CMS Proposed Rule on 2025 Policy and Technical Changes to Medicare Advantage and Medicare Part D

On November 6, CMS released their annual Medicare Advantage (MA) and Part D Proposed Rule for 2025 (fact sheet) which governs requirements for MA and Part D plans. Among its provisions, the proposed rule implements changes related to Star Ratings, marketing and communications, agent/broker compensation, health equity, dual eligible special needs plans (D-SNPs), utilization management, network adequacy, and other programmatic areas. Comments on the rule are due January 5, 2024. **The summary below does not reflect a complete summary of the provisions of the rule. Rather, it includes a chosen subset of sections most relevant.**

NOTE: Page numbers refer to the pdf page numbers in the unofficial published inspection document made available on the federal register prior to the official publication of the rule.

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I. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit Program Policies: Past Performance (section II, pgs 15-17)

Proposed Changes

CMS proposes to change "Was subject to the imposition of an intermediate sanction" to "Was under an intermediate sanction" at §§ 422.502(b)(1)(i)(A) and 423.503(b)(1)(i)(A).

CMS proposes to incorporate Federal bankruptcy as a basis for application denials due to past performance and to conform the two paragraphs by changing the text to "Filed for or is currently in Federal or State bankruptcy proceedings" from "Filed for or is currently in State bankruptcy proceedings," at § 422.502(b)(1)(i)(C) and "Filed for or is currently under State bankruptcy proceedings" at § 423.503(b)(1)(i)(C).

At § 422.502(b)(1)(i)(B), CMS proposes technical changes to the reference to the requirement to maintain fiscally sound operations from § 422.504(b)(14) to the correct reference at § 422.504(a)(14). CMS also proposes to remove the duplication of § 422.502(b)(1)(i)(A) and (B).

Background/Rationale

CMS is proposing this revision because MA organizations and Part D sponsors may have a sanction imposed in one 12-month past performance review period and effective for all or part of the subsequent 12-month review period. Since an intermediate sanction may be active during multiple consecutive review periods, the proposed language clarifies that an organization's application may be denied as long as the organization is under sanction, not just during the 12-month review period when the sanction was imposed. The proposal reflects CMS' stated intent to deny applications from MA organizations and Part D sponsors with an active sanction, and CMS previously codified that intermediate sanctions are a basis for denial of an application from an MA organization or Part D sponsor in the January 2021 Medicare Advantage and Part D Final Rule.

CMS proposes to revise the regulation so that applications from MA organizations or Part D sponsors that have filed for or are in State or Federal bankruptcy proceedings may be denied on the basis of past performance. CMS believes bankruptcy may result in the closure of an organization's operations and entering into a new or expanded contract with such an organization is not in the best interest of the MA or Prescription Drug program or the beneficiaries they serve.

II. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. Expanding Network Adequacy Requirements for Behavioral Health (section III.A, pgs 18-25)

Proposed Changes

CMS proposes at § 422.116(b) to add new provider specialties to the list and corresponding time and distance standards at § 422.116(d)(2). Specifically, CMS proposes adding Outpatient Behavioral Health as a new facility-specialty in § 422.116(b)(2) and incorporating time and distance requirements in § 422.116(d)(2). The new combined behavioral health specialty type can include marriage and family therapists (MFT), mental health counselors (MHC), Opioid Treatment Programs (OTPs), Community Mental Health Centers, and those of the following who regularly furnish or will regularly furnish behavioral health counseling or therapy services, including, but not limited to, psychotherapy or prescription of medication for substance use disorders: physician assistants, nurse practitioners, and clinical nurse specialists; addiction medicine physicians; or outpatient mental health and substance use treatment facilities.

CMS proposes that MA organizations are allowed to include contracted individual practitioners, group practices, or facilities that are applicable under this specialty type on their facility Health Services Delivery (HSD) tables.

CMS proposes base time and distance standards in each county type for the new specialty type as follows:

Provider/Facility type	Large Metro		Metro		Micro		Rural		Counties with Extreme Access Considerations (CEAC)	
	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance
Outpatient Behavioral Health	20	10	40	25	55	40	60	50	110	100

CMS proposes adding the new Outpatient Behavioral Health facility-specialty type to the list at § 422.116(d)(5) of the specialty types that will receive the credit if the MA organization's contracted network of providers includes one or more telehealth providers of that specialty type that provide additional telehealth benefits, as defined in § 422.135, for covered services.

