

**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 (CMS-4185-F)
Final Rule Summary**

On April 5, 2019, the Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services (HHS) placed on public display a final rule providing for policy and technical changes to Medicare Advantage (MA), Part D prescription drug plans, PACE and Medicaid for 2020 and 2021.¹ The rule, set to be published in the *Federal Register* on April 16, 2019, implements certain provisions of the Bipartisan Budget Act of 2018 (BBA 2018, P.L. 115-119), including expanding the ability of MA plans to provide additional telehealth services as a basic benefit, and revising the appeals and grievances requirements and better integrating standards for enrollees in Dual Eligible Special Needs Plans (D-SNPs). In addition, it makes changes to methodologies and other updates to the Part C and D Star Ratings for 2022 and 2023 and makes several revisions and additions to the preclusion list provisions finalized in the April 2018 MA/PD final rule.²

The final rule does not address provisions of the proposed rule involving the MA Risk Adjustment Data Validation (RADV) program. These include CMS’ intent to use extrapolation to estimate contract-level improper payments and several proposed methodological changes. Because CMS later extended the comment period for those RADV provisions until April 30, 2019 (83 FR 66661), CMS intends to address those changes in later rulemaking.

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¹ <https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-06822.pdf>.

² 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 (82 FR 16440, CMS-4182-F).

I. Provisions of the Rule

A. Implementing the Bipartisan Budget Act of 2018 Provisions

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits

Section 50323 of the BBA 2018 established in Section 1852(m) of the Social Security Act (the Act) that an MA plan can, beginning in plan year 2020, provide “additional telehealth benefits” and treat them as basic benefits for the purpose of calculating bids to submit to CMS and in receiving payment from CMS.

Prior to the BBA 2018, “basic benefits” for the purpose of setting MA bids and payments to MA plans could only include services covered under original Medicare. With respect to telehealth services, that included only certain specified services provided within specific geographical/patient settings and using specific telehealth technologies.³ MA plans were permitted to offer additional telehealth services beyond those payable under Parts A and B, but if they did so, the additional telehealth benefits were required to be provided through supplemental benefits and could not be considered as part of the basic benefits.

CMS codifies new 42 CFR section 422.135, setting the standards for plans to offer additional telehealth basic benefits, largely as proposed with certain substantive and non-substantive modifications. (Substantive changes from the proposed rule are described in greater detail below.) In addition, CMS finalizes conforming provisions largely as proposed. Under the finalized rules, plans can continue to offer supplemental telehealth benefits for those services that do not meet the requirements for coverage under original Medicare or under the MA additional telehealth benefit under BBA 2018.

a. Definitions

New section 422.135(a) defines “additional telehealth benefits” consistent with the definition in BBA 2018 as those 1) furnished by an MA plan for which benefits are available under Medicare Part B but which are not payable under section 1834(m) and 2) that have been identified by the MA plan as clinically appropriate to furnish through electronic exchange and; in an addition in the final rule; “when the physician or practitioner providing the service is not in the same location as the enrollee.”

³ Section 1834(m) of the Act and §410.78 limit payment for Medicare telehealth services under traditional Medicare by authorizing payment only for specified services provided using an interactive audio and video telecommunications system that permits real-time communication between a Medicare beneficiary and either a physician or specified other type of practitioner, and by specifying where the beneficiary may receive telehealth services (eligible originating sites). Eligible originating sites are limited as to the type of geographic location (generally rural) and the type of care setting. The statute grants the Secretary the authority to add to the list of Medicare telehealth services based on an established annual process but does not allow for exceptions to the restrictions on types of practitioners that can furnish those services or on the eligible originating sites.

As proposed, CMS does not provide a specific definition of “clinically appropriate,” an approach that it describes as aligning with existing regulations for MA contracting (§422.504(a)(3)(iii)) requires an MA organization to provide all benefits covered by Medicare “in a manner consistent with professionally recognized standards of care.”) CMS indicates that it prefers to allow MA plans to independently determine clinical appropriateness for the applicable year and notes that providers, too, must also ensure that the services they provide are clinically appropriate to properly deliver care via telehealth.

CMS notes in the preamble that in accordance with §422.112(b)(3), all MA coordinated care plans are required to coordinate MA benefits with community and social services generally available in the plan service area. Therefore, CMS expects that MA coordinated care plans offering additional telehealth benefits will coordinate care for enrollees receiving services through electronic exchange in the same manner as for enrollees receiving the service in-person.

“Electronic exchange” is defined, as proposed, as electronic information and telecommunications technology. CMS declines to specify or provide examples of electronic information and telecommunications technology in regulation text and explicitly notes in the preamble that future technology that is within the scope of the phrase “electronic information and telecommunications technology” may be used for the purposes of providing MA additional benefits.

CMS notes that existing protections for MA beneficiaries apply with respect to telehealth benefits as they do for other MA benefits including the right of a beneficiary to appeal a decision to not provide a benefit. CMS audits of plans’ timeliness and clinical appropriateness of determinations and appeals apply as well.

Commenters asked CMS for additional clarity on the differences between additional telehealth benefits under BBA 2018 and basic telehealth benefits that are required because they are covered by Parts A or B. CMS summarizes the basic telehealth benefits required to be covered under Parts A and B including recent changes and additions to those benefits in the Calendar Year 2019 Physician Fee Schedule final rule (83 FR 59482-59491). In addition, CMS describes other BBA 2018 provisions that removed limitations on geography or originating sites for certain types of care and services – renal dialysis and related clinical assessments, mobile stroke units and telehealth stroke services, and treatment of an individual with a substance use disorder and co-occurring mental health disorder. Any services falling outside the scope of those required services could potentially be offered as MA additional telehealth benefits starting January 1, 2020 as long as they meet the other requirements described in new §422.135.

b. General Rule

New section 422.135(b) establishes the general rule that an MA plan may treat additional telehealth benefits as basic benefits so long as the requirements of new section 422 are met. The finalized provision, unchanged from the proposed rule, preserves the ability of an MA plan to provide telehealth services as supplemental benefits if they do not meet all of the rules for being considered basic benefits.

c. Requirements for New Benefits

CMS finalizes new section 422.135(c) with a number of modifications further described below. Section 422.135(c) provides the rules for MA plans covering additional telehealth benefits as basic benefits. They must:

- (1) Provide an enrollee with the choice of receiving a Part B service as an additional telehealth benefit or in-person.
- (2) Advise each enrollee of their choice of receiving a Part B service as an additional telehealth benefit or in-person. CMS does not finalize, however, its proposed requirement that this be done at a minimum in the plan's Evidence of Coverage, stating that it has historically used sub-regulatory guidance to address this level of detail.
- (3) Comply with existing provider selection and credentialing requirements (in 42 CFR 422.204) and when providing additional telehealth benefits, ensure provider contracts require the provider to comply with any applicable state licensing requirements and other applicable state laws for the state in which the enrollee is located and receiving the service.
- (4) Make information about coverage of additional telehealth benefits available to CMS upon request including statistics on use or cost, manner(s) or method of electronic exchange, evaluations of effectiveness, and demonstration of compliance with additional telehealth benefit requirements.

CMS had proposed in §422.135(c)(3) to require that plans identify in the plan's provider directory, those providers offering services for additional telehealth benefits and in-person visits or offering services exclusively for additional telehealth benefits. CMS did not finalize this requirement in response to commenters' concerns that more flexibility would be necessary. Some requested that if such a rule were retained, CMS should use more general terminology rather than requiring plans to explicitly list each service in the Evidence of Coverage as well as its availability via telehealth and/or in-person only. CMS agreed that more flexibility may be needed and instead it will address these provider directory elements in future sub-regulatory guidance.

d. Requirement to Use Contracted Providers

As proposed, new section 422.135(d) requires an MA plan to only furnish additional telehealth benefits through contracted providers. If offering telehealth services through non-contracted providers, the telehealth benefit may not be part of the basic benefits. They could, however, be supplemental benefits. CMS states that it is retaining this requirement because MA plans must be able to review and pre-certify the qualifications and compliance of contracted providers to ensure that telehealth services are furnished consistent with clinically appropriate standards of care and that all state licensure and credentialing requirements are met.

CMS requested comments on whether this restriction should be placed on all MA plan types or whether it should only apply to certain types of plans – for example, only to plan types that cover all medically necessary services whether they are provided by contracted or non-contracted

providers (such as local/regional PPOs). In finalizing the requirement, CMS clarifies in the preamble that if a PPO plan furnishes MA additional telehealth benefits, then the PPO plan requirement at §422(a)(1)(v) (that the PPO must furnish all services both in-network and out-of-network) will not apply to the MA additional telehealth benefits as opposed to all other benefits covered by the PPO which must be covered on both an in-network and out-of-network basis.

e. Bidding

CMS finalizes as proposed, new section 422.135(d), allowing that an MA plan can include additional telehealth benefits in its bid for basic benefits in accordance with provisions in existing section 422.254 which describes the process for submitting bids.

CMS also finalizes its proposed change to section 422.254(b)(3) establishing that in submitting a bid that includes additional telehealth benefits, capital and infrastructure costs and investments related to those benefits cannot be included, per BBA 2018. CMS includes a change from the proposed rule, however, to clarify that those capitol and infrastructure costs that may not be included are those that are *directly incurred or paid by the MA plan*. In the preamble, CMS explains that any items or services 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 cannot provide enrollees with items such as internet service or install telecommunication systems in an enrollee's home as an additional telehealth benefit.

CMS notes, in reply to comments, that it will provide additional information about how the annual bid submission process will work for MA additional telehealth benefits in developing annual bid guidance.

f. Cost Sharing

As proposed, new 422.135(f) establishes that MA plans offering additional telehealth benefits are permitted to maintain differential cost sharing for a Part B service furnished in person versus through electronic exchange. Some commenters, including the Medicare Payment Advisory Commission (MedPAC), expressed concerns about such differential cost sharing. MedPAC recommended that CMS ensure that access to in-person services is not made prohibitively expensive such as to effectively allow plans to discriminate against individuals needing in-person care. CMS reviews its reasoning for permitting differential cost sharing and identifies other rules that offer protections against such discrimination: (1) Section 1852(m)(4) of the Act and finalized §422.135(c)(1) preserve the enrollee's right to choose whether to access the service in-person or through electronic exchange. In addition, CMS states that it will view steering and inhibiting access to in-person services as violations of §422.100(f)(2) (which provides for CMS review and approval of cost sharing to ensure that MA organizations are not designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services) and preventing an enrollee from exercising his or her rights under section 1852(m)(4) of the Act. CMS states that if an MA plan chooses to require differential cost sharing, it expects the primary purpose would be to parallel the actual cost of administering the

service and not to steer beneficiaries or inhibit access. The agency intends to actively monitor complaints and to take compliance or enforcement actions as necessary.

g. Network Adequacy

CMS had requested comments for feedback on what impact additional telehealth benefits should have on MA network adequacy policies. Responses to this question were mixed. Some commenters were supportive of changes to consider telehealth providers in network adequacy assessments and in time and distance standards. Others recommended that only in-person services should be considered. Some recommended a complete study of the matter, including a recommendation to analyze the issue only after there is a higher market saturation of telehealth providers of Part B services. CMS responds that it will continue to consider and research this issue.

h. Other Conforming and Applicable Provisions

CMS finalizes as proposed conforming provisions in sections 422.100(a) and (c)(1) to include additional telehealth benefits as basic benefits. Those existing sections fall within 42 CFR subpart C which describes benefits and beneficiary protections. By conforming definitions in sections 422.100(a) and (c)(1) to include additional telehealth benefits as basic benefits, CMS ensures that additional telehealth benefits are subject to all of the coverage and access protections described in subpart C as they apply to all other basic benefits. Other minor technical changes are finalized: in section 422.100 to clarify that basic benefits include all items and services available under Parts A and B of Medicare except for hospice care and coverage for organ acquisitions for kidney transplants. References to basic benefits for the purpose of the MA bidding process are conformed in several other places as well (i.e., in sections 422.252, 422.254, and 422.264).

