the enrollee. Diagnosis codes determine the risk scores, which in turn determine the risk-adjusted payments. As a result, MA organizations and providers must focus attention on complete, truthful, and accurate diagnosis reporting according to the official ICD-10-CM coding guidelines.

As the ICD-10-CM guidelines emphasize, "accurate coding cannot be achieved" without "consistent, complete documentation in the medical record." Diagnoses submitted for payment by MA organizations must be supported by medical record documentation. This requirement has been in place since the beginning of the MA program. It has been explained in every edition of the Medicare Managed Care Manual, with which MA organizations agree to comply as a condition of their participation. (See the 2013 Medicare Managed Care Manual, § 40; 2004 Medicare Managed Care Manual, § 111.1, Ex. 30 & § 111.4; 2001 Medicare Managed Care Manual, § 110.4.) It has also been emphasized in numerous trainings provided to MA organizations and their subcontractors.

The diagnosis data submitted by MA organizations must conform to all relevant national standards. (See 42 CFR 422.310(d)(1).) As discussed earlier, the Clinical Modification of the International Classification of Disease, published by the federal government, is the chief national standard for diagnosis coding. It is the coding system on which MA risk adjustment is run. Medical record documentation is a core principle of the ICD-10-CM diagnosis coding system and was equally central to the Ninth Revision (ICD-9-CM), which preceded it. A federal court of appeals has recognized the requirement of medical record documentation for diagnosis codes submitted for payment by MA organizations. *United States ex rel. Swoben v. United Health Ins. Co.*, 848 F.3d 1161, 1168, 1176 (9th Cir. 2016). When MA organizations certify that their diagnosis codes are "accurate" and "truthful" to the "best knowledge, information, and belief" of the certifying individual, the existence of adequate medical record documentation is one important standard by which accuracy and truthfulness are measured (42 CFR 422.504(l)(1)). As we have previously explained, our "risk adjustment methodology provides that a specific amount be paid if an enrollee has a particular condition" (75 FR 19745). The medical record

documentation requirement is "designed to ensure that the enrollee in fact has th[e] condition" for which an MA organization is requesting payment under the risk adjustment model (75 FR 19745).

The current risk adjustment model employed in adjusting MA plan payments is known as the CMS Hierarchical Condition Category (CMS-HCC) model. It functions by categorizing ICD-10-CM codes into disease groups called Hierarchical Condition Categories, or HCCs. Each HCC includes diagnosis codes that are related clinically and have similar cost implications. The CMS-HCC model is recalibrated approximately every 2 years to reflect newer treatment and coding patterns in Medicare FFS. This recalibration is made through the annual advance notice of methodological changes authorized by 42 U.S.C. 1395w-23(b)(2). Since 2007, when a demographic data-only payment method was completely phased-out for MA plans, 100 percent of payment has been risk-adjusted. The statute continues to provide us the authority to add to, modify, or substitute for risk adjustment factors if the changes will improve the determination of actuarial equivalence.

b. Risk Adjustment Data Validation Initiatives

MA enrollee HCCs are assigned based on data submitted to us by MA organizations via the Risk Adjustment Payment System (RAPS) and Encounter Data System (EDS). The HCCs contribute to an enrollee's risk score, which is used to adjust a base payment rate. Essentially, the higher the risk score for an enrollee, the higher the expected health care cost for the enrollee. The HCC data that MA organizations submit to CMS via the RAPS and EDS systems is self-reported by the MA organization and does not go through a validation review before being incorporated into a given beneficiary's risk-profile. Since there is an incentive for MA organizations to potentially over-report diagnoses so that they can increase their payment, the

Department audits plan-submitted diagnosis data a few years later to ensure they are supported by medical record documentation.

Verifiable medical record documentation is key to accurate payment and successful data validation. We annually select MA organizations for risk adjustment data validation (RADV) audits.[23] RADV audits are intended to confirm the presence of risk adjustment conditions (that is, diagnoses that map to HCCs) as reported by MA organizations for their enrollees and confirmed via medical record documentation. RADV audits occur after the final risk adjustment data submission deadline for the MA contract year. The audits validate the HCC data submitted by MA organizations by reviewing hospital inpatient, hospital outpatient, and physician/practitioner provider medical records. The focus of this medical record review activity is on diagnoses related to the enrollee's HCC profile. Risk adjustment discrepancies are identified when the enrollee's HCCs used for payment (based upon MA organization-submitted data) differ from the HCCs assigned based on the medical record, pursuant to the RADV audit process. Risk adjustment discrepancies can be aggregated to determine an overall level of payment error. In turn, payment error for a sample of contract enrollees can be extrapolated to calculate a contract-level payment error estimate. Although we have the authority to extrapolate from a statistically valid sample to calculate a contract-level audit recovery, we have not yet done so.

From 1999 until 2003, our payment validation activity for the MA program had both an educational and audit focus and was intended to improve the accuracy of the risk adjustment data that was being submitted to CMS for payment. Payment adjustments were limited to enrollee-level adjustments for those enrollees sampled in the payment validation audit. At the time, only

[23] Any changes to the CMS-HCC payment model are published in the annual payment notice.

10 percent of the MA payment amount was risk adjusted. As a result, payment recovery amounts for the small number of plans audited was very small. Since payment year 2004 was the first year for which MA payments were based on the current HCC risk adjustment model, we considered payment years 2004 through 2006 as pilot years for the purpose of RADV and no payment recovery activity occurred.

Payment recovery resumed for payment year 2007, when we audited 37 MA contracts and recouped $13.7 million. Payment adjustments were again limited to enrollee-level adjustments for those enrollees sampled in the payment validation audit. (Although we suggested that we would make contract-level payment adjustments for the payment year 2007 audits, we did not ultimately do so.) In the course of that audit process, as in previous years, we reviewed medical record documentation provided by each audited MA organization to substantiate conditions reported by the organization for beneficiaries in each audit sample. After CMS' findings were reported to each MA organization, any organization that disagreed with CMS' determinations could challenge them through a three-stage administrative process established by regulation in 2010. (See 42 CFR 422.311). This dispute and appeals process is currently ongoing.

No payment validation audits were conducted for payment years 2008, 2009, or 2010. In those years, we were considering the development of a methodology for calculating payment adjustments based on statistical RADV MA contract-level payment error audit findings. The development of contract-level RADV audits would enable us to make contract-level payment adjustments rather than simply adjusting payments for specific enrollees from an audit sample, as we had done previously.

On December 20, 2010, we proposed a methodology on the CMS website for selecting a statistically-valid sample of enrollees from each audited MA contract and extrapolating from the results of that sample audit to calculate a contract-level payment adjustment. We invited public comment on this proposed methodology, and received more than 500 comments, which we carefully reviewed. On February 24, 2012, we published what we described as the final methodology for RADV contract-level payment error calculation.[24] That methodology described sampling techniques and the statistical calculation to be used to extrapolate from the sample selected. In brief, up to 201 enrollees from each audited MA contract would be selected according to certain criteria, including their continuous enrollment in the contract for the entire data collection year and January of the payment year; their lack of end-stage renal disease (ESRD) status and hospice status for that entire period; their enrollment in Medicare Part B coverage for the entire data collection year; and their submission of at least one diagnosis during the data collection year leading to at least one CMS-HCC assignment in the payment year. The RADV-eligible enrollees would be ranked by risk score and then divided into three equal strata. An equal number of enrollees would then be randomly selected from each stratum (67 enrollees per stratum in the case of an audit of 201 enrollees). After medical records were reviewed, payment errors would be calculated for each selected enrollee based on the number of months the person was enrolled in the selected MA contract (and was not in ESRD or hospice status) during the payment year. A payment error rate for each stratum would be calculated, and then an overall payment error rate for the audited contract, computed at a ninety-nine percent confidence interval. We stated that this methodology would be applied to the next round of RADV audits,

[24] Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits, *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf.

which would be conducted on payment year 2011. Audits for payment years 2011, 2012, and 2013 have been conducted according to this methodology, at a total cost of approximately $150 million to the agency, but have not yet been finalized. These audits are in addition to RADV and related MA audits conducted by the Office of Inspector General, which are conducted pursuant to OIG's independent authorities at sections 2(1) and 4(a)(1) of the Inspector General Act.

We also stated in 2012 that, after using this methodology to calculate a preliminary payment recovery amount, we would apply a FFS Adjuster as an offset before finalizing the audit recovery. The FFS Adjuster was intended to account for any effect of erroneous diagnosis codes in the data from Medicare Parts A and B (often referred to as "Fee-For-Service" Medicare) that are used to calibrate the MA risk adjustment model. We stated that the FFS Adjuster would calculate a permissible level of payment error (for example, a percentage of the total payments made on an MA contract in a given year) and limit RADV audit recovery to payment errors above that level. The FFS Adjuster was never intended to set a permissible rate for the submission of erroneous diagnosis codes. We stated that the FFS Adjuster would be calculated based on a RADV-like review of records submitted to support the Medicare Part A and B diagnosis codes. That review is now complete, and will be discussed later.

c. Discussion of Proposals

(1) Extrapolation

The Secretary intends to recover overpayments based on extrapolated audit findings through the use of statistically valid random sampling techniques. Although we described our February 2012 publication as the final methodology to be used to calculate contract-level RADV audit recoveries for payment year 2011, it has never been implemented. As we stated earlier, audits for payment years 2011, 2012, and 2013 have been conducted according to this

methodology, but contract-level recoveries have not yet been sought. We are now providing additional notice and again welcoming public input on the agency's methodology for calculating a contract-level payment error in RADV audits, including the sample sizes used in these contract-level audits. CMS is not required to set forth the methodology for calculating an extrapolated payment error through regulatory provisions (it does not do so in Parts A and B, where Medicare Administrative Contractors (MACs) may use any statistically valid sampling and extrapolation methodology they determine to be appropriate), however, in the interest of transparency, we are updating stakeholders on our plans to use various sampling and extrapolation methodologies in RADV audits, as CMS deems appropriate.[25] All audits will be based on statistically valid sampling and extrapolation methodologies.

In addition to the contract-level methodology described earlier, we have identified other potential methodologies for sampling and extrapolation, which would calculate improper payments made on the audited MA contract for a particular sub-cohort or sub-cohorts in a given payment year, and the agency may also use such a methodology to calculate improper payments made to the audited MA contract. For example, a sub-cohort could be the enrollees for whom a particular HCC or one of a related set of HCCs (such as the three diabetes HCCs) was reported. After choosing an MA contract and a sub-cohort or sub-cohorts to audit, we would select a statistically significant sample of enrollees for the sub-cohort or sub-cohorts. After reviewing the medical records of those enrollees, we would use statistical extrapolation to calculate and recoup the improper payments made to the audited MA contract for covering enrollees for the sub-cohort or sub-cohorts in that payment year. We would use the same statistical calculation

[25] The Office of the Inspector General, which is required by law to conduct audits and follow generally accepted government auditing standards, does not seek comment on its methodology for risk adjustment audit work that may lead to overpayment recoveries from MA organizations.

for this sub-cohort-level extrapolation as we do for the contract-level extrapolation (although we welcome comment as to whether to stratify the sample population for the sub-cohort audits, as we currently anticipate doing for the contract-level audits).

We believe that, because any sub-cohort is necessarily a subset of the enrollees covered through a particular MA contract, we could often use a much smaller sample size to calculate a statistically significant extrapolated recovery for a sub-cohort than would be required to calculate a contract-level recovery (up to 201 enrollees, according to our anticipated contract-level methodology). This smaller sample size would allow us to spread our audit resources across a wider range of MA contracts, while still generating statistically significant recoveries. This sub-cohort-based audit methodology would allow us to focus on cohorts of enrollees that appear to raise programmatic concerns.

We invite comment on both the contract-level audit methodology published in February 2012, and our proposal for an extrapolated audit methodology based on sub-cohorts of enrollees. We also seek comment on whether there are particular situations in which one methodology may be preferable to the other, and whether the agency should revise the contract-level audits that have been conducted but not finalized for payment years 2011, 2012, and 2013. Neither proposed methodology is meant to displace our longstanding authority to audit the medical records of particular enrollees who we believe may be associated with improper payments or to use any statistically valid audit methodology. [26]

[26] We may begin to conduct RADV audits for payment years 2014 and 2015 before this proposal is finalized, pursuant to our longstanding authority to review the medical records of any MA enrollee and recoup any improper payments identified. Although we would design these audits so that that the individuals selected would form a statistically significant sample that would support an extrapolated recovery, we would not seek to recover on an extrapolated basis until the rule is final. At the very least, these audits would support enrollee-level recoveries.

If we finalize one or more sampling and extrapolation methodologies through this rulemaking, we would make any future changes to that methodology (or those methodologies) through the Health Plan Management System.

We are also considering whether to explicitly expand the MA organizations' RADV appeal rights, particularly in light of the upcoming auditing and recoveries in the MA program. One option would be to permit appeal of the RADV payment error calculation methodology used in a RADV audit similar to practices in the Part A and Part B space of Medicare FFS. We invite comments on this matter.

(2) Application to Payment Year 2011 and Subsequent Years

We intend to apply the finalized RADV payment error methodology or methodologies to payment year 2011, and all subsequent years. (However, we do not expect to use a sub-cohort-based methodology, if finalized, for any payment year before 2014.) Section 1871(e)(1)(A) of the Act authorizes retroactive application of rules where "(i) such retroactive application is necessary to comply with statutory requirements; or (ii) failure to apply the change would be contrary to the public interest." We are considering whether application of the finalized methodology or methodologies to payment year 2011, and all subsequent years, would require the exercise of this statutory authority to engage in retroactive rulemaking. We invite comment on the subject.

In any case, we believe that failure to apply the finalized RADV payment error methodology or methodologies to those payment years would be contrary to the public interest. The public has a substantial interest in the recoupment of millions of dollars of public money improperly paid to private insurers. The public also has a significant interest in providing incentives for those insurers to claim only proper payments in the future, which would be

promoted by the recoupment of funds improperly paid in the past. Given the amount of improper payments identified under the MA program (estimated to be $14.35 billion in FY 2017, [27] the $650 million in recovered improper payments represents, if this policy was finalized, 3 years improper payment for 30 plans), the interest in determining an accurate recovery amount for each audited MA plan, and the importance of protecting the overall integrity of the program, we believe that it is in the public interest for CMS to apply the RADV payment error methodology or methodologies adopted through this rulemaking to payment year 2011 and all subsequent years. In applying this methodology (or these methodologies) to those payment years, CMS would be acting in compliance with the IPERIA statute[28] as well as its own fiduciary responsibility to recover funds due and owing to the Medicare Trust Funds. We note also that our February 2012 publication put MA organizations on notice that CMS expected to calculate a contract-level payment error for payment year 2011 and beyond by extrapolating from its review of a statistically valid sample of enrollees, and that (as explained earlier) MA organizations have never been entitled to receive or retain payments associated with HCCs that cannot be validated

[27] CMS has historically reported high levels of payment error in the Part C program. The Part C error rate has ranged between 11 percent and 9 percent between fiscal years (FY) 2011 and 2014, respectively. In FY 2017, the reported Part C error rate was 8.31 percent or $14.35 billion.

[28] Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA, Pub. L. 112-248). The RADV program is a corrective audit activity developed by CMS to address provisions included in the IPIA of 2002, as amended by the IPERA of 2010, and further amended by IPERIA. These statutes require that government agencies annually estimate and report improper payments. RADV audits were initiated because Part C payment error was out of compliance with IPIA. The IPERIA requires the Office of Management and Budget (OMB) to annually identify agencies for greater levels of oversight and review, and with that agency "establish annual targets and semi-annual or quarterly actions for reducing improper payments associated with each high-priority program." In November 2009, Executive Order (E.O.) 13520 was signed in an effort to reduce improper payments by increasing transparency in government and holding agencies accountable for reducing improper payments. In March 2010, OMB issued guidance for agencies regarding the implementation of E.O. 13520 entitled Part III to OMB Circular A-123, Appendix C (Appendix C). Appendix C outlines the responsibilities of agencies, determines the programs subject to E.O. 13520, defines supplemental measures and targets for high priority programs, and establishes reporting requirements under E.O. 13520 and procedures to identify entities with outstanding payments. One of those remedies is payment recapture audits, a requirement that any program that expends at least $1million must implement payment recapture audits. A recovery audit, or payment recapture audit, is a review process designed to identify erroneous payments. Additionally, it is a corrective control activity designed to identify and recapture erroneous payments, and, as such, is a management function and responsibility.

by medical records. Application of the finalized RADV payment error methodology or methodologies to payment year 2011 and all subsequent years therefore would not upset any settled interest.

If the finalized contract-level audit methodology differs from the one we published in February 2012, we will also consider whether to apply the new contract-level payment error methodology to payment years 2011, 2012, and 2013, or to only apply it to payment year 2014 and subsequent years, and to finalize the audits for those earlier payment years according to the methodology published in February 2012. We invite comment on this subject, as well. In any event, and however audits for prior years are ultimately handled, we believe that it is vitally important for the health of the MA program to have extrapolated recoveries available for future audit years.

(3) Implementation

This proposal would announce CMS' intention to recover improper payments based on extrapolation of payment error from RADV audit samples to MA organization specified populations. CMS would calculate and recover improper payments based on extrapolation methodologies. MA organizations would be required to remit extrapolated recovery amounts from audit findings as calculated by CMS through its payment system, Medicare Advantage and Prescription Drug system (MARx). MARx is the CMS system that makes monthly payments and payment adjustments to the MA organizations and Part D sponsors. Overpayment recoveries of all types are considered payment adjustments which are done as offsets to the plans' monthly payments. RADV recovery amounts are included in this category. In the month the plan has been notified that the recovery amount will be offset, the MARx system makes an offset to the plans monthly payment equal to the amount of the recovery amount. In the event the recovery amount

exceeds the payment in 1 month, the recovery will be spread across adjustments for multiple months until the full amount is recovered. CMS may likewise require MA organizations to remit such recovery amounts based upon audit findings by OIG.

(4) Recoupment of Improper Payments in Part C

Improper payments identified by CMS outside of the RADV audit process or self-identified by the MA organization that are not returned in accordance with §§ 422.330, and are identified and/or estimated through extrapolation or other estimation methodologies as a result of CMS audits will be recovered following CMS audit processes including payment offset. We propose that MA organizations be required to remit funds that CMS calculates as improper payments through the extrapolated RADV audit findings in accordance with §§ 422.310(e). RADV audit results can be appealed by MA organizations using the regulatory administrative appeals process outlined in § 422.311.

(5) FFS Adjuster

After our 2012 RADV publication, we conducted an extensive study regarding the presence and impact of diagnosis error in FFS claims data. Our study suggests that errors in FFS claims data do not have any systematic effect on the risk scores calculated by the CMS-HCC risk adjustment model, and therefore do not have any systematic effect on the payments made to MA organizations.[29]

The study began by auditing 8,630 outpatient claims paid through Medicare Part B in a given year. We reviewed the medical records associated with each claim (a small subset of the medical records associated with each beneficiary) to determine whether the diagnosis associated

[29] We are aware of the district court's recent ruling in *United HealthCare Insurance Co. v. Azar*, No. 16-cv-157 (D.D.C. September 7, 2018), and the government is reviewing that decision and considering its response. In any event, that ruling was made on the basis of the administrative record before the court, which did not include the results of our study.

with the claim was supported by medical record documentation. A discrepancy rate for each CMS-HCC was then calculated. For example, the data set contained 484 claims submitted with a diagnosis of chronic obstructive pulmonary disease, which is CMS-HCC 108. Of those diagnoses, 388 were supported by medical record documentation, and 96 were not, for a discrepancy rate of 19.8 percent. To account for the fact that the data set contained extremely small samples of many CMS-HCCs—for example, one diagnosis of extensive third degree burns and two diagnoses of severe head injury—we calculated a high, low, and baseline discrepancy rate. Each CMS-HCC was assigned one of these three mean discrepancy rates depending on its relationship to the bassline discrepancy rate: CMS-HCCs with a discrepancy rate significantly higher than the baseline were assigned to the high category, and those with a discrepancy rate significantly lower than the baseline were assigned to the low category. All other CMS-HCCs were assigned the baseline discrepancy rate. These rates were 46.2 percent, 33.8 percent, and 20.9 percent.

In a given year, multiple claims are submitted for Medicare Part B services received by a given beneficiary and associated with a given diagnosis. For example, an average beneficiary with metastatic cancer or acute leukemia, which is CMS-HCC 7, has seven claims associated with that diagnosis. Because we were interested in determining whether a given beneficiary had a documented diagnosis in a given year, and not whether any particular claim was associated with medical record documentation, we used the claim-level discrepancy rates described above to calculate beneficiary-level discrepancy rates.[30]

[30] For example, metastatic cancer or acute leukemia was assigned the baseline discrepancy rate of 33.8%. We therefore reasoned that each of the seven claims associated with the average beneficiary for whom such a diagnosis was reported had a 66.2% chance of being supported by medical record documentation, and only one instance of medical record support was necessary to make the diagnosis valid for that year. If each beneficiary with such a reported diagnosis has 7 claims associated with that diagnosis, and each claim has a 66.2% chance of being

After calculating this beneficiary-level discrepancy rate for each HCC, we ran fifty simulations in which we removed diagnoses from a data set of more than 1.4 million Medicare Part A and B beneficiaries at the beneficiary-level discrepancy rate.[31] After removing diagnoses at the indicated rates, we used each simulated "corrected" data set to recalibrate the CMS-HCC risk adjustment model, applied the recalibrated risk coefficients to a data set of MA beneficiaries, and compared their original risk scores to the risk scores calculated with the recalibrated model. We found that the difference between the risk scores was very small, and that the recalibrated risk scores tended to be slightly lower than the original risk scores. Therefore, we concluded that diagnosis error in FFS claims data does not lead to systematic payment error in the MA program.

An executive summary of the findings and a technical appendix describing the data and methodology can be found at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.html. Because it appears that diagnosis error in FFS claims data does not lead to systematic payment error in the MA program, we propose not to include an FFS Adjuster in any final RADV payment error methodology.

Moreover, even if we had found that diagnosis error in FFS claims data led to systematic payment error in the MA program, we no longer believe that a RADV-specific payment adjustment would be appropriate. RADV audits are used to recover payments based on diagnoses that are not supported by medical record documentation, which thus should not have been reported to CMS. If a payment has been made to an MA organization based on a diagnosis

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supported by medical record documentation, then 99.95% of all beneficiaries will have at least one instance of medical record support, and only 0.05% of beneficiaries will lack any medical record documentation of their reported diagnosis.

[31] For metastatic cancer and acute leukemia, 1 in 2,000 diagnoses was removed (corresponding to an error rate of 0.05%).

code that is not supported by medical record documentation, that entire payment is in error and should be recovered in full, because the payment standard has not been met, and the MA organization is not entitled to any payment for that diagnosis. RADV audits do not address issues with the accuracy of payments based on diagnosis codes that are supported by medical record documentation. Consequently, an adjustment to RADV recoveries to remedy payment accuracy concerns is inappropriate. For this reason, we believe that it would not be appropriate to correct any systematic payment error in the MA program through a payment adjustment that was only applied to audited contracts. Doing so would introduce inequities between audited and unaudited plans, by only correcting the payments made to audited plans.

Because our study suggests that diagnosis error in FFS claims data does not lead to systematic payment error in the MA program and because we believe it would be inequitable to correct any systematic errors in the payments made to audited plans only, we would not include an FFS Adjuster in any RADV extrapolated audit methodology. We welcome public comments on this study.

d. Proposed Changes

In this section, we discuss the proposed changes to the regulation in Parts 422 and 423 governing the MA Program. We are proposing to apply extrapolation to plan year audits for payment year 2011 forward.

The following is a summary of the proposed changes included in this proposed revision:

We propose to revise § 422.300 to include "collection of improper payments."

We propose to amend § 422.310(e) Validation of risk adjustment data, to apply extrapolation to plan year audits for payment year 2011 forward.

We propose to amend § 422.310(e) Validation of risk adjustment data, by adding a requirement to set forth the provision for MA organizations to remit improper payments based on RADV audits and established in accordance with stated methodology, in a manner specified by CMS.

We propose to amend § 422.311, the RADV audit dispute and appeal process section, by adding language to clarify that recovery of improper payments from MA organizations will be conducted according to the Secretary's payment error extrapolation and recovery methodologies and that CMS will apply extrapolation to plan year audits for payment year 2011 forward.