Background/Rationale

The amendment by the Consolidated Appropriations Act (CAA), 2023, adds a new benefit category under Part B for MFT and MHC services. Because MA organizations are required to coverall virtually all Part B covered services, these new services must be covered as defined and furnished, by MFTs and MHCs.

The CMS proposal to amend MA network adequacy requirements to introduce a combined behavioral health specialty type aims to enhance access to behavioral health services for enrollees. CMS cites the feedback received in response to the January 2022 proposed rule Request for Information (RFI), highlighting the need to expand network adequacy standards for outpatient behavioral health physicians and professionals treating substance use disorders. CMS believes this proposed change is consistent with the explanation in the April 2023 final rule that a meaningful access standard for the OTP specialty type is achievable under a combined behavioral health specialty type.

CMS is proposing a combined facility-specialty type instead of creating separate provider-specialty types due to data from the U.S. Department of Labor, Bureau of Labor Statistics, which indicates that MFTs and MHCs predominantly offer services in outpatient behavioral health settings. Analysis of Place of Service codes on Medicare claims supports this observation, and there are currently limited or no claims from MFTs and MHCs in the Medicare program. By consolidating these provider types into an "Outpatient Behavioral Health" facility category, CMS aims to gather more data on the utilization patterns of these providers nationwide. CMS believes that this information is crucial for developing time and distance standards, and that this proposal aligns with existing practices, as other provider specialties like physical therapy, occupational therapy, and speech therapy have traditionally been categorized as facility types for network adequacy purposes, despite individual providers delivering the care.

CMS plans on monitoring the appropriateness of maintaining this proposed new behavioral health specialty type as a facility-specialty type for network adequacy review purposes, in addition to monitoring whether network adequacy for OTPs is best measured under a combined facility type for network adequacy review purposes.

Regarding the telehealth credit, CMS notes the significance of Medicare Fee-for-Service (FFS) claims data, revealing that telehealth was the second most common place of service for claims with a primary behavioral health diagnosis in 2020.

Comments

CMS solicits general comments on the above proposals.

B. Improvements to Drug Management Programs (§§ 423.100 and 423.153) (section III.D, pgs 79-94)

1. Definition of Exempted Beneficiary § 423.100

Proposed Changes

CMS proposes to amend the regulatory definition of “exempted beneficiary” at § 423.100 by replacing the reference to “active cancer-related pain” with “cancer-related pain”.

Background/Rationale

CMS' rationale for amending the regulatory definition of "exempted beneficiary" is to expand the definition to more broadly refer to enrollees being treated for cancer-related pain to include beneficiaries undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only. The change also aligns with the 2022 CDC Guideline regarding applicability in individuals with cancer.

2. Drug Management Program Notices: Timing and Exceptions § 423.153(f)(8)

Proposed Changes

CMS proposes to redesignate existing § 423.153(f)(8)(ii) as § 423.153(f)(8)(iii), and to revise the text at § 423.153(f)(8)(ii) to specify that, for such exempted beneficiaries, the sponsor must provide the alternate second notice within 3 days of determining the beneficiary is exempt, even if that occurs less than 30 days from the date of the initial notice.

CMS proposes to add at § 423.153(f)(8)(i)(A) a window of up to 3 days to allow for printing and mailing the second notice or alternate second notice.

Background/Rationale

CMS' rationale for removing the requirement stems from observations made when overseeing programs and auditing Part D sponsors where initial notices were sometimes sent to Part D enrollees qualifying as exempted beneficiaries under § 423.100, often because the sponsor does not have the necessary information at the time of the initial notice. CMS recognizes that sponsors may already be sending alternate second notices before the 30-day period elapses, thus the proposed change aims to explicitly require the sending of such notices to exempted beneficiaries sooner than 30 days after providing the initial notice. CMS notes that if finalized, the Part D Drug Management Program Retraction Notice for Exempted Beneficiaries would be obsolete since sponsors would instead send the alternate second notice.

Presently, sponsors are required to furnish these notices not more than the earlier of the date they determine the relevant information or 60 days after the initial notice. With the proposed technical change CMS aims to strike a balance, offering sponsors sufficient time to print and mail notices while ensuring beneficiaries promptly receive information about Drug Management Program (DMP) limitations. CMS emphasizes that sponsors should still issue these notices as soon as possible upon making a determination. CMS believes that sponsors have ample time to plan for the printing and mailing days in advance, ensuring beneficiaries continue to receive timely information about changes to their access to Part D drugs and their appeal rights.