CMS explicitly points out that the following existing MA beneficiary coverage and access protections apply to the offering of additional telehealth benefits: assuring adequate access to services (in section 422.112); confidentiality, accuracy, and timeliness of enrollee recordkeeping (in section 422.118); standards for communications and marketing (in section 422.2268); and non-discrimination (in sections 422.100(f)(2) and 422.110(a)).

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 (ACA) apply as well.

i. Regulatory Impact Analysis

CMS provides a discussion of the impact of the additional telehealth benefits and cites literature that addresses many of those impacts. Unlike the proposed rule, CMS incorporates these costs and savings into the final Regulatory Impact Analysis.

Four major areas that CMS expects will be impacted by the ability to provide additional telehealth benefits and to incorporate those benefits into basic bids are:

- Impact on the Medicare Trust Fund. To the extent that telehealth benefits are simply re-classified as basic benefits instead of supplemental benefits, MA plan bids will rise. That would have the effect of transferring some amount of cost from enrollees to the Medicare Trust Fund. CMS estimates that the impact on the Trust Fund will be an increase in costs of \$80 million over the 10-year period from 2020 to 2029. Annually those costs will rise from about \$6 million to \$10 million over the period.
- Savings for enrollees because of decreased travel time to providers. CMS estimates an average travel savings per visit equals \$9.09 taking into account both mileage savings and saved time. CMS assumes that a typical MA enrollee is seen for 6 visits per year multiplied and 2.49 percent, in 2020 are telehealth visits. The percentage of visits that are telehealth are assumed to grow at a rate of 1.089 per year. Together those assumptions arrive at a savings of \$30 million in 2020, growing to \$88 million in 2029. Over 10 years those amounts total \$557 million. In the RIA of the proposed rule, CMS had suggested the savings for enrollees to be a fraction of those amounts.
- Savings from preventing illness resulting from increased access to services. CMS does not estimate this impact but identifies literature that supports this potential impact.
- Increased costs from increased utilization. CMS also does not estimate this impact and asserts that it is likely to be offset, all or in part, by savings because the increased access to services would prevent some illness.

2. Dual Eligible Special Needs Plans (D-SNPs)

D-SNPs enroll beneficiaries who are entitled to both Medicare and Medicaid and offer the opportunity of enhanced benefits by combining the benefits available through those two programs. CMS notes that as of June 2018 approximately 2.3 million dual eligible beneficiaries (dual eligibles) are enrolled in 412 D-SNPs, and roughly 170,000 dual eligibles are enrolled in fully integrated dual eligible special needs plans (FIDE SNPs).⁴

Section 50311(b) of the BBA 2018 established new requirements for D-SNPs to integrate Medicare and Medicaid benefits as well as imposed enrollment sanctions for MAOs that fail to comply with those requirements. It also required the unification of Medicare and Medicaid grievance and appeals procedures for D-SNPs. The effective date for these requirements is January 1, 2021; CMS declines to delay implementation beyond that date.

a. Integration Requirements

Under the statute, D-SNPs must meet one or more of the following requirements for integration of Medicare and Medicaid benefits to the extent permitted under state law:

- In addition to existing contracting requirements, contract with the state Medicaid agency to coordinate long-term services and supports (LTSS), behavioral health services, or both,

⁴ In a FIDE SNP, the same organization receives capitation payments to cover both Medicare and Medicaid services.

by meeting an additional minimum set of requirements. Examples include (i) notifying the state in a timely manner of hospitalizations, emergency room visits, and hospital or nursing home discharges of enrollees, (ii) assigning one primary care provider for each enrollee, or (iii) sharing data that would benefit the coordination of Medicare and Medicaid items and services. These minimum requirements must be included in the contract of the D-SNP plan with the state Medicaid agency.

- Either (i) meet the requirements of FIDE SNP (other than the requirement that the plan have similar average levels of frailty as the PACE program) or (ii) enter into a capitated contract with the state Medicaid agency to provide LTSS, behavioral health services, or both.
- In the case of a D-SNP offered by a parent organization that is also the parent organization of a Medicaid managed care organization (MCO) providing LTSS or behavioral services, the parent organization must assume clinical and financial responsibility for benefits provided to beneficiaries enrolled in both the D-SNP and the Medicaid MCO.

CMS implements these statutory provisions and adds requirements and clarifications to existing regulations to codify policy and guidance with respect to D-SNPs.

CMS reports that commenters were generally supportive of its proposals; some encouraged the agency to pursue further integration policies while other emphasized the need for state flexibility. It will monitor the implementation of its policies to determine impacts on beneficiaries and on markets and assess the need for further rulemaking. CMS clarifies that the D-SNP integration policies do not apply to Medicare-Medicaid Plans (MMPs) offered under the Financial Alignment Initiative.

Definitions (§422.2)

CMS proposed adding and defining, or revising existing definitions of terminology relating to D-SNPs to clearly establish minimum requirements for these plans and to specify different types of D-SNPs based on the degree to which they integrate benefits at the plan level. Generally, CMS finalizes these proposed definitions without any policy change; it does make occasional minor language and technical changes to correct errors in the proposed text as well as to clarify the language in response to concerns raised by commenters.

D-SNP. The definition of the term D-SNP is consolidated and clarified to require, at a minimum, the following: The plan is a specialized MA plan that:

1. Coordinates the delivery of Medicare and Medicaid services for individuals eligible for those services;
2. May provide coverage of Medicaid services, including LTSS and behavioral health services for individuals eligible for those services;
3. Has a contract with the applicable state Medicaid agency; and
4. Beginning January 1, 2021, meets one or more of the following integration requirements:
 - a. The plan is a highly integrated dual eligible (HIDE) SNP.

- b. The plan is a FIDE SNP.
- c. For a plan that is neither a HIDE SNP nor FIDE SNP, the plan will notify the state Medicaid agency of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full-benefit dual eligibles.

The definition as finalized is intended to clarify that a D-SNP must (among other requirements) coordinate the delivery of Medicare and Medicaid services and that it either may provide coverage of Medicaid services or arrange for the benefits to be provided; CMS does not intend to require D-SNPs to cover Medicaid services. Regardless of whether Medicaid services are provided under a capitated or other arrangement with a state Medicaid agency, the D-SNP must coordinate the enrollees' Medicare and Medicaid services. Additionally, to the extent a D-SNP does cover Medicaid services, it must document in its contract with the state Medicaid agency its duty to cover those services.

CMS interprets the statutory requirement for D-SNPs to "arrange for benefits" as requiring, at a minimum, these plans to coordinate delivery of Medicare and Medicaid benefits. CMS notes that "coordinate" would encompass a wide range of activities to facilitate meaningful access to these benefits; merely directing a beneficiary to call the MCO or state agency would not suffice. Many commenters requested that additional detail be added to the definition of D-SNP regarding the scope of activities the agency believes are required as part of coordinating delivery of those services. CMS believes that plans and states must have the flexibility to test different approaches and thus avoids including much detail in the regulation text. However, it anticipates issuing subregulatory guidance for additional examples or guiding principles on the issue.

CMS notes with respect to the integration requirements that the statutory phrase "to the extent permitted under State law" could result in D-SNPs failing to qualify as HIDE SNPs or FIDE SNPs in a number of states. Many states do not permit dual eligibles to enroll in managed care for Medicaid services; other states carve out LTSS and behavioral health services from Medicaid managed care.

HIDE SNP. CMS defines the term HIDE SNP to mean a D-SNP offered by a MAO that provides coverage, consistent with state policy, of LTSS, behavioral health services, or both under a capitated contract that is between the MA organization (MAO) and the Medicaid agency or that is between the MAO's parent organization (or other entity owned or controlled by the parent organization) and the Medicaid agency. HIDE SNPs must meet all D-SNP requirements (e.g., providing and coordinating benefits across the programs). CMS notes that any FIDE SNP would also be a HIDE SNP; however, not all HIDE SNPs qualify to be FIDE SNPs. In response to comment, CMS clarifies that the definition itself does not require that a HIDE SNP limit its enrollment to dual eligibles who qualify for LTSS, behavioral health services, or both, but the plan must cover these services for individuals eligible for them. CMS notes that the state Medicaid agency may impose enrollment restrictions. CMS also clarifies that a HIDE SNP is eligible for passive enrollment.

The definitions of HIDE SNP and FIDE SNP include the qualifying phrase “consistent with state policy” which is intended to acknowledge various state coverage policies for LTSS and behavioral health services. CMS interprets the phrase as permitting “certain carve outs where consistent with or necessary to accommodate state policy” unless specifically prohibited (e.g., the 180-day minimum coverage requirement for nursing facility services contained in the definition of FIDE SNP). Thus, a carve out by a state of a minimal scope of services is permissible as long as the applicable services described in the definition of FIDE SNP are covered under the Medicaid MCO contract. However, if a state carved out LTSS entirely from capitation, no D-SNP in that state could qualify as a FIDE SNP.

FIDE SNP. CMS makes technical revisions to the definition of FIDE SNP to conform to other policies it finalizes. CMS adds behavioral health services to the scope of services that may be covered under the contract, and it codifies the requirement that the contract provide coverage of nursing facility services for at least 180 days during a plan year.

CMS distinguishes among D-SNPs based on the degree of integration of Medicaid benefits at the plan level. The final rule includes a table (shown below) showing differences between FIDE SNPs and HIDE SNPs.

TABLE 1—ATTRIBUTES OF FIDE SNPs and HIDE SNPs

	FIDE SNP	HIDE SNP
Must have a contract with the state Medicaid agency that meets the requirements of a Medicaid MCO.	Yes	No
May provide coverage of Medicaid services via a PIHP or a PAHP.	No	Yes
Must provide coverage of applicable Medicaid benefits through the same entity that contracts with CMS to operate as an MA plan.	Yes	No. The state Medicaid contract may be with: (1) the MAO offering the D-SNP; (2) the MAO’s parent organization; or (3) another entity owned and controlled by the MAO’s parent organization.
Must have a capitated contract with the state Medicaid agency to provide coverage of long-term services and supports (LTSS), consistent with state policy.	Yes	No, if it otherwise covers behavioral health services.
Must have a capitated contract with the state Medicaid agency to provide coverage of behavioral health services, consistent with state policy.	No. Complete carve-out of behavioral health coverage by the state Medicaid agency is permitted.	No, if it otherwise covers LTSS.