D. Implementing Other Changes

1. Clarification Regarding Accreditation for Quality Improvement Programs

Section 1852(e) of the Act requires each MA organization to have an ongoing quality improvement program to improve the quality of care provided to its enrollees and establishes the requirements for the quality improvement programs. Section 1852(e) (4) of the Act requires the Secretary to deem that an MA Organization has met all of the requirements for any one out of the six program areas listed in section 1852(e)(4)(B) of the Act if the MA Organization is accredited in that area by an accrediting organization that has been approved by CMS and that uses the same (or stricter) standards than CMS uses to evaluate compliance with the applicable requirements. Section 1852(e)(4)(B)(i) of the Act references the quality improvement programs in section 1852(e) of the Act. Thus, an MA Organization could be deemed to meet CMS' requirements related to quality improvement programs by a CMS-approved accrediting organization.

Section 722(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the MMA) revised the quality improvement program requirements in the Act. Section 1852(e) of the Act was revised by adding a new clause "(2) Chronic Care Improvement Programs" and renumbering the existing clauses accordingly (that is, existing clause "(2) Data" became "(3) Data"). Section 722(a) of the MMA also revised section 1852(e)(4)(B)(i) of the Act. Prior to the MMA, section 1852(e)(4)(B)(i) of the Act indicated that the requirements in clauses (e)(1) (general requirements for quality improvement programs) and (e)(2) (the collection, analysis, and reporting of data related to quality improvement programs) could be deemed. Consistent with the changes made to section 1852(e) of the Act described earlier, section 722(a) of the MMA amended section 1852(e)(4)(B)(i) of the Act to provide, "(i)

Paragraphs (1) through (3) of this subsection (relating to quality improvement programs)." However, the printed and online versions of section 1852(e)(4)(B)(i) of the Act continue to cross-reference clauses (e)(1) and (e)(2) erroneously. Therefore, we are clarifying in this proposed rule that the requirements in section 1852(e)(3) of the Act and the subsections of § 422.152 related to section 1852(e)(3) of the Act may be deemed.

2. Delete the Reference to Quality Improvement Projects in § 422.156(b)(1)

Section 1852(e) of the Act requires each MAO to have an ongoing Quality Improvement (QI) Program for the purpose of improving the quality of care provided to its enrollees. Our regulations at § 422.152 outline the QI Program requirements MA Organizations. Section 422.152(a)(3) requires each MA Organization to conduct quality improvement projects (QIPs) for its enrollees, and § 422.152(d) establishes the requirements for the QIPs. Effective January 1, 2019, CMS eliminated the requirements for QIPs in §§ 422.152(a)(3) and 422.152(d) in the April 2018 final rule (83 FR 16440). However, the reference to QIPs was not deleted in § 422.156(b)(1), which says QIPs are exempt from the process for deeming compliance based on accreditation. Therefore, we are proposing a technical correction in this rule that would delete the phrase "the quality improvement projects (QIPs) and" from § 422.156(b)(1).

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 et seq.), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this rule that contain proposed "collection of information" requirements as defined under 5 CFR 1320.3 of the PRA's implementing regulations.

A. Wage Data

To derive average costs for the private sector, we used data from the U.S. Bureau of Labor Statistics' (BLS's) May 2017 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 2 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 2: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Business Operation Specialist	13-1000	34.54	34.54	69.08
Lawyer	23-1011	68.22	68.22	136.44
Programmer	15-1311	40.95	40.95	81.90

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. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding the Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

Proposed revisions to the Evidence of Coverage (EOC) model to take into account the new type of benefit will be submitted to OMB for approval under control number 0938-1051 (CMS-10260).

As described in section II.A.1. of this proposed rule, section 50323 of the Bipartisan Budget Act of 2018 allows MA plans to provide "additional telehealth benefits" to enrollees

starting in plan year 2020 and treat them as basic benefits for purposes of bid submission and payment by CMS. In this rule, we propose to codify requirements at § 422.135, which would authorize and set standards for MA plans to offer additional telehealth benefits.

More specifically, MA plans would be required to advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange. This notification would appear in the EOC document, which is already required and provided in model form by CMS to MA plans. There is a one-time cost for CMS to formulate the required template notification language in our EOC model for all plans to adopt without edit. Since CMS's burden to revise the model is outside the scope of the PRA, the federal cost estimate is scored in section IV.C.1. of this proposed rule. The revised template, however, is subject to the PRA and will be submitted to OMB for their review and approval.

MA plans would also be required to use their provider directory to identify any providers offering services for additional telehealth benefits and in-person visits or offering services exclusively for additional telehealth benefits. Like the EOC, the provider directory is already required and provided in model form by CMS, with MA plans obligated to and responsible for populating the document with the relevant information about the providers in the MA plan's contracted network. It is difficult to assess the additional burden associated with this requirement because the provider directory model already requires plans whose providers may have restrictions on access to include a notation next to the provider's listing indicating such restrictions. We are unsure what, if any, additional burden may be associated with this new data field and we seek information that may inform the burden.

Finally, MA plans would be required to make information about coverage of additional telehealth benefits available to CMS upon request. We do not anticipate requesting this

information from more than 9 MA plans in a given year because historically we have not received a large number of complaints about coverage of benefits that might warrant us requesting information from many plans. However, we would like to reserve the right to ask for this information if necessary. Since we estimate fewer than ten respondents, the information collection requirement is exempt (5 CFR 1320.3(c)) from the requirements of the PRA.

2. ICRs Regarding Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)

The following proposed requirements and burden will be submitted to OMB for approval under control number 0938-0753 (CMS-R-267).

As described in section II.A.2.a. of this proposed rule, we propose to establish new requirements in accordance with amendments to section 1859(f)(8) of the Act (made by section 50311(b) of the Bipartisan Budget Act of 2018), which stipulates that all dual eligible special needs plans (D-SNPs) meet certain new minimum criteria for Medicare and Medicaid integration for 2021 and subsequent years. We also propose to codify the various forms of integrated care provided by D-SNPs that have evolved since their establishment nearly 15 years ago.

In § 422.107(d), we propose that any D-SNP that is not a fully integrated dual eligible special needs plan (FIDE SNP) or a highly integrated dual eligible special needs plan (HIDE SNP), as defined in proposed § 422.2, would be subject to an additional contracting requirement. Under the additional contracting requirement, the D-SNP would notify the state Medicaid agency and/or individuals or entities designated by the state Medicaid agency of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full-benefit dual eligible individuals, as determined by the state Medicaid agency.

We also propose modifications to existing requirements for the contract between states and D-SNPs at § 422.107(b) and (c). These modifications would include requirements that D-SNPs: document their responsibility to provide, as applicable, or coordinate the delivery of Medicaid benefits; specify the categories and criteria for dual eligible individuals to be enrolled in the plan; and specify the Medicaid benefits covered by the MA organization offering the D-SNP or under a risk contract with a Medicaid managed care organization offered by the D-SNP's parent organization or another entity that is owned and controlled by its parent organization.

The primary burden arising from the proposals would consist of the following:

- Burden to the state to--

++ Execute D-SNP contract modifications; and

++ Set the terms of the notification, including its method, timing, and scope, and for some states, receive a notification from D-SNPs about enrollees' hospital and SNF admissions.

- Burden to the D-SNP to--

++ Execute a contract modification with the state Medicaid agency;

++ Notify the state Medicaid agency or its designee(s) about enrollees' hospital and SNF admissions.

a. Burden to States

(1) Contract Modifications with D-SNPs (§ 422.107)

For the initial year, we expect it would take 24 hours at $136.44/hr for a lawyer to update the state Medicaid agency's contract with every D-SNP in its market. Since half of the cost would be offset by federal financial participation for Medicaid administrative activities, we have adjusted our estimates for state agencies by 50 percent. Given the market penetration of D-SNPs

in certain states relative to others, we recognize that this estimate reflects an average cost across all states and territories with D-SNPs. We expect that the state Medicaid agency would establish a uniform requirement for all D-SNPs operating in their market. As of June 2018, there were 42 states, plus the District of Columbia and one territory (Puerto Rico), in which D-SNPs were available to MA enrollees. In aggregate, we estimate a one-time first year burden of 1,056 hours (44 respondents * 24 hr/response) at a cost of $72,040 (1,056 hr * $136.44/hr * 0.50)).

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

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

(2) Notification (§ 422.107(d))

To address differences among the states in available infrastructure, population sizes, and mix of enrollees, this rule proposes broad flexibility identifying the groups for which the state Medicaid agency wishes to be notified and how the notification should take place. Flexibilities include: (1) consideration of certain groups who experience hospital and SNF admissions; (2) protocols and timeframes for the notification; (3) data sharing and automated or manual

notifications; and (4) use of a stratified approach over several years starting at a small scale and increasing to a larger scale. We would also allow states to determine whether to receive notifications directly from D-SNPs or to require that D-SNPs notify a state designee such as a Medicaid managed care organization, section 1915(c) waiver case management entity, area agency on aging, or other organization.

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

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

remaining 26 states – that is, 13 states – would build an automated system for receiving notification of hospital and SNF admissions consistent with this proposed rule.

We estimate that, on average, this work could be accomplished in a month with one programmer and one business analyst to define requirements. Accordingly, we estimate a one-time burden of 2,080 hours (13 states * 40 hr per week * 4 weeks) per worker. Since half of the cost would be offset by 50 percent federal financial participation for Medicaid administrative activities, we estimate a cost of $85,176 (2,080 hr * $81.90/hr * 0.50) for a programmer and a cost of $71,843 (2,080 hr * $69.08/hr * 0.50) for a business analyst. In aggregate, we estimate a burden of 4,160 hours (2,080 hr for a programmer + 2,080 hr for a business analyst) at a cost of $157,019 ($85,176 for a programmer + $71,843 for a business analyst) for the update.

Because of the possible wide variability in states' approaches in implementing this requirement, we solicit comment on and any other suggestions for modeling state approaches and costs related to this provision. In addition, we believe that we have no reasonable way of estimating or illustrating burden in later years. The expected behavior among states is unknown relative to how often they will modify their notification mechanisms. Given the uncertainty involved in estimating state behavior, we are estimating a minimum of zero burden in future years on plans. The maximum burden would be the estimated first-year cost. However, we believe the maximum estimate is unlikely to be accurate since it would involve developing an automated notification system from the beginning rather than modifying an existing system. We solicit public comment on our assumptions.

b. Burden on Plans

(1) Contract Modifications with State Medicaid Agencies (§ 422.107)

For the initial year, we expect it would take 8 hours at $136.44/hr for a lawyer to update their plan's contract with the state Medicaid agency. Since states are identifying the high-risk populations for which they wish to be notified, it is reasonable to project that every D-SNP contract would negotiate one contract modification with the state Medicaid agency. There are 190 D-SNP contracts as of June 2018, of which 37 contracts, or 12.7 percent (about one-eighth), are FIDE SNPs.[32] We do not have a precise count of D-SNPs that will likely meet the proposed definition of a HIDE SNP. We assume another 12.7 percent of the 190 D-SNP contracts would be HIDE SNP contracts. Since the notification requirements are only applicable to D-SNPs that are not FIDE SNPs or HIDE SNPs, we expect that the number of contracts needing modification is 190 D-SNP contracts, less 37 FIDE SNP contracts, less 37 HIDE SNP contracts, or 116 D-SNP contracts. In aggregate, we estimate a one-time first year burden of 928 hours (116 D-SNPs * 8 hr) at a cost of $126,616 (928 hr * $136.44/hr).

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

Given the uncertainty involved in estimating state behavior, we are estimating a minimum of zero burden in subsequent years on plans. The maximum burden would be the first

[32] Centers for Medicare & Medicaid Services (2018, June). *SNP Comprehensive Report*. Retrieved from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.

year costs. However, we believe this estimate is unlikely to be accurate given our expectation that contractual changes after the first year would be iterative at most. We solicit public comment on our assumptions and whether there are reasonable ways of modeling state behavior.

(2) Notifications to State Medicaid Agencies or Their Designees (§ 422.107(d))

We have noted previously the broad flexibility in notification options for states. We also note that MA organizations are already required to have systems that are sufficient to organize, implement, control, and evaluate financial and marketing activities, the furnishing of services, the quality improvement program, and the administrative and management aspects of the organization (§ 422.503(b)(4)(ii)). Independent of the state Medicaid agency's selection of high-risk populations, protocols, and notification schedules, an MA organization's most likely method of sharing this notification would be through the use of an automated system that could identify enrollees with criteria stipulated by the states and issue electronic alerts to specified entities. We do not believe that this work is very complex. Therefore, we estimate it could be accomplished in a month with one programmer and one business analyst to define requirements. The burden would be at the contract, not the plan, level and, as noted in section II.A.2.a. of this proposed rule, we estimate 116 affected D-SNP contracts. Accordingly, we estimate a first year burden of 18,560 hours (116 contracts * 40 hr * 4 weeks) per worker. The cost for programming would be $1,520,064 (18,560 hr * $81.90/hr) for a programmer and $1,282,125 (18,560 hr * $69.08/hr) for a business analyst. In aggregate, we estimate a burden of 37,120 hours (18,560 hr for a programmer + 18,560 hr for a business analyst) at a cost of $2,802,189 ($1,520,064 + $1,282,125).

Table 3 summarizes the burden of this provision.

TABLE 3: INDIVIDUAL AND AGGREGATE BURDEN OF PROPOSED D-SNP INTEGRATION REQUIREMENTS

Item	Number of Respondents	Hours per Respondent	Total Hours	Cost per Hour	Aggregate Total Cost (in $), First Year (Adjusted)	Aggregate Cost, Years 2 and 3
Initial update by state Medicaid agency of its contracts with D-SNPs	44 (States)	24	1,056	136.44	72,040	0
Initial establishment of system for notification of hospital and SNF admissions by state Medicaid agency	13	160	2,080	81.90	85,176	0
	13	160	2,080	69.08	71,843	0
Subtotal (State Burden)	*44*	*344*	*5,216*	*varies*	*229,059*	*0*
Initial update by D-SNPs of their contracts with the state Medicaid agency	116 (D-SNPs)	8	928	136.44	126,616	0
Initial notification of hospital and SNF admissions by D-SNPs to state Medicaid agency	116	160	18,560	81.90	1,520,064	0
	116	160	18,560	69.08	1,282,125	0
Subtotal (D-SNP Burden))	*116*	*328*	*38,048*	*varies*	*2,928,805*	*0*
TOTAL	160	Varies	43,264	Varies	3,157,864	0

As indicated earlier, depending on each state's capacity, this initial year burden may suffice for several years or may change annually if states expand and change their criteria annually. Consequently, we are only estimating the initial year burden. The second and third year burden could therefore range between $0 and the full $3.1 million cost estimated for the first year. We are estimating, for years 2 and 3, a minimum of zero burden (the lower end of the range) because it is our understanding that most states and plans would not incur programming or contract related burden in years 2 and 3. We acknowledge that some states and plans may incur such burden. However, we have no reliable way to estimate the burden currently. We seek public input to help us confirm whether our zero burden estimate for years 2 and 3 is reasonable.

3. ICRs Regarding Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560 through 422.562, 422.566, 422.629 through 422.634, 438.210, 438.400, and 438.402)

As described in section II.A.2.b. of this rule, we propose to establish, for inclusion in contracts for applicable integrated plans as defined in proposed § 422.2 no later than 2021, procedures unifying Medicare and Medicaid grievances and appeals procedures in accordance with the newly enacted amendments to section 1859(f) of the Act. We also propose to establish

new regulations to require all dual eligible special needs plans (D-SNPs) to assist beneficiaries with Medicaid coverage issues and grievances at § 422.562(a)(5). The proposed requirements and burden will be submitted to OMB for approval under control number 0938-0753 (CMS-R-267).

As of June 2018, the CMS website listed 190 D-SNP contracts with 412 D-SNP plans that have at least 11 members. The universe of D-SNPs to which our proposed unified grievance and appeals procedures would apply is comprised of D-SNPs that are either fully integrated dual eligible special needs plans (FIDE SNPs) or highly integrated dual eligible special needs plans (HIDE SNPs) with exclusively aligned enrollment – that is, where all of the plan's membership receives Medicare and Medicaid benefits from the same organization. Currently, exclusively aligned enrollment occurs in only eight states: Florida, Idaho, Massachusetts, Minnesota, New Jersey, New York, Tennessee, and Wisconsin. Currently, there are only 37 D-SNPs operating under 34 contracts with 150,000 enrollees that could be classified as FIDE SNPs or HIDE SNPs which operate in states with exclusively aligned enrollment. The 150,000 enrollment figure for contract year 2018 is projected to grow to 172,000 (150,000 * 1.145)[33] enrollees by 2021, the first year that compliance with these provisions would be required. While unifying grievance and appeals provisions would necessitate states with exclusively aligned enrollment policies to modify their Medicaid managed care plan contracts to incorporate the new requirements, it would impose this burden on fewer than 10 states and would not impose additional burden for plans from a contracting standpoint, thereby falling below the threshold for PRA purposes.

We believe that our proposed requirements related to integrated organization determinations and integrated grievances should not be altogether unfamiliar to applicable

[33] Table IV.C1, "Private Health Enrollment" in 2018 Trustee Report, accessible at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf

integrated plans because, in general terms, we have proposed to adopt whichever of the current MA D-SNP or Medicaid managed care plan contract requirements under parts 422 and 438, respectively, was more protective of the rights of the beneficiary and/or provided the most state flexibility, consistent with the statutory requirements of section 1859(f)(8) of the Act. Furthermore, we believe that by unifying Medicare and Medicaid integrated organization determination and grievance requirements for applicable integrated plans (that is, FIDE SNPs and HIDE SNPs with exclusively aligned enrollment), we are ultimately reducing the level of burden on these organizations.

The burden associated with the implementation of our proposed integrated organization determination and integrated grievance procedures is summarized in section IV.B.3.a. of this proposed rule. As detailed in IV.B.3.b. of this proposed rule, the PRA exempts the information collection activities undertaken to administer our proposed unified appeals procedures. As detailed in IV.B.3.c. of this proposed rule, we believe the requirements for all D-SNPs to assist enrollees with Medicaid coverage issues and grievances in proposed § 422.562(a)(5) is also exempt from the PRA.

a. Integrated Organization Determinations and Integrated Grievances (§§ 422.629, 422.630, and 422.631)

Section 422.631 would require each applicable integrated plan to issue one integrated organization determination, so that all requests for benefits covered by applicable integrated plans would be subject to the same integrated organization determination process. In § 422.631(d)(1), we would require that an applicable integrated plan send an integrated notice when the organization determination is adverse to the enrollee. The proposed notice would include information about the determination, as well as information about the enrollee's appeal

rights for both Medicare and Medicaid covered benefits. Though integrating information on Medicare and Medicaid appeal rights would be a new requirement, we note that requirements 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 this proposed provision would have minimal impact on plans based on our understanding of how plans that would meet the definition of an applicable integrated plan under the proposed 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 would only issue a Medicaid denial (one notice). Under this proposed rule, it would do 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 in most, if not all, states would issue 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). This proposed rule would codify this practice for applicable integrated plans.

Also under current law, if the plan covered a service such as durable medical equipment or home health services under Medicaid, but denied the service under Medicare's rules, it would issue a Medicare denial even though the service was actually covered by the plan based on its Medicaid contract. Under this proposed rule, a plan covering both Medicare and Medicaid benefits would no longer need 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 estimate the reduction in plan burden resulting from our

proposed unified appeals requirements. However, we solicit feedback on the burden imposed on integrated plans by having to send such a Medicare denial notice when the service is covered by the plan under Medicaid rules. We are developing an integrated denial notice for use by applicable integrated plans. This form, and its associated requirements and burden, will be submitted to OMB for approval separately from this proposed rule once it is developed.

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

Under § 422.630(c), enrollees of applicable integrated plans could file integrated grievances with the plan orally or in writing, in alignment with current Medicare and Medicaid requirements, or with the state, in states that have existing processes for accepting Medicaid grievances in place in accordance with § 438.402(c)(3). Because this proposed provision simply

extends an existing avenue for filing grievances, in states where it exists, for enrollees to file Medicaid benefits grievances with the state, we do not expect this proposal to increase the volume of grievances that either states or applicable plans would be responsible for handling. Section 422.630(d) would permit an enrollee to file an expedited grievance, which is available under current law for Medicare-covered, but not Medicaid-covered, benefits. We estimate that the availability of an expedited grievance for Medicaid benefits would have a negligible impact on information collection activities because applicable integrated plans would already have procedures in place to handle expedited grievances for Medicare-covered services, which could be leveraged for Medicaid-covered services. Furthermore, the availability of the expedited resolution pathway (where under current law there is only one resolution pathway for Medicaid-covered services) would have no impact on the volume of grievances.

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

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

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

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

(1) Updates to Policies and Procedures

There would be an initial one-time burden for plans to update their policies and procedures to reflect the proposed new integrated organization determination and grievance procedures. Under §§ 422.630 and 422.631, we estimate it would take 8 hours at $69.08/hr for a business operations specialist to revise current policies and procedures. In aggregate, we estimate a one-time burden of 272 hours (8 hr * 34 contracts) at a cost of $18,790 (272 hr * $69.08/hr).

While there might be some update burden in future years, we consider this unlikely and, even if it were to occur, it would not be on the same magnitude as in the first year. We are therefore estimating a zero burden for years 2 and 3, though we acknowledge the unlikely possibility that costs could be as high as in year 1 – that is, $18,790.

(2) Record Maintenance

D-SNPs, like other MA plans, are currently required to maintain records for grievances (§ 422.504(d)). However, § 422.629(h) would require 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.

There would be an initial one-time burden for plans to revise their systems for record-keeping related to integrated grievances. We anticipate this task would take a programmer 3 hours at $81.90/hr. Three hours is consistent with the per-response time estimated in the recent Medicaid Managed Care May 2016 final rule (81 FR 27498). In aggregate, we estimate a one-time burden of 102 hours (3 hr * 34 contracts) at a cost of $8,354 (102 hr * $81.90/hr).

(3) Grievance Notice Consolidation

Section 422.630(e) would require that applicable integrated plans issue a notice upon resolution of the integrated grievance, unless the grievance was made orally and the enrollee did not request a written response. We assume in our analysis that plans issue two separate Medicare and Medicaid grievance resolution notices under current practice when a grievance is made in writing, whereas under this proposal they would issue one consolidated notice. To calculate savings, we must add the cost of notification and the cost of grievance review.

(4) Cost of Notification

To calculate the savings due to Medicare and Medicaid notice consolidation, we utilize the following figures: (1) the number of enrollees in the exclusively aligned plans in contract year 2021, which is 172,000; (2) the time of notification using either a standard notice or a copy

of the decision prepared by the reviewer (traditionally such a routine notification is estimated as 1 minute per notification (1/60 of an hour)); (3) the hourly wage for a business operations specialist; and (4) the percent of total enrollees expected to file a grievance (the recent Medicaid Managed Care May 2016 final rule (81 FR 27498) estimates a 2 percent filing rate, while the burden under OMB control number 0938-0753 (CMS-R-267) estimates 6.8 percent (17 percent of enrollees that are dissatisfied * 40 percent of dissatisfied enrollees who file a grievance)).

For purposes of specificity, we assume the average of these two estimates, 4.4 percent (1/2 * [6.8 percent + 2 percent]) represents the percent of enrollees filing a grievance with the integrated plan. Therefore, we estimate the annual savings due to notifications as 126 hours (1 minute * 172,000 enrollees * 0.044) at a cost of $8,704 (126 hours * $69.08/hr). The aggregate savings for years 2 and 3 are 252 hours (1 minute x 172,000 enrollees * 0.044 * 2 years) at a cost of $17,408 (252 hours * $69.08 * 2 years).

(5) Cost of Grievance Review

We assume the review will be done by a business operations specialist. Based on the Medicaid Managed Care May 2016 final rule (81 FR 21498), we assume the average grievance takes 30 minutes for a business operations specialist to resolve. Thus, the aggregate annual savings for review is 3,784 hours (172,000 enrollees * 0.044 * 0.5 hr) at a cost of $261,399 (3,784 hr * $69.08/hr). We estimate the aggregate savings for years 2 and 3 to be 7,568 hours (172,000 enrollees * 0.044 x 0.5 hr * 2 years) at a cost of $522,797, (3,784 hr * $69.08/hr * 2 years).