3. OMS Criteria Request for Feedback

Comments

CMS solicits feedback on their newly developed risk assessment data analysis methodology for determining the top risk factors for Part D enrollees at high-risk for one of two outcomes: (1) having a new opioid poisoning (overdose) or (2) developing newly diagnosed OUD, and possible future changes. They specifically seek feedback on using the model to enhance minimum/supplemental OMS criteria in the future, avoiding stigma/misapplication of a potential at-risk beneficiary (PARB) using model variables, implementation considerations, and potential unintentional consequences for medication access.

C. Codification of Complaints Resolution Timelines and Other Requirements Related to the Complaints Tracking Module (42 CFR 417.472(l), 422.125, 423.129, and 460.119) (section III.E, pgs 94-102)

Proposed Changes

CMS proposes to codify existing guidance for the timeliness of complaint resolution by plans in the Complaints Tracking Module (CTM) at §§ 422.504(a)(15) and 423.505(b)(22) that Cost plans and PACE organizations also address and resolve complaints in the CTM.

CMS proposes to codify the existing priority levels for complaints based on how quickly a beneficiary needs to access care or services and to codify a new requirement for plans to make first contact with individuals filing non-immediate need complaints within three (3) calendar days. CMS notes that this time frame would not apply to immediate need complaints because those complaints need to be resolved within two calendar days.

CMS proposes to add language to §§ 417.472(l) and 460.119 to codify in the Cost plan regulations and PACE regulations, respectively, the requirement that Cost plans and PACE organizations address and resolve complaints in the CTM.

CMS proposes to codify the timeliness requirements for MA organizations and Part D plans at new §§ 422.125 and 423.129, codifying at §§ 422.125(a) and 423.129(a) the definitions of "immediate need" and "urgent" complaints, and codifying at §§ 422.125(b) and 423.129(b) the current timeframes reflected in section 70.2 of chapter 7 of the Prescription Drug Benefit Manual for resolving immediate need and urgent complaints (two and seven days respectively). CMS' proposal to codify the definitions of "immediate need" and "urgent" complaints in substantially the same way as they are currently defined in guidance for MA and Part D-related complaints includes situations where a beneficiary has access to enough of a drug or supply to last fewer than 2 days or from 3 to 14 days.

CMS proposes requiring resolution within 30 days of receipt for all other part D and on-Part D complaints in the CTM.

CMS proposes requiring plans to contact the individual filing a complaint within three (3) calendar days of the complaint being assigned to a plan at §§ 422.125(c) and 423.129(c).

Background/Rationale

Regarding the definitions of immediate and urgent complaints, CMS proposes this change recognizing that some complaints to an MA organization (or Cost plan or PACE organization) may overlap with Part

D access, and that non-Part D MA, Cost plan, and PACE complaints relate not just to access to physician services but to drugs and supplies that may be covered by the MA plan, Cost plan, or PACE organization's non-Part D benefit.

Regarding the calendar day deadlines, CMS highlights that the two-day timeframe for resolving plan related immediate need complaints aligns with the current practice by plans and logically follows from the definition of an "immediate need" complaint. For urgent complaints, CMS believes that allowing more than a week to elapse before resolving such complaints would pose an unacceptable risk of beneficiaries not receiving timely replacements for drugs or supplies. Therefore, the proposed seven-calendar day deadline aims to ensure timely resolution, minimizing risks and disruptions to beneficiaries' access to essential medications and supplies.

CMS aligns the proposed change for a 30-day resolution timeframe for all other Part D and non-Part D complaints in the CTM with existing practices and guidance outlined in section 70.2 of chapter 7 of the Prescription Drug Benefit Manual with the aim of preventing complaints from lingering for extended periods without resolution. The proposed change also corresponds with the period provided in regulations (§§ 422.564(e) and 423.564(e)) for addressing grievances. CMS highlights recent evidence which indicates a high efficacy of resolving non-immediate need or urgent complaints within the proposed 30-day timeframe. Specifically, 98% of such complaints were reportedly resolved by plans within 30 days in 2022, thus CMS believes that a 30-day resolution period is both feasible and effective.

CMS has observed that delays in contacting complainants about the progress of their complaints, particularly those without assigned priority levels, can lead to unnecessary frustration for beneficiaries. CMS notes that the absence of a specified timeframe for reaching out to complainants has allowed plans to wait until the resolution timeframe is nearly elapsed, especially for uncategorized complaints with a 30-day resolution period. CMS highlights that a specific three calendar day timeframe for contacting individuals filing complaints through the CTM would allow for timely updates, address concerns promptly, and enhance overall customer service. CMS believes that the specificity in this timeframe allows for better monitoring and intervention by CMS to ensure compliance and prevent prolonged resolution delays.