	FIDE SNP	HIDE SNP
Must have a capitated contract with the state Medicaid agency to provide coverage of a minimum of 180 days of nursing facility services during the plan year.	Yes	No

Aligned Enrollment; Exclusively Aligned Enrollment. Because many of CMS’ proposals for D-SNPs are based on the concept of aligned enrollment, CMS finalizes its proposed definition of the term with some clarifying modifications. Aligned enrollment refers to the enrollment in a D-SNP of full-benefit dual eligible individuals whose Medicaid benefits are covered under a Medicaid MCO contract between the State and one of the following: (i) the D-SNP’s MAO, (ii) the D-SNP’s parent organization, or (iii) another entity that is owned and controlled by the D-SNP’s parent organization. CMS notes that aligned enrollment would not occur if the MAO (or its parent organization) contracted with a state for prepaid inpatient health plans (PIHPs) or for prepaid ambulatory health plans (PAHPs) in the state Medicaid program. Aligned enrollment, as opposed to exclusively aligned enrollment, occurs when some but not all of the D-SNPs enrollees are covered under this arrangement.

Where a state Medicaid policy requires D-SNPs to only enroll individuals with aligned enrollment, CMS refers to this as exclusively aligned enrollment. CMS clarifies that the concept of exclusively aligned enrollment is only relevant to CMS’ policies for integrated grievance and appeals procedures (described below).

D-SNPs and Contracts with States (§422.107)

CMS implements additional minimum contract requirements for integration imposed under the BBA 2018 as well as clarifies its regulations on contract requirements.

Under the final rule, D-SNPs (other than HIDE SNPs or FIDE SNPs) must comply with a new minimum contract requirement to notify, or arrange for another entity to notify, the state Medicaid agency, or individuals or entities designated by the state Medicaid agency, or both of hospital and skilled nursing facility admissions for at least one group of high-risk full-benefit dual eligible individuals, identified by the state Medicaid agency. CMS believes that this policy will promote integration of Medicare and Medicaid benefits by increasing care coordination activity around care transitions while limiting administrative burden on states and plans as well as ensuring flexibility for states. While providers expressed concerns that the burden of the notification requirement will fall on them, CMS believes that states and D-SNP “will consider any potential impacts on providers.”

In the case of care coordination for individuals with substance use disorder, CMS acknowledges complications imposed under HIPAA and 42 CFR Part 2 with respect to the notification requirement. CMS notes that the final rule does not change requirements for D-SNPs to comply

with those laws and regulations; D-SNPs to which the notification requirement applies will have to do so in compliance with HIPAA and 42 CFR Part 2 which may limit their ability to notify the state Medicaid agency as well as coordinate care for those individuals (absent patient consent).

CMS declines to set a uniform federal requirement for the timing of the notification requirement, leaving it to the states to determine the deadline for the notice.

As it did in the proposed rule, CMS believes that giving states flexibility to identify the subpopulations of high-risk, full-benefit dual eligibles on which D-SNPs must focus their notification efforts provides states flexibility and the ability to test different approaches. State Medicaid agencies will have significant latitude to set notice protocols and procedures, including whether the notice is provided by automated or manual procedures. CMS declines to extend the notification policy to all full benefit dual eligibles.

CMS finalizes other revisions to its minimum contract requirements in response to questions from stakeholders and to conform to other policies in the final rule. Some revisions clarify the duty of D-SNPs to play active roles in helping beneficiaries access Medicare and Medicaid services, and others require greater specificity in the eligibility requirements for enrollment (e.g., Medicaid nursing home level of care). CMS requires a description of the Medicaid benefits covered by the D-SNP under a capitated contract with the state Medicaid agency (or under a risk contract); the agency notes this change permits it to identify the particular Medicaid services covered under capitated contracts for FIDE SNPs and HIDE SNPs. However, the agency declines to accept a commenter's suggestion that a list of covered services be included in the contract. CMS also clarifies that its modifications are not intended to impact state Medicaid agency processes for contract submission and approval.

CMS had considered establishing limits on the enrollment of partial-benefit dual eligible individuals in D-SNPs. Because Medicaid eligibility for partial-benefit dual eligible individuals is limited to payment of Medicare premiums, and if applicable, deductibles and cost-sharing, there are no Medicaid services that the plan must integrate or coordinate on their behalf. MedPAC does not believe that D-SNPs can do much more for this population than other MA plans; other commenters opposed limits of any kind on enrollment of partial-benefit dual eligibles. CMS questions the benefit of enrollment of this population in D-SNPs relative to the challenges associated with permitting that enrollment; it may consider rulemaking in the future.

Suspension of Enrollment for Failure to Meet Requirements During the Initial Period (§422.752)

During plan years 2021 through 2025, if CMS determines that a D-SNP has failed to comply with the integration requirements imposed by section 50311(b) of BBA 2018, the agency may suspend enrollment in that D-SNP in the same manner and using the same procedures as would apply in the case of certain violations by an MAO (e.g., where an MAO substantially violates requirements to provide required medically necessary items and services; imposes higher premiums than allowed; misrepresents certain information etc.). If CMS suspends enrollment in

a D-SNP under this authority, the plan must submit a corrective action plan indicating how it will comply with the integration requirements.

CMS amends its regulation to require an enrollment suspension during plan years 2021 through 2025 for noncompliance with benefits integration requirements as opposed to outright termination. However, CMS notes that if the D-SNP fails to submit an acceptable corrective action plan or fails to carry out an acceptable corrective action plan, the agency may take other corrective actions, including contract termination. CMS notes that sanctioned plans will have access to existing appeal rights and remedies.

b. Unified Grievance and Appeals Procedures for D-SNPs and Medicaid Managed Care Plans at the Plan Level

Section 50311(b) of BBA 2018 directs the Secretary, by April 1, 2020, to establish a unified grievances and appeals process which brings together, to the extent feasible, procedures unifying grievances and appeals procedures under specified statutory provisions of Medicare and Medicaid for those programs' items and services provided by D-SNPs. These new procedures apply in place of otherwise applicable grievance and appeals procedures.

Under section 1859(f)(8)(B) of the Act, as added by BBA 2018, the unified procedures must meet the following conditions:

- Be most protective for enrollees.
- Be compatible with unified timeframes and consolidated access to external review.
- Provide for a single written notice (written in plain English and available in additional languages) that includes all relevant grievance and appeal rights.
- Provide a single pathway for resolution.
- Establish unified timelines for filing, acknowledging and resolving a grievance or appeal.
- Require plans to process, track, and resolve grievances and appeals and to provide timely notice of decisions and permit enrollees to track the status of their grievance or appeal.
- Incorporate existing law and regulations that provide for continuation of benefits pending appeal.

CMS focuses on two main areas of policy modifications. First, it establishes requirements for all D-SNPs to help their enrollees who are full-benefit dual eligibles with Medicaid-related coverage issues and grievances. Second, the agency creates an integrated grievance and appeals system for a limited set of D-SNPs (i.e., “applicable integrated plans”) pursuant to terms, conditions and definitions established in regulations.

While BBA 2018 required the use of the unified procedures for D-SNP contracts for 2021 and subsequent years, CMS believes that a state may adopt (and could require the use of) the unified grievance and appeals procedures for integrated D-SNPs and Medicaid plans as soon as the CMS regulation is final.

CMS reports that commenters were generally supportive. The agency clarifies that issues or grievances concerning drugs covered under Part D will continue to be addressed under the separate Part D appeals system; appeals for non-Part D drugs will use the unified appeals system. Network providers noted that there is no grievance or appeals process for their complaints against plans; CMS dismisses this as a matter of contract negotiation between providers and plans. Some commenters expressed concern about the impact of the new system on their Star Ratings; CMS does not believe plan ratings will be negatively impacted.

Assisting with Medicaid Coverage Issues and Grievances (§422.562(a)(5))

Under the final regulation, all D-SNPs must help enrollees with Medicaid coverage issues and grievances, including authorization for or appeals related to Medicaid-related services. Generally, D-SNPs should help enrollees file grievances, request coverage, and request appeals to resolve Medicaid coverage issues—whether the coverage is provided under Medicaid fee-for-service, a MCO, a PIHP or a PAHP.

CMS includes in the regulatory text examples of the type of assistance all D-SNPs must provide their enrollees, noting that the examples do not comprise an exhaustive list. With respect to requesting authorization of Medicaid services and navigating Medicaid appeals and grievances, examples include providing help identifying a point of contact and contacting that individual as well as obtaining documentation (e.g., medical records) to support an authorization for or appeal related to Medicaid services. Other examples include coaching to promote self-advocacy, completing forms, and taking procedural steps for a grievance or appeal.

CMS clarifies that assistance with appeals does not mean a D-SNP is obligated to represent the enrollee in Medicaid appeals or to resolve the coverage issue. While CMS acknowledges that full compliance with its proposal requires D-SNPs and states to maintain data sharing for D-SNPs to determine the type and source of Medicaid coverage of their enrollees, it nonetheless expects D-SNPs to take steps to access that information for effective care coordination for their enrollees. CMS also clarifies that D-SNPs are only required to offer assistance and, if that offer is accepted, to provide the assistance.

A D-SNP must provide this assistance “whenever it becomes aware of an enrollee’s need” for help for a Medicaid-covered service. The regulation text states that the enrollee does not need to make a specific request for assistance, but the text does not require the plan to use its programs (e.g., care coordination or case management) to identify these issues. CMS believes that D-SNPs can identify potential Medicaid coverage issues in their regular assessments and care management processes, during a coverage request for Medicaid covered services, or from communications from the enrollee or family member. CMS clarifies that it is not establishing new requirements for assistance with Medicare covered services for partial-benefit dual eligibles.

D-S NPs must provide CMS, upon request, documentation showing how assistance is provided to enrollees under the plan. CMS notes that initially it plans to monitor compliance at a high level and would not require proof that a beneficiary declined assistance. It will provide more detail about the scope and content of the documentation requirement in subregulatory guidance.

Concerned that beneficiaries may complain about the assistance provided when the ultimate outcome of the appeal is not the one they sought, some commenters worry about the impact of those complaints on their Star ratings or in CMS audits. The agency does not believe the assistance requirement will increase beneficiary complaints but says it will review its criteria to ensure they capture complaints appropriately.

Unified Grievance and Appeals for Applicable Integrated Plans

CMS does not believe that it is feasible to implement a fully unified grievance and appeals system for D-SNPs and Medicaid managed care plans that do not have the same enrollees or where the organizations offering the D-SNP and the Medicaid plan are unaffiliated or competitors. CMS notes that in most states, the majority of D-SNP enrollees have Medicaid coverage through a different organization's MCO, through a PAHP or PIHP, or through a state's Medicaid fee-for-service system, and the D-SNP has no control over Medicaid grievance and appeals processes. However, CMS believes it can establish a fully unified grievance and appeals system when one organization is responsible for both Medicare and Medicaid coverage, albeit through different contracts. The agency also notes that states may include additional integration requirements in their contracts with D-SNPs.

CMS finalizes its proposal to limit the requirement for use of the unified system for enrollees of FIDE SNPs and HIDE SNPs that have exclusively aligned enrollment and the affiliated Medicaid MCO through which enrollees receive Medicaid services (defined as applicable integrated plans). CMS notes that this subset of plans represents 37 plans in 8 states that cover roughly 150,000 enrollees. As a technical matter, CMS adds a new contract requirement for applicable integrated plans to use the unified grievance and appeals system. CMS also includes the January 1, 2021 effective date in the regulation text. CMS also clarifies that the unified grievance and appeals system policies do not apply to MMPs offered under the Financial Alignment Initiative.

Applicable Integrated Plan. CMS creates the new term “applicable integrated plan” which means a FIDE SNP or HIDE SNP with exclusively aligned enrollment and a Medicaid MCO through which the D-SNP or its parent organization (or another entity owned and controlled by the parent organization) covers Medicaid services for all dual eligibles enrolled in the D-SNP and MCO. The definition excludes PAHPs and PIHPs.