(6) Storage

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

b. Unified Appeals Procedures (§§ 422.629, 422.633, and 422.634)

The implementing regulations of the PRA at 5 CFR 1320.4 exclude information collection activities during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. We conclude that a beneficiary's appeal of an adverse integrated coverage determination as proposed in this rule, and the subsequent information collection activities necessitated by that integrated appeal – for example, acknowledgement of integrated reconsiderations at § 422.629(g), recordkeeping related to integrated appeals at § 422.629(h), and notification of the applicable integrated plan's integrated reconsideration determination at § 422.633(f)(4) – are exempt from the PRA on the basis that an appeal is submitted in response to an administrative action against a specific individual. Therefore, this exemption would cover any information collection activities undertaken after the integrated organization determination by an applicable integrated plan.

c. Assisting with Medicaid Coverage Issues and Grievances (§ 422.562(a)(5))

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

d. Summary

The burden associated with the individual components of our proposed provisions for unified grievance and appeals procedures for applicable integrated plans, as well as aggregate cost, are summarized in Table 4A.

TABLE 4A: SUMMARY OF PROPOSED D-SNP UNIFIED GRIEVANCE AND APPEALS PROCEDURES BURDEN (OMB 0938-0753)

Item	Number of Respondents	Hours per Respondent	Total Hours	Cost per Hour	Aggregate Cost (in $), First Year	Aggregate Cost, Years 2 and 3
Updates to Policies and Procedures	34	8	272	$69.08	18,790	0
Record Maintenance	34	3	102	$81.90	8,354	0
Grievance Notice Consolidation	7,568	1/60	(378)	$69.08	(8,704)	(17,408)
Grievance Review	7,568	0.5	(11,352)	$69.08	(261,399)	(522,797)
Total	7,602	varies	(11,356)	varies	(242,959)	(540,205)

4. ICRs Regarding Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§ 423.153)

As described in section II.A.3. of this proposed rule, section 50354 of the Bipartisan Budget Act of 2018 requires the establishment of a process under which the sponsor of a PDP that provides prescription drug benefits under Medicare Part D may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format standardized extracts of Medicare Parts A and B claims data about its plan enrollees. In this rule we propose to add a new § 423.153(g) to implement the process for requesting this data.

More specifically, in order to receive this data, PDP plans would be required to request the data and complete an attestation. We have not finalized the operational aspects of this provision. Therefore, this segment of the rule does not constitute a means for notice and comment as referenced in 5 CFR1320.8(d)(3) and CMS will seek a comment through separate **Federal Register** notices per the Paperwork Reduction Act.

5. ICRs Regarding Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184,

and §§ 422.166(i)(1) and 423.186(i)(1))

As described in section III.B.1. of this proposed rule, we are proposing measure updates for the 2022 and 2023 Star Ratings, enhancements to the cut point methodology for non-CAHPS measures, and a policy for calculating the Part C and D Star Ratings when extreme and uncontrollable circumstances occur. The proposed provisions would not change any respondent requirements or burden pertaining to any of CMS's Star Ratings-related PRA packages, including: OMB control number 0938-0732 for CAHPS (CMS-R-246), OMB control number 0938-0701 for HOS (CMS-10203), OMB control number 0938-1028 for HEDIS (CMS-10219), OMB control number 0938-1054 for Part C Reporting Requirements (CMS-10261), and OMB control number 0938-0992 for Part D Reporting Requirements (CMS-10185). Since the proposed provisions would not impose any new or revised information collection requirements (that is, reporting recordkeeping, or third-party disclosure requirements) or burden, we are not making changes under any of the aforementioned control numbers.

6. ICRs Regarding Improving Clarity of the Exceptions Timeframes for Part D Drugs (§§ 423.568, 423.570, and 423.572)

The proposed provisions would not impose any new or revised information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) or burden. Consequently, the provisions are not subject to the PRA.

7. ICRs Regarding Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6))

As described in section III.C.1. of this proposed rule, the proposed provisions would not involve activities for plan sponsors and MA organizations outside of those described in the April 2018 final rule. The proposed provisions are, generally speaking, clarifications of intended

policy and would not impose any new or revised information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) or burden. Consequently, the provisions are not subject to the PRA.

8. ICRs Regarding Medicare Advantage Risk Adjustment Data Validation Provisions (§§ 422.300, 422.310(e), and 422.311(a))

As described in section III.C.2. of this proposed rule, we are proposing that extrapolation may be utilized as a valid part of audit authority in Part C, as it has been historically a normal part of auditing practice throughout the Medicare program. We are also proposing that this extrapolation authority be applied to the payment year 2011 RADV contract-level audits and all subsequent audits to reduce the Part C improper payment rate. Additionally, we are proposing not to apply a FFS Adjuster to audit findings.

The proposed provisions would not impose any new or revised information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) or burden since the utilization of extrapolation will not affect the existing process for MA organizations submitting medical record documentation pursuant to RADV audits. Consequently, the provisions are not subject to the PRA.

C. Summary of Proposed Information Collection Requirements and Burden

TABLE 4B: ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulatory Reference	Provision Brief Title	OMB and CMS Control Numbers	Item	Respondents	Hours per Respondent	Total Hours	Cost per Hour	Total Cost, Year 1	Aggregate Cost, Years 2 and 3
§ 422.107	Integration	0938-0753 (CMS-R-267).	Initial update of States of their Contracts with D SNPs	44	24	1,056	136.44	72,040[1]	0
§ 422.107	Integration	0938-0753 (CMS-R-267).	Initial notification systems for State Medicaid Agencies	13	160	2,080	81.90	85,176[1]	0
§ 422.107	Integration	0938-0753 (CMS-R-267).	Initial notification systems for State Medicaid Agencies	13	160	2,080	69.08	71,843[1]	0
Subtotal (State Burden)				*57*	*Varies*	*5,216*	*Varies*	*229,059*	*0*
§ 422.107	Integration	0938-0753 (CMS-R-267).	Initial updates of D-SNPs of their Contracts with the State	116	8	928	136.44	126,616	0
§ 422.107	Integration	0938-0753 (CMS-R-267).	Initial notification of D-SNPs to Medicaid Agencies	116	160	18,560	81.90	1,520,064	0
						18,560	69.08	1,282,125	
§§ 422.630 and 422.631	Unified Appeals and Grievances	0938-0753 (CMS-R-267).	Initial Update on Grievance Procedures	34	8	272	69.08	18,790	0
§§ 422.630, and 422.631	Unified Appeals and Grievances	0938-0753 (CMS-R-267).	Record Maintenance	34	3	102	81.90	8,354	n/a
§§ 422.630, and 422.631	Unified Appeals and Grievances	0938-0753 (CMS-R-267).	Notification Requirements	7,568	(0.0167)	(126)	69.08	(8,704)	(17,408)
§§ 422.630, and 422.631	Unified Appeals and Grievances	0938-0753 (CMS-R-267).	Grievance Review Requirements	7,568	(0.5)	(3,784)	69.08	(261,399)	(522,797)
Subtotal				*15,436*	*Varies*	*34,512*	*Varies*	*2,685,846*	*540,205*
Total				*15,493*	*Varies*	*39,728*	*Varies*	*2,914,905*	*540,205*

NOTE: Reflects 50 percent reduction to Federal Matching program.

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to the Office of Management and Budget (OMB) for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, please visit CMS's website at: https://www.cms.gov/Regulations-andGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html, or call the Reports Clearance Office at (410) 786–1326.

We invite public comments on these proposed information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule and identify the rule (CMS-4185-P) and where applicable the ICR's CFR citation, CMS ID number, and OMB control number.

See the **DATES** and **ADDRESSES** sections of this proposed rule for further information.

IV. Regulatory Impact Analysis

A. Statement of Need

This rule proposes to implement specific provisions of the Bipartisan Budget Act of 2018 related to additional telehealth benefits, MA dual eligible special needs plans (D-SNPs), and Part D sponsors' access to Medicare claims data. The rule also proposes to improve quality and accessibility; clarify certain program integrity policies; reduce burden on providers, MA organizations, and Part D sponsors through providing additional policy clarification; and implement other technical changes regarding quality improvement. Although satisfaction with the MA and Part D programs remains high, these proposals are responsive to input we received from stakeholders while administering the programs, as well as through our requests for comment. CMS decided to modify the MA and Part D Prescription Drug Plan Quality Rating System in response to comments from the proposed rule entitled Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, The Medicare Prescription Drug Benefit Programs, and the PACE program (November 28, 2017, 82 FR 56336).

In this proposed rule, we are proposing policies to continue to drive affordable private plan options for Medicare beneficiaries that meet their unique healthcare needs, such as through supporting innovation in telehealth among MA plans to provide more options and additional benefits for MA enrollees. These proposed provisions align with the Administration's focus on the interests and needs of beneficiaries, providers, MA plans, and Part D sponsors.

B. Overall Impact

We examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving

Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act (the Act), section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

This proposed rule affects MA plans and Part D sponsors (NAICS category 524114) with a minimum threshold for small business size of $38.5 million (http://www.sba.gov/content/small-business-size-standards). This proposed rule additionally affects hospitals (NAICS subsector 622) and a variety of provider categories, including physicians and specialists (NAICS subsector 621).

To clarify the flow of payments between these entities and the federal government, note that MA organizations submit bids (that is, proposed plan designs and projections of the revenue needed to provide those benefits, divided into three categories—basic benefits, supplemental benefits, and Part D drug benefits) in June 2019 for operation in contract year 2020. These bids project payments to hospitals, providers, and staff as well as the cost of administration and profits. These bids in turn determine the payments from the Medicare Trust Fund to the MA organizations that pay providers and other stakeholders for their provision of covered benefits to enrollees. Consequently, our analysis will focus on MA organizations.

There are various types of Medicare health plans, including MA plans, Part D sponsors, demonstrations, section 1876 cost plans, prescription drug plans (PDPs), and Program of All-Inclusive Care for the Elderly (PACE) plans. Forty-three percent of all Medicare health plan organizations are not-for-profit, and 31 percent of all MA plans and Part D sponsors are not-for-profit. (These figures were determined by examining records from the most recent year for which we have complete data, 2016.)

There are varieties of ways to assess whether MA organizations meet the $38.5 million threshold for small businesses. The assessment can be done by examining net worth, net income, cash flow from operations, and projected claims as indicated in their bids. Using projected monetary requirements and projected enrollment for 2018 from submitted bids, 32 percent of the MA organizations fell below the $38.5 million threshold for small businesses. Additionally, an analysis of 2016 data—the most recent year for which we have actual data on MA organization net worth—shows that 32 percent of all MA organizations fall below the minimum threshold for small businesses.

If a proposed rule may have a significant impact on a substantial number of small entities, the proposed rule must discuss steps taken, including alternatives, to minimize burden on small entities. While a significant number (more than 5 percent) of not-for-profit organizations and small businesses are affected by this proposed rule, the impact is not significant. To assess impact, we use the data in Tables 18 A and B, which show that the raw (not discounted) net effect of this proposed rule over 10 years is $20.8 million. Comparing this number to the total monetary amounts projected to be needed just for 2020, based on plan submitted bids, we find that the impact of this rule is significantly below the 3 to 5 percent threshold for significant

impact. Had we compared the 2020 impact of the proposed rule to projected 2020 monetary need, the impact would be still less.

Consequently, the Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities, and we have met the requirements of the RFA. In addition, section 1102(b) of the Act requires us to prepare a regulatory analysis for any final rule under title XVIII, title XIX, or Part B of Title XI of the Act that may have significant impact on the operations of a substantial number of small rural hospitals. We are not preparing an analysis for section 1102(b) of the Act because the Secretary certifies that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $150 million. This proposed rule is not anticipated to have an effect on state, local, or tribal governments, in the aggregate, or on the private sector of $150 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this proposed rule does not impose any substantial costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this proposed rule, then we should estimate the cost associated with regulatory review. There are currently 750 MA contracts (which also includes PDPs), 50 State Medicaid

Agencies, and 200 Medicaid Managed Care Organizations (1,000 reviewers total). We assume each entity will have one designated staff member who will review the entire rule. Other assumptions are possible and will be reviewed after the calculations.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this rule is $107.38 per hour, including fringe benefits and overhead costs (http://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it will take approximately 12.5 hours for each person to review this proposed rule. For each entity that reviews the rule, the estimated cost is therefore, $1,342 (12.5 hours * $107.38). Therefore, we estimate that the total cost of reviewing this regulation is $1,342,000 ($1,342 * 1000 reviewers).

Note that this analysis assumed one reader per contract. Some alternatives include assuming one reader per parent entity. Using parent organizations instead of contracts would reduce the number of reviewers to approximately 500 (assuming approximately 250 parent organizations), and this would cut the total cost of reviewing in half. However, we believe it is likely that reviewing will be performed by contract. The argument for this is that a parent organization might have local reviewers; even if that parent organization has several contracts that might have a reader for each distinct geographic region, to be on the lookout for effects of provisions specific to that region.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget (OMB).

C. Anticipated Effects

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§

422.100, 422.135, 422.252, 422.254, and 422.264)

As stated in the preamble, section 50323 of the Bipartisan Budget Act of 2018 allows MA plans to provide "additional telehealth benefits" to enrollees starting in plan year 2020 and treat them as basic benefits for purposes of bid submission and payment by CMS. We propose to codify requirements at § 422.135, which would authorize and set standards for MA plans to offer additional telehealth benefits. The proposed regulation has the following impacts.

There are two primary aspects of the proposed additional telehealth provision that could affect the cost and utilization of MA basic benefits, with a corresponding impact on Medicare program expenditures. The most direct effect is the reclassification of certain telehealth services covered by MA plans pre-Bipartisan Budget Act of 2018 from supplemental benefits to basic benefits. This change will lead to higher basic benefit bids, as the cost of additional telehealth benefits will be included in the development of the basic benefit bid. The impact on the basic benefit bid may be muted due to the exclusion of capital and infrastructure costs and investments related to additional telehealth benefits from the bid.

Prior to estimating the impact on the bid, we point out several other sources of impact. Many studies have argued that telehealth will increase utilization of medical services by making them more accessible. However, the increased utilization could lead to increased savings or cost. The increased utilization could lead to significant savings due to prevention of future illness. Alternatively, the increased utilization could lead to increased costs if enrollees start seeing doctors for complaints on which they did not traditionally seek medical advice. We cite below studies for each possibility. Additionally, if there are increased telehealth visits, providers may request increased face-to-face visits to protect themselves from liability.

Consequently, there are four potential impacts of this provision, which we discuss in

more detail later in this section. The four areas are as follows:

- Impact on the Medicare Trust Fund
- Savings for Enrollees due to Decreased Travel Time to Providers
- Savings from Illness Prevention due to Increased Access to Services
- Increased Costs if Unnecessary Medical Visits Increase

Because of the wide variability in potential impact, we solicit comments on best practices in telehealth and the resulting savings.

a. Impact on the Medicare Trust Fund

Superficially, there appears to be no program change since the provision simply reclassifies certain benefits as basic instead of supplemental. Thus, the same benefits are provided. However, a closer look at the language and assumptions of the provision show that, while collectively additional telehealth benefits will yield a negligible change in program spending, there is a small transfer of costs (0.002 percent of the MA baseline) from enrollees to the Medicare Trust Fund, associated with reclassifying these benefits from supplemental to basic benefits. Supplemental benefits are generally paid with rebates while basic benefits are paid by a capitation rate, calculated with reference to the bid. For the plans to provide benefits through rebates requires additional funding since the amount of rebates provided by the Medicare Trust Fund averages only $0.66 on the dollar. Thus, the effect of this provision is that either the enrollee pays a lower supplemental premium or receives richer supplemental benefits. In either case, the enrollee saves and the Medicare Trust Fund incurs a cost. It follows that this provision creates a transfer from enrollees to the Medicare Trust Fund. After accounting for infrastructure costs, and backing out the Part B premium, the extra cost to the Medicare Trust Fund is projected

to be $80 million over 10 years. The calculations for the first 10 annual estimates are presented in Table 6 of this rule and discussed in the narrative.

In order to estimate the 10-year impact (2020 through 2029) of the proposed additional telehealth benefits provision on the Medicare Trust Fund, we considered the following six factors.

- We first estimated the costs of additional telehealth benefits that are to be transferred from supplemental benefits to basic benefits. Using the 2019 submitted bid information, we estimated that $0.09 per member per month (pmpm) would be transferred. We computed $0.09 by examining and averaging the largest organizations' telehealth benefits, particularly under the category "Web and Phone Based Technology." The reason for basing estimates on the largest organizations is that only the largest organizations included the category "Web and Phone Based Technology" as a separate line item in their bids. The other organizations had multiple, non-telehealth benefits, in the same line as the telehealth benefits, and so we were not able to distinguish the costs between telehealth and non-telehealth for the smaller organizations. Information from the 2018 Medicare Trustees Report[34] shows that the applicable medical-inflation trend that should be applied to the $0.09 pmpm is 5.2 percent per year; the average trend can be derived from information in Table IV.C3 of this report.

- We applied the pmpm amounts to the projected MA enrollment for the years 2020 through 2029. The source of the projected MA enrollment is Table IV.C1 of the 2018 Medicare Trustees Report.

- We assumed that 15 percent of the additional telehealth benefits would be considered capital and infrastructure expenses. As discussed in the preamble, these expenses are excluded

[34] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf

from the Medicare Trust Fund payments for additional telehealth benefits. We obtained the 15 percent assumption by subtracting the 85 percent required Medical Loss Ratio (MLR) from 100 percent. We used the MLR as a proxy for the medical share of provider payments.

- We applied the average rebate percentage of 66 percent, which is based on the expected submitted bid information, including expected enrollment and expected average Star Ratings.

- We applied a factor of 86 percent to the calculation, which represents the exclusion or the backing out of the Part B premium.

- However, per OMB guidance, ordinary inflation should be carved out of estimates, while medical inflation, which outpaces ordinary inflation (as well as enrollment growth), may be retained. The source of the ordinary inflation is Table IV.D1 of the 2018 Medicare Trustees Report. It is 2.6 percent per year for each of the years 2020 through 2029.

Combining these six factors, we calculated the net costs to the Medicare Trust Fund to be $6.1 million in 2020, $6.5 million in 2021, $6.9 million in 2022, $7.3 million in 2023, and $7.7 million in 2024. We calculated the net costs to the Medicare Trust Fund for years 2025 through 2029 to be $8.2 million, $8.5 million, $9.0 million, $9.5 million, and $9.9 million, respectively. The calculations of impact for 2020 through 2029 are summarized in Table 6. The total cost for all 10 years is found in the right-most column of Table 6, titled "Net Costs."

TABLE 5: CALCULATIONS OF NET COSTS PER YEAR TO THE MEDICARE TRUST FUND FOR ADDITIONAL TELEHEALTH BENEFITS

Year	Enrollment (thousands)	PMPM Cost	Number of Months per Year	Gross Amount ($ in millions) (A)	Infrastructure Costs (B)	Average Rebate Percentage (C)	Backing out of Part B Premium (D)	Net Cost ($millions) (A * (1-B) * (1-C) * (D) * (E))	Ordinary Inflation (F)	Net Costs ($millions) (A * (1-B)) * (1 - C) * (D) (E)/ (1+(F))^(year-2019)
2020	21,995	0.09	12	25.0	15%	66%	86%	6.2	2.6%	6.1
2021	22,873	0.10	12	27.3	15%	66%	86%	6.8	2.6%	6.5
2022	23,739	0.10	12	29.8	15%	66%	86%	7.4	2.6%	6.9
2023	24,584	0.11	12	32.5	15%	66%	86%	8.1	2.6%	7.3
2024	25,395	0.12	12	35.3	15%	66%	86%	8.8	2.6%	7.7
2025	26,198	0.12	12	38.4	15%	66%	86%	9.5	2.6%	8.2
2026	26,986	0.13	12	41.6	15%	66%	85%	10.2	2.6%	8.5
2027	27,737	0.14	12	44.9	15%	66%	85%	11.0	2.6%	9.0
2028	28,455	0.14	12	48.5	15%	66%	85%	11.9	2.6%	9.5
2029	29,101	0.15	12	52.2	15%	66%	85%	12.8	2.6%	9.9
Raw Total										79.6

b. Savings for Enrollees Due to Decreased Travel Time to Providers

Additional telehealth benefits will save enrollees the cost of traveling to providers. Currently, original Medicare telehealth benefits are used to bring healthcare services to MA enrollees, including those in rural locations. Stakeholders have informed CMS that MA enrollees like the use of telehealth services to reduce travel times and have greater access to providers that may not otherwise be available.

The analysis assumes a replacement of some face-to-face provider visits with telehealth visits and no additional increase in overall provider visits. Although, as discussed later in this section, there are studies suggesting the possibility of increased provider visits due to ease of access of telehealth, these studies are mainly theoretical and furthermore suggest methods to curb the unwanted increase in visits; it might therefore, be very reasonable to assume that there is no increase. Another important point to bear in mind is that increased telemonitoring does not cost the enrollee extra time. Once a system is set up to electronically transfer medical measurements, the enrollee does not have to spend extra time for this transmission. A provider will only intervene if a medical measurement indicates the possibility of an adverse medical event. However, in such a case, the expected adverse medical event might be resolvable with a phone call or medication adjustment and is less costly time-wise than an actual face-to-face provider visit.

An additional concern with this estimation is that it does not take into account that the current MA program already has certain telehealth benefits, such as phone hotlines and telemonitoring. Therefore, it is not accurate to estimate the effect of telehealth in general without differentiating the former allowance of telehealth and the new allowances afforded by this provision.

We believe that the primary driver of telehealth savings is not the authority under the law to use it, but rather, increased availability of telehealth technology and implementation. For example, although current MA guidelines allow some telehealth services as supplemental benefits, only the largest plans have provided specific, line item data on it in their bid submissions.

Another example, illustrating that availability, not authority under the law, is the primary driver of telehealth savings, is found in national usage of telehealth. Although telehealth has always been allowed by commercial plans, it is rapidly increasing now because of increased availability and ease of implementation. Studies continually point to the growth potential for using telehealth; these studies emphasize that telehealth is not being used where it could be and that the issues are feasibility and availability.[35]

Thus, allowing plans to offer additional telehealth benefits, or reclassify their current supplemental telehealth benefits as basic benefits, would not, by itself, increase telehealth usage. Rather, the increased telehealth usage comes when telehealth technologies are readily available and easy to implement. The goal of this provision is to foster an atmosphere where both commercial and MA plans will be equally interested in the increasingly accessible technology and seek to incorporate it in their offerings.

In summary, we acknowledge the possibility that the estimates below, assuming no increase in provider visits and not taking into account current telehealth practices, may have elements of overestimation. Because of our uncertainties, we invite industry comments on our analysis.

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[35] See https://www.ncbi.nlm.nih.gov/pubmed/23406075. Also see Harry Wang, Director Health and Mobile Product Research, Parks Associates "Virtual Health Care will revolutionize the Industry If we let it", Forbes, 2014, accessible at https://www.forbes.com/sites/ciocentral/2014/04/03/virtual-health-care-visits-will-revolutionize-the-industry-if-we-let-it/#4ee9a9e97c25

To estimate the impact on enrollee travel time, we need four estimates:

- Average travel time and average travel distance per visit: While it is difficult to estimate the savings in reduced travel time quantitatively, since distances from enrollees to providers vary significantly, to estimate the travel time to providers we use a former CMS standard that providers should be located within 30 minutes or 30 miles of each enrollee. While this standard has since been replaced by a more sophisticated measurement of access, we can use it as a proxy. The former CMS standard was used because it is formulated simply in terms of time (one-half hour) and miles (30 miles) and does not differentiate among provider types. The current standards for access involve sophisticated algorithms, which involve more than two parameters (time and mileage), and additionally differ by geographic location and provider types. Therefore, the current standards were not suitable. We therefore assume that the midpoint, 15 minutes or 0.25 hour, represents the typical travel time to providers per enrollee visit. [36] We similarly believe that 15 miles (one-half of 30 miles) is the average travel distance per provider visit. We note the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of employment, and educational attainment. CMS estimates cost per hour for enrollees using the occupational title "All Occupations" (occupation code 00-0000) from the BLS, with a mean wage of $24.34/hour. Thus, the net savings per enrollee per telehealth visit to providers would be $17.57 ($24.34 hourly wage * 0.25 minutes travel time * 2 (round trip) + 15 miles * 2 (round trip) * 18 cents a mile (cost of gasoline for medical transportation[37])). This is summarized in Table 7.