Comments

CMS solicits comments on whether the three-day timeframe is appropriate and whether a longer or shorter timeframe would better balance the needs of beneficiaries with the capacity of plans to respond to complaints.

D. Additional Changes to an Approved Formulary— Biosimilar Biological Product Maintenance Changes and Timing of Substitutions (§§ 423.4, 423.100, and 423.120(e)(2)) (section III.F, pgs 103-131)

1. Substituting Biosimilar Biological Products for their Reference Products as Maintenance

Proposed Changes

CMS proposes that removal of a reference biologic from the formulary when a biosimilar biologic is added to the formulary be considered a "maintenance change", regardless of whether the biosimilar is classified as interchangeable by the FDA in a December 2022 proposed rule (87 FR 79452). Interchangeable biosimilars will be eligible for *immediate substitution.* CMS also proposes addition of a new term to the December 2022 proposed rule: "biosimilar biological product", in addition to the already defined term, "interchangeable biological product", where the former term would be inclusive of the latter.

Background/Rationale

The December 2022 proposed rule consists of many provisions which are not to be implemented prior to CY2025. As a result of several comments received on the December 2022 proposed rule, CMS has made several revisions.

In December 2022 proposed rule, CMS did not specify whether non-interchangeable biosimilars were eligible for maintenance or immediate substitution changes. CMS received many comments, ranging from encouraging CMS to consider removal of a reference biologic as a maintenance change when any biologic biosimilar is added to the formulary to not considering any substitutions as a maintenance change. CMS chose to propose categorizing removal of a reference biologic as a maintenance change when a non-interchangeable biologic biosimilar was being added to the formulary because of prohibitive state pharmacy laws, where pharmacists are not permitted to substitute the reference biologics with non-interchangeable biosimilar. Maintenance change categorization would require Part D sponsors to provide a 30-day advanced notice to beneficiaries prior to the effective date, giving them time to switch their prescription to the newly marketed biologic biosimilar.

Comments

CMS solicits comments on proposed changes to maintenance changes, definition of biosimilar biologics.

2. Updated Proposal Related to Timing of Substitutions

Proposed Changes

CMS proposes removal of "at the same time" in proposed definition of *maintenance change* in § 423.100 in the December 2022 proposed rule and replace it with "within 90 days of" to allow plan sponsors to make a negative change by removal of reference brand/biologic product within 90 days of addition of a corresponding drug (i.e., biosimilar biologic or generic) to their formulary.

CMS also proposes that negative changes be considered *immediate substitutions* in § 423.120(e)(2)(i) in December 2022 proposed rule if they occur within 30 days of addition of corresponding drug to the formulary.

Background/Rationale

The proposed December 2022 rule implied that for removal of a reference biologic from the formulary, the biosimilar biologic must be added to the formulary at the same time. Part D sponsors may want to make a less expensive non-interchangeable biosimilar available to beneficiaries earlier than the timeline

they must follow for a maintenance negative change, which requires notification to beneficiaries and submission to CMS. Changing to a 90-day window would allow sponsors to do so, without having to delay the addition of the biosimilar biologic to their formularies. This change is also consistent with the prior sub-regulation CMS has issued on this topic.

Comments

CMS solicits comments on these proposed time frames and whether a different timeframe may be more appropriate for Part D sponsors, and rationale for the different timeframes.

3. Miscellaneous Changes

Proposed Changes

CMS proposes to make a technical change in its definition of "corresponding drug" in the December 2022 proposed rule in § 423.100 by clarifying that "an unbranded biological product of a biological product" refers to "an unbranded biological product marketed under the same BLA as a branded name biological product."

Background/Rationale

Prior CMS language was not abundantly clear on what "an unbranded biological product of a biological product" meant.

E. Parallel Marketing and Enrollment Sanctions Following a Contract Termination (§§ 422.510(e) and 423.509(f)) (section III.G, pgs 131-133)

Proposed Changes

CMS proposes to add paragraph (e) to § 422.510 and paragraph (f) to § 423.509, which details marketing and enrollment sanctions will automatically take effect after a termination is imposed. CMS further proposes to state that the marketing and enrollment sanctions will go into effect 15 days after CMS issues a contract termination notice. These proposals would be effective beginning in contract year 2025.