Other Terms. CMS finalizes proposals to create definitions for “integrated organization determination,” “integrated appeal,” “integrated reconsideration,” and “integrated grievance” to distinguish the unified system from the otherwise applicable grievance and appeals systems and

to clarify their application to applicable integrated plans and the unified grievance and appeals system.

- An integrated organization determination includes both MA organization determinations and adverse benefit determinations for Medicaid services made by applicable integrated plans. In response to comment, CMS clarifies that an integrated organization determination includes prior authorizations and that prior authorizations must be resolved within 72 hours.
- An integrated reconsideration is an appeal of an adverse integrated organization determination by an applicable integrated plan and includes both Medicare reconsiderations and Medicaid appeals.
- An integrated appeal encompasses integrated reconsiderations as well as additional stages of the appeals process and any additional post-plan level unified appeal process that may be established in the future.
- An integrated grievance is a dispute or complaint (other than an integrated organization determination) about an applicable integrated plan or an enrollee's provider; integrated grievances do not include MA appeals procedures or Medicare QIO complaints.

(1) Plan-level Unified System

Generally, the approach CMS used to develop its policy was to compare the policies and standards for elements of the grievance and appeal system applicable under the Medicare Advantage program to those applicable under Medicaid and to use the policy or standard that was more beneficial to the enrollee for each element.

CMS establishes a federal floor for the system permitting states to, at their discretion, implement standards that are more protective for enrollees, for example, with respect to timeframes or notices. D-SNP contracts with state Medicaid agencies will have to include any more protective standards adopted by the state for grievances and appeals. Some commenters supported the policies as beneficiary protections; others expressed concern that shortened deadlines would not permit plans the time to collect necessary information for decisions and also that states with differing timeframes would increase compliance burdens on plans operating in multiple states. CMS notes that the statute requires adoption of standards most protective to the beneficiary and to take into account states differences; additionally, it believes that state flexibility to set policies above federal minimum requirements is a consistent feature of Medicaid grievance and appeals policy.

Evidence. The plan must afford an enrollee a reasonable opportunity (in person and in writing) to present evidence and testimony and make legal and factual arguments for integrated grievances and reconsiderations. This includes informing enrollees of limited time available where the timeframe is expedited.

Assistance. The plan must provide reasonable assistance to enrollees in completing forms and taking other procedural steps. CMS does not specify the technical forms of assistance.

Acknowledgement. The plan must send enrollees written acknowledgement of receipt of all integrated grievances and reconsiderations.

Recordkeeping. The plan must follow Medicaid's grievance and appeals recordkeeping requirements which include a general description of the reason for the appeal or grievance, date of receipt, date of the review, resolution at each level and date of resolution, name of the enrollee, and date of plan notification to the enrollee. The records must be accessible to the state and available to CMS upon request.

Prohibition on Punitive Action. The plan may not take any punitive action against a provider for requesting a determination or reconsideration or for supporting an enrollee's request for these actions. CMS clarifies that the plan must ensure that these requirements are also followed by all of the plan's delegated or subcontracted entities or individuals.

Information to Providers. The plan must provide information on the integrated grievance and appeals system to providers (and subcontractors) when entering into contracts. This includes information on the right to file, and the requirements and timeframes for filing, integrated grievances and reconsiderations as well as the right to assistance in filing.

Review of Decisionmaking. As a general rule, individuals who hear and decide integrated grievances and appeals must consider all evidence and information submitted by the enrollee whether or not that information was submitted or considered in the initial adverse determination. An individual who decides an integrated grievance may not have been involved in any previous level of review (including as a subordinate of a person involved in a previous level of review); the individual must have appropriate clinical expertise for review of clinical issues. For integrated organization determinations, a physician or other appropriate practitioner with relevant medical or other expertise must review plan determinations where the plan expects to issue a partially or fully adverse medical necessity decision based on initial review of the request. An individual who makes an integrated reconsideration determination may not have been involved in any previous level of review (including as a subordinate of a person involved in a previous level of review); if the appeal is of a medical necessity denial, the individual must be a physician or other appropriate practitioner with appropriate clinical expertise.

Parties. Generally, any of the following persons may be a party to an integrated grievance, integrated organization determination, or an integrated reconsideration: (i) an enrollee, (ii) his or her representative (including legal representative of the estate of a deceased enrollee), (iii) an enrollee's assignee (i.e., a physician or other provider that formally agrees to waive any right to payment for the service), and (iv) any other provider or entity that has an appealable interest in the proceeding. Where a provider makes the request on behalf of the enrollee, the provider must notify (but is not required to get written authorization from) the enrollee. However, where a provider requests that benefits continue while an appeal is pending, the enrollee must give the

provider or representative written consent to pursue the appeal on his or her behalf. Enrollees, their authorized representatives, and providers may seek expedited integrated organization determinations.

In response to comments, CMS clarifies a number of points. Only a provider who has furnished or intends to furnish a service to an enrollee is permitted to file organization determinations or reconsideration requests on behalf of that enrollee without getting their written consent; when the provider does so, the enrollee must be notified of the request. Further, the agency clarifies that the policy permitting providers to request reconsiderations on an enrollee's behalf without the enrollee's written consent applies (i) only to pre-service appeals and (ii) to both standard and expedited reconsideration requests. CMS drops its proposal to require an authorized representative of an enrollee to get written consent from the enrollee to request continuation of benefits.

(2) Integrated Grievances

CMS finalizes its proposals for integrated grievances with minor technical and clarifying changes. Applicable integrated plans (hereafter referred to as plans) must provide meaningful procedures to hear and resolve enrollee grievances in a timely manner. The process applies to any grievance between the enrollee and the plan (or any entity or individual through which the plan covers health care services). CMS clarifies that grievances pertain to all of the contracted providers of a plan, including those that provide services that might not be strictly construed as health care services (such as Medicaid non-emergency transportation). Plans are responsible for the acts or decisions of their contracted vendors or providers.

Enrollees may file grievances at any time. Filing may be done orally or in writing to the plan or, where a state has a process for accepting Medicaid grievances, to the state. A few commenters suggested a "no wrong door" policy so that grievances that are filed with the wrong entity are not dismissed. CMS will consider this for future rulemaking and notes that it will work with states to permit enrollees to file Medicaid grievances with the state. Enrollees may file an expedited grievance where the plan extends the timeframe for resolving an organization determination or reconsideration or if the complaint involves the plan's refusal to grant the enrollee's expedited determination or reconsideration of a complaint relating to the refusal, suspension or termination of services.

Plans must resolve standard grievances expeditiously (taking into account the enrollee's health status), and in no case later than 30 days after receipt of the request. Responses must be in writing where the request was submitted in writing or where it involves quality of care. A response may be made orally where the request was made orally, unless the enrollee requests a response in writing. The 30-day timeframe may be extended by 14 days if the enrollee requests an extension or if the plan can justify the need for additional information and shows how the delay is in the best interest of the enrollee. If the plan extends the timeframe, it must promptly

notify the enrollee orally and follow up with written notice within 2 days. CMS notes that these are minimum standards and that states may require standards more beneficial to enrollees through their contracts with plans.

(3) Integrated Organization Determinations

CMS finalizes its proposals for integrated organization determinations without substantive change. Plans must adopt a uniform process for integrated organization determinations for all covered benefits. Requests may be made in writing or orally, but a payment request must be submitted in writing. However, a plan may adopt a policy where determination requests for payment may be made orally. Requests for expedited determinations may also be made orally or in writing; expedited determinations will be made when the plan determines or the provider indicates that the standard timeframe could seriously jeopardize the enrollee's life, health, or ability to attain, maintain or regain maximum function.

Plans must send written notice where the determination is adverse to the enrollee within the applicable timeframe (described below). The notice will contain information on all applicable appeal rights and contain information on the determination (including the date it was made and the date it takes effect), the rationale, the procedures for exercising appeal rights, the circumstances under which expedited appeals are available, and rights for continuation of benefits during the appeal (where applicable).

Timeframes for sending the notice are as follows:

- Where a previously approved service is being reduced, suspended or terminated, at least 10 days before the date on which the termination, suspension or reduction takes effect.
- For other non-expedited determinations, no later than 14 days after receipt of the request.
- For expedited determinations, no later than 72 hours after receipt of the request.

A plan may extend the timeframe for determinations by up to 14 days if (i) the enrollee or provider seeks the extension or (ii) the plan can show the extension is in the best interest of the enrollee and the additional information needed would likely lead to approval of the request. When a plan extends the timeframe, it must send written notice to the enrollee expeditiously and in no case later than the expiration of the extension; the notice must inform the enrollee of their right to file an expedited grievance if they disagree with the extension.

Plans must request information from noncontract providers within 24 hours of an initial request for expedited determination; noncontract providers must make efforts to provide all necessary information expeditiously. CMS clarifies that ultimately the plan is responsible for meeting the requirements of this process even where information from noncontract providers is involved.

CMS notes that it intends to develop a model notice to be used exclusively for integrated organization determinations that will be tailored to contain information relevant to the unified appeals process.

(4) Integrated Reconsiderations

CMS finalizes its proposed policies for integrated reconsiderations with some clarification and non-substantive changes.

There is a limit of one level of plan reconsideration. Where states have established external medical review, an enrollee may use that review process for Medicaid covered services only.

An enrollee has 60 days from the date of an adverse determination to file for reconsideration. An oral inquiry seeking to appeal an adverse determination will be treated as a request for reconsideration. Extensions of that 60-day timeframe are permissible for good cause.

An enrollee (or provider on the enrollee's behalf) may request (orally or in writing) expedited reconsideration which the plan must grant if it determines (or the provider indicates) the time for standard resolution would jeopardize the enrollee's life, health, or ability to attain, maintain or regain maximum function. The plan may deny the request for expedited reconsideration which results in an automatic transfer to the standard 30-day timeframe for making a decision; the plan must promptly notify the enrollee orally as well as in writing within 2 days.

If an enrollee (or representative) requests his or her case file, the plan must provide the file, including medical records and other evidence related to the reconsideration, free of charge and sufficiently in advance of the resolution timeframe for appeals.

Similar to requirements for integrated organization determinations, plans must request information from noncontract providers within 24 hours of an initial request; noncontract providers must make efforts to provide all necessary information expeditiously. The plan is responsible for meeting the requirements of this process even where information from noncontract providers is involved.

Applicable integrated plans must resolve expedited reconsiderations as expeditiously as the enrollee's health condition requires but no later than 72 hours and must resolve standard reconsiderations within 30 days. The timeframe for either type of reconsideration may be extended by 14 days if (i) the enrollee or provider seeks the extension or (ii) the plan can show the extension is in the best interest of the enrollee and the additional information needed would likely lead to approval of the request. When a plan extends the timeframe, it must send written notice to the enrollee expeditiously and in no case later than the expiration of the extension; the notice must inform enrollees of their right to file an expedited grievance if they disagree with the extension.

Notice of the reconsideration decision must be sent to the enrollee within the applicable timeframes; CMS also requires the plan to make reasonable efforts to provide prompt oral notice of the determination. The notice must state the decision and the date it was completed, and explain its basis. If applicable the notice must explain the next level of appeal and the steps the enrollee must take to exercise appeal rights as well as the right to seek continued Medicaid-covered benefits pending the appeal.

(5) Effect

When a plan fails to make a timely determination at any point in the appeals process, CMS will treat that failure as an adverse determination, giving the enrollee the right to proceed to the next level of appeal.