[36] This would result in 30 minutes (2 * 15 minutes) roundtrip. The following article using independent sources estimates 37 minutes, which is close to our estimate: https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1130
[37] https://www.irs.gov/newsroom/standard-mileage-rates-for-2018-up-from-rates-for-2017

- Average number of visits per enrollee: The Center for Disease Control (CDC) estimates that in 2014, 65-year-olds and older average 5.89 visits per person.[38]

- Number of MA enrollees: Table IV.C1 of the 2018 Medicare Trustees Report provides the projected MA enrollment.

- Percent, per year, of provider visits that are telehealth: Ideally, we would like an estimate on the number of total visits and telehealth visits for 65-year-olds. However, these data are not available. Therefore, we use the best available proportions. We proceed as follows.

The CDC website cited above estimates 885 million provider visits in 2014. This is an aggregate number over all age groups; the 885 million was not broken out further by age group.

Absent information on the proportion of telehealth visits among total visits by 65-year-olds to providers, we use general averages (across all age groups) with the understanding that some accuracy is lost. The Statista website suggests 22 million telehealth visits in 2014.[39] This implies that 2.49 percent (22/885) of all physician visits were for telehealth.

Inferring growth rates from the numbers on the Statista website, the projected low and high growth rate for telehealth services is 1.089 percent and 1.22 percent respectively. Other websites give similar ranges. For example, in three places Becker gives three estimates for telehealth growth rates of 14.3 percent, 16.5 percent, and 27.5 percent.[40] Because of this variability, we use the lower estimate for projected telehealth growth, which is about 1.089 percent. These numbers can be used to estimate the proportion of provider visits that will be telehealth in future years. For example, in 2015, we assume 1.089 (growth rate) * 2.49 percent

[38] https://www.cdc.gov/nchs/products/databriefs/db292.htm
[39] https://www.statista.com/statistics/820756/number-of-telehealth-visits-in-us/
[40] See https://www.beckershospitalreview.com/healthcare-information-technology/telemedicine-to-attract-7m-patient-users-by-2018-12-statistics-on-the-thriving-market.html; https://www.beckershospitalreview.com/telehealth/global-telemedicine-market-to-experience-16-5-annual-growth-rate-through-2023.html ; https://www.beckershospitalreview.com/healthcare-information-technology/the-growth-of-telehealth-20-things-to-know.html;

(proportion of provider visits that are telehealth in 2014) = 2.71 percent of provider visits will be telehealth visits.

Multiplying these four numbers together—average savings per visit ($17.57) * visits per enrollee (5.89) * number of MA enrollees * percent of provider visits that are telehealth (2.49 percent * 1.089 per year)—we arrive at a conservative estimate of $60 million, growing to $100 million in 2024, and $170 million in 2029. Had we used the higher projected visits, we would have obtained $60 million, growing to $540 million. The results are summarized in Table 8.

We emphasize that these results are have a tendency toward underestimation for the following reasons:

- We have only estimated the impact on physician visits and have not taken into account telehealth surgery and telemonitoring.
- We have assumed an 8.9 percent growth rate.
- We have applied the growth rate in telehealth for all age groups to the 65 and older population.

On the other hand, we have not carved out current MA telehealth utilization (an overestimating effect). However, we believe this is a good starting point for estimation of savings to enrollees. In other words, the use of the 2.49 percent estimate, above, would be reasonable if MA enrollees currently have negligible access to telehealth and then, as a result of this proposed rule, begin using telehealth at a rate similar to the national average. However, there is presently some telehealth coverage in MA, so the preceding method most likely yields a substantial overestimate of the impact of the telehealth provision, and thus the results are used for illustrative purposes only. As such, we welcome comments, especially from groups that have data relevant to 65-year-olds, on the rule-induced incremental use of telehealth.

These illustrative estimates do not reflect the possible effect of increased unnecessary medical visits, that is, medical visits made because of the ease of access of telehealth in situations when enrollees normally would not seek medical care. We discuss our rationale in section IV.C.1.d. of this proposed rule.

TABLE 7: TRAVEL SAVINGS PER PROVIDER VISIT, TELEHEALTH

Label	Item	Amount	Source
(A)	One way travel to provider	0.25 hours	Former CMS standard of provider availability within 30 minutes (we use midpoint of 30 and 0 minutes, or 15 minutes). An alternative source cited above suggests 18.5 minutes one way.
(B)	Travel to and from provider	2	
(C)	Wages for enrollee per hour	$24.34	OMB guidance, use of occupational code 00-0000 on BLS website
(D)	Mileage cost per mile for medical travel	$0.18	IRS website
(E)	Mileage	15 miles	Former CMS standard of provider availability within 30 miles (we use midpoint of 30 and 0 miles, or 15 miles).
(F)	Wage savings per provider visit	$12.17	(A) * (B) * (C)
(G)	Mileage savings per provider visit	$5.40	(A) * (E) * (D)
	Total savings per visit	$17.57	(F) + (G)

TABLE 8: ILLUSTRATION OF POTENTIAL TRAVEL SAVINGS PER YEAR, TELEHEALTH

Year	Total Savings (in millions) to Enrollees in Travel time from Telehealth	MA Enrollment	Savings per Telehealth Visit	Provider Visits per Enrollee	Percentage of Provider Visits that use Telehealth
2020	$59.7	23,181	$17.57	5.89	2.49%
2021	$67.5	24,062	$17.57	5.89	2.71%
2022	$76.2	24,972	$17.57	5.89	2.95%
2023	$85.9	25,858	$17.57	5.89	3.21%
2024	$96.7	26,708	$17.57	5.89	3.50%
2025	$108.7	27,549	$17.57	5.89	3.81%
2026	$121.9	28,375	$17.57	5.89	4.15%
2027	$136.4	29,161	$17.57	5.89	4.52%
2028	$152.4	29,913	$17.57	5.89	4.92%
2029	$169.7	30,590	$17.57	5.89	5.36%

c. Savings From Illness Prevention Due to Increased Access to Services

Telehealth savings due to increased prevention may arise from easier access to services. The additional telehealth benefits to be included in the MA basic benefit bid stem from the Bipartisan Budget Act of 2018 amendment of section 1852 of the Act. These services will likely represent a mix of replacement of pre-Bipartisan Budget Act of 2018 face-to-face encounters and

additional services. We believe that increased coverage of the additional telehealth benefits will generally result in an aggregate reduction in use of emergency room visits and inpatient admissions because the relative increased ease of receiving healthcare services should improve health outcomes and reduce avoidable utilization that results from untreated conditions exacerbating illness. Several studies predict that telehealth can significantly reduce illness through prevention. We mention four areas: (1) healthcare management; (2) medication therapy management (MTM); (3) transitional care programs; and (4) post-hours telemonitoring.

(1) Healthcare Management

Telehealth has been shown to increase efficiency through better healthcare management.[41] MA enrollees who choose telehealth are better able to manage their conditions through the use of technology for treatment plan management and medication management. Treatment often involves changes to the patient's lifestyle, such as weight management, smoking cessation, and dietary changes. Using technology to conduct lifestyle counseling remotely makes it more likely that the provider and patient will work collaboratively on the treatment plan.

(2) Medication Therapy Management (MTM)[42]

Additionally, telehealth can help significantly with patients who need multiple medications. Remote medication management can reduce the multiple patient visits often necessary to get the appropriate mix of medications. One recent meta-study on MTM

[41] Armaignac, Donna Lee, Saxena, Anshul, Rubens, Muni, Valle, Carlos, Williams, Lisa-Mae, Veledar, Emir, and Gidel, Louis (2018). "Impact of Telemedicine on Mortality, Length of Stay, and Cost Among Patients in Progressive Care Units: Experience From a Large Healthcare System." Critical Care Medicine, 46(5): 728–735.
[42] Our current MA program allows telemonitoring, hospital readmission prevention programs, and post-discharge in home medication reconciliation.

summarizes seven studies, showing that using comprehensive medication reviews (the principle driver of MTM savings) reduced hospitalizations, readmissions, drugs, and mortality.[43]

(3) Transitional Care Programs

Telehealth has been used to provide transitional care for discharged hospital patients. One study found a savings of $1,333 per beneficiary, half of which was due to reduced inpatient follow-up care.[44]

(4) Post-Hours Telemonitoring

A study reviewing after-hours telemedicine (in which a nurse would transmit data about patients with a change in condition) reported savings of $4,000 per skilled nursing facility bed, which translates into savings of $5 million against a cost of $1 million for implementing the program.[45]

d. Increased Costs if Unnecessary Medical Visits Increase

There are two primary concerns regarding telehealth savings.[46] The first concern is that the direct-to-consumer telehealth visits are more likely to result in follow-up appointments, testing, or prescriptions. Compared to similar visits to other settings, direct-to-consumer telehealth could increase spending (by MA plans, providers, the government, and/or patients). For example, given liability concerns, direct-to-consumer telehealth physicians may be more

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[43] Evan A. DeZeeuw, PharmD; Ashley M. Coleman, PharmD; and Milap C. Nahata, PharmD, MS, "Impact of Telephonic Comprehensive Medication Reviews on Patient Outcomes ",Am J Manag Care. 2018;24(2):e54-e58

[44] Keith Kranker, PhD; Linda M. Barterian, MPP; Rumin Sarwar, MS; G. Greg Peterson, PhD; Boyd Gilman, PhD; Laura Blue, PhD; Kate Allison Stewart, PhD; Sheila D. Hoag, MA; Timothy J. Day, MSHP; and Lorenzo Moreno, PhD "Rural Hospital Transitional Care Program Reduces Medicare Spending",Am J Manag Care. 2018;24(5):256-260

[45] David Chess, MD; John J. Whitman, MBA; Diane Croll, DNP; and Richard Stefanacci, DO "Impact of After-Hours Telemedicine on Hospitalizations in a Skilled Nursing Facility"The Amer. J. of Manage Care,24(8), 2018, e54-e56

[46] J. Scott Ashwood, Ateev Mehrotra, David Cowling, , and Lori Uscher-Pines, "Direct-To-Consumer Telehealth May Increase Access To Care But Does Not Decrease Spending," Health Affairs, Vol. 36, No. 3: Delivery System Innovation, accessible at https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1130

likely to recommend that patients have a subsequent in-person visit with a provider. Therefore, although the telehealth visit is less costly, the per-episode cost of a direct-to-consumer telehealth visit could be greater than that of a visit in other settings.

The second concern is that the convenience of direct-to-consumer telehealth may drive many patients to seek care for an illness when they would not have sought care if telehealth had not been available. Instead of saving money by substitution (that is, replacing more expensive visits to physician offices or emergency departments), direct-to-consumer telehealth may increase spending by new utilization (that is, increasing the total number of patient visits).

To document these concerns, the Health Affairs article cited above presents a study on commercial health plan enrollees with specific illnesses. The study showed an increase of $45 per year per telehealth user. The authors acknowledge that a key attraction of telehealth for commercial health plans and employers is the potential savings involved in replacing physician office and emergency department visits with less expensive virtual visits; however, increased convenience may tap into unmet demand for health care, and new utilization may increase overall healthcare spending.

The article acknowledges various limitations of the study: (1) it applies to commercial health plan enrollees; (2) only one telehealth company in California was used; (3) the users had a low telehealth usage, and study results could differ if telehealth becomes more popular; and (4) only one medical condition was studied (which is frequently dealt with by telehealth).

The article also mentions various approaches that could be used to reduce extra costs, for example, increasing cost sharing to prevent indiscriminate use of telehealth on conditions that one would not ordinarily see a provider.

In conclusion, although telehealth has a significant potential to produce savings, this potential is counterbalanced by several factors, which might reduce these savings or produce increased costs for MA plans, providers, the government, and/or patients (such as increased in-person visits and increased utilization patterns). Additionally, several telehealth services—telemonitoring and remote access technologies (including web/phone based hotlines)—are allowed under current guidelines; many MA plans already offer these services as supplemental benefits.

As regards to the illustrative calculation of a $6 to $10 million transfer from enrollee to government and a savings to enrollees of $60 to $100 million per year, arising from reduced travel times, we now summarize the simplifying assumptions below.

First, the transfer from enrollee to government reflects an assumption that the same number of services will occur, but their classification will change from supplemental to basic. This simplifying assumption is certainly contradicted by the expected growth rate in telemonitoring. However, we have argued above that increased use of telemonitoring will result in significant healthcare savings due to prevention of future illnesses. Therefore, a $6 to $10 million estimate of cost per year may be outweighed by healthcare savings.

Second, the savings of $60 to $100 million per year arising from reduced travel time to providers reflects several simplifying assumptions such as applying proportions of telehealth services of provider visits in the general population to the aged population and ignoring the current extent of telehealth services in MA plans.

Thirdly, we have disregarded the possible cost impact of telehealth arising from enrollees indiscriminately using telehealth for provider services in situations where provider assistance was not previously sought. As noted previously, this negative effect was found in one

commercial provider on a population with a very low telehealth usage. Furthermore, there are possible methods to prevent indiscriminate use of telehealth services. The majority of the articles we cited and reviewed previously were very positive about health savings and did not mention increased costs. Therefore, we determined the best approach is to assume the increased costs from telehealth will not arise.

Fourth, we ignore the current usage of telehealth by MA plans who may furnish telehealth as a supplemental benefit. Our primary reason for ignoring this is the lack of adequate data. Other reasons for ignoring this are that only large plans have listed supplemental telehealth as a line-item in their bid documentation, and articles generally show that even where allowed (such as in commercial plans) telehealth is not used to its full potential.

In light of the information provided previously, all our estimates of impact should be seen as reasonable first attempts at estimation with the intent to solicit comments from the industry on their experiences and whether such assumptions are warranted or should lead to modifications in our estimates.

There is one additional negligible cost, mentioned in section III.B.1. of this proposed rule, which arises from the proposed provision at § 422.135(c)(2) requiring that MA plans advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange. This notification would appear in the Evidence of Coverage (EOC) document, which is already required and provided in model form by CMS to MA plans. There is a one-time cost for CMS staff to formulate the required template notification language in our EOC model for all plans to adopt without edit.

We estimate it would take a CMS Central Office staff person 1 hour to produce language for such a model. The typical Central Office employee is at the GS-13 level. The 2018 wages

for the Baltimore area, available at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/AK_h.pdf, indicate an approximate hourly wage of $50 (with the Step 3 hourly wage being slightly below and the Step 4 hourly wage being slightly above). We further allow 100 percent for fringe benefits and overhead costs. Thus, the expected burden to the federal government is a negligible cost of $100 (1 hour * $50 wage per hour * 2).

2. Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)

As stated in the preamble, 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 and enrollment sanctions for those MA organizations that fail to comply with the new standards. We propose to add a revised definition for "D-SNP" at § 422.2 and establish at § 422.107 revisions to the existing minimum state Medicaid agency contracting requirement for D-SNPs other than FIDE SNPs and HIDE SNPs, which are also defined at § 422.2.

As noted in the preamble, many of the changes we are proposing would unify and streamline existing requirements, which should reduce burden and are therefore not expected to have impact. For example:

• Passive enrollment: The reference to the proposed definition of a HIDE SNP at § 422.2 would not materially change the plan types that are eligible for passive enrollment; rather, the existing rule simply refers to them as the D-SNPs that meet a high standard of integration under the supplemental benefit authority at § 422.102(e).

• Enhanced Supplemental Benefits: We also propose clarifying at § 422.102(e) that not only are HIDE SNPs that meet minimum quality and performance standards eligible to offer

supplemental benefits, but FIDE SNPs that similarly meet minimum quality and performance standards may do so as well. While this amendment does not change what has occurred in practice, we believe it clarifies the types of plans that are eligible to offer enhanced supplemental benefits.

Additional costs were presented in the Collection of Information (COI) section of this proposed rule. However, the COI made an assumption which must be modified for purposes of this Regulatory Impact Analysis (RIA) section: the cost to State Medicaid agencies for updating their contracts was reduced by 50 percent reflecting the Federal administrative matching rate for state Medicaid agency expenditures. This is correct for the COI since federal costs are never listed in the COI. However, for the purposes of the RIA section they should be listed. More specifically, the total cost should be listed as a true cost (that is payment for services and goods) to the state agencies, half of which is transferred to the federal government. The simplest way to describe the impact of this provision is simply to redo the summarizing table in the COI section. The assumptions and sources underlying the numbers in this table have been presented in the COI section. This is presented in Table 9.

Table 9 notes which numbers are true savings or costs and which numbers or parts of estimates are transfers. Since the impacts are for services such as updating manuals or updating software, the cost and savings impact are true costs or savings (which in some cases reflect a transfer to the federal government). Table 9 also notes who bears the cost (states or MA plans). As can be seen, the aggregate cost of this provision is a first year cost of $3.4 million, $0.2 million of which are transfers between the Federal government and states. As noted in the section, although additional updates may be necessary in future years, we are scoring this as $0 as a best estimate given uncertainty regarding the need for additional changes by states and plans

after the first year.

TABLE 9: COST OF INTEGRATION

Item	Respondents	Hours per Respondent	Total Hours	Cost per Hour	Total Cost	Nature of Cost Impact. To Whom and Whether True Impact or Transfer.
Initial update by state Medicaid agency of its contracts with D-SNPs*	44(States)	24	1,056	$136.44	$144,081	50% true cost of services to state; 50% transfer to Federal government
Initial update by D-SNPs of their contracts with the state Medicaid agency	116 (D-SNPs)	8	928	$136.44	$126,616	True cost of services to MA Plans
Initial establishment of system for notification of hospital and skilled nursing facility admissions by state Medicaid agency*	13 (States)	160	2,080	$81.90	$170,352	50% true cost of services to State; 50% transfer to Federal government
	13(States)	160	2,080	$69.08	$143,686	50% true cost of services to State; 50% transfer to Federal government
Initial notification of hospital and skilled nursing facility admissions by D-SNPs to state Medicaid agency	116(D-SNPs)	160	18,560	$81,90	$1,520,064	True cost of services to MA Plans
	116 (D-SNPs)	160	18,560	$69.08	$1,282,125	True cost of services to MA Plans
Total	Varies	Varies	43,264	Varies	$3,386,924	

3. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560 – 562, 422.566, 422.629 – 634, 438.210, 438.400, and 438.402)

Proposed changes to the appeals and grievances provisions at §§ 422.629 through 422.634 focus on creating MA and Medicaid appeal and grievances processes that are unified for D-SNPs that also have comprehensive Medicaid managed care contracts (or are the subsidiary of a parent organization or share a parent organization with the entity with a comprehensive Medicaid managed care contract). The proposal addresses appeals at the plan level. Currently, Medicaid and MA appeals and grievance processes differ in several key ways. These differences hinder a streamlined grievance and appeals process across Medicare and Medicaid managed care sectors and create unnecessary administrative complexity for plans that cover dual eligible individuals for both Medicare and Medicaid services. Our proposed revisions would allow

enrollees in a D-SNP that is also a Medicaid managed care plan through which the enrollees get Medicaid coverage to better understand the grievance and appeals processes and generally receive a resolution of their grievances and appeals more quickly.

There are six areas where this provision will have an impact.

- Certain Medicare Parts A and B benefits that the D-SNP has tried to terminate would be provided during the pendency of the integrated appeal at the plan level. This is estimated in detail below. The cost to the Medicare Trust Fund and beneficiaries (in the form of cost sharing) is $0.4 million in 2021 and $0.5 million in 2022-2024, growing modestly due to expected enrollment growth, to $0.6 or $0.7 million in the next few years.

- Applicable integrated plans' grievance policies and procedures and grievance notices would be updated. As discussed in the Collection of Information section, there would be a one-time first year cost of $18,790 for updates of applicable integrated plans' policies and procedures on grievances and an annual savings of $270,103 reflecting savings from Medicare and Medicaid grievance consolidation). Thus, there would be an annual savings of $0.3 million.

- Notice templates for the unified appeals for use by applicable integrated plans would be created by CMS, which is estimated to be a one-time negligible cost of about $1,000 for the work of Federal employees.

- Subregulatory guidance on integrated grievance and appeals would be developed by CMS staff, which is estimated to be a one-time negligible cost of about $2,000.

- Applicable integrated plans' appeals policies and procedures and appeals notices would be updated to comply with the unified appeals requirements, which is estimated to be a one-time negligible cost of $9,395 (4 hours per contract * 34 contracts * $69.08, the hourly wage of a business operations specialist).

- Enrollees of applicable integrated plans who wish to receive a copy of their appeal case file would request that plans send it to them at plan expense, which we estimate to cost about $38,637 annually.

The aggregate cost of this provision is $0.2 million a year. Industry would save $0.3 million each year in reduced services because grievances in Medicare and Medicaid are unified. However, this $0.3 million savings would be offset by an increase in cost of $0.5 million reflecting increased services. The $0.5 million cost (as well as the 0.3 million savings) are ultimately borne by the Medicare Trust Fund in the form of payments and beneficiaries in the form of increased cost-sharing.

We present details on these six areas in the sections that follow.

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

One of the provisions related to appeals integration may marginally impact the ways MA sponsors bid for their D-SNPs, which could marginally impact Medicare spending. We propose that the existing standards for continuation of benefits at § 438.420 apply to applicable integrated plans for Medicare benefits under Parts A and B and Medicaid benefits in our proposed integrated appeals requirements at § 422.632. Under our proposal, and as is applicable to Medicaid managed care plans currently, if an applicable integrated plan decides to stop or reduce a benefit that the enrollee is currently authorized to receive, the enrollee could request that the benefit continue to be provided at the currently authorized level while the enrollee's appeal is pending through the integrated reconsideration. Currently, MA plans in general are not required to provide benefits pending appeal, whereas in Medicaid it has been a long-standing feature.

It is our expectation that the new integrated appeals provisions will result in an increase in expenditures by applicable integrated plans for Medicare covered services because they will

be required to continue coverage for services during the pendency of the reconsideration request, or first-level appeal under our proposal.

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

The assumptions, sources and calculations are summarized in Tables G5 and G6 in this rule and further clarified as follows.

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

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

The next step is to determine the average level of benefit subject to the appeals. Table 1 in the report Medicare Part C QIC Reconsideration Data for 2016[47] contains data on the number

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

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

Taking the product of the number of applicable integrated plan service reconsiderations in 2021 (568) and average benefit value in 2021 ($774) yields an estimated cost in 2021 of $439,632 (that is, 568 * $774) due to an increase in Medicare expenditures stemming from the unified appeals procedures for applicable integrated plans. We believe that this figure represents an upper bound of the cost given that not all applicable services will be rendered during the extended period of benefit continuation being proposed in this regulation. These calculations are summarized in Table 10.

Using the 2021 estimates as a basis, estimates for 2021 through 2029 are presented in Table 11. The following assumptions were used in creating Table 11:

• As described earlier in this section, the numbers in the row for 2021 come from Table 10.

• The projected FIDE SNP enrollment for 2022 through 2029 was obtained by multiplying the estimated 2021 FIDE SNP enrollment of 172,000, using SNP enrollment growth factors inferred from Table IV.C1 in the 2018 Trustees Report.

• The projected cost per appeal for 2022 through 2029 was obtained by first multiplying the estimated 2021 cost per appeal of $774 by FFS per capita growth rates obtained from internal documentation for the Table of FFS USPCC, non-ESRD estimates in attachment II of the 2019 Rate Announcement and Call Letter (https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf).

The results are summarized in Table 11. As can be seen, there is an estimated true cost (reflecting purchase of goods and services) of $0.4 million in 2021 and $0.5 million in 2022 through 2024. Eighty-six percent of this cost is transferred from the plans to the Medicare Trust Fund. The remainder of this cost is born by beneficiary cost sharing. The cost of appeals between 2025 and 2029 is $0.5 to 0.6 million for the Medicare Trust Fund and $0.1 million for beneficiaries.