CMS also proposes at paragraph (e)(2) of § 422.510 and paragraph (f)(2) of § 423.509,that MA organizations and Part D sponsors would continue to be afforded the same appeals rights and procedures specific to contract terminations; however, there would not be a separate appeal for the sanction.

Additionally, CMS also proposes that if an MA organization or Part D sponsor appeals the contract termination, the marketing and enrollment sanctions would not be stayed pending the appeal.

Lastly, CMS proposes that the sanction would remain in effect until the effective date of the termination, or if the termination decision is overturned on appeal, until the final decision to overturn the termination is made by the hearing officer or Administrator.

Background/Rationale

If CMS terminates an MA organization or Part D sponsor contract(s) during the plan year but the termination is not effective until January 1 of the following year, the MA organization or Part D sponsor could potentially continue to market and enroll eligible beneficiaries into plans under the terminating contract(s) unless CMS imposes separate marketing and enrollment sanctions on the terminating contract(s).A terminating contract that continues to market to and enroll eligible beneficiaries would cause confusion and disruption for beneficiaries who enroll in the period of time between when the termination action is taken and the January 1 effective date of the termination.

F. Update to Multi-Language Insert Regulation (§§ 422.2267 and 423.2267) (section III.H, pgs 134-143)

Proposed Changes

CMS proposes to update §§ 422.2267(e)(31) and 423.2267(e)(33) to require that notice of availability of language assistance services and auxiliary aids and services be provided in the 15 most common languages in a State.

CMS proposes to modify the language of notice to be a model communication material rather than a standardized communication material and thus that CMS would no longer specify the exact text that must be used in the required notice. The proposal would require MA organizations and Part D sponsors to provide enrollees a notice of availability of language assistance services and auxiliary aids and services that, at a minimum, state that MA organizations and Part D sponsors provide language assistance services and appropriate auxiliary aids and services free of charge. Additionally, the Notice of Availability must be provided in English and at least the 15 languages most spoken by individuals with limited English proficiency in the relevant State and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

CMS also proposes at §§ 422.2267(e)(31)(ii) and 423.2267(e)(33)(ii) that if there are additional languages in a particular service area that meet the 5-percent service area threshold beyond the languages described in §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i), the Notice of Availability must also be translated into those languages, similar to the current MLI requirements at §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i).

Background/Rationale

Individuals with limited English proficiency (LEP) experience obstacles to accessing health care in the United States. Language barriers negatively affect the ability of patients with LEP to comprehend their diagnoses and understand medical instructions when they are delivered in English and impact their comfort with post-discharge care regimens. The multi-language insert (MLI) is a standardized communications material that informs enrollees and prospective enrollees that interpreter services are available in Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese. These are the 15 most common non-English languages in the United States. As a result of the conflict between the MLI requirements at §§ 422.2267(e)(31) and 423.2267(e)(33) and the Medicaid requirement at § 438.10(d)(2), any applicable integrated plans (AIPs) that provide integrated Medicare and Medicaid materials for enrollees must

currently include the MLI in the 15 most common languages nationally as well as the Medicaid tagline in the prevalent non-English languages in the State if they want to comply with both Medicare and Medicaid regulatory requirements. This can result in a very long multi-page list of statements noting the availability of translations services in many languages in the enrollee materials. This lengthy list can be a distraction from the main information conveyed in the material.

CMS believes rulemaking regarding a non-English notice of the availability of language assistance services and auxiliary aids and services is needed to more closely reflect the actual languages spoken in the service area. Additionally, CMS believes it is in the best interest of enrollees for the requirements to align with the Medicaid translation requirements because it will allow D-SNPs that are AIPs to provide a more applicable, concise Notice of Availability to enrollees that do not distract from the main purpose of the document.

CMS also believes this proposal would make it easier for individuals to understand the full scope of available Medicare benefits, increasing their ability to make informed health care decisions, and promote a more equitable health care system by increasing the likelihood that MA enrollees have access to information and necessary health care.

G. Expanding Permissible Data Use and Data Disclosure for MA Encounter Data (§ 422.310) (section III.I, pgs 148-162)

1. Expanding and Clarifying the Programs for which MA Encounter Data may be Used for Certain Allowable Purposes

Proposed Changes

CMS proposes to add "and Medicaid program" to the current MA encounter data use purposes codified at § 422.310(f)(1)(vi) and (vii). These additions would enable CMS to use the data and release it for the purposes of evaluation and analysis and program administration for Medicare, Medicaid, or Medicare and Medicaid combined purposes.