CMS finalizes its proposed policies for appeals after the integrated reconsideration level with some clarification and non-substantive changes. After the reconsideration level, CMS specifies two different appeals processes based on whether the benefits involved are Medicare or Medicaid covered services. Subsequent appeals for Medicare benefits will use existing MA processes for review by an independent review entity and duties for the plan to forward the case file under the same timeframes. For Medicaid benefits, CMS will use the Medicaid appeals processes; thus, enrollees would have 120 days from an adverse reconsideration to initiate a state fair hearing.

Parties are bound by appeals determinations unless the case is appealed to the next applicable level. Where a case is appealed under both MA and Medicaid processes simultaneously, the plan is bound by decisions favorable to the enrollee from state fair hearings, external medical reviews and independent review entities.

When an appeal decision on Medicaid benefits is favorable to the enrollee, the plan must authorize or provide the disputed benefit as expeditiously as the enrollee's health requires but no later than 72 hours from the date of receipt of the decision notice. Favorable appeal decisions for Medicare benefits follow the same rules as currently apply under the MA appeals processes.

Continuation of Benefits Pending Appeal

CMS interprets the language of the statute to require continuation of benefits rules to all Medicare Parts A and B and Medicaid benefits under the unified appeals processes; MA supplemental benefits are not included. These rules currently apply only in very limited circumstances under Medicare (e.g., extension of an inpatient hospital stay for beneficiaries who appeal a discharge notice to the Quality Improvement Organization (QIO)). CMS proposed to incorporate the Medicaid continuation of benefits rules into the unified appeals process; it finalizes that proposal with a modification and some clarification.

Medicaid MCOs must cover certain Medicaid benefits while an appeal is pending if all of the following conditions are met:

- The enrollee files a timely request for appeal.
- The appeal involves termination, suspension, or reduction of previously authorized services.
- The services were ordered by an authorized provider.
- The period under the original authorization has not expired.
- The enrollee files a timely request to continue the benefits.

CMS applies the Medicaid standards to permit enrollees of applicable integrated plans to request that benefits continue to be provided while the appeal is pending through the integrated reconsideration level of appeal. CMS defines timely filing as the later of (i) 10 days from the date the plan sent notice of an adverse determination or (ii) the effective date of the adverse determination.

Benefits continued or reinstated pursuant to an enrollee request would continue until the plan issued an adverse integrated reconsideration or until the enrollee withdrew the request. For Medicaid services, benefits would continue after an adverse integrated reconsideration if the enrollee files a request for a state fair hearing within 10 days of the notice of adverse reconsideration; benefits would no longer be continued if the enrollee withdraws the request for a state fair hearing or if the decision of that hearing is adverse to the enrollee.

Plans may not recover costs of services furnished under continuation of benefits pending the integrated reconsideration. In the case of Medicaid benefits, CMS agrees with commenters who argued that its policy eliminated the ability of states to recover costs of Medicaid services provided after the integrated reconsideration is final and pending a state fair hearing. This would have created an inconsistency for state Medicaid appeals processes, and CMS believes it might also dissuade states from pursuing exclusively aligned enrollment (and thereby the unified appeals system). Thus, CMS permits states, consistent with their state rules, to recover costs of services continued pending the state fair hearing phase of appeal pursuant to the state Medicaid procedures for continuation of benefits and recovery of costs.

Unifying Medicare and Medicaid Appeals Subsequent to Integrated Reconsideration

In the proposed rule, CMS described the many issues that it believes impede its ability to unify D-SNP and Medicaid appeals subsequent to the plan reconsideration level. Once the plan makes its final decision on an appeal, the Medicare and Medicaid appeals processes are entirely separate. For example, MA requires all adverse plan appeal decisions to be reviewed by an independent review entity. Medicaid MCO regulations state that no external review can be required before permitting the beneficiary to have a state fair hearing. There are other differences including amount in controversy requirements and Medicaid timeline and procedural rules that vary by state. CMS also notes that the BBA 2018 amendments do not permit the agency to waive other provisions of MA law relating to grievances and appeals. CMS asked for

comment and suggestions for viable paths forward. CMS received 6 comments on this issue which it will consider going forward.

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

Section 50354 of the BBA 2018 requires the Secretary of HHS to establish a process for Prescription Drug Plans (PDPs) to request, beginning in 2020, to receive data extracts of Medicare Parts A and B claims for their PDP plan enrollees. Under the statute, PDP sponsors may use the data to optimize therapeutic outcomes through improved medication use, to improve care coordination, or for other appropriate purposes as determined by the Secretary. It explicitly prohibits the information from being used for certain other purposes: (i) to inform Part D coverage determinations; (ii) to conduct retroactive reviews; (iii) to facilitate enrollment changes to a different PDP or a MA-PD plan; (iv) to inform marketing of benefits; and (v) any other purpose as determined by the Secretary as needed to protect the identity and the security of personal health information of Medicare enrollees.

CMS finalizes without change, new 423.153(g) to implement section 50354 of BBA 2018 as described further below.

a. Data Extracts

Under finalized 423.153(g), beginning in 2020 a PDP sponsor will be able to request a data extract of claims data for Medicare Parts A and B items and services furnished to its enrollees. The data that may be requested will be standardized extracts (CMS will not customize data extracts).

As proposed, CMS will not permit data requests for subsets of enrolled beneficiaries and will allow requests to be submitted without an end date so that unless the plan sponsor notifies CMS that it no longer wants the data, the sponsor leaves the Part D program, or CMS makes a determination or has a reasonable belief that unauthorized uses or disclosures have taken place, the request will remain in effect.

The data will be provided at least quarterly (with a 3-month lag) on a specified release date and in an electronic format to be determined by CMS. The first data extract will be available to PDP sponsors no earlier than August 15, 2020 and will reflect data for the period beginning January 1, 2020 and ending March 1, 2020. Retroactive requests will not be permitted.

Extracts will include data on all seven types of claims for services provided to an enrollee (inpatient, outpatient, carrier, durable medical equipment, hospice, home health, and skilled nursing facility data) and will include dates of services. The following fields will be included initially: 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). Any proposed future changes to the data elements would be made through rulemaking.

A plan sponsor receiving Medicare claims data under this final rule will be required to attest that it will adhere to the permitted uses and limitations described below. In addition, claims data will continue to be subject to all other applicable laws including those protecting the privacy of protected health care information and protections in 42 CFR Part 2 that govern the privacy of certain substance abuse health information.

b. Permitted Uses and Limitations of Data

Consistent with the statute, CMS defines the permitted uses and limitations of the data in (g)(2) and (g)(3). CMS finalizes its proposal without change that in addition to the two statutory uses identified in the BBA 2018 (to optimize therapeutic outcomes through improved medication use and to improve care coordination so as to prevent adverse health outcomes), PDP sponsors may also use the data for certain activities described in 45 CFR Part 164. Those regulations describe national standards to protect the privacy and security of health information under Health Insurance Portability and Accountability Act of 1996 (HIPAA). Certain additional uses will be permitted that conform to permitted uses of protected health information under HIPAA:

- Certain quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines; patient safety activities; population-based activities relating to improving health or reducing health care costs; case management and care coordination.
- Reviewing the competence or qualifications of health care professionals; evaluating practitioner and provider performance and health plan performance; conducting training programs; accreditation, certification, licensing, and credentialing activities.
- Fraud and abuse detection or compliance activities.
- Disclosures that are required by law.

CMS also codifies without change proposed (g)(4) which describes the limitations on the use of the data consistent with those described in the statute. The data cannot be used to:

- Inform coverage determinations under Part D;
- Conduct retroactive reviews of medically accepted indications determinations;
- To facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization; nor
- To inform marketing of benefits.

In addition, as proposed, CMS will require plan sponsors to contractually bind any contractors that have access to the data, as well as any other potential downstream data recipients, to the terms and conditions imposed on the plan sponsor under these rules.

CMS received a number of comments related to the permissible uses and limitations of the data. In response to commenters' recommendations to expand the permitted uses of the claims data,

(for example for value-based contracting), CMS declines but notes that it will continue to assess whether there are other permissible uses.

In response to a request for examples about how a sponsor may use the data for fraud and abuse in a way that would not impact an individual Medicare enrollee's coverage determination, CMS provides the following examples: (1) PDP sponsors could use data to create algorithms to detect fraud and abuse to inform future policies or procedures; and (2) PDP sponsors could use the data for internal and external audits or to identify fraud and abuse activities by providers and suppliers.

CMS declines, in response to recommendations, to supplement the Medicare claims data with other elements such as risk scores, lab results, or other recommended additions. CMS states that the data that will be made available will provide a comprehensive clinical picture of each member that will include utilization, cost and diagnostic information.

B. Improving Program Quality and Accessibility

In the April 2018 MA/PD final rule, CMS codified the Star Rating methodology that had been developed over the years through the call letter process. As a result, any changes to the methodology, the addition of new measures, and substantive changes to existing measures must now be made through notice and comment rulemaking. The related regulations for Part C contracts appear at §§422.160, 422.162, 422.164, and 422.166, and those for Part D contracts at §§423.180, 423.182, 423.184, and 423.186.

In this rule CMS finalizes changes to the methodology for determining the measure-specific cut points used to distinguish Star Ratings for measures other than the Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures. Other provisions address substantive changes to the specifications of three Star Ratings measures; data integrity and data review, and a new policy for adjusting Star Ratings to account for the effects of extreme and uncontrollable circumstances that occur during a performance period.

1. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System

a. Measure-Level Star Ratings

Background. As adopted in the April 2018 MA/PD final rule, the cut-points that are used to divide the distribution of measure scores into Star Ratings groupings are determined by using a hierarchical clustering method that minimizes differences within star categories and maximizes differences across star categories. Only data from the current measurement period are used. The cut points can change from one year to the next when there are differences in overall measure performance or differences in the distribution of scores. Comments from stakeholders in the past overwhelmingly suggested changes to how the cut points are determined, with commenters seeking stable, predictable cut points that are not unduly influenced by outlier performance. Recommendations included a cap to limit the year-to-year movement of cut points and announcement of the cut points before the plan preview period or before the start of the

measurement period. In finalizing the clustering methodology, CMS committed to incorporating the feedback it received and to making changes to the methodology in a future rule. A Technical Expert Panel (TEP) on the Star Ratings was convened in May 2018. More information on the TEP meeting is available at https://www.rand.org/pubs/conf_proceedings/CF391.html. (The link that is provided in the proposed rule is broken.)

Final Rule. CMS finalizes the two changes it had proposed to the hierarchical clustering methodology used to determine star rating cut points for non-CAHPS measures. Both changes modify the regulations at §§422.166(a)(2)(i) and 423.186(a)(2)(i).