TABLE 10: IMPACT OF INTEGRATED APPEALS PROVISION OF FIDE SNPS

Row ID	Item Description	Number	Data Source
	MMP Appeals: 2016		
(A)	Appeals	1,232	2016 Parts C and D Reporting Requirements PUF (not incl. Part D MTM data) from site https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html Sum of service reconsiderations partially favorable and adverse for organization type "Demo"
(B)	Enrollment	368,841	2016 Parts C and D Reporting Requirements PUF (not incl. Part D MTM data) from site https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html Sum of enrollment for organization type "Demo"
(C)	MMP appeals per 1000	3.3	(C) =(A) / (B) * 1000
	FIDE SNP Appeals 2021		
(D)	Enrollment 2018	150,000	Internal CMS enrollment extract in HPMS data system for July 2018
(E)	DE SNP enrollment growth: '18-'21	14.5%	Table IV.C1, "Private Health Enrollment" in 2018 Trustee Report, accessible at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf
(F)	Enrollment 2021	172,000	(F) = (D)*(1+(E))
(G)	MMP Appeals per 1000 in 2016	3.3	Row (C)
(H)	FIDE SNP appeals 2021	568	(H) = (F)/1000 * (G)
	Cost of FIDE SNP Appeals: CY 2021		
(I)	Average benefit per appeal (2016)	$737	Data obtained from CMS Appeal & Grievance Contractor
(J)	Inflation: 2016 – 2021	19.5%	Ratio of CY 2021 and CY 2016 entries in table "Comparison of Current and Previous Estimates of the FFS USPCC - Non ESRD" in the 2019 Rate Announcement and Call letter accessible at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf
(K)	Carving out Ordinary Inflation 2016-2021	13.80%	Product of the urban consumer price index (CPI-U) increase factors for 2016-2020 inclusive. Data were obtained from Table V.B2 in the 2017 CMS Trustee Report accessible at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf
(L)	Average benefit per appeal (2021)	$774	(L) = (I) * (1 + (J)) / (1+(K))
(M)	Aggregate amount of appeal (2021)	$440,000	(M) = (L) * (H)

TABLE 11: NET COST PER YEAR TO THE MEDICARE TRUST FUND FOR INTEGRATED PLAN APPEALS

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

b. Updating Plan Grievance Policies and Procedures and Consolidation of Plan Notifications

As detailed in the Collection of Information section of this proposed rule, there are only 34 contracts representing 37 D-SNPs that we currently believe would be classified as a HIDE SNP or FIDE SNP and operate in states that have policies requiring exclusively aligned enrollment across MA and Medicaid managed care plans. The analysis presented in the Collection of Information section for unified grievance and appeals estimates initial one-time cost of $18,790 and $8,374 and annual savings, due to reduction of notifications, of $270,103. Thus, the annual savings is $0.2 million in the first year and $0.3 million annually thereafter.

c. Creation of New Grievance and Appeal Notice Templates

When MA plans send out notifications to enrollees, they usually have the option to use templates created by CMS. To address the proposed new unified grievance and appeal procedures, CMS Central Office staff must create new notice templates. We estimate that three new notice templates must be created. We estimate each new template will require 3 hours of work by a GS level 13, step 5 (GS-13-5), employee. The 2018 hourly wages for a GS-13-5

Federal employee is $52.66.[48] We allow 100 percent for Fringe Benefits and overtime. Thus the expected one-time negligible initial cost is $1,000 (actually, $948 = 3 templates * 3 hours per template * $52.66 hourly wage * 2 for overtime and fringe benefits).

d. Subregulatory Guidance in CMS Manuals on the New Grievance and Appeals Procedures

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

e. 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. Using our estimate for grievance procedures, we estimate for appeals an initial one-time negligible cost of $9,395 (that is, 4 hours per contract * 34 contracts * $69.08, the hourly wage of a business operations specialist including 100 percent for fringe benefits and overhead).

f. Sending Appeal Files to Enrollees Who Request Them

Medicaid managed care regulations currently require plans to send, for free, appeal case files to enrollees who appeal while, in contrast, MA regulations require sending such files at a reasonable cost. Our proposal would require 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.

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

Livanta,[49] a Quality Improvement Organization, estimates the cost per case file as $40-$100. 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,[50] 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.[51] Based on our experience, we assume that 10 percent of all appeals would require a file sent. Finally, as indicated in the Collection of Information section, there are 37 D-SNPS 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).

In conclusion, the primary driver of costs of this provision are the effects on the Medicare Trust Fund and beneficiary cost sharing presented in Tables G5 and G6. These costs are offset by annual savings of $0.3 million due to unification of grievance procedures. Other costs are considered negligible (below a $50,000 threshold for E.O. 13773 accounting). A summary by

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

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

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

year is presented in Table 12.

TABLE 12: SUMMARY OF COSTS (MILLIONS) FOR GRIEVANCE INTEGRATION PROVISION

	Unification of Grievance Procedures	Cost to Medicare Trust Fund	Cost Sharing for MA Enrollees	Total
2020	----	-----		0
2021	(0.2)	$0.4	$------	0.2
2022	(0.3)	$0.4	$0.1	0.2
2023	(0.3)	$0.4	$0.1	0.2
2024	(0.3)	$0.4	$0.1	0.2
2025	(0.3)	$0.5	$0.1	0.3
2026	(0.3)	$0.5	$0.1	0.3
2027	(0.3)	$0.5	$0.1	0.3
2028	(0.3)	$0.5	$0.1	0.3
2029	(0.3)	$0.6	$0.1	0.4

We note that these costs and savings are true costs and savings since they reflect payment for additional or fewer economic resources (reduced notifications and increased appeals). The increased appeals costs are a cost to MA plans, which transfer this cost to enrollees and the Medicare Trust Fund (the government).

4. Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§ 423.153)

As described in section II.A.3. of this proposed rule, section 50354 of the Bipartisan Budget Act of 2018 requires the establishment of a process under which the sponsor of a PDP that provides prescription drug benefits under Medicare Part D may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format standardized extracts of Medicare claims data about its plan enrollees. In this rule we propose to add a new § 423.153(g) to implement the process for requesting these data.

To estimate the impact we require a model of operationalizing this provision, without

however committing to a particular operationalizing process. We outline a process which--

- Meets all regulatory requirements; and
- Requires as little burden as possible to make and grant requests.

We solicit comments from stakeholders on this proposed operationalization.

Electronic request and transfer are superior (have less burden) than paper processes. We could therefore add functionalities to the CMS HPMS system (or other CMS systems) which would allow the following functions:

- Request of claims data for the current and future quarters for enrollees of the PDP requesting the data.
- Request to no longer receive data.
- Attestation that all regulatory requirements will be complied with. The attestation would be in the form of a screen listing all regulatory requirements; the authorized PDP HPMS user would have to electronically attest by clicking a button.

Such a process would combine request and attestation. The receipt of the submission would verify completeness of request. Furthermore, there would be no burden in request (under 1 minute of work).

The HPMS contractors estimate that this would be a one-time update costing approximately $200,000.

Besides requesting the data, data must be transmitted to the requesting sponsor. Ideally, data would be transmitted electronically but we do not yet have such an API. Instead, we would treat requested data like data requested for research. Typically, such data is downloaded onto hard drives and mailed to requestors.

The data could come from the Chronic Condition Warehouse (CCW). We asked our contractors the cost of downloading quarterly such data and sending it out. The cost varies by sponsor size. Currently, based on CMS public data, there are 63 PDP sponsors. Their size and the quarterly cost per sponsor of providing them with data, should they request it, is summarized in Table 13.

TABLE 13: COST PER PDP SPONSOR PER QUARTER FOR TRANSMITTING CLAIMS DATA

PDP Size in Enrollees	Number of Sponsors	Cost per Quarter per Sponsor for Transmission of Claims Data
Above 5 million	1	$26,500
1 million – 5 million	6	$17,500
100,000 – 1 million	11	$10,500
Under 100,000	45	$10,500

To complete the annual impact analysis we need an estimate of proportions for each plan size that would request data. For example, we are certain that the 1 PDP sponsor with over 5 million enrollees will request data. Thus the annual burden for that plan size is 1 * 4 quarters x $26,500 per quarter = $106,000. Similarly, if we assume that all six PDP sponsors with enrollments between 1 and 5 million would request data then the annual burden is 6 sponsors * 4 quarters * $17,500 per quarter per sponsor = $420,000. If we assume that only three-quarters of these six sponsors request data then the annual burden would be 0.75 * $420,000 = $315,000. In the absence of any other basis for the decision, it is reasonable to assume that the proportion goes down as the size goes down. In the absence of data, we could use a descent of simple fractions (1, three-fourths, one-half, one-fourth). Note, that 50 percent of plans with under 100,000 enrollees have under 10,000 enrollees. It is very unlikely that such plans would have the resources to use the data. Thus an assumption that only 50 percent of plans under 100,000 request data is reasonable. However, we consider multiple scenarios. Table 14 presents for a

variety of scenarios of proportions and their total impact. The average of the five scenarios is $1.5 million while the median is $1.3 million. The range of impacts is $0.8 million - $2.9 million. For purposes of E.O. 13771 accounting we are listing the impact as $1.5 million annually, with a $0.2 million one-time cost in the first year. We do not trend this estimate by year since the number of PDP sponsors has remained at 63 since 2015.

TABLE 14: ANNUAL BURDEN OF PROVIDING CLAIMS DATA TO PDP SPONSORS

Scenario Label	Proportion of sponsors with over 5 million enrollees requesting data	Proportion of sponsors with 1 - 5 million enrollees requesting data	Proportion of sponsors with 100,000 – 1 million enrollees requesting data	Proportion of sponsors with under 100,000 enrollees requesting data	Aggregate annual burden based on Costs provided in Table 13
A	100 percent	75 percent	50 percent	33 percent	$1.3 million
B	100 percent	100 percent	75 percent	50 percent	$1.8 million
C	100 percent	50 percent	33 percent	25 percent	0.9 million
D	100 percent	100 percent	100 percent	100 percent	$2.9 million
E	100 percent	100 percent	50 percent	0 percent	$0.8 million

We do not anticipate any further burden. It is most likely that the PDP sponsor would exclusively use the data. In the event that downstream entities are shared any data they are already bound in their contracts by all Medicare regulations including the regulations of this provision. Even if there would be a need to modify contracts to address the regulatory requirements of using such data, it would require at most one hour of work of a GS-12 or GS-13 staff member and one hour of review by a GS-15. A total of 2 hours of work by Federal employees would have a burden significantly less than $1,000. Hence, we are not further scoring this negligible impact.

5. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i)(1) and 423.186(i)(1))

We are proposing some measure specification updates. These type of changes are routine and do not have an impact on the highest ratings of contracts (that is, overall rating for MA-PDs, Part C summary rating for MA-only contracts, and Part D summary rating for stand-alone prescription drug plans). Hence, there will be no, or negligible, impact on the Medicare Trust Fund.

We are also proposing some adjustments for disasters. The proposed policy would make adjustments to take into account the potential impact on contracts when there are extreme and uncontrollable circumstances affecting them. This policy is in response to the multiple disasters in 2017 and 2018, including several hurricanes and wildfires. We are proposing a policy to permit an adjustment to Star Ratings when extreme and uncontrollable circumstances occur during the performance period or measurement period for MA and Part D plans.

We are also proposing enhancements to the current methodology to set Star Ratings cut points. The intent of the changes is to increase the stability and predictability of cut points from year to year. This proposal is consistent with the CMS goal to increase transparency. We believe this provision would also have minimal impact on the highest ratings of contracts. Specifically, simulations of the proposal using the 2018 Star Ratings show that the QBP ratings overall would increase for less than 1 percent of MA enrollees.

6. Improving Clarity of the Exceptions Timeframes for Part D Drugs (§§ 423.568, 423.570, and 423.572)

We are proposing to limit the amount of time an exception request can be held open to 14 calendar days, meaning that there will be an outside limit to how long the request is in a pending status while the Part D plan sponsor attempts to obtain the prescribing physician's or other prescriber's supporting statement. Under current manual guidance, plan sponsors are instructed that an exception request should only be held open for a reasonable period of time if a supporting statement is needed. We believe that no more than 14 calendar days is a reasonable period of time to have an exception request open and this proposal seeks to codify that standard. We do not expect this proposal to have any new impact on the number of pending appeals or pose a potential burden to plan sponsors, as we expect plans are already making and notifying enrollees of decisions on exception requests under a similar reasonable timeframe. Based on findings from plan sponsor audits, this proposed timeframe is generally consistent with how plans sponsors have operationalized the current standard that cases only be held open for a reasonable period of time pending receipt of a prescriber's supporting statement. Therefore, we do not expect that plan sponsors would need to hire more staff or adjust their operations in a manner that would affect costs. Consequently, we expect the impact of this proposed requirement to be negligible.

7. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6))

We do not anticipate any additional cost or savings associated with our proposed preclusion list provisions. As we indicated in section III. of this proposed rule, the proposed provisions would not involve activities for plan sponsors and MA organizations outside of those

described in the April 2018 final rule. Our proposed provisions are, generally speaking, clarifications of our intended policy and do not constitute new requirements. Hence, the expected impact is negligible.

8. Medicare Advantage Risk Adjustment Data Validation Provisions (§§ 422.300, 422.310(e), and 422.311(a))

a. Proposals

This proposed rule would create regulations to govern the collection of *extrapolated* audit findings. As CMS develops its approach to statistical sampling and extrapolation, it is taking account of the recommendations of the 2016 General Accounting Office (GAO) report on CMS audit practices.[52] For example, CMS has been randomly selecting 30 plans for audit based on factors unrelated to payment error. In recent years, only half of those audited plans have had findings; the other half have had no net findings of improper payments. The GAO has recommended that CMS select plans that historically have high error rates either from the National audits as published in the Report of the Chief Financial Officer or from prior CMS audits. This recommendation would probably increase the number of findings, and hence the amount collected through the audits. CMS has accepted all GAO findings and intends to develop its sampling and extrapolation methodology consistent with them.

To clarify in more detail how the proposed rules would impact the recovery audit process we note the following facts:

- RADV recovery for payment years 2011, 2012, and 2013 included 30 MA contracts per payment year. For each contract, 200 enrollees have been selected. The aggregate cost to the government for each audit is $54 million.

[52] https://www.gao.gov/products/GAO-16-76

- National audits are for the purpose of payment error measurement in the Part C program. A nationally representative sample of 600 enrollees are selected from approximately 200 plans. Each plan contributes between 1 to 15 enrollees with many plans contributing under 10 enrollees. The annual cost to the government of a national audit is between $6 to 10 million. No recovery is made through the national audits.

- Findings from the national and contract-level audits will be used to predict beneficiaries at most risk for improper payment. CMS will use these estimates to target plans at most risk for improper payment for RADV audit.

- By better targeting audits to improper payment, CMS expects any sentinel effect of RADV to continue to reduce the historical Part C error rate.

b. Expected Impact of These Provisions

While we cannot fully estimate the quantitative impact of this provision, we can clearly identify certain components of impact. We start with some basic facts mentioned in the preceding narrative.

- With extrapolated audit findings, we would realize a positive ROI. The cost per year for a RADV audit is $54 million. Non-extrapolated recoveries would result in a $10 to 15 million collection per audit.

- Extrapolating audit findings does not increase the cost burden on the plan. The cost to the plan of complying with a RADV audit is neither the subject of nor affected by this provision. This provision addresses recovering extrapolated or non-extrapolated audit findings. While extrapolation does increase the level of the audit recovery, because returning improper payments is not a cost, the decision to extrapolate does not impact the cost to the plan.

- The audits for payment years 2011, 2012, and 2013 suggest that audited MA contracts received $650 million in of improper payments in those 3 years.
- This $650 million would be a transfer from the government to insurers since money paid for human coding error which CMS paid the contracts to pay their providers is no longer being done, meaning that the contracts must take responsibility for the improper provider payments.
- These audits cover 3 years, with 30 contracts audited each year.
- Roughly half the contracts each year had no net findings of improper payments.

Using these data we can conclude as follows:

- The audits for payment years 2011, 2012, and 2013 suggest that audited MA contracts were responsible for $650 million of improper payments in those 3 years.
- $650 million divided by 3 audit years is $217 million per audit year.
- $217 million per audit year divided by 15 contracts with audit findings per year is $14.5 million per contract with audit findings per year.
- If GAO recommendations are adopted which would facilitate focusing on contracts with expected findings, and the level of audit findings holds constant, then $14.5 million per contract with audit findings per year times 30 contract with audit findings per year would produce $435 million in audit collections per year.
- This level of recovery would produce $381 million in aggregate savings per year (that is, $435 million - $54 million, since the cost of audits would remain at $54 million).

This numerical bulleted argument is summarized in Table 15.

It might seem natural to trend the $381 million based on non-inflation factors. The following considerations argue against trending. Therefore, we are leaving the estimate of dollar savings to

the Medicare Trust Fund at $381 million per year at each year for the next 10 years with an additional $650 million the first year. A 10-year table is presented in Table 16. The arguments against trending are the following:

- The error rate of improper payments per year, as indicated in the reports of the Chief Financial Officer have been declining and are likely to continue to decline. Importantly, although we have about 10 years of data we have insufficient data to extrapolate since performance error is rarely linear. Thus trending would involve non-linear functions and would require more data.

- The aggregate amount paid to contracts is increasing due to enrollment growth. The Office of the Actuary at CMS annually publishes a Trustee Report which contains projected enrollment.[53]

- The $381 million is based on current error rates and enrollment growth. But we have already indicated that 50 percent of contracts audited had no net audit findings. We have already indicated that acceptance of GAO recommendations would facilitate targeting contracts with higher rates and have therefore assumed there would be findings in all 30 contracts audited.

For these reasons, we are leaving the annual estimate as a dollar savings to the Medicare Trust Fund of $381 million for 2021 and future years, and a dollar savings of $1.03 billion to the Medicare Trust Fund in 2020 ($381 million savings per year plus an estimated $650 million in audit recoveries for payment years 2011 through 2013). All other things being equal, the increase in enrollment will cause the nominal dollars in error to increase. The historical decline in the error rate may or may not offset the increase due to increasing enrollment making a

[53] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html

projection difficult. For this reason we hold the estimate of $381 million constant in the projection.

A table of collection for 10 years is summarized in Table 16.

TABLE 15: EXPECTED SAVINGS PER YEAR FROM RADV PROVISION

Label	Item	Amount ($ in millions)	Source or Calculation
(A)	Estimated Collection 2011-2013	$650	
(B)	Number of years, 2011-2013	3	
(C)	Estimated Collection per year, 2011-2013	$217	(C) = (A)/(B)
(D)	Number of contracts audited	30	
(E)	Percent of contracts with findings	50%	
(F)	Current Number of contracts with findings	15	(F) = (D)*(E)
(G)	Estimated Collection per year per contract	$14.5	(G)=(C)/(F)
(H)	Expected number of contracts with findings	30	If GAO report recommendations are adopted
(I)	Estimated collection per year	$435	(I)=(G)*(H)
(J)	Audit Cost per year	$54	Constant cost of auditing 200 beneficiaries per contract.
(K)	Estimated savings per year	$381	(K)= (I) - (J)

TABLE 16: IMPACT PER YEAR FROM RADV (IN MILLIONS)

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Cost of Audit	(54)	(54)	(54)	(54)	(54)	(54)	(54)	(54)	(54)	(54)
Estimated Collection Prior Years	650	0	0	0	0	0	0	0	0	0
Estimated Collection This year	435	435	435	435	435	435	435	435	435	435
Estimated Total Savings	1031	381	381	381	381	381	381	381	381	381

The estimated 10-year dollar savings to the Medicare Trust Fund could be $4.5 billion ($381 million per year * 10 years + initial $650 million recovery).

The savings come from recovered inaccurate payments of $381 million a year by the Medicare Trust Fund to plans. This money is a reduction in spending of the Medicare Trust Fund (to the plans); there will be no money transferred to enrollees. We expect that ultimately this provision could incentivize plans to submit more accurate risk-adjustment data.

The intent of this rule is to continue the sentinel effect on the reduction of the Part C error rate. The decline in the Part C error rate has correlated with the announcement of the agencies intent to use extrapolated recoveries on payment years 2011 through 2013. We believe that forgoing the extrapolation on those audits would diminish the agency's credibility going forward and consequently reduce the sentinel effect. The dollar savings to the Medicare Trust Fund are presented in Table 16. In any case, RADV audits will still continue.

D. Alternatives Considered

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

Section 1852(m)(2)(A)(i) of the Act, as added by the Bipartisan Budget Act of 2018, defines additional telehealth benefits as services that are identified for the applicable year as clinically appropriate to furnish using electronic information and telecommunications technology when a physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not at the same location as the plan enrollee (which we refer to as "through electronic exchange"). We considered various alternative definitions of "clinically appropriate" but decided not to propose specific regulation text defining the term. We are proposing to implement the statutory requirement for additional telehealth

benefits to be provided only when "clinically appropriate" to align with existing CMS rules for contract provisions at § 422.504(a)(3)(iii), which requires each MA organization to agree to provide all benefits covered by Medicare "in a manner consistent with professionally recognized standards of health care."

The statute does not specify who or what entity identifies the services for the year. We considered various alternatives, including retaining the authority as an agency to specify what services are clinically appropriate to furnish each year. MA plans could have been required to comply with an annual list of clinically appropriate services identified by CMS. However, we rejected this alternative as too restrictive; we believe MA plans are in the best position and it is in their own interest to stay abreast of professional standards necessary to determine which services are clinically appropriate. Thus, we are proposing to interpret this provision broadly by not specifying the Part B services that an MA plan may offer as additional telehealth benefits for the applicable year, but instead allowing MA plans to independently determine which services each year are clinically appropriate to furnish in this manner. Our proposed definition of additional telehealth benefits at § 422.135(a) provides that it is the MA plan (not CMS) that identifies the appropriate services for the applicable year.

We also considered alternatives to implement how telehealth benefits are provided through "electronic exchange." CMS considered defining the specific means of "electronic exchange." However, we decided to define "electronic exchange" at § 422.135(a) as "electronic information and telecommunications technology," as the former is a concise term for the latter, which is the statutory description of the means used to provide the additional telehealth benefits. We are not proposing specific regulation text that defines or provides examples of electronic information and telecommunications technology. We considered providing a

complete list of means of providing electronic information and telecommunications technology. Although we provided examples of electronic information and telecommunications technology in the preamble, we did not provide a comprehensive list because the technology needed and used to provide additional telehealth benefits will vary based on the service being offered. We believe this broad approach will avoid tying the authority in the proposed new regulation to specific information formats or technologies that permit non-face-to-face interactions for furnishing clinically appropriate services.

2. Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)

We propose to require D-SNPs that-- (1) do not meet the HIDE SNP or FIDE SNP integration standard; and (2) do not have a parent organization assuming clinical and financial responsibility for Medicare and Medicaid benefits to notify the state Medicaid agency or its designee when a high-risk full-benefit dual eligible enrollee has a hospital or skilled nursing facility admission. We considered several alternatives to this proposal, as explained in section II.A.2.a.(2). of this rule, including examples provided in the Bipartisan Budget Act of 2018: notifying the state in a timely manner of enrollees' emergency room visits and hospital or nursing home discharges; assigning each enrollee a primary care provider; and data sharing that benefits the coordination of items and services under Medicare and Medicaid. However, we believe our proposal is preferable to the alternatives when considering the degree to which it meets our criteria of-- (1) meaningfully improving care coordination and care transitions and health outcomes for dually eligible beneficiaries; (2) minimizing burden on plans and states relative to the improvements in care coordination and transitions; (3) providing flexibility to state Medicaid agencies; (4) enabling CMS to assess compliance with minimal burden on CMS, plans,

and providers; and (5) adhering to the letter and spirit of the Bipartisan Budget Act of 2018. However, we soliciting comment on these alternatives.

3. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560, 422.562, 422.566, 422.629 through 422.634, 438.210, 438.400, and 438.402)

We propose to create unified grievance and appeals procedures for certain D-SNPs (FIDE SNPs and HIDE SNPs) with exclusively aligned enrollment, which we propose defining as occurring when such a D-SNP limits enrollment to full-benefit dual eligible individuals whose Medicaid benefits are covered by the D-SNP itself, or by a Medicaid managed care organization that is the same organization, the D-SNP's parent organization, or another entity that is owned and controlled by the D-SNP's parent organization. Because most D-SNP enrollees are not enrolled in D-SNPs with exclusively aligned enrollment, we considered the feasibility of broadening the scope of these unified procedures to apply to more D-SNPs – that is, to D-SNPs without exclusively aligned enrollment. However, in most states, the majority of D-SNP enrollees have Medicaid coverage either through a different organization's Medicaid MCO, in a prepaid ambulatory or inpatient health plan (PAHP or PIHP), or through a state's Medicaid fee-for-service system. In these circumstances, the D-SNP has no control over the Medicaid grievance and appeals process. Even a D-SNP that has a Medicaid managed care organization operated by such plan's parent organization available to its enrollees, but whose members may instead enroll in other Medicaid plans, can only unify the procedures for Medicaid appeals and grievances of those enrollees who are also simultaneously enrolled in the Medicaid managed care organization controlled by such plan's parent organization. Therefore, we do not believe that it is feasible at this time to implement fully unified grievance and appeals systems for

D-SNPs and Medicaid managed care plans that do not have the same enrollees or where the organizations offering the D-SNPs and Medicaid plans are unaffiliated or even competitors.

E. Accounting Statement and Table

The following table summarizes costs, savings, and transfers by provision.

As required by OMB Circular A-4 (available at https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/), in Table 17, we have prepared an accounting statement showing the savings and transfers associated with the provisions of this proposed rule for calendar years 2020 through 2029. Table 17 is based on Tables 18 A and B which lists savings, costs, and transfers by provision.

TABLE 17: ACCOUNTING STATEMENT - CLASSIFICATIONS OF ESTIMATED SAVINGS, COSTS, AND TRANSFERS
Negative Numbers Indicate Savings

FROM CALENDAR YEARS 2020 TO 2024 [$ in millions]	Savings			Whom is Saving, Spending or Transferring
	Discount Rate			
	7%	3%	Period Covered	
Net Annualized Monetized Savings	2.17	2.12	CYs 2019-2029	
Annualized Monetized Savings	-----	-----	CYs 2019-2029	
Annualized Monetized Cost	2.17	2.12	CYs 2019-2029	Plans, Part D sponsors, State Agencies and the Federal Government.
Transfers	0.03	0.02	CYs 2019-2029	The State Agencies transfer 50% of their costs to the Federal Government though matching programs.

The following Table 18 summarizes savings, costs, and transfers by provision and formed a basis for the accounting table. For reasons of space, Table 18 is broken into Table 18A (2020 through 2024) and Table 18B (2025 through 2029). In these tables savings are indicated as negative numbers in columns marked savings while costs are indicated as positive numbers in columns marked costs. Transfers may be negative or positive with negative numbers indicating savings to the Medicare Trust Fund and positive numbers indicating costs to the Medicare Trust Fund. All numbers are in millions. The row "aggregate total by year" gives the total of costs and savings for that year but does not include transfers. Tables 18 A and B form the basis for Table 16 and for the calculation to the infinite horizon discounted to 2016 and mentioned in the conclusion.

TABLE 18A: AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2020 TO 2024

	2020 Savings	2020 Cost	2020 Transfers	2021 Savings	2021 Cost	2021 Transfers	2022 Savings	2022 Cost	2022 Transfers	2023 Savings	2023 cost	2023 Transfers	2024 Savings	2024 Cost	2024 Transfers
Total Savings	0.0			0.0			0.0			0.0			0.0		
Total Costs		4.9			1.7			1.7			1.7			1.7	
Aggregate Total	4.9			1.7			1.7			1.7			1.7		
Total Transfers			0.2			0.0			0.0			0.0			0.0
D-SNP Integration		3.2	0.2												
D-SNP Grievance & Appeals					0.2			0.2			0.2			0.2	
Claims Data		1.7			1.5			1.5			1.5			1.5	
Star Ratings				0.0			0.0			0.0			0.0		
Preclusion				0.0			0.0			0.0			0.0		
RADV	0.0			0.0			0.0			0.0			0.0		

TABLE 18B: AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2025 TO 2029

	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers	2028 Savings	2028 Cost	2028 Transfers	2029 Savings	2029 Cost	2029 Transfers
Total Savings	0.0			0.0			0.0			0.0			0.0		
Total Costs		1.8			1.8			1.8			1.8			1.9	
Aggregate Total	1.8			1.8			1.8			1.8			1.9		
Total Transfers			0.0			0.0			0.0			0.0			0.0
D-SNP Integration															
D-SNP Grievance & Appeals		0.3			0.3			0.3			0.3			0.4	
Claims Data		1.5			1.5			1.5			1.5			1.5	
Star Ratings	0.0			0.0			0.0								
Preclusion	0.0			0.0			0.0			0.0			0.0		
RADV	0.0			0.0			0.0			0.0			0.0		

F. Conclusion

As indicated in Table 17, we estimate that this proposed rule generates net annualized cost of approximately $2 million per year over 2020 through 2029. As discussed in the narrative of this Regulatory Impact Section, the Medicare Trust Fund is expected, over the next 10 years, to have an aggregate reduction in dollars spent of $4.5 billion arising from recovery of incorrect payments to plans.

G. Reducing Regulation and Controlling Regulatory Costs

The Department believes that this proposed rule, if finalized, is considered a deregulatory action under Executive Order 13771. The Department estimates that this rule generates $ 1.5 million in annualized costs at a 7-percent discount rate, discounted relative to 2016, over a perpetualtime horizon.

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 438

Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend CFR chapter IV as set forth below:

PART 422—MEDICARE ADVANTAGE PROGRAM

1. The authority citation for part 422 is revised to read as follows:

AUTHORITY: 42 U.S.C. 1302 and 1395hh.

2. Section 422.2 is amended—

a. By adding definitions of ‘‘Aligned enrollment’’ and “Dual eligible special needs plan” in alphabetical order;

b. By revising the definition of “Fully integrated dual eligible special needs plan”;

c. By adding the definition of "Highly integrated dual eligible special needs plan" in alphabetical order; and

d. In the definition of "Preclusion list" by revising the introductory text and paragraphs (1)(i), (2)(i), (2)(ii)(C) and adding paragraph (3).

The additions and revisions read as follows:

§ 422.2 Definitions.

* * * * *

Aligned enrollment refers to the enrollment in a dual eligible special needs plan of full-benefit dual eligible individuals whose Medicaid benefits are covered by such plan or by a Medicaid managed care organization, as defined in section 1903(m) of the Act, that is the same organization, its parent organization, or another entity that is owned and controlled by its parent organization. When State policy limits a dual eligible special needs plan's membership to individuals with aligned enrollment, this condition is referred to as exclusively aligned enrollment.

* * * * *

Dual eligible special needs plan or D-SNP means a specialized MA plan for special needs individuals who are entitled to medical assistance under a State plan under XIX of the Act that provides, as applicable, and coordinates the delivery of Medicare and Medicaid services, including long-term services and supports and behavioral health services, for individuals who are eligible for such services. Such a plan must have a contract with the State Medicaid agency consistent with § 422.107 that meets the minimum requirements in § 422.107(c); and, beginning January 1, 2021, must satisfy one or more of the following criteria for the integration of Medicare and Medicaid benefits:

(1) Meets the additional requirement specified in § 422.107(d) in its contract with the State Medicaid agency;

(2) Is a highly integrated dual eligible special needs plan; or

(3) Is a fully integrated dual eligible special needs plan.

* * * * *

Fully integrated dual eligible special needs plan means a dual eligible special needs plan—

(1) That provides dual eligible individuals access to Medicare and Medicaid benefits under a single entity that holds both an MA contract with CMS and a Medicaid managed care organization contract under section 1903(m) of the Act with the applicable State;

(2) Whose capitated contract with the State Medicaid agency includes coverage of specified primary care, acute care, behavioral health, and long-term services and supports, consistent with State policy, and provides coverage of nursing facility services for a period of at least 180 days during the plan year;

(3) That coordinates the delivery of covered Medicare and Medicaid services using aligned care management and specialty care network methods for high-risk beneficiaries; and

(4) That employs policies and procedures approved by CMS and the State to coordinate or integrate beneficiary communication materials, enrollment, communications, grievance and appeals, and quality improvement.

* * * * *

Highly integrated dual eligible special needs plan means a dual eligible special needs plan offered by an MA organization that also has, or whose parent organization or another entity that is owned and controlled by its parent organization has, a capitated contract with the

Medicaid agency in the State in which the dual eligible special needs plan operates that includes coverage of long-term services and supports, behavioral health services, or both, consistent with State policy.

* * * * *

Preclusion list means a CMS compiled list of individuals and entities that—

(1) * * *

(i) The individual or entity is currently revoked from Medicare for a reason other than that stated in § 424.535(a)(3) of this chapter.

* * * * *

(2) * * *

(i) The individual or entity has engaged in behavior, other than that described in § 424.535(a)(3) of this chapter, for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare.

(ii) * * *

(C) Any other evidence that CMS deems relevant to its determination; or

(3) The individual or entity, regardless of whether they are or were enrolled in Medicare, has been convicted of a felony under federal or state law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph (3) are:

(i) The severity of the offense;

(ii) When the offense occurred; and

(iii) Any other information that CMS deems relevant to its determination.

* * * * *

3. Section 422.60 is amended by revising paragraph (g)(2)(i) to read as follows:

§ 422.60 Election process.

* * * * *

(g) * * *

(2) * * *

(i) Operate as a fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan.

* * * * *

4. Section 422.100 is amended by revising paragraphs (a) and (c)(1) to read as follows:

§ 422.100 General requirements.

(a) *Basic rule.* Subject to the conditions and limitations set forth in this subpart, an MA organization offering an MA plan must provide enrollees in that plan with coverage of the basic benefits described in paragraph (c)(1) of this section (except that additional telehealth benefits may be, but are not required to be, offered by the MA plan) and, to the extent applicable, supplemental benefits as described in paragraph (c)(2) of this section, by furnishing the benefits directly or through arrangements, or by paying for the benefits. CMS reviews these benefits subject to the requirements of this section and the requirements in subpart G of this part.

* * * * *

(c) * * *

(1) Basic benefits are all items and services (other than hospice care or coverage for organ acquisitions for kidney transplants) for which benefits are available under parts A and B of Medicare, including additional telehealth benefits offered consistent with the requirements at § 422.135.

* * * * *

5. Section 422.102 is amended by revising paragraph (e) introductory text to read as follows:

§ 422.102 Supplemental benefits.

* * * * *

(e) *Supplemental benefits for certain dual eligible special needs plans.* Subject to CMS approval, fully integrated dual eligible special needs plans and highly integrated dual eligible special needs plans that meet minimum performance and quality-based standards may offer additional supplemental benefits, consistent with the requirements of this part, where CMS finds that the offering of such benefits could better integrate care for the dual eligible population provided that the special needs plan—

* * * * *

6. Section 422.107 is amended by—

a. Revising the section heading;

b. In paragraph (a) by removing the term "dual-eligible" and adding in its place the term "dual eligible";

c. By revising paragraphs (b) and (c)(1), (2), and (3);

d. By redesignating paragraph (d) as paragraph (e);

e. By adding a new paragraph (d); and

f. By adding paragraph (e)(2).

The revisions and additions read as follows:

§ 422.107 Special needs plans and dual eligibles: Contract with State Medicaid Agency.

* * * * *

(b) *General rule.* MA organizations seeking to offer a dual eligible special needs plan must have a contract consistent with this section with the State Medicaid agency.

(c) * * *

(1) The MA organization's responsibility to provide, as applicable, and coordinate the delivery of Medicaid benefits, including long-term services and supports and behavioral health services, for individuals who are eligible for such services.

(2) The category(ies) and criteria for eligibility for dual eligible individuals to be enrolled under the SNP, including as described in the Act at sections 1902(a), 1902(f), 1902(p), and 1905.

(3) The Medicaid benefits covered by the MA organization offering the SNP under a capitated contract with the State Medicaid agency or covered for the SNP's enrollees under a risk contract as defined in § 438.2 of this chapter with a Medicaid managed care organization, as defined in section 1903(m) of the Act, offered by the SNP's parent organization or another entity that is owned and controlled by its parent organization.

* * * * *

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

SNP authorizes another entity or entities to perform this notification, the SNP must retain responsibility for complying with this requirement.

(e) * * *

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

* * * * *

7. Section 422.111 is amended by revising paragraph (b)(2)(iii) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(2) * * *

(iii) By a dual eligible special needs plan, prior to enrollment, for each prospective enrollee, a comprehensive written statement describing cost sharing protections and benefits that the individual is entitled to under title XVIII and the State Medicaid program under title XIX.

* * * * *

8. Section 422.135 is added to subpart C to read as follows:

§ 422.135 Additional telehealth benefits.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Additional telehealth benefits means services that meet the following:

(1) Are furnished by an MA plan for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act; and

(2) Have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange.

Electronic exchange means electronic information and telecommunications technology.

(b) *General rule*. An MA plan may treat additional telehealth benefits as basic benefits covered under the original Medicare fee-for-service program for purposes of this part 422 provided that the requirements of this section are met. If the MA plan fails to comply with the requirements of this section, then the MA plan may not treat the benefits provided through electronic exchange as additional telehealth benefits, but may treat them as supplemental benefits as described in § 422.102, subject to CMS approval.

(c) *Requirements*. An MA plan furnishing additional telehealth benefits must:

(1) Furnish in-person access to the specified Part B service(s) at the election of the enrollee.

(2) Advise each enrollee, at a minimum in the MA plan's Evidence of Coverage required at § 422.111(b), that the enrollee may receive the specified Part B service(s) through an in-person visit or through electronic exchange.

(3) Identify, in the MA plan's provider directory required at § 422.111(b)(3)(i), any providers offering services for additional telehealth benefits and in-person visits or offering services exclusively for additional telehealth benefits.

(4) Comply with the provider selection and credentialing requirements provided in § 422.204, and, when providing additional telehealth benefits, ensure through its contract with the provider that the provider meet and comply with applicable state licensing requirements and other applicable laws for the state in which the enrollee is located and receiving the service.

(5) Make information about coverage of additional telehealth benefits available to CMS upon request. Information may include, but is not limited to, statistics on use or cost, manner(s)

or method of electronic exchange, evaluations of effectiveness, and demonstration of compliance with the requirements of this section.

(d) *Requirement to use contracted providers*. An MA plan furnishing additional telehealth benefits may only do so using contracted providers. Coverage of benefits furnished by a non-contracted provider through electronic exchange may only be covered as a supplemental benefit.

(e) *Bidding*. An MA plan that fully complies with this section may include additional telehealth benefits in its bid for basic benefits in accordance with § 422.254.

(f) *Cost sharing*. MA plans offering additional telehealth benefits may maintain different cost sharing for the specified Part B service(s) furnished through an in-person visit and the specified Part B service(s) furnished through electronic exchange.

§ 422.156 [Amended]

9. Section 422.156 is amended in paragraph (b)(1) by removing the phrase "the quality improvement projects (QIPs) and".

10. Section 422.162 is amended in paragraph (a) by adding the definitions of "Absolute percentage cap", "Cut point cap", "Guardrail", "Mean resampling", "Restricted range", and "Restricted range cap" in alphabetical order to read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

(a) * * *

Absolute percentage cap is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.

* * * * *

Cut point cap is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut point. A cut point cap can restrict upward movement, downward movement, or both.

* * * * *

Guardrail is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.

* * * * *

Mean resampling refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchal clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.

* * * * *

Restricted range is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outer fence outliers (first quartile - 3*Interquartile Range (IQR) and third quartile + 3*IQR).

Restricted range cap is a cap applied to non-CAHPS measures that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated using the prior year's measure score distribution.

* * * * *

11. Section 422.164 is amended by adding paragraphs (f)(1)(v), (g)(1)(iii)(O), and (h) to read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(f) * * *

(1) * * *

(v) CMS will exclude any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s).

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(O) CMS will reduce a measure rating to 1 star for the applicable appeals measure(s) if a contract fails to submit Timeliness Monitoring Project data for CMS's review to ensure the completeness of the contract's IRE data.

* * * * *

(h) *Review of sponsors' data*. (1) A request for CMS or the IRE to review a contract's appeals data must be received no later than June 30 of the following year.

(2) A request for CMS to review a contract's Complaints Tracking Module (CTM) data must be received no later than June 30 of the following year.

12. Section 422.166 is amended by revising paragraph (a)(2)(i) and adding paragraph (i) to read as follows:

§ 422.166 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data, and a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for three years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first three years in the program.

* * * * *

(i) *Extreme and uncontrollable circumstances*. In the event of extreme and uncontrollable circumstances that may negatively impact operational and clinical systems and contracts' abilities to conduct surveys needed for accurate performance measurement, CMS will calculate the Star Ratings as specified in paragraphs (i)(2) through (10) of this section for each contract that is an affected contract during the performance period for the applicable measures.

(1) *Identification of affected contracts.* A contract that meets all of the following criteria is an affected contract:

(i) The contract's service area is within an "emergency area" during an "emergency period" as defined in section 1135(g) of the Act.

(ii) The contract's service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).

(iii) As specified in paragraphs (i)(2) through (10) of this section, a certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

(2) *CAHPS adjustments.* (i) A contract, even if an affected contract, must administer the CAHPS survey unless exempt under paragraph (i)(2)(ii) of this section.

(ii) An affected contract will be exempt from administering the CAHPS survey if the contract completes both of the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in paragraph (i)(1)(iii) of this section in the prior calendar year.

(B) Requests and receives a CMS approved exception.

(iii) An affected contract with an exception defined in paragraph (i)(2)(ii) of this section will receive the contract's CAHPS measure stars and corresponding measure scores from the prior year.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the contract will receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure.

(3) *HOS adjustments.* (i) An affected contract must administer the HOS survey unless exempt under paragraph (i)(3)(ii) of this section.

(ii) An affected contract will be exempt from administering the HOS survey if the contract completes the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in (i)(1)(iii) of this section during the measurement period.

(B) Requests and receives a CMS approved exception.

(iii) Affected contracts with an exception defined in paragraph (i)(3)(ii) of this section will receive the prior year's HOS and Healthcare Effectiveness Data and Information Set (HEDIS)-HOS measure stars and corresponding measure scores.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract will receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each HOS and HEDIS-HOS measure.

(4) *HEDIS adjustments.* (i) An affected contract must report HEDIS data unless exempted under paragraph (i)(4)(ii) of this section.

(ii) An affected contract will be exempt from reporting HEDIS data if the contract completes the following:

(A) Demonstrates an inability to obtain both administrative and medical record data that are required for reporting HEDIS measures due to a FEMA-designated disaster in the prior calendar year.

(B) Requests and receives a CMS approved exception.

(iii) Affected contracts with an exception defined in paragraph (i)(4)(ii) of this section will receive the prior year's HEDIS measure stars and corresponding measure scores.

(iv) Affected contracts that do not have an exception defined in paragraph (i)(4)(ii) of this section may contact National Committee for Quality Assurance (NCQA) to request modifications to the samples for measures that require medical record review.

(v) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract will receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each HEDIS measure.

(5) *New measure adjustments.* For affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, CMS will apply a hold harmless provision by comparing the result of the contract's summary and/or overall rating with and without including all of the applicable new measures. If the "with" result is lower than the "without" result, then CMS will use the "without" result as the final rating.

(6) *Other Star Ratings measure adjustments.* (i) For all other measures except those measures identified in this paragraph (i)(6)(ii) of this section, affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance will receive the higher of the previous or current year's measure Star Rating and then use the corresponding measure score.

(ii) CMS will not adjust the scores or Star Ratings for the following measures, unless the exception in paragraph (i)(6)(iii) of this section applies.

(A) Part C Call Center – Foreign Language Interpreter and TTY Availability.

(B) Part D Call Center – Foreign Language Interpreter and TTY Availability.

(iii) CMS will adjust the measures listed in paragraph (i)(6)(ii) of this section using the adjustments listed in paragraph (i)(6)(i) of this section for contracts affected by extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study.

(7) *Exclusion from improvement measures.* Any measure that reverts back to the data underlying the previous year's Star Rating due to the adjustments made in paragraph (i) of this section will be excluded from both the count of measures and the applicable improvement measures for the current and next year's Star Ratings for the affected contract.

(8) *Missing data.* For an affected contract that has missing data in the current or previous year, the final measure rating will come from the current year unless any of the exceptions described in paragraphs (i)(2)(ii), (i)(3)(ii), and (i)(4)(ii) of this section apply.

(9) *Cut points for non-CAHPS measures.* (i) CMS will exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

(ii) The cut points calculated as described in paragraph (i)(9)(i) of this section will be used to assess all affected contracts' measure Star Ratings.

(10) *Reward Factor.* (i) CMS will exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds for the Reward Factor described in paragraph (f)(1) of this section.

(ii) All affected contracts will be eligible for the Reward Factor based on the calculations described in paragraph (i)(10)(i) of this section.

13. Section 422.222 is amended by revising paragraph (a) to read as follows:

§ 422.222 Preclusion list.

(a)(1)(i) Except as provided in paragraph (a)(1)(ii) of this section, an MA organization must not make payment for a health care item or service furnished by an individual or entity that is included on the preclusion list, defined in § 422.2.

(ii) With respect to MA providers that have been added to an updated preclusion list, the MA organization must do all of the following:

(A) No later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received an MA service or item from the individual or entity added to the preclusion list in this update;

(B) Must ensure that reasonable efforts are made to notify the individual or entity described in paragraph (a)(1)(ii) of this section of a beneficiary who was sent a notice under paragraph (a)(1)(ii)(A) of this section; and

(C) Must not deny payment for a service or item furnished by the newly added individual or entity , solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (a)(1)(ii)(A) of this section.

(2)(i) CMS sends written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice must contain the reason for the inclusion and inform the individual or entity of their appeal rights. An individual or entity may appeal their inclusion on the preclusion list, defined in § 422.2, in accordance with part 498 of this chapter.

(ii) If the individual's or entity's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:

(A) The notice described in paragraph (a)(2)(i) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the individual's or entity's appeal rights concerning the revocation.

(B) The appeals of the individual's or entity's inclusion on the preclusion list and the individual's or entity's revocation shall be filed jointly by the individual or entity and, as applicable, considered jointly by CMS under part 498 of this chapter.

(3)(i) Except as provided in paragraph (a)(3)(ii) of this section, an individual or entity will only be included on the preclusion list after the expiration of either of the following:

(A) If the individual or entity does not file a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list upon the expiration of the 60-day period in which the individual or entity may request a reconsideration; or

(B) If the individual or entity files a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list effective on the date on which CMS, if applicable, denies the individual's or entity's reconsideration.

(ii) An OIG excluded individual or entity is added to the preclusion list effective on the date of the exclusion.

(4) Payment denials based upon an individual's or entity's inclusion on the preclusion list are not appealable by beneficiaries.

(5)(i) Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the individual's or entity's reenrollment bar.

(ii) Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the individual or entity had they been enrolled and then revoked.

(iii) Except as provided in paragraph (a)(5)(iv) of this section, an individual or entity, regardless of whether they are or were enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are:

(A) The severity of the offense.

(B) When the offense occurred.

(C) Any other information that CMS deems relevant to its determination.

(iv) In cases where an individual or entity is excluded by the OIG, the individual or entity shall remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

* * * * *

14. Section 422.252 is amended by revising the definition of "MA monthly basic beneficiary premium", "MA monthly MSA premium", "Monthly aggregate bid amount", "Plan basic cost sharing", and "Unadjusted MA statutory non-drug monthly bid amount" to read as follows:

§ 422.252 Terminology.

* * * * *

MA monthly basic beneficiary premium means the premium amount (if any) an MA plan (except an MSA plan) charges an enrollee for basic benefits as defined in § 422.100(c)(1), and is calculated as described at § 422.262.

MA monthly MSA premium means the amount of the plan premium for coverage of basic benefits as defined in § 422.100(c)(1) through an MSA plan, as set forth at § 422.254(e).

* * * * *

Monthly aggregate bid amount means the total monthly plan bid amount for coverage of an MA eligible beneficiary with a nationally average risk profile for the factors described in § 422.308(c), and this amount is comprised of the following:

(1) The unadjusted MA statutory non-drug monthly bid amount for coverage of basic benefits as defined in § 422.100(c)(1);

(2) The amount for coverage of basic prescription drug benefits under Part D (if any); and

(3) The amount for provision of supplemental health care benefits (if any).