Under this proposal, a state receiving MA encounter data for care coordination may therefore disclose MA encounter data to Medicaid managed care plans to coordinate services for enrolled dually eligible individuals.

CMS also proposes to add a new subsection § 422.310(f)(3)(v) to allow for MA encounter data to be released to States for the purpose of coordinating care for dually eligible individuals when CMS determines that releasing the data to a State Medicaid agency before reconciliation is necessary and appropriate to support activities and uses authorized under paragraph (f)(1)(vii).

Background/Rationale

These proposals related to disclosure of MA encounter data are focused on expanding allowable disclosures of these data to support not only the Medicare program or Medicare-Medicaid demonstrations, but also the Medicaid program in the interest of improving care for individuals who are eligible for

Medicaid. Further, CMS believes these proposed disclosures would improve States' ability to understand and improve care provided to dually eligible individuals is appropriate and consistent with intention in prior rulemaking.

For example, CMS notes that access to MA encounter data could support States' analysis of geographic trends to create targeted community outreach and education, including identification of geographic areas with higher rates of dementia, diabetes, or emergency room visit overutilization; and evaluation of current Medicaid initiatives, including tracking efficacy of opioid overuse and misuse programs by monitoring service utilization for those with opioid dependency, evaluating appropriate and inappropriate use of antibiotic and psychotropic medications, and analyzing deaths among individuals with opioid use disorder.

Comments

CMS welcomes comments on the proposal.

2. **Adding an Additional Condition Under Which MA Encounter Data May Be Released Prior to Reconciliation**

Proposed Changes

CMS proposes to add a new subsection § 422.310(f)(3)(v) to allow for MA encounter data to be released to States for the purpose of coordinating care for dually eligible individuals when CMS determines that releasing the data to a State Medicaid agency before reconciliation is necessary and appropriate to support activities and uses authorized under paragraph (f)(1)(vii). The proposed amendments to § 422.310(f)(1)(vii) would expand the scope of that provision to include using the data to support administration of the Medicaid program.

CMS proposes that these amendments to § 422.310(f) would be applicable upon the effective date of the final rule if these proposals are finalized as proposed.

Background/Rationale

CMS believes there will be increased utility of MA encounter data for Medicaid programs if the data is released before final reconciliation for coordination of care under the allowable purpose. Currently, there is a 13-month data lag after the end of the MA risk adjustment data year. Without timely, comprehensive beneficiary data, which are not currently available to States for all MA enrollees, CMS notes that States cannot conduct care coordination for dually eligible individuals in MA.

Comments

CMS welcomes comments on the proposal.

3. **Solicitation of Comments on Use of MA Encounter Data to Support Required Medicaid Quality Reporting**

Comments

CMS is soliciting comments on making MA encounter data available to States to support Child and Adult Core Set reporting as efficiently as possible while complying with § 422.310(f) and balancing considerations related to the timeliness of quality reporting with accuracy and completeness.

Background/Rationale

In accordance with current regulation text at § 422.310(f)(2), States may request MA encounter data for the purpose described at § 422.310(f)(1)(iv)—to conduct quality review and improvement activities—which could support Medicaid Child and Adult Core Set reporting. However, the limitations in paragraph (f)(3) on sharing MA encounter data before final reconciliation would frustrate CMS' desire for States to use the data to support timely Child and Adult Core Set reporting. The August 2023 final rule establishes a schedule through which Core Set reporting to CMS begins in the fall of 2024, applicable to data collected during the 2024 reporting period. However, the current release schedule of MA encounter data in accordance with § 422.310(f)(3) limits available MA encounter data to between 13 and 25 or more months after the service was rendered.

This means that based on the current limitations in paragraph (f)(3), States would be unable to report on 2023 services received by dually eligible individuals enrolled in an MA plan to CMS in the fall of 2024 for the Child and Adult Core Set measures. With over half of dually eligible individuals enrolled in MA plans, CMS believes it is essential that State Child and Adult Core Set reporting eventually include that population.

H. Standardize the Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) Appeals Process (section III.J, pgs 163-171)

Proposed Changes

CMS proposes to delete § 422.311(c)(5)(ii)(C), which requires MA organizations requesting both a medical record review determination appeal and payment error calculation appeal to file their written requests for both appeals within 60 days of the issuance of the RADV audit report before the reconsideration level of administrative appeal.

They also propose to amend § 422.311(c)(5)(iii) by providing that MA organizations who request a medical record review determination appeal may only request a payment error calculation appeal after the completion of the medical record review determination administrative RADV appeal process. At § 422.311(c)(5)(ii)(B), CMS is proposing to specify that MA organizations will forgo their medical record review determination appeal if they choose to only file a payment error calculation appeal.