First, CMS finalizes that it will use “mean resampling,” a technique under which the 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 cut points for each threshold for a measure are then set as the mean of the resulting 10 sets of measure-specific cut points. Second, CMS finalizes use of a “guardrail” to restrict the movement of cut points for measures that have been in the Star Ratings program for more than three years. The guardrail is a bidirectional cap that restricts the upward and downward movement in a measure-specific cut point for a year when compared to the previous year. Specifically, guardrails will be set at an absolute five percentage point cap for all measures scored on a 0 to 100 scale and a “restricted range cap,” or one that excludes outliers, will be used for measures not scored on a 0 to 100 scale. The restricted range cap will be set at 5 percent of the “restricted range,” which is defined as the difference between the minimum and maximum measure score values using the prior year measure scores when excluding “outer fence outliers.” An outer fence outlier is a measure score that exceeds certain upper or lower boundary values. Specifically, the upper outer fence will be set to equal the third quartile plus 3 times the interquartile range, and the lower outer fence would be set to equal the first quartile minus 3 times the interquartile range.⁵

Many comments were received on these proposed changes, and CMS discusses additional analysis it conducted in response. In one case CMS simulated the impact of the proposed changes on the 2018 Star Ratings (as some commenters had done themselves using public data). It found “relatively modest” changes in 2018 Star Ratings: 6 percent of MA-PD contracts would have received a rating that is a half star higher, and 5 percent a half star lower. At the same time 5 percent of PDPs would have ratings increase by half a star and 7 percent would decrease by half a star. CMS concluded that there is not a disproportionately negative effect for contracts with a higher percentage of low-income subsidy beneficiaries.

CMS also examined options for removal of outliers in response to comments and will consider proposing outlier removal in future rulemaking to allow stakeholders to comment on potential methodologies. (It notes that outlier removal was not proposed, and the public did not have the opportunity to comment on these options.) The two methods CMS specifically examined are “trimming” and “Tukey outer fence outlier deletion.” Under trimming, all contracts with scores

⁵ CMS notes that the first quartile is the median of the lower half of the performance scores while the third quartile is the median of the upper half of the performance scores. The difference between the first and third quartiles is the interquartile range.

below the 1st percentile or above the 99th percentile are removed prior to clustering. CMS found that using this method with a 5 percent guardrail in 2018 would have resulted in 2 percent of MA-PD contracts and 4 percent of PDPs seeing a star rating increase of half a star and 17 percent of MA-PDs a decrease of half a star. No PDP Star Ratings would have decreased. Under the Tukey outer fence outlier deletion standard statistical method, outliers are defined as values below a certain point (first quartile – 3.0 X (third quartile-first quartile)) or above a certain point (third quartile + 3.0 X (third quartile-first quartile)). CMS estimates that using this method with a 5 percent guardrail would have resulted in 2018 Star Ratings that are half a star higher for 2 percent of MA-PD contracts and 2 percent of PDP contracts, and ratings that are half a star lower for 16 percent of MA-PD contracts and 18 percent of PDP contracts. CMS will continue to examine these two methods and others as it considers proposing outlier deletion in future rulemaking.

With respect to the guardrails, CMS reports that about half the commenters supported setting the guardrails at 5 percent as proposed, while others supported various other options. In the proposed rule, CMS had indicated that it was considering alternatives such as a 3 percent cap. In the end, CMS continues to believe that guardrails at 5 percent balance predictability of cut points with allowing cut points to keep pace with changes in measure scores. If cut points do not keep pace with changes in scores over time, CMS may propose in the future how to adjust the cut points to account for significant changes in industry performance. CMS does not agree with commenters suggesting that guardrails be used for new measures as well as those in place for 3 years because it believes that doing this would prevent cut points from keeping pace with the initial performance improvement that occurs with new measures and would diminish incentives for performance improvement.

Responding to commenters, CMS explains that any measures returning to Star Ratings after being moved to display will be treated as new measures. The hierarchical clustering methodology with mean resampling will be used for the first 3 years after the measure returns to Star Ratings and the guardrail will only be applied after that point.

CMS agrees with a commenter that recalculation of base cut points is appropriate prior to applying the guardrails. When the guardrails and mean resampling are implemented for the 2022 Star Ratings, CMS will rerun the 2021 Star Ratings thresholds with mean resampling so that an apples-to-apples comparison will be made in applying the 5 percent guardrail.

Many other alternatives to the final methodology that were suggested by commenters are discussed. In responding, CMS notes that it will post example measure data for a Part C and a Part D measure in the Health Plan Management System (HPMS) at the beginning of the second plan preview for contracts to check the CMS programming. Additionally, all Healthcare Effectiveness Data and Information Set (HEDIS) data from 1997 on are available at <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenrolldata/ma-hedis-public-use-files.html>. These data are available in September of each year and can be used to simulate and validate Star Ratings calculations. CMS does not agree with a suggestion that the Medicare Plan Finder be used to communicate an explanation for why 2019 Star Ratings for PDPs decreased and the role of changes in cut points. It believes that too much methodological detail would be overwhelming to those who use the Plan

Finder website, and expects that the finalization of resampling and guardrails will help mitigate significant changes in cut points from year to year.

CMS will continue to solicit feedback from stakeholders and the TEP on the cut point methodology and is specifically continuing to analyze the impact of outliers in the data for possible future rulemaking.

Finally, CMS reports that some commenters requested an additional comment period after CMS released more information on mean resampling, but declines noting that 47 comments were received on the methodology and that some commenters had conducted simulations of the proposals. CMS therefore believes that the public understood the proposal and were able to submit comments effectively.

Definitions of *absolute percentage cap*, *cut point cap*, *guardrail*, *restricted range*, and *restricted range cap* are finalized for addition to the regulatory text at §422.162 and §423.182. No comments were received on these definitions. The definition of *mean resampling* is finalized with a change to clarify that by leaving out one of the 10 groups for each run, 90 percent of the measure scores are used for each run of the clustering algorithm.

In the impact analysis section of the final rule CMS estimates a minimal impact of the changes to how cut points are calculated on the highest ratings of contracts. It reports that simulations using the 2018 Star Ratings show that the Quality Bonus Payment ratings would increase for less than 1 percent of MA enrollees.

b. Updating Measures

Substantive modifications are made to three existing Star Ratings program measures: two Part C measures and one Part D measure. Each of the changes was previously discussed in the Final Rate Notice and Call Letters for 2018 or 2019. (The April 2018 MA/PD final rule requires that new measures be added, or existing measures substantively modified through notice and comment rulemaking and only after the potential changes are announced and comments are solicited through the call letter process.) Detailed specifications on all Star Ratings measures are available in the *Medicare Part C & D Star Ratings Technical Notes*⁶; Table 2A in the final rule provides a high-level summary of the three measures.

- Controlling High Blood Pressure (Part C) has been modified by the measure steward, the National Committee for Quality Assurance (NCQA), to reflect new guidelines on target blood pressure from the American College of Cardiology and the American Heart Association. In addition, NCQA has made other changes to the measure specifications. Because of the changes in clinical guidelines, CMS will move the updated measure to the display page for the 2020 and 2021 Star Ratings and return the updated measure to the 2022 Star Ratings using data from the 2020 measurement year. The updated measure will

⁶ The November 2018 update to the technical notes for 2019 can be found at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html> in the downloads section under “2019 Part C and D Medicare Star Ratings Data (v 11 15 2018).”

have a weight of 1 for the first year (which the regulations require for all new measures) and a weight of 3 for subsequent years. CMS notes that it will share with NCQA suggestions from commenters about other changes to the measure specifications.

- MPF Price Accuracy (Part D) is being modified by CMS in an effort to better measure the reliability of the advertised drug prices posted for a contract on the Medicare Plan Finder tool. The updated measure, which has a process measure weight of 1, will be a display measure for 2020 and 2021, and CMS will use it in 2022 in place of the current measure, which remains in the Star Ratings program until it is replaced. The specific updates being made to the MPF price accuracy measure are detailed in the final rule and include changes to the calculation of the measure score and increasing the claims included in the measure. Responding to comments, CMS states its view that beneficiaries appreciate information on both the magnitude and frequency of price inaccuracies; notes that sponsors who perform well on this measure typically update their pricing files at least every other week and typically closer to the submission dates; and addresses other concerns.
- Plan All-Cause Readmissions (Part C) is being modified by the NCQA to treat observation stays as hospital discharges and readmissions and to remove individuals with high frequency hospitalizations. In addition, as the new specifications are adopted CMS will also expand the measure to add ages 18-64 (it currently only uses the 65+ age group) and to use NCQA's new recommended minimum denominator (150). The measure will be moved to display for the 2021 and 2022 Star Ratings and returned with updates for the 2023 Star Ratings using data from the 2021 measurement year. The updated measure will have a weight of 1 for the first year and a weight of 3 for subsequent years. CMS notes that is considered keeping the legacy measure in the Star Ratings while displaying the updated measure but concludes that the significant data collection burden on plans would not be justified by the value gained in retaining the legacy measure.

CMS discusses comments it received on measures that were not part of the proposed rule and therefore outside the scope of the final rule. It will consider these comments for the future and among other items (1) notes its support for electronic modes of data collection for Star Ratings measures; (2) indicates that it has begun to consider measures relevant to the ESRD population; (3) states that it is considering options to publicly post Patient Safety Report User Guides or add more information to the Star Ratings Technical Notes to aid progress in improving prescription drug patient safety measures; and (4) rejects the Net Promoter Score as a replacement for the CAHPS measures.

c. Improvement Measures

In calculating improvement measure scores, CMS first identifies eligible measures as those that have numeric value scores in both the current and prior year and excludes measures that have substantive specification changes and those that are already focused on MA organization improvement. CMS finalizes its proposal to add an additional rule (§§ 422.164(f)(1)(v) and 423.184(f)(1)(v)) to exclude from the improvement measure for a contract any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year.

d. Data Integrity

CMS finalizes a modification to the rules (§§422.164(g) and 423.184(g)) that specify how it will reduce a contract's measure rating when it determines that measure data are inaccurate, incomplete or biased. Under the modified provision, a 1-star rating will be assigned to an appeals measure (both appeals timeliness and upheld measures for Part C and Part D) if the contract fails to submit applicable Timeliness Monitoring Project (TMP) data to CMS to ensure completeness of the contract's independent review entity data. CMS believes the ratings adjustment is needed to avoid falsely assigning a high star to a contract when an MAO or Part D sponsor has refused to submit data for CMS to evaluate its performance.

Responding to the many comments it received opposing scaled reductions as "data integrity penalties," CMS states that the downgrade "is not a penalty or punitive" but it needed to reflect that the underlying data are not reliable and to avoid high ratings on measures where the sponsoring organization failed to provide the information needed to ensure that performance is accurately reflected. Without the downgrade policy, sponsors could game the Star Ratings, which would be unfair to other sponsors that follow rules and to beneficiaries who would receive inaccurate information on how a plan handles appeals. Commenters offered a variety of suggestions for changes in the policy that CMS states are outside the scope of this rulemaking. The use of TMP data for scaled reductions of the appeals measures was finalized in the April 2018 MA-PD final rule, and the issue for this rulemaking was only the specific proposal for a reduction to 1 star for contracts that do not submit any TMP data. CMS will consider the suggestions of commenters for the future.

e. Review of Sponsors' Data

With a change regarding the effective date, CMS codifies (at §§ 422.164(h)(1) and 423.184(h)(1)) a policy regarding the deadlines for an MA organization or Part D plan sponsor to request CMS or the independent review entity (IRE) to review a contract's appeals or CMS to review a contract's Complaints Tracking Module (CTM) data. The MA organization or Part D plan sponsor may request CMS or the IRE to review its data, provided that the request is made by the annual deadline set forth for the applicable the Star Ratings year. CMS will use the annual call letter process or an HPMS memo to set the deadline. The proposed rule would have established a specific deadline of June 30 of the following year, but CMS is not finalizing this date in regulation in order to provide more flexibility with the deadline contingent on when the data are available for plans to review.