* * * * *

Plan basic cost sharing means cost sharing that would be charged by a plan for basic benefits as defined in § 422.100(c)(1) before any reductions resulting from mandatory supplemental benefits.

* * * * *

Unadjusted MA statutory non-drug monthly bid amount means a plan's estimate of its average monthly required revenue to provide coverage of basic benefits as defined in § 422.100(c)(1) to an MA eligible beneficiary with a nationally average risk profile for the risk

factors CMS applies to payment calculations as set forth at § 422.308(c).

15. Section 422.254 is amended by—

a. Revising paragraph (b)(1)(i);

b. Adding paragraph (b)(3)(i);

c. Reserving paragraph (b)(3)(ii); and

d. Revising paragraphs (b)(4), (c)(3)(i), and (e)(2).

The revisions and addition read as follows:

§ 422.254 Submission of bids.

* * * * *

(b) * * *

(1) * * *

(i) The unadjusted MA statutory non-drug monthly bid amount, which is the MA plan's estimated average monthly required revenue for providing basic benefits as defined in § 422.100(c)(1).

* * * * *

(3) * * *

(i) MA plans offering additional telehealth benefits as defined in § 422.135(a) must exclude any capital and infrastructure costs and investments relating to such benefits from their bid submission.

(ii) [Reserved]

(4) The bid amount is for plan payments only but must be based on plan assumptions about the amount of revenue required from enrollee cost-sharing. The estimate of plan cost-sharing for the unadjusted MA statutory non-drug monthly bid amount for coverage of basic

benefits as defined in § 422.100(c)(1) must reflect the requirement that the level of cost sharing MA plans charge to enrollees must be actuarially equivalent to the level of cost sharing (deductible, copayments, or coinsurance) charged to beneficiaries under the original Medicare fee-for-service program option. The actuarially equivalent level of cost sharing reflected in a regional plan's unadjusted MA statutory non-drug monthly bid amount does not include cost sharing for out-of-network Medicare benefits, as described at § 422.101(d).

* * * * *

(c) * * *

(3) * * *

(i) The provision of basic benefits as defined in § 422.100(c)(1);

* * * * *

(e) * * *

(2) The amount of the MA monthly MSA premium for basic benefits (as defined in § 422.252);

* * * * *

16. Section 422.264 is amended by revising paragraph (a) to read as follows:

§ 422.264 Calculation of savings.

(a) *Computation of risk adjusted bids and benchmarks*—(1) *The risk adjusted MA statutory non-drug monthly bid amount* is the unadjusted MA statutory non-drug monthly bid amount (defined at § 422.254(b)(1)(i)), adjusted using the factors described in paragraph (c) of this section for local plans and paragraph (e) of this section for regional plans.

(2) The *risk adjusted MA area-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of basic benefits defined in § 422.100(c)(1) by a

local MA plan, adjusted using the factors described in paragraph (c) of this section.

(3) The *risk adjusted MA region-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of basic benefits defined in § 422.100(c)(1) by a regional MA plan, adjusted using the factors described in paragraph (e) of this section.

* * * * *

17. Section 422.300 is revised to read as follows:

§ 422.300 Basis and scope.

This subpart is based on 42 U.S.C. 1106, 1128j(d), 1852, 1853, 1854, and 1858. It sets forth the rules for making payments to MA organizations offering local and regional MA policies, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), collection of risk adjustment data, conditions for use and disclosure of risk adjustment data, collection of improper payments and other payment rules. See § 422.458 for rules on risk sharing payments to MA regional organizations.

18. Section 422.310 is amended by revising paragraph (e) to read as follows:

§ 422.310 Risk adjustment data.

*** * * * ***

(e) *Validation of risk adjustment data*. MA organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS. There may be penalties for submission of false data. MA organizations must remit improper payments based on RADV audits and established in accordance with stated methodology, in a manner specified by CMS. For RADV audits, CMS may extrapolate RADV Contract-Level audit findings to Payment Year 2011 forward.

*** * * * ***

19. Section 422.311 is amended by revising paragraph (a) to read as follows:

§ 422.311 RADV audit dispute and appeal processes.

(a) *Risk adjustment data validation (RADV) audits.* In accordance with §§ 422.2 and 422.310(e), the Secretary annually conducts RADV audits to ensure risk adjusted payment integrity and accuracy. Recovery of improper payments from MA organizations will be conducted according to the Secretary's payment error extrapolation and recovery methodologies. CMS will apply extrapolation to plan year audits for payment year 2011 forward.

* * * * *

20. Section 422.504 is amended by adding paragraph (g)(1)(iv) to read as follows:

§ 422.504 Contract provisions.

*** * * * ***

(g) ***** ***** *****

(1) ***** ***** *****

(iv) The enrollee shall not have any financial liability for services or items furnished to the enrollee by an MA contracted individual or entity on the preclusion list, as defined in § 422.2 and as described in § 422.222.

*** * * * ***

21. Section 422.560 is amended by adding paragraphs (a)(4) and (b)(5) to read as follows:

§ 422.560 Basis and scope.

(a) * * *

(4) Section 1859(f)(8) of the Act provides for, to the extent feasible, unifying grievances and appeals procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) of the Act for Medicare and Medicaid covered items and services provided by specialized MA plans for special needs individuals described in subsection 1859(b)(6)(B)(ii) of the Act for individuals who are eligible under titles XVIII and XIX. Procedures established under section 1859(f)(8) of the Act apply in place of otherwise applicable grievances and appeals procedures with respect to Medicare and Medicaid covered items and services provided by applicable integrated plans.

(b) * * *

(5) Requirements for applicable integrated plans with respect to procedures for integrated grievances, integrated organization determinations, and integrated reconsiderations.

*** * * * ***

22. Section 422.561 is amended by adding definitions of ''Applicable integrated plans'', "Integrated appeal", "Integrated grievance", "Integrated organization determination", and "Integrated reconsideration" in alphabetical order to read as follows:

§ 422.561 Definitions.

*** * * * ***

Applicable integrated plan means:

(1) A fully integrated dual eligible special needs plan with exclusively aligned enrollment or a highly integrated dual eligible special needs plan with exclusively aligned enrollment, and

(2) The Medicaid managed care organization, as defined in section 1903(m) of the Act, through which such dual eligible special needs plan, its parent organization, or another entity that is owned and controlled by its parent organization covers Medicaid services for dually eligible

individuals enrolled in such dual eligible special needs plan and such Medicaid managed care organization.

* * * * *

Integrated appeal means any of the procedures that deal with, or result from, adverse integrated organization determinations by an applicable integrated plan on the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service. Integrated appeals cover procedures that would otherwise be defined and covered, for non-applicable integrated plans, as an appeal defined in § 422.561 or the procedures required for appeals pursuant to §§ 438.400 through 438.424 of this chapter. Such procedures include integrated reconsiderations.

Integrated grievance means a dispute or compliant that would be defined and covered, for grievances filed by an enrollee in non-applicable integrated plans, under § 422.564 or §§ 438.400 through 438.416 of this chapter. Integrated grievances do not include appeals procedures and QIO complaints, as described in § 422.564(b) and (c). An integrated grievance made by an enrollee in an applicable integrated plan is subject to the integrated grievance procedures in §§ 422.629 and 422.630.

Integrated organization determination means an organization determination that would otherwise be defined and covered, for a non-applicable integrated plan, as organizational determinations under § 422.566 and an adverse benefit determination under § 438.400(b) and § 431.201 (definition of action) of this chapter. An integrated organization determination is made by an applicable integrated plan and is subject to the integrated organization determination procedures in §§ 422.629, 422.631, and 422.634.

Integrated reconsideration means a reconsideration that would otherwise be defined and covered, for a non-applicable integrated plan, as a reconsideration under § 422.580 and appeal under § 438.400(b) of this chapter. An integrated reconsideration is made by an applicable integrated plan and is subject to the integrated reconsideration procedures in §§ 422.629 and 422.632 through 422.634.

*** * * * ***

23. Section 422.562 is amended by—

a. Revising paragraph (a)(1)(i);

b. By adding paragraph (a)(5); and

c. By revising paragraph (b).

The revisions and addition read as follows:

§ 422.562 General provisions.

(a) * * *

(1) * * *

(i) A grievance procedure as described in § 422.564 or § 422.630 as applicable, for addressing issues that do not involve organization determinations;

* * * * *

(5) An MA organization that offers a dual eligible special needs plan has the following additional responsibilities --

(i) The dual eligible special needs plan must offer to assist an enrollee in that dual eligible special needs plan with obtaining Medicaid covered services and resolving grievances, including requesting authorization of Medicaid services, as applicable, and navigating Medicaid appeals and grievances in connection with the enrollee's own Medicaid coverage, regardless of whether

such coverage is in Medicaid fee-for-service or a Medicaid managed care plan, such as a Medicaid MCO, PIHP, or PAHP as defined in § 438.2 of this chapter. If the enrollee accepts the offer of assistance, the plan must provide the assistance. Examples of such assistance include:

(A) Explaining to an enrollee how to make a request for Medicaid authorization of a service and how to file appeal following an adverse benefit determination, such as:

(*1*) Assisting the enrollee in identifying the enrollee's specific Medicaid managed care plan or fee-for-service point of contact;

(*2*) Providing specific instructions for contacting the appropriate agency in a fee-for-service setting or for contacting the enrollee's Medicaid managed care plan, regardless of whether the Medicaid managed care plan is affiliated with the enrollee's dual eligible special needs plan; and

(*3*) Assisting the enrollee in making contact with the enrollee's fee-for-service contact or Medicaid managed care plan.

(B) Assisting a beneficiary in filing a Medicaid grievance or a Medicaid appeal.

(C) Assisting an enrollee in obtaining documentation to support a request for authorization of Medicaid services or a Medicaid appeal.

(ii) The dual eligible special needs plan must offer to provide the assistance described in paragraph (a)(5)(i) of this section whenever it becomes aware of an enrollee's need for a Medicaid-covered service. Offering such assistance is not dependent on an enrollee's specific request.

(iii) The dual eligible special needs plan must offer to provide and actually provide assistance as required by paragraph (a)(5)(i) of this section using multiple methods.

(A) When an enrollee accepts the offer of assistance described in paragraph (a)(5)(i) of this section, the dual eligible special needs plan may coach the enrollee on how to self-advocate.

(B) The dual eligible special needs plan must also provide an enrollee reasonable assistance in completing forms and taking procedural steps related to grievances and appeals, including when assisting with Medicaid appeals.

(iv) The dual eligible special needs plan must, upon request from CMS, provide documentation demonstrating its compliance with this paragraph (a)(5).

(v) The obligation to provide assistance under paragraph (a)(5)(i) of this section does not create an obligation for a dual eligible special needs plan to represent an enrollee in a Medicaid appeal.

(b) *Rights of MA enrollees.* In accordance with the provisions of this subpart, enrollees have the following rights:

(1) The right to have grievances between the enrollee and the MA organization heard and resolved, as described in §§ 422.564 or 422.630, as applicable.

(2) The right to a timely organization determination, as provided under §§ 422.566 or 422.631, as applicable.

(3) The right to request an expedited organization determination, as provided under §§ 422.570 or 422.631(e), as applicable.

(4) If dissatisfied with any part of an organization determination, the following appeal rights:

(i) The right to a reconsideration of the adverse organization determination by the MA organization, as provided under §§ 422.578 or 422.633, as applicable.

(ii) The right to request an expedited reconsideration, as provided under §§ 422.584 or 422.633(f), as applicable.

(iii) If, as a result of a reconsideration, an MA organization affirms, in whole or in part, its adverse organization determination, the right to an automatic reconsidered determination made by an independent, outside entity contracted by CMS, as provided in § 422.592.

* * * * *

24. Section 422.566 is amended by revising paragraph (a) to read as follows:

§ 422.566 Organization determinations.

(a) *Responsibilities of the MA organization*. Each MA organization must have a procedure for making timely organization determinations (in accordance with the requirements of this subpart) regarding the benefits an enrollee is entitled to receive under an MA plan, including basic benefits as described under § 422.100(c)(1) and mandatory and optional supplemental benefits as described under § 422.102, and the amount, if any, that the enrollee is required to pay for a health service. The MA organization must have a standard procedure for making determinations, in accordance with § 422.568, and an expedited procedure for situations in which applying the standard procedure could seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with §§ 422.570 and 422.572; for an applicable integrated plan, the MA organization must comply with §§ 422.629 through 422.634 in lieu of §§ 422.566(c) and (d), 422.568, 422.570 and 422.572 with regard to the procedures for making determinations, including integrated organization determinations and integrated reconsiderations, on a standard and expedited basis.

*** * * * ***

25. Section 422.629, 422.630, 422.631, 422.632, 422.633, and 422.634 are added to Subpart M under the center heading, "Requirements Applicable to Certain Integrated Dual Eligible Special Needs Plans" to read as follows:

Subpart M—Grievances, Organization Determinations and Appeals

*** * * * ***

Requirements Applicable to Certain Integrated Dual Eligible Special Needs Plans

Sec.

Requirements Applicable to Certain Integrated Dual Eligible Special Needs Plans

§ 422.629 General requirements for applicable integrated plans.

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

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

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

(c) *State flexibilities*. A State may, at its discretion, implement standards for timeframes or notice requirements that are more protective for the enrollee than required by this section and §§ 422.630 through 422.634. The contract under § 422.107 must include any standards that differ from the standards set forth in this section.

(d) *Evidence*. The applicable integrated plan must provide the enrollee a reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments for integrated grievances, integrated reconsiderations. The applicable integrated plan must inform the enrollee of the limited time available for presenting evidence sufficiently in advance of the resolution timeframe for appeals as specified in this section if the case is being considered under an expedited timeframe for the integrated grievance or integrated reconsideration.

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

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

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

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

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

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

(ii) The date of receipt.

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

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

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

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

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

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

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

(j) *Information to providers and subcontractors*. The applicable integrated plan must provide information about the integrated grievance and integrated appeal system to all providers and subcontractors at the time they enter into a contract including, at minimum, information on

integrated grievance, integrated reconsideration, and fair hearing procedures and timeframes as applicable. Such information must include:

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

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

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

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

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

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

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

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

(B) A grievance that involves clinical issues.

(3) *Integrated organization determinations*. If the applicable integrated plan expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the integrated organization determination must be reviewed by a physician or other appropriate

health care professional with sufficient medical and other expertise, including knowledge of Medicare and Medicaid coverage criteria, before the applicable integrated plan issues the integrated organization determination. Any physician or other health care professional who reviews an integrated organization determination must have a current and unrestricted license to practice within the scope of his or her profession.

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

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

(ii) If deciding an appeal of a denial that is based on lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), are a physician or other appropriate health care professional who have the appropriate clinical expertise, in treating the enrollee's condition or disease, and knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision.

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

(i) The enrollee or his or her representative;

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

appeal is pending, pursuant to § 422.632 and consistent with state law, the provider or authorized representative must obtain the written consent of the enrollee to request the appeal on behalf of the enrollee; or

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

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

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

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

(ii) A provider.

§ 422.630 Integrated grievances.

(a) *General rule*. In lieu of complying with § 422.564, and the grievance requirements of §§ 438.402, 438.406, 438.408, 438.414, and 438.416 of this chapter, each applicable integrated plan must comply with this section. Each applicable integrated plan must provide meaningful procedures for timely hearing and resolving integrated grievances between enrollees and the applicable integrated plan or any other entity or individual through which the applicable integrated plan provides health care services.

(b) *Timing*. An enrollee may file an integrated grievance at any time with the applicable integrated plan.

(c) *Filing*. An enrollee may file an integrated grievance orally or in writing with the applicable integrated plan, or with the State for an integrated grievance related to a Medicaid benefit, if the State has a process for accepting Medicaid grievances.

(d) *Expedited grievances*. An applicable integrated plan must respond to an enrollee's grievance within 24 hours if:

(1) The complaint involves the applicable integrated plan's decision to invoke an extension relating to an integrated organization determination or integrated reconsideration.

(2) The complaint involves the applicable integrated plan's refusal to grant an enrollee's request for an expedited organization determination under § 422.631 or integrated reconsideration under § 422.633.

(e) *Resolution and notice*. (1) The applicable integrated plan must resolve standard integrated grievances as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 calendar days from the date it receives the integrated grievance.

(i) All integrated grievances submitted in writing must be responded to in writing.

(ii) Integrated grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All integrated grievances related to quality of care, regardless of how the integrated grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO with regard to Medicare covered services. For any complaint submitted to a QIO, the applicable integrated plan must cooperate with the QIO in resolving the complaint.

(2) The timeframe for resolving the integrated grievance may be extended by 14 calendar days if the enrollee requests an extension or if the applicable integrated plan justifies the need for additional information and documents how the delay is in the interest of the enrollee. When the applicable integrated plan extends the timeframe, it must:

(i) Make reasonable efforts to promptly notify the enrollee orally of the reasons for the delay, and

(ii) Send written notice to the enrollee of the reasons for the delay immediately, but no later than within 2 calendar days. This notice must explain the right to file an integrated grievance if the enrollee disagrees with the decision to delay.

§ 422.631 Integrated organization determinations.

(a) *General rule*. An applicable integrated plan must adopt and implement a process for enrollees to request that the plan make an integrated organization determination. The process for requesting that the applicable integrated plan make an integrated organization determination must be the same for all covered benefits.

(b) *Requests*. The enrollee, or a provider on behalf of an enrollee, may request an integrated organization determination orally or in writing, except for requests for payment, which must be in writing (unless the applicable integrated plan or entity responsible for making the determination has implemented a voluntary policy of accepting verbal payment requests).

(c) *Expedited integrated organization determinations*. (1) An enrollee, or a provider on behalf of an enrollee, may request an expedited integrated organization determination.

(2) The request can be oral or in writing.

(3) The applicable integrated plan must complete an expedited integrated organization determination when the applicable integrated plan determines (based on a request from the enrollee or on its own) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

(d) *Timeframes and notice*—(1) *Integrated organization determination notice*. The applicable integrated plan must send an enrollee a written notice of any adverse decision on an integrated organization determination (including a determination to authorize a service or item in an amount, duration, or scope that is less than the amount previously requested or authorized for an ongoing course of treatment) within the timeframes set forth in this section. For an integrated organization determination not reached within the timeframes specified in this section (which constitutes a denial and is thus an adverse decision), the applicable integrated plan must send a notice on the date that the timeframes expire. Such notice must describe all applicable Medicare and Medicaid appeal rights. Integrated organization determination notices must be written in plain language, be available in a language and format that is accessible to the enrollee, and explain:

(i) The applicable integrated plan's determination;

(ii) The date the determination was made;

(iii) The date the determination will take effect;

(iv) The reasons for the determination;

(v) The enrollee's right to file an integrated reconsideration and the ability for someone else to file an appeal on the enrollee's behalf;

(vi) Procedures for exercising enrollee's rights to an integrated reconsideration;

(vii) Circumstances under which expedited resolution is available and how to request it; and

(viii) If applicable, the enrollee's rights to have benefits continue pending the resolution of the integrated appeal process.

(2) *Timing of notice*—(i) *Standard integrated organization determinations.* (A) The applicable integrated plan must send a notice of its integrated organization determination at least 10 days before the date of action (that is, before the date on which a termination, suspension, or reduction becomes effective), in cases where a previously approved service is being reduced, suspended, or terminated, except in circumstances where an exception is permitted under §§ 431.213 and 431.214 of this chapter.

(B) For other integrated organization determinations that are not expedited integrated organization determinations, the applicable integrated plan must send a notice of its integrated organization determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from when it receives the request for the integrated organization determination.

(ii) *Extensions*. The applicable integrated plan may extend the timeframe for a standard or expedited integrated organization determination by up to 14 calendar days if:

(A) The enrollee or provider requests the extension; or

(B) The applicable integrated plan can show that:

(*1*) The extension is in the enrollee's interest; and

(*2*) There is need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request, if received.

(iii) *Notices in cases of extension*. (A) When the applicable integrated plan extends the timeframe, it must notify the enrollee in writing of the reasons for the delay as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension, and inform the enrollee of the right to file an expedited integrated grievance if he or she disagrees with the applicable integrated plan's decision to grant an extension.

(B) If the applicable integrated plan extends the timeframe for making its integrated organization determination, it must send the notice of its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(iv) *Expedited integrated organization determinations*. (A) The applicable integrated plan must provide notice of its expedited integrated organization determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(B) If the applicable integrated plan denies the request for an expedited integrated organization determination, it must:

(*1*) Automatically transfer a request to the standard timeframe and make the determination within the 14-day timeframe established in this paragraph for a standard integrated organization determination. The 14-day period begins with the day the applicable integrated plan receives the request for expedited integrated organization determination.

(*2*) Give the enrollee prompt oral notice of the denial and transfer and subsequently deliver, within 3 calendar days, a written letter that—

(*i*) Explains that the applicable integrated plan will process the request using the 14-day timeframe for standard integrated organization determinations;

(*ii*) Informs the enrollee of the right to file an expedited integrated grievance if he or she disagrees with the applicable integrated plan's decision not to expedite;

(*iii*) Informs the enrollee of the right to resubmit a request for an expedited integrated organization determination with any physician's support; and

(*iv*) Provides instructions about the integrated grievance process and its timeframes.

(C) If the applicable integrated plan must receive medical information from noncontract providers, the applicable integrated plan must request the necessary information from the

noncontract provider within 24 hours of the initial request for an expedited integrated organization determination. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the applicable integrated plan in meeting the required timeframe. Regardless of whether the applicable integrated plan must request information from noncontract providers, the applicable integrated plan is responsible for meeting the timeframe and notice requirements of this section.

§ 422.632 Continuation of benefits while the applicable integrated plan reconsideration is pending.

(a) *Definition*. As used in this section, timely files means files for continuation of benefits on or before the later of the following:

(1) Within 10 calendar days of the applicable integrated plan sending the notice of adverse integrated organization determination.

(2) The intended effective date of the applicable integrated plan's proposed adverse integrated organization determination.

(b) *Continuation of benefits*. The applicable integrated plan must continue the enrollee's benefits under Parts A and B of title XVIII and title XIX if all of the following occur:

(1) The enrollee files the request for an integrated appeal timely in accordance with § 422.633(e);

(2) The integrated appeal involves the termination, suspension, or reduction of previously authorized services;

(3) The services were ordered by an authorized provider;

(4) The period covered by the original authorization has not expired; and

(5) The enrollee timely files for continuation of benefits.

(c) *Duration of continued or reinstated benefits*. If, at the enrollee's request, the applicable integrated plan continues or reinstates the enrollee's benefits, as described in paragraph (b) of this section, while the integrated reconsideration is pending, the benefits must be continued until:

(1) The enrollee withdraws the request for an integrated reconsideration;

(2) The applicable integrated plan issues an integrated reconsideration that is unfavorable to the enrollee related to the benefit that has been continued;

(3) For an appeal involving Medicaid benefits:

(i) The enrollee fails to file a request for a State fair hearing and continuation of benefits, within 10 calendar days after the applicable integrated plan sends the notice of the integrated reconsideration;

(ii) The enrollee withdraws the appeal or request for a State fair hearing;

(iii) A State fair hearing office issues a hearing decision adverse to the enrollee.

(d) *Recovery of costs*. In the event the appeal or State fair hearing is adverse to the enrollee, the applicable integrated plan or State agency may not pursue recovery for services provided, to the extent that the services were furnished solely under of the requirements of this section.

§ 422.633 Integrated reconsideration.

(a) *General rule*. An applicable integrated plan may only have one level of integrated reconsideration for an enrollee.

(b*) External medical reviews*. If a State has established an external medical review process, the requirements of § 438.402(c)(1)(i)(B) of this chapter apply to each applicable

integrated plan that is a Medicaid managed care organization, as defined in section 1903 of the Act.

(c) *Case file*. Upon request of the enrollee or his or her representative, the applicable integrated plan must provide the enrollee and his or her representative the enrollee's case file, including medical records, other documents and records, and any new or additional evidence considered, relied upon, or generated by the applicable integrated plan (or at the direction of the applicable integrated plan) in connection with the appeal of the integrated organization determination. This information must be provided free of charge and sufficiently in advance of the resolution timeframe for appeals as specified in this section.

(d) *Timing*. (1) An enrollee has 60 calendar days from the date on the adverse organization determination notice to file a request for an integrated reconsideration with the applicable integrated plan.