CMS proposes at § 422.311(c)(5)(iii)(A) and (B) to specify that this process is complete when the medical record review determination appeals process has been exhausted through the three levels of

appeal, or when the MA organization does not timely request a medical record review determination appeal during either the hearing officer or CMS Administer review stages.

CMS proposes at § 422.311(c)(5)(iii)(B) that an MA organization whose medical record review determination appeal has been completed, has 60 days from the issuance of a revised RADV audit report to file a written payment error calculation appeal, and clarifies that an MA organization's request for medical record review determination reconsideration must specify all audited HCCs from an audit report that they wish to dispute. CMS is also revising § 422.311(c)(6)(i)(A) to clarify an MA organization's request must specify any and all audited HCCs from an audit report that the MA organization wishes to dispute.

CMS proposes to revise § 422.311(c)(6)(iv)(B) to clarify that the reconsideration official's decision is final unless it is reversed or modified by a final decision of the hearing officer as defined at § 422.311(c)(7)(x). CMS is proposing to add § 422.311(c)(6)(v) to clarify that the reconsideration official's written decision will not lead to the issuance of a revised audit report until the decision is considered final in accordance with § 422.311(c)(6)(iv)(B).

CMS proposes to clarify at revised § 422.311(c)(7)(ix) that if the hearing officer's decision is considered final, the Secretary will recalculate the MA organization's RADV payment error and issue a revised RADV audit report superseding all prior RADV audit reports for the specific MA contract audit.

Additionally, CMS proposes to revise § 422.311(c)(8)(iii) to add the requirement that if the CMS Administrator doesn't decline to review within 90 days of the receipt of either the MA organization or CMS's timely request for review, the hearing officer's decision becomes final. Providing further clarification that CMS and the MA organization may submit comments within 15 days of the date of the issuance of the notification that the Administrator has elected to review the hearing decision. At § 422.311(c)(8)(v) CMS proposes to clarify the requirement of the Administrator to render a final decision in writing within 60 days of issuing the acknowledgement notice, as determined by the date on which the final decision is made, not the date it is delivered to parties. At § 422.311(c)(8)(vi) CMS is clarifying the scenarios in which the hearing officer's decision becomes final after a request for Administrator review has been made.

CMS proposes to add new § 422.311(c)(8)(vii) which states that once the Administrator's decision is considered final, the Secretary will recirculate the MA organization's RADV payment error and issue a revised RADV audit report superseding all prior reports. Additionally, CMS is proposing to add § 422.311(c)(9) to specify what actions constitute final agency action. They specify that in cases when a MA organization appeals a payment error calculation after an MRRD appeal has completed the administrative appeals process, the MRRD payment error calculation final decisions will not be considered final agency action until the related payment error calculation appeal has been completed though the administrative appeals process and a final revised audit report has been issued.

CMS also proposes to revise § 422.311(a) to remove the word "annually."

Background/Rationale

CMS proposes revisions to the timing of when a medical record review determination and a payment error calculation appeal can be requested and adjudicated, specifically noting that the current regulatory language is somewhat ambiguous regarding this point.

If finalized, CMS believes that clarifying and simplifying this regulatory text will create consistency in RADV payment calculations and the process that follows it. Stating that previous language addressed possibilities in multiple ways, CMS believes if finalized, these changes will alleviate administrative burden on both CMS and MA organizations. In addition to the above, CMS wishes to clarify what actions related to the RADV audit appeals process constitute final agency action and believe that if finalized, these rule changes will clarify the requirements for a final decision to be provided in the RADV process.

CMS believes that, if finalized, these rule changes will clarify the proposals surrounding an MA organization forgoing their medical record review determination appeal and being able to permit an MA organization to submitting only one medical record review determination reconsideration request per audited contract. Additionally, CMS believes that issues surrounding the audit report will be revised to create more efficient clarifications on the process.

III. Benefits for Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. Definition of "Basic Benefits" (§ 422.2) (section IV.A, pgs 172-173)

Proposed Changes

CMS proposes to revise the definition of "basic benefits" at § 422.2 from "all Medicare-covered benefits" to "Part A and Part B benefits". They also seek to update the exceptions in this section to also include, beginning in 2021, organ acquisitions for kidney transplants (which includes costs covered under section 1881(d) of the Act), in addition to hospice services.