Responding to a comment, CMS reports that it has worked with the IRE (MAXIMUS) to add a late indicator in the website for Part C Appeals data so that plans can monitor the timeliness of their cases. This will also allow plans to request any needed adjustments to their Part C appeals prior to Star Ratings calculations. In addition, CMS notes that Part D appeals and CTM reports are posted in HPMS quarterly; approximately two months following the close of the quarter. Part C reconsideration information is updated daily and available to MA organizations at

www.medicareappeal.com website. With the addition of the late indicator, CMS believes that plans can fully monitor their data throughout the year.

f. Extreme and Uncontrollable Circumstances

CMS finalizes with modifications its proposal to codify a process for adjusting the Star Ratings to account for the effects of extreme and uncontrollable circumstances occurring during the performance period that may negatively impact operational and clinical systems and contracts' abilities to administer the surveys needed for accurate performance measurement. The rules are codified at §§422.166(i) and 423.186(i). In the proposed rule, CMS described the policy as similar to the one in place under the 2019 Final Rate Notice and Call Letter, except that the difference-in-differences adjustment for survey data included in the call letter was not proposed because CMS found that this adjustment showed no consistent impact on the Star Ratings and eliminating it simplifies the calculations.

Under the final rule, in order to be considered an “affected contract” for purposes of this adjustment, an MA or Part D contract must meet all 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 Social Security 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).⁷
- A 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.

In addition to these overall criteria, additional rules are adopted for contracts to receive specific Star Ratings adjustments:

- For the CAHPS survey, which is administered early in the calendar year, an affected MA or PDP contract must administer the survey unless it receives an exemption. The exemption applies if the contract has at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme circumstance and it demonstrates to CMS that the required sample cannot be contacted because a substantial number of enrollees are displaced due to a FEMA-designated disaster in the prior calendar year. A contract that requests and receives an exemption receives the CAHPS measure stars and corresponding measure scores from the prior year. Affected contracts that do not receive an exemption from administering the survey and that meet the 25 percent affected enrollees minimum receive, for each CAHPS measure, the higher of the previous year’s Star Rating or the current Star Rating (and corresponding measure score). A new policy for multiple-year affected contracts (discussed below) is applied.

⁷ CMS offers the following links to more information about section 1135(g) emergency declarations <https://www.phe.gov/emergency/news/healthactions/section1135/Pages/default.aspx>, and major disaster areas <https://www.fema.gov/disasters>.

- A parallel exemption process and Star Rating adjustment rules apply with respect to the health outcomes survey (HOS). In this case, because of the timing of the HOS data collection, the adjustment will be made to the Star Ratings for the year after completion of the follow-up HOS that is administered 2 years after the baseline survey. For example, the 2023 Star Ratings are based on data collection from April through June 2021 and reflect experiences over the previous 12 months, and uncontrollable circumstances occurring in 2020 may affect the 2023 Star Ratings. In this case the affected contract will receive the higher of the 2022 or 2023 Star Ratings and corresponding measure score for each HOS measure. A new policy for multiple-year affected contracts (discussed below) is applied.
- For HEDIS data, a contract that meets the 25 percent affected enrollee minimum may apply to CMS for an exemption by demonstrating an inability to obtain the required administrative and medical record data due to a FEMA-designated disaster in the previous calendar year. Contracts requesting and receiving an exemption will receive the prior year's HEDIS measure stars and corresponding measure scores. An affected contract without an exemption and meeting the 25 percent affected enrollee minimum will receive, for each HEDIS measure, the higher of the previous year's Star Rating or the current Star Rating (and corresponding measure score). All contracts that are required to report HEDIS data and do not have an exemption may request from NCQA modifications to the samples for measures that require medical record review. (The proposed rule would have limited this permission to affected contracts that do not receive an exemption.) A new policy for multiple-year affected contracts (discussed below) is applied.
- For new measures, CMS will apply a hold harmless provision for an affected contract meeting the 25 percent enrollee minimum. The contract will receive the higher of its summary or overall rating with and without all the new measures.
- For all other measures, an affected contract meeting the 25 percent enrollee minimum will receive the higher of the previous or current year's Star Rating. The Part C and Part D call center foreign language interpreter and TTY availability measures are excluded from this policy because CMS believes they are completely within the control of the plan and would not be impacted by natural disasters and other extreme circumstances. They will only be included where there are communications issues due to loss of electricity or infrastructure during the call center study.

In a change from the proposed rule, CMS finalizes a policy to address contracts that are affected by separate disasters in consecutive years. It received several comments on this topic. Specifically, the new policy identifies multiple-year affected contracts as those that have at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of separate extreme and uncontrollable circumstances that began in successive years. In order to avoid carrying forward very old data, CMS finalizes that such a contract will receive for each measure the higher of the current year's Star Ratings or what the previous year's rating would have been absent any adjustments that considered the previous year's disaster. CMS believes this policy will avoid carrying forward very old Star Ratings data for many years. This multiple-year affected contract policy will apply for CAHPS, HOS, HEDIS, new, and other measures.

A change to the regulatory text is also adopted to address situations in which an extreme and uncontrollable circumstance spans two years. In this case, CMS clarifies that the start date of the incident period will be used to determine which Star Ratings year could be affected, regardless of whether the incident period lasts until another calendar year. Nonsubstantive changes are also made to the regulatory text from what was proposed (e.g., use of the term “exemption” in place of “exception.”)

Responding to comments, CMS states that the 25 percent enrollee minimum threshold was chosen to avoid including in this policy contracts with few affected enrollees and therefore little impact on measure scores and Star Ratings.

CMS had proposed to follow underlying rules that would exclude a measure from consideration for the improvement measure when a contract has received the prior year score on a measure. That proposal is finalized with a modification to clarify that a contract affected by extreme and uncontrollable circumstances does not have the option of reverting to the prior year’s improvement rating. This change was necessary because of the new policy adopted in this rule regarding multiple-year affected contracts, which would have made this option difficult to operationalize and interpret.

If an affected contract has not received one of the described exemptions and it has missing data for either the current or previous year, the final measure rating will come from the current year.

The calculation of the cut points for the non-CAHPS measures using the clustering algorithm will be modified to exclude numeric values from affected contracts with 60 percent or more enrollees in FEMA-designated Individual Assistance areas. While the values from affected contracts are excluded from the calculation, the cut points will still apply to these contracts. Similarly, numeric values from these contracts will be excluded from calculation of the performance summary and variance thresholds for the Reward Factor, although affected contracts will remain eligible for the Reward Factor. CMS will continue to review the impact of the extreme and uncontrollable circumstances policy on the Star Ratings to determine whether other adjustments need to be proposed in the future.

g. Response to Other Comments

CMS discusses comments it received on issues other than those described in the proposed rule. In doing so it reports it is working toward using more outcome measures and increasing the weight of patient experience measures and discusses work related to adjustments for socioeconomic status, including the Categorical Adjustment Index and how to best incorporate information provided by stratified reporting of certain measures.

2. Improving Clarity of the Exceptions Timeframes for Part D Drugs

CMS finalizes, with a modification, its proposal to change the timeframes around Part D exception requests to address cases where the prescriber’s supporting statement has not been timely received by the plan sponsor. Under current requirements, the plan must notify the

enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision on an exceptions request as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the prescriber's supporting statement (24 hours in the case of an expedited decision).

Under the final rule, effective January 1, 2020, the regulations continue to require that a plan sponsor must notify the enrollee and prescriber of its decision as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the prescriber's supporting statement. The new policy provides that if a supporting statement is not received by the end of 14 days from receipt of the exceptions request, the plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the 14-day period has ended (24 hours in the case of an expedited determinations). The change is made in regulatory text at §§423.568, 423.570, and 423.572.

CMS had proposed simply that the deadline would end the earlier of 72 hours after receipt of the supporting statement or 14 days after receipt of the exceptions request, whichever is earlier. In modifying the language that was proposed CMS addresses concerns from commenters about lack of clarity regarding situations in which a prescriber's supporting statement is received late in the 14-day period. The final language establishes 14 days from receipt of the exceptions request as the outer limit for receipt of the prescriber's supporting statement and continues the current and proposed requirement that the plan sponsor have 72 hours (or 24 hours in expedited cases) to notify the enrollee and prescriber of its decision. In explaining the change, CMS emphasizes its expectation that plan sponsors will not routinely have exceptions requests pending for 14 days. When an exceptions request is received, the plan sponsor is responsible for promptly requesting any documentation needed to support the request. Readers are referred to a February 22, 2017 CMS memorandum to MA organizations and PDP sponsors entitled "Updated Guidance on Outreach for Information to Support Coverage" for guidance on best practices related to outreach. It can be found at: <https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/HPMS-Guidance-on-Outreach-for-Information-to-Support-Coverage-Decisions-2017Feb22.pdf>. (The link provided in the final rule appears to be broken.)

While CMS believes this policy is in alignment with current guidance, revisions will be made to the Part C & Part D appeals manual guidance as needed.

Responding to a comment, CMS notes that the final rule covers all types of exceptions request, including tiering and formulary exceptions, but it does not apply to other types of coverage determinations that do not involve an exceptions request, such as when an enrollee seeks to satisfy a prior authorization requirement or other utilization management requirement.

C. Clarifying Program Integrity Policies

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

In lieu of requiring prescribers of Part D drugs and providers of MA items and services to enroll in Medicare as a means of protecting beneficiaries and the Medicare program from waste, fraud and abuse, on April 16, 2018 CMS finalized its preclusion list policy. Generally, under the preclusion list policy, demonstrably problematic prescribers and providers will be placed on a preclusion list and payment for Part D drugs and MA services prescribed or furnished by these individuals and entities is prohibited. In response to further stakeholder inquiries, CMS proposed additional changes to and clarifications of its preclusion list policy, including a number of technical changes.

a. Appeals Process for Certain Individuals Placed on Preclusion List

CMS proposed to revise its policy that an individual or entity whose enrollment is revoked will not be placed on the preclusion list until their first level of appeal is exhausted. Because the individual or entity could first appeal the revocation and then appeal placement on the preclusion list, there could be a lengthy delay (as long as 9 months) before placement on the list is made. CMS finalizes its proposal to make the two appeals processes run concurrently as opposed to sequentially; thus, an individual or entity whose enrollment is revoked could be placed on the list in 5 months. However, CMS must provide the individual or entity contemporaneous notice of both the revocation action and the placement on the preclusion list.

CMS notes that this policy does not affect appeals of OIG exclusions which are handled through a separate process.

Providers or prescribers who are successful on appeal will be reinstated back to the preclusion effective date and may resubmit claims that were denied during the preclusion period. CMS does not finalize its proposal to require plans to waive claims filing deadlines but notes that plans should pay claims that were rejected during the preclusion period using their usual claims processing procedures. A beneficiary that paid out of pocket for a Part D drug that was rejected due to the prescriber's preclusion which was subsequently overturned on appeal should submit a request for reimbursement. CMS will use subregulatory guidance to address how beneficiaries would know about a prescriber's reinstatement.

b. Timing of Addition to Preclusion List

CMS finalizes its proposal to clarify in its regulations that an individual or entity will be included on the preclusion list after the expiration of the following:

- For prescribers or providers that do not file a request for reconsideration, at the end of the 60-day period during which the prescriber or provider may seek reconsideration.
- For prescribers or providers that file a request for reconsideration, on the date CMS denies the reconsideration.

However, where prescribers or providers are excluded by the OIG, they are added to the preclusion list effective on the date of that OIG exclusion.