(2) Oral inquires seeking to appeal an adverse integrated organization determination must be treated as a request for an integrated reconsideration (to establish the earliest possible filing date for the appeal).

(3) *Extending the time for filing a request*—(i) *General rule.* If a party or physician acting on behalf of an enrollee shows good cause, the applicable integrated plan may extend the timeframe for filing a request for an integrated reconsideration.

(ii) *How to request an extension of timeframe*. If the 60-day period in which to file a request for an integrated reconsideration has expired, a party to the integrated organization determination or a physician acting on behalf of an enrollee may file a request for integrated reconsideration with the applicable integrated plan. The request for integrated reconsideration and to extend the timeframe must—

(A) Be in writing; and

(B) State why the request for integrated reconsideration was not filed on time.

(e) *Expedited integrated reconsiderations*. (1) An enrollee may request, or a provider may request on behalf of an enrollee, an expedited review of the integrated reconsideration.

(2) The request can be oral or in writing.

(3) The applicable integrated plan must grant the request to expedite the integrated reconsideration when it determines (for a request from the enrollee), or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request), that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

(4) If an applicable integrated plan denies an enrollee's request for an expedited integrated reconsideration, it must automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe established in paragraph (f)(1) of this section for a standard integrated reconsideration. The 30-day period begins with the day the applicable integrated plan receives the request for expedited integrated reconsideration. The applicable integrated plan must give the enrollee prompt oral notice of the decision, and give the enrollee written notice within 2 calendar days. The written notice must:

(i) Include the reason for the denial;

(ii) Inform the enrollee of the right to file a grievance if the enrollee disagrees with the decision not to expedite, including timeframes and procedures for filing a grievance; and

(iii) Inform the enrollee of the right to resubmit a request for an expedited determination with any physician's support.

(5) If the applicable integrated plan must receive medical information from noncontract providers, the applicable integrated plan must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited integrated reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the applicable integrated plan in meeting the required timeframe. Regardless of whether the applicable integrated plan must request information from noncontract providers, the applicable integrated plan is responsible for meeting the timeframe and notice requirements of this section.

(f) *Resolution and notification*. The applicable integrated plan must make integrated reconsidered determinations as expeditiously as the enrollee's health condition requires but no later than the timeframes established in this section.

(1) *Standard integrated reconsiderations*. The applicable integrated plan must resolve integrated reconsiderations within 30 calendar days of receipt of the request or as expeditiously as the enrollee's health condition requires for the integrated reconsideration. This timeframe may be extended as described in paragraph (f)(3) of this section.

(2) *Expedited integrated reconsiderations*. The applicable integrated plan must resolve expedited integrated reconsiderations within 72 hours of receipt of the request or as expeditiously as the enrollee's health condition requires for the integrated reconsideration. This timeframe may be extended as described in paragraph (f)(3) of this section. The applicable integrated plan must make reasonable efforts to provide prompt oral notice of the expedited resolution to the enrollee.

(3) *Extensions*. (i) The applicable integrated plan may extend the timeframe for resolving integrated reconsiderations by 14 calendar days if:

(A) The enrollee requests the extension; or

(B) The applicable integrated plan can show that:

(*1*) The extension is in the enrollee's interest; and

(*2*) There is need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request, if received.

(ii) If the applicable integrated plan extends the timeframe for resolving the integrated reconsideration, it must make reasonable efforts to give the enrollee prompt oral notice of the delay, and give the enrollee written notice within 2 calendar days. The notice must include the reason for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the decision to grant an extension.

(4) *Notice of resolution*. The applicable integrated plan must send a notice to enrollees that includes the integrated reconsidered determination, within the resolution timeframes set forth in this section. The notice of determination must be written in plain language and available in a language and format that is accessible to the enrollee, and must explain:

(i) The resolution of and basis for the integrated reconsideration and the date it was completed.

(ii) For integrated reconsiderations not resolved wholly in favor of the enrollee:

(A) An explanation of the next level of appeal available under the Medicare and Medicaid programs, and what steps the enrollee must take to pursue the next level of appeal under each program; and

(B) The right to request and receive Medicaid-covered benefits while the next level of appeal is pending, if applicable.

§ 422.634 Effect.

(a) *Failure of the applicable integrated plan to send timely notice of a determination.* If the applicable integrated plan fails to adhere to the notice and timing for an integrated organization determination or integrated reconsideration, this failure constitutes an adverse determination for the enrollee. For an integrated organization determination, this means that the enrollee may request an integrated reconsideration (to the next applicable level in the appeal process). For integrated reconsiderations of Medicare benefits, this means the applicable integrated plan must forward the case to the independent review entity, in accordance with the timeframes under paragraph (b) of this section and § 422.592. For integrated reconsiderations of Medicaid benefits, this means that an enrollee or other party may file for a State fair hearing, or if applicable, a State external medical review in accordance with § 438.402(c) of this chapter.

(b) *Adverse integrated reconsiderations*. (1) Subject to paragraph (b)(2) of this section, when the applicable integrated plan affirms, in whole or in part, its adverse integrated organization determination involving a Medicare benefit:

(i) The issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with CMS, in accordance with § 422.592 and §§ 422.594 through 422.619; and

(ii) For standard integrated reconsiderations, the applicable integrated plan must prepare a written explanation and send the case file to the independent review 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 (or no later than the expiration of an extension described in § 422.633(f)(3)). The applicable integrated plan must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(iii) For expedited integrated reconsiderations, the applicable integrated plan must prepare a written explanation and send the case file to the independent review entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than within 24 hours of its affirmation (or no later than the expiration of an extension described in § 422.633(f)(3)). The applicable integrated plan must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(2) When the applicable integrated plan affirms, in whole or in part, its adverse integrated organization determination involving a Medicaid benefit, the enrollee or other party (that is not the applicable integrated plan) may initiate a State fair hearing no later than 120 calendar days from the date of the applicable integrated plan's notice of resolution. If a provider is filing for a State fair hearing on behalf of the enrollee as permitted by State law, the provider will need the written consent of the enrollee, if he or she has not already obtained such consent.

(c) *Final determination*. The reconsidered determination of the applicable integrated plan is binding on all parties unless it is appealed to the next applicable level. In the event that the enrollee pursues the appeal in multiple forums and receives conflicting decisions, the applicable integrated plan is bound by, and must act in accordance with, decisions favorable to the enrollee.

(d) *Services not furnished while the appeal is pending*. If an applicable integrated plan, or a State fair hearing with regard to a Medicaid benefit, reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. Reversals by the Part C independent review entity, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the

Medicare Appeals Council must be effectuated under same timelines applicable to other MA plans as specified in §§ 422.618 and 422.619.

(e) *Services furnished while the appeal is pending*. If the applicable integrated plan or the State fair hearing officer reverses a decision to deny, limit, or delay Medicaid-covered benefits, and the enrollee received the disputed services while the integrated reconsideration was pending, the applicable integrated plan or the State must pay for those services, in accordance with State policy and regulations. If the applicable integrated plan reverses a decision to deny, limit, or delay Medicare-covered benefits, and the enrollee received the disputed services while the integrated reconsideration was pending, the applicable integrated plan must pay for those services.

26. Section 422.752 is amended by adding paragraph (d) to read as follows:

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

* * * * *

(d) *Special rule for non-compliant dual eligible special needs plans.* Notwithstanding any other provision of this section, CMS must impose during plan years 2021 through 2025 intermediate sanctions specified at § 422.750(a) on an MA organization with a contract to operate a dual eligible special needs plan if CMS determines that the dual eligible special needs plan fails to comply with at least one of the criteria for the integration of Medicare and Medicaid benefits provided in the definition of a dual eligible special needs plan at § 422.2. If CMS imposes such an intermediate sanction, the MA organization must submit to CMS a corrective action plan in a form, manner, and timeframe established by CMS. The procedures outlined in § 422.756 apply to the imposition of the intermediate sanction under this provision.

PART 423— VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

27. The authority citation for part 423 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395w—101 through 1395w—152, and 1395hh.

28. Section 423.100 is amended in the definition of "Preclusion list" by revising paragraphs (1)(i), (2)(i), (2)(ii)(C) and adding paragraph (3) to read as follows:

§ 423.100 Definitions.

* * * * *

Preclusion list * * *

(1) * * *

(i) The prescriber is currently revoked from Medicare for a reason other than that stated in § 424.535(a)(3) of this chapter.

* * * * *

(2) * * *

(i) The prescriber has engaged in behavior, other than that described in § 424.535(a)(3) of this chapter, for which CMS could have revoked the prescriber to the extent applicable had the prescriber been enrolled in Medicare.

* * * * *

(ii) * * *

(C) Any other evidence that CMS deems relevant to its determination; or

(3) The prescriber, regardless of whether the prescriber is or was enrolled in Medicare, has been convicted of a felony under federal or state law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph are:

(i) The severity of the offense;

(ii) When the offense occurred; and

(iii) Any other information that CMS deems relevant to its determination.

* * * * *

29. Section 423.120 is amended by—

a. Revising paragraphs (c)(6)(i) through (v) and (c)(6)(vi) introductory text; and

b. Adding paragraphs (c)(6)(vii) and (viii).

The revisions and additions read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(c) * * *

(6)(i) Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must reject, or must require its PBM to reject, a pharmacy claim for a Part D drug if the prescriber who prescribed the drug is included on the preclusion list, defined in § 423.100.

(ii) Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary if the request pertains to a Part D drug that was prescribed by a prescriber who is identified by name in the request and who is included on the preclusion list, defined in § 423.100.

(iii) A Part D plan sponsor may not submit a prescription drug event (PDE) record to CMS unless it includes on the PDE record the active and valid NPI of the prescriber of the drug, and the prescriber is not included on the preclusion list, defined in § 423.100, for the date of service.

(iv) With respect to Part D prescribers that have been added to an updated preclusion list, the Part D plan sponsor must do all of the following:

(A) Subject to all other Part D rules and plan coverage requirements, and no later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received a Part D drug prescribed by a prescriber added to the preclusion list in this update;

(B) Must ensure that reasonable efforts are made to notify the prescriber described in paragraph (c)(6)(iv) of this section of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(A) of this section; and

(C) Must not reject a pharmacy claim or deny a beneficiary request for reimbursement for a Part D drug prescribed by the prescriber, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (c)(6)(iv)(A) of this section.

(v)(A) CMS sends written notice to the prescriber via letter of their inclusion on the preclusion list. The notice must contain the reason for the inclusion on the preclusion list and inform the prescriber of their appeal rights. A prescriber may appeal their inclusion on the preclusion list under this section in accordance with part 498 of this chapter.

(B) If the prescriber's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:

(*1*) The notice described in paragraph (c)(6)(v)(A) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the prescriber's appeal rights concerning the revocation.

(*2*) The appeals of the prescriber's inclusion on the preclusion list and the prescriber's revocation shall be filed jointly by the prescriber and, as applicable, considered jointly by CMS under part 498 of this chapter.

(C)(*1*) Except as provided in paragraph (c)(6)(v)(C)(*2*) of this section, a prescriber will only be included on the preclusion list after the expiration of either of the following:

(*i*) If the prescriber does not file a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list upon the expiration of the 60-day period in which the prescriber may request a reconsideration.

(ii) If the prescriber files a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list effective on the date on which CMS, if applicable, denies the prescriber's reconsideration.

(2) An OIG excluded prescriber is added to the preclusion list effective on the date of the exclusion.

(vi) CMS has the discretion not to include a particular prescriber on (or, if warranted, remove the prescriber from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to prescriptions. In making a determination as to whether such circumstances exist, CMS takes into account—

* * * * *

(vii)(A) Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the prescriber's reenrollment bar.

(B) Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the prescriber had the prescriber been enrolled and then revoked.

(C) Except as provided in paragraph (c)(6)(vii)(D) of this section, a prescriber, regardless of whether the prescriber is or was enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are --

(*1*) The severity of the offense;

(*2*) When the offense occurred; and

(*3*) Any other information that CMS deems relevant to its determination.

(D) In cases where a prescriber is excluded by the OIG, the prescriber must remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(viii) Payment denials under paragraph (c)(6) of this section that are based upon the prescriber's inclusion on the preclusion list are not appealable by beneficiaries.

* * * * *

30. Section 423.153 is amended by revising the section heading and adding paragraph (g) to read as follows:

§ 423.153 Prescription drug plan sponsors' access to Medicare Parts A and B claims data extracts.

* * * * *

(g) *Parts A and B claims data extracts*—(1) *General rule.* (i) Beginning in plan year 2020, a PDP sponsor may submit a request to CMS for the data described in paragraph (g)(2) of this section about enrollees in its prescription drug plans.

(ii) CMS will make the data requested in paragraph (g)(1)(i) of this section available to eligible PDP sponsors, in accordance with all applicable laws. The data will be provided at least quarterly on a specified release date, and in an electronic format to be determined by CMS.

(iii) If CMS determines or has a reasonable belief that the PDP sponsor has violated the requirements of this paragraph (g) or that unauthorized uses, reuses, or disclosures of the Medicare claims data have taken place, at CMS' sole discretion, the PDP sponsor may be denied further access to the data described in paragraph (g)(2) of this section.

(2) *Data described.* The data that may be requested under paragraph (g)(1) of this section are standardized extracts of claims data under Medicare parts A and B for items and services furnished under such parts to beneficiaries who are enrolled in a plan offered by the PDP sponsor at the time of the disclosure.

(3) *Purposes.* A PDP sponsor must comply with all laws that may be applicable to data received under this provision, including state and federal privacy and security laws, and, furthermore subject to the limitations in paragraph (g)(4) of this section may only use or disclose the data provided by CMS under paragraph (g)(1) of this section for the following purposes:

(i) To optimize therapeutic outcomes through improved medication use, as such phrase is used in paragraph (d)(1)(i) of this section.

(ii) To improve care coordination so as to prevent adverse health outcomes, such as preventable emergency department visits and hospital readmissions.

(iii) For activities falling under paragraph (1) of the definition of "health care operations" under 45 CFR 164.501.

(iv) For activities falling under paragraph (2) of the definition of "health care operations" under 45 CFR 164.501.

(v) For "fraud and abuse detection or compliance activities" under 45 CFR 164.506(c)(4)(ii).

(vi) For disclosures that qualify as "required by law" disclosures at 45 CFR 164.103.

(4) *Limitations.* A PDP sponsor must comply with the following requirements regarding the data provided by CMS under this paragraph (g):

(i) The PDP sponsor will not use the data to inform coverage determinations under Part D;

(ii) The PDP sponsor will not use the data to conduct retroactive reviews of medically accepted indications determinations;

(iii) The PDP sponsor will not use the data to facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization;

(iv) The PDP sponsor will not use the data to inform marketing of benefits.

(v) The PDP sponsor will contractually bind its contractors that have access to the Medicare claims data, and any other potential downstream data recipients, to the terms and conditions imposed on the PDP Sponsor under this paragraph (g).

(5) *Ensuring the privacy and security of data*. As a condition of receiving the requested data, the PDP sponsor must attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data listed in paragraphs (g)(3) and (4) of this section.

31. Section 423.182 is amended in paragraph (a) by adding the definitions of "Absolute percentage cap", "Cut point cap", "Guardrail", "Mean resampling", "Restricted range", and "Restricted range cap" in alphabetical order to read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

(a) * * *

Absolute percentage cap is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.

* * * * *

Cut point cap is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut point. A cut point cap can restrict upward movement, downward movement, or both.

* * * * *

Guardrail is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.

* * * * *

Mean resampling refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchal clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.

* * * * *

Restricted range is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outer fence outliers (first quartile - 3*Interquartile Range (IQR) and third quartile + 3*IQR).

Restricted range cap is a cap applied to non-CAHPS measures that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated using the prior year's measure score distribution.

* * * * *

32. Section 423.184 is amended by adding paragraphs (f)(1)(iv), (g)(1)(ii)(M), and (h) to read as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(f) * * *

(1) * * *

(iv) CMS will exclude any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s).

* * * * *

(g) * * *

(1) * * *

(ii) * * *

(M) CMS will reduce a measure rating to 1 star for the applicable appeals measure(s) if a contract fails to submit Timeliness Monitoring Project data for CMS's review to ensure the completeness of the contract's IRE data.

* * * * *

(h) *Review of sponsors' data.* (1) A request for CMS or the IRE to review a contract's appeals data must be received no later than June 30 of the following year.

(2) A request for CMS to review a contract's Complaints Tracking Module (CTM) data must be received no later than June 30 of the following year.

33. Section 423.186 is amended by revising paragraph (a)(2)(i) and adding paragraph (i) to read as follows:

§ 423.186 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data, and a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for three years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first three years in the program.

* * * * *

(i) *Extreme and uncontrollable circumstances.* In the event of extreme and uncontrollable circumstances that may negatively impact operational and clinical systems and contracts' abilities to conduct surveys needed for accurate performance measurement, CMS will calculate the Star Ratings as specified in paragraphs (i)(2) through (8) of this section for each contract that is an affected contract during the performance period for the applicable measures.

(1) *Identification of affected contracts.* A contract that meets all of the following criteria is an affected contract:

(i) The contract's service area is within an "emergency area" during an "emergency period" as defined in section 1135(g) of the Act.

(ii) The contract's service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).

(iii) As specified in paragraphs (i)(2) through (8) of this section, a certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

(2) *CAHPS adjustments.* (i) A contract, even if an affected contract, must administer the CAHPS survey unless exempt under paragraph (i)(2)(ii) of this section.

(ii) An affected contract will be exempt from administering the CAHPS survey if the contract completes both of the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in paragraph (i)(1)(iii) of this section in the prior calendar year.

(B) Requests and receives a CMS approved exception.

(iii) An affected contract with an exception defined in paragraph (i)(2)(ii) of this section will receive the contract's CAHPS measure stars and corresponding measure scores from the prior year.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the contract will receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure.

(3) *New measure adjustments.* For affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, CMS will apply a hold harmless provision by comparing the result of the contract's summary and/or overall rating with and without including all of the applicable new measures. If the "with" result is lower than the "without" result, then CMS will use the "without" result as the final rating.

(4) *Other Star Ratings measure adjustments.* (i) For all other Part D measures except those measures identified in this paragraph (i)(4)(ii) of this section, affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance will receive the higher of the previous or current year's measure Star Rating and then use the corresponding measure score.

(ii) CMS will not adjust the scores of the Star Ratings for the Part D Call Center – Foreign Language Interpreter and TTY Availability measure, unless the exception listed in paragraph (i)(4)(iii) of this section applies.

(iii) CMS will adjust the measure listed in paragraph (i)(4)(ii) of this section using the adjustments listed in paragraph (i)(4)(i) of this section for contracts affected by extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study.

(5) *Exclusion from improvement measures.* Any measure that reverts back to the data underlying the previous year's Star Rating due to the adjustments made in paragraph (i) of this section will be excluded from both the count of measures and the applicable improvement measures for the current and next year's Star Ratings for the affected contract.

(6) *Missing data.* For an affected contract that has missing data in the current or previous year, the final measure rating will come from the current year unless an exception described in paragraph (i)(2)(ii) of this section applies.

(7) *Cut points for non-CAHPS measures.* (i) CMS will exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

(ii) The cut points calculated as described in paragraph (i)(7)(i) of this section will be used to assess all affected contracts' measure Star Ratings.

(8) *Reward factor.* (i) CMS will exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds for the reward factor described in paragraph (f)(1) of this section.

(ii) All affected contracts will be eligible for the reward factor based on the calculations described in paragraph (i)(8)(i) of this section.

34. Section 423.568 is amended by revising paragraph (b) to read as follows:

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

* * * * *

(b) *Timeframe for requests for drug benefits*. When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first.

* * * * *

35. Section 423.570 is amended by revising paragraph (d)(1) to read as follows:

§ 423.570 Expediting certain coverage determinations.

* * * * *

(d) * * *

(1) Make the determination within the 72-hour timeframe established in § 423.568(b) for a standard determination. The 72-hour period begins on the day the Part D plan sponsor receives the request for expedited determination. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first.

* * * * *

36. Section 423.572 is amended by revising paragraph (a) to read as follows:

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) *Timeframe for determination and notification*. Except as provided in paragraph (b) of this section, a Part D plan sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the physician's or other prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first.

* * * * *

PART 438—MANAGED CARE.

37. The authority for part 438 is revised to read as follows:

Authority: 42 U.S.C. 1302.

38. Section 438.210 is amended by—

a. Revising paragraphs (c) and (d) introductory text;

b. Adding paragraph (d)(4); and

c. Revising paragraph (f).

The addition and revisions read as follows:

§ 438.210 Coverage and authorization of services.

* * * * *

(c) *Notice of adverse benefit determination.* Each contract must provide for the MCO, PIHP, or PAHP to notify the requesting provider, and give the enrollee written notice of any

decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. For MCOs, PIHPs, and PAHPs, the enrollee's notice must meet the requirements of § 438.404. For Medicaid contracts with an applicable integrated plan, as defined in § 422.561 of this chapter, in lieu of the provisions in this paragraph governing notices of adverse benefit determinations, the provisions set forth in §§ 422.629 through 422.634 of this chapter apply to determinations affecting dually eligible individuals who are also enrolled in a dual eligible special needs plan with exclusively aligned enrollment, as defined in § 422.2 of this chapter.

(d) *Timeframe for decisions.* Each MCO, PIHP, or PAHP contract must provide for the following decisions and notices:

* * * * *

(4) For Medicaid contracts with an applicable integrated plan, as defined in § 422.561 of this chapter, timelines for decisions and notices must be compliant with the provisions set forth in in §§ 422.629 through 422.634 of this chapter in lieu of §§ 438.404 through 438.424.

* * * * *

(f) *Applicability date.* (1) Subject to paragraph (f)(2) of this section, this section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.210 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

(2) Provisions in this section affecting applicable integrated plans, as defined in § 422.561 of this chapter, are applicable no later than January 1, 2021.

39. Section 438.400 is amended by adding paragraph (a)(4) and revising paragraph (c) to read as follows:

§ 438.400 Statutory basis, definitions, and applicability.

(a) * * *

(4) Section 1859(f)(8)(B) of the Act requires that the Secretary, to the extent feasible, establish procedures unifying grievances and appeals procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) of the Act for items and services provided, by specialized MA plans for special needs individuals described in section 1859(b)(6)(B)(ii), under Titles XVIII and XIX of the Act.

* * * * *

(c) *Applicability.* (1) Subject to paragraph (c)(2) of this section, this subpart applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, states, MCOs, PIHPs, and PAHPs are required to continue to comply with subpart F contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

(2) Provisions in this section affecting applicable integrated plans, as defined in § 422.561 of this chapter, are applicable no later than January 1, 2021.

40. Section 438.402 is amended by revising paragraph (a) to read as follows:

§ 438.402 General requirements.

(a) *The grievance and appeal system.* Each MCO, PIHP, and PAHP must have a grievance and appeal system in place for enrollees. Non-emergency medical transportation PAHPs, as defined in § 438.9, are not subject to this subpart F. An applicable integrated plan as defined in § 422.561 of this chapter is not subject to this subpart F, and is instead subject to the requirements of §§ 422.629 through 422.634 of this chapter.

* * * * *

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

41. The authority for part 498 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7j, and 1395hh.

42. Section 498.5 is amended by revising paragraph (n)(1) to read as follows:

§ 498.5 Appeal rights.

* * * * *

(n) * * *

(1)(i) Any individual or entity that is dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list (as defined in § 422.2 or § 423.100 of this chapter) may request a reconsideration in accordance with § 498.22(a).

(ii)(A) If the individual's or entity's inclusion on the preclusion list is based on a Medicare revocation under § 424.535 of this chapter and the individual or entity receives contemporaneous notice of both actions, the individual or entity may request a joint reconsideration of both the preclusion list inclusion and the revocation in accordance with § 498.22(a).

(B) The individual or entity may not submit separate reconsideration requests under paragraph (n)(1)(ii)(A) of this section for inclusion on the preclusion list or a revocation if the individual or entity received contemporaneous notice of both actions.

* * * * *

Dated: October 17, 2018.

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Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: October 18, 2018.

_____

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

[FR Doc. 2018-23599 Filed: 10/26/2018 4:15 pm; Publication Date: 11/1/2018]