The preclusion list will also include a reinstatement date to indicate that the prescriber or provider is no longer precluded; this will be published upon reinstatement. CMS will not provide advance notice of reinstatement. Additionally, records of the prescriber's or provider's placement on the list will not be removed from the file.

c. Effective Date

Generally, the effective date for the revised policies to the preclusion list contained in this rule is January 1, 2020. However, the effective date for the consolidated appeals proposal is 60 days after the date of publication in the *Federal Register* of the final rule.

CMS notes that the January 1, 2019 effective date for the preclusion list policies finalized in the April 2018 final rule still applies.

d. Claims Denial and Beneficiary Notice

In the April 2018 final rule, CMS established two different policies for when claims may be denied with respect to a prescriber or provider who is placed on the preclusion list. One policy, intended to be in place only for the initial rollout of the preclusion list policy, afforded plans 30 days to intake preclusion list data and another 60 days for the plan to notify the beneficiary and work to transition the beneficiary to another prescriber or provider. The second policy, applicable to updates of the preclusion list, made claims denial effective upon placement on the preclusion list.

CMS reconsidered this policy, citing concerns about beneficiary notice and access to medicines and other services, and finalizes the following revised policies. For claims denials for preclusion list updates, plans must notify beneficiaries within 30 days of the posting of the updated list that their provider or prescriber was placed on the preclusion list, and then 60 days after notice was sent to beneficiaries, the MAO or plan sponsor must deny claims from that individual or entity. This will provide between 60 and 90 days from when the list is updated and when claims denial would begin.

CMS notes that where there is no claims history for the previous 12 months, the plan is not required to either notify beneficiaries or to provide the 60-day grace period during which claims are paid.

The beneficiary notice itself should state that the precluded provider or prescriber is no longer available to furnish plan items or services and offer to assist the enrollee in transitioning to a new network provider or prescriber. Plans must also provide the beneficiary notice for non-network providers who provided services to the beneficiary and who have been placed on the preclusion

list; the notice must include the date on which the plan will stop paying claims from the precluded provider.

CMS clarifies that its MA regulation on the preclusion list policy applies to both contracted and noncontracted parties. CMS also notes that existing OIG notice procedures for beneficiaries about individuals or entities excluded from federal health care programs are not supplanted by the notice requirements for claims denials that plans must provide when prescribers or providers are added to the preclusion list.

CMS reminds stakeholders that the OIG exclusion list takes precedence over the preclusion list, and providers and prescribers who are excluded by the OIG will have their claims denied or rejected immediately without regard to the preclusion list 60-day grace period described above. Further, plans will not be required to provide the advance beneficiary notice for prescribers and providers who are excluded by the OIG.

CMS states that the preclusion list will indicate a “claims denial/reject date” which will be the close of the 90-day period and the latest point at which claims must be denied or rejected. CMS notes that a MAO or a plan sponsor is not required to terminate a precluded provider or prescriber but may do so under the terms of the contract.

In response to a question, CMS clarifies that urgent care and emergency services are not exempt from the claim denial requirements of the final rule.

e. Reasonable Efforts to Notify Precluded Prescriber or Provider of Beneficiaries Who Were Given the Beneficiary Notice

The proposed revised regulations included a requirement that the MAO or plan sponsor use reasonable efforts to notify the prescriber or provider of beneficiaries who received the beneficiary notice that the prescriber or provider was placed on the preclusion list. CMS clarifies that reasonable notice involves using available contact information the plan has for the prescriber or provider in order to copy them on the notice mailed to the beneficiary. Acknowledging that a plan may not have this information for noncontract providers or prescribers, CMS modifies this requirement. The “reasonable effort” requirement will only apply to claims from precluded providers or prescribers where the following two conditions are met:

1. The MAO or plan sponsor has sufficient information on file to either copy the provider or prescriber or send a new notice stating the provider or prescriber may not see plan enrollees due to their precluded status; and
2. The claim is received after the claim denial/reject date in the preclusion list file.

CMS states that this policy clarification does not affect the agency’s duty to notify each provider and prescriber of their inclusion on the preclusion list.

f. Beneficiary Appeals

CMS codifies its policy that beneficiaries do not have any right to appeal a claim denial because a prescriber or provider is on the preclusion list.

g. Felony Convictions

As established in the April 2018 final rule, the two general categories for a prescriber or provider to be placed on the preclusion list are 1) prescribers or providers with a currently revoked Medicare enrollment who are under a reenrollment bar and 2) prescribers or providers engaging in behavior for which CMS could have revoked Medicare enrollment had the prescriber or provider been enrolled. CMS had proposed to revise its definition of preclusion list to separately identify as a third category those prescribers and providers that have been convicted of a felony (under federal or state law) within the previous ten years that CMS finds detrimental to the best interests of the program. CMS finalizes this proposal. In determining whether to place an individual or entity on the preclusion list, CMS will consider the following factors: (i) the seriousness of the offense, (ii) when the offense occurred, and (iii) any other relevant information.

CMS also clarifies the length of a prescriber's or provider's placement on the preclusion list:

- With respect to prescribers and providers who are not placed on the list because of a felony conviction or OIG exclusion:
 - Where the enrollment of the prescriber or provider is revoked, placement on the list is for the period of the reenrollment bar; and
 - For unenrolled prescribers and providers, placement on the list is for the period of the reenrollment bar that would have applied had they been enrolled.
- With respect to prescribers and providers placed on the list because of a felony conviction (whether Medicare-enrolled or not), placement on the list is for the 10-year period that begins on the date of the conviction. CMS notes this is a maximum period and it may impose a shorter timeframe taking into consideration the factors described above.
- With respect to prescribers and providers placed on the list because of an OIG exclusion, placement on the list lasts until the later of the CMS-imposed preclusion period or reinstatement by the OIG.

CMS clarifies that in deciding whether to place an individual or entity on the preclusion list, or the length of that placement, it will consider whether there are exceptional circumstances about beneficiary access to care.

h. Beneficiary Liability

During previous rulemaking, CMS indicated that generally a beneficiary should not be financially liable if the MA provider that furnished an item or service is on the preclusion list. CMS amends its contracting requirement regulations for MAOs to specify that the contract requires the organization to ensure enrollees do not have any financial liability for items and

services furnished by a contracted individual or entity that is on the preclusion list. CMS acknowledges that this policy is limited to contract providers.

Thus, MAO provider agreements must include provisions acknowledging the preclusion list requirements, prohibiting a precluded network provider from seeking payment from plan enrollees, and making the provider financially liable for any items, services or drugs ordered, prescribed or furnished after the payment prohibition begins. CMS acknowledges, however, that if the MAO agreement with a precluded provider is terminated, there is no legal mechanism to apply the beneficiary hold harmless policies, and CMS would not be able to prohibit the provider from seeking payment from the beneficiary.

i. Other Issues

In the rare case where Medicaid is the primary payer for a drug furnished to a Part D eligible individual, CMS states that the preclusion list policy does not apply because the drug would be adjudicated through the Medicaid claims system.

CMS clarifies that if a plan offers benefits for both Part B and Part D drugs, the preclusion list policy prohibiting payment for Part D drugs will also apply to Part B drugs covered by the plan. In the case of a pharmacy placed on the preclusion list, CMS notes the regulations only apply to pharmacy claims for Part A or B drugs covered under Part C (as well as supplemental items and services furnished by the pharmacy); thus, the pharmacy may continue to dispense Part D drugs unless the prescription is from a precluded prescriber.

D. Implementing Other Changes

CMS finalizes as proposed two additional changes that address drafting errors. First, it clarifies that an MA organization is deemed to meet all three requirements of Quality Improvement Programs in section 422.152. Those requirements, as provided for in section 1852(e)(3) of the Act may be deemed met if an MA organization is accredited by an accrediting organization approved by CMS which uses the same or stricter standards than CMS uses to evaluate compliance with such requirements. Second, it removes a reference to quality improvement projects inadvertently overlooked when CMS eliminated the requirements for such projects in the April 2018 final rule.

II. Regulatory Impact Analysis

CMS examined the impact of the rule as required by Executive Order 12866 and provides an analysis that presents the rule's cost and benefits. CMS estimates that the final rule will, on net, generate annual savings of between \$25 million and \$86 million per year for each of 2020 through 2029, for a 10-year total of \$534 million. The Medicare Trust Fund is estimated to experience reduced spending over that same period of about \$4.5 billion arising from recovery of incorrect payments to plans. The estimates differ significantly from those presented in the proposed rule which was estimated to increase costs by about \$2 million per year. The largest difference between the two estimates is the inclusion of savings of \$30.9 million in 2020 rising

to \$88.5 million in 2029 attributed to the telehealth provisions. Those estimates were not incorporated in the proposed rule’s Regulatory Impact Analysis.

Summary of Costs and Savings

Provision	Description	Impact
<p>Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits</p> <p>(§§422.100, 422.135, 422.252, 422.254, and 422.264)</p>	<p>Consistent with section 50323 of the Bipartisan Budget Act of 2018, MA plans have the ability to provide “additional telehealth benefits” to enrollees starting in plan year 2020 and treat them as basic benefits.</p>	<p>Expected to produce \$557 million in savings for enrollees over 10 years from reduced travel time to and from providers. The impact of paying for MA additional telehealth benefits out of the Medicare Trust Fund (as basic benefits) versus out of the rebates (as supplemental benefits) results in a transfer of \$80 million from the Medicare Trust Fund to enrollees over 10 years.</p>
<p>Integration Requirements for Dual Eligible Special Needs Plans</p> <p>(§§422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)</p>	<p>Consistent with section 50311(b) of the BBA 2018, establishes, effective 2021, Medicare and Medicaid integration standards D-SNPs. Effective 2021 through 2025, requires 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.</p>	<p>For the initial year of implementation, additional \$3.4 million cost to MA plans and a \$0.5 million cost to state Medicaid agencies are estimated. Half of those amounts would be a transfer to the federal government, in order to transition to the new requirements. After that, impact will be negligible.</p>
<p>Unified Grievances and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level</p> <p>(§§422.560 – 562, 422.566, 422.629 – 422.634, 438.210, 438.400, and 438.402)</p>	<p>Consistent with section 50311(b) of BBA 2018, unifies 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.</p>	<p>The provision is estimated to increase savings, from the increased efficiency of a unified process, and raise costs from the requirement to provide benefits while appeals are pending. Over 10 years, CMS estimates that (1) plans will save \$0.7 million from the increased efficiency of unified appeals and grievance processes; this savings is passed to the Medicare Trust Fund; (2) the Medicare Trust Fund will incur a \$4.2 million expense for providing benefits while appeals are pending; and (3) enrollees will incur an extra \$0.7 million in cost sharing for benefits while appeals are pending.</p>
<p>MA and Part D Prescription Drug Plan Quality Rating System</p> <p>(§§422.162(a) and</p>	<p>Several measure specification updates, adjustments due to extreme and uncontrollable circumstances, and an enhanced cut point methodology are finalized. The</p>	<p>Negligible impact.</p>

Provision	Description	Impact
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))	measure changes are routine and do not have a significant impact on the ratings of contracts. The policy for disasters will hold contracts harmless from decreases in ratings from the prior year when there are extreme and uncontrollable circumstances affecting them. The methodology to set Star Ratings cut points will help increase the stability and predictability of cut points from year to year.	
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))	Makes several revisions to the MA and Part D preclusion list policies that were finalized in the April 2018 final rule.	Negligible Impact

Source: Excerpt from Table on pages 8-10 of public display document.