Background/Rationale

These are technical changes to align with the definition of basic benefits established in section 1852(a)(1)(B)(i) of the 21st Century Cures Act. CMS does not expect this change to have additional economic impact or paperwork burden.

B. Evidence as to Whether a Special Supplemental Benefit for the Chronically Ill Has a Reasonable Expectation of Improving the Health or Overall Function of an Enrollee (42 CFR 422.102(f)(3)(iii) and (iv) and (f)(4)) (section IV.B, pgs 174-188)

Proposed Changes

CMS proposes to redesignate § 422.102(f)(3) to § 422.102(f)(4) and establish at new § 422.102(f)(3) requirements for MA plans that include an item or service as SSCBI in its bid. To demonstrate that item or service is reasonably expected to improve or maintain the health or overall function of a chronically ill enrollee, Medicare Advantage Organizations (MAOs) must establish a bibliography of relevant and acceptable evidence of the impact of that item/service. The bibliography must include a working hyperlink or the entire document and be made available to CMS upon request. CMS is proposing to only apply this requirement to primarily health-related SSBCI and non-primarily health-related SSCBI, not those offering reduced cost sharing. CMS also does not intend for this requirement to apply to the Value-Based Insurance Design (VBID) Model.

CMS proposes to interpret "relevant and acceptable evidence" as including large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, designed to investigate the item or service's impact on health or overall function, or large systematic reviews or meta-analyses summarizing literature of the same. MA plans must include all relevant acceptable evidence published within 10 years preceding the month in which its bid is submitted, not just supportive evidence. In the absence of publications that meet these standards, bibliographies may include case studies, federal policies or reports, internal analyses or any other investigation of the item/service's impact.

CMS proposes at redesignated § 422.102(f)(4)(iii) to specify that MA plans must apply its written policies based on objective criteria to determine whether an enrollee is eligible to receive a SSBCI.

CMS proposes to amend redesignated paragraph (f)(4)(iv) to require MA plans document each instance where it determines an enrollee is ineligible to receive an SSBCI.

CMS proposes to add § 422.102(f)(5) to codify CMS' authority to decline to approve a MAO's bid if CMS determines the MAO has not demonstrated through relevant and acceptable evidence that an SSBCI has reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MAO is targeting. CMS would establish a specific basis for declining a bid, and their authority to enforce compliance with other regulations, to negotiate bids, and its authority to review benefits for discrimination would not be limited by this proposal. CMS also proposes that CMS may annually evaluate the SSBCI items/services included in a bid for compliance, regardless of whether the SSBCI was approved in previous years.

CMS proposes a technical edit to § 422.102(f)(1)(i)(A)(2) to replace the second "of" in this provision with "or", to read: "[h]as a high risk of hospitalization or other adverse health outcomes[.]"

Background/Rationale

CMS has noted that the number and scope of SSCBI offered by plans have significantly increased since the 2019 HPMS memo was issued. As these benefits have become a more significant part of the MA program, CMS believes they need to update the review and approval processes to appropriately manage the growth and development of new offerings and ensure compliance with statutory requirements at 1852(a)(3)(D). CMS believes that adopting greater review and scrutiny of these benefits is also important to maintain good stewardship of Medicare dollars, including MA rebates, and ensure that the SSBCI offered the most likely to improve or maintain the health or overall function of chronically ill enrollees.

CMS' goal is to ensure that SSBCI innovation continues in a manner that is grounded, as much as possible, in research and that MAOs and CMS are aware of the most current research relevant to SSBCI

offerings. CMS also recognizes that there is relatively less clinical research related to the impact of items/services typically offered as SSCBI for individuals with chronic conditions generally, let alone specific populations. They do not want mixed research results or lack of rigorous research to reduce SSBCI innovation. Therefore, they offered a more flexible definition of "relevant and acceptable evidence" to encompass a wider range of publications.

While MAOs are currently required to have established written policies that identify the eligibility criteria to determine an enrollee's eligibility to receive an SSBCI, CMS seeks to clarify that the MA plan must apply the written policies when making SSBCI eligibility determinations.

Denials when an enrollee requests an SSBCI are subject to the rules in subpart M, including those related to denial notices. CMS believes that fully documenting denials, MAOs will be better positioned to address appeals, submissions to independent review entities, and simplify oversight for CMS, should they request this documentation.

Section 1854(a)(5)(C) of the Act details that CMS is not obligated to accept any or every bid submitted by a MAO. CMS may reject bids that propose significant increases in cost sharing or decreases in benefits offered under the plan. CMS also has authority to negotiate and reject bids under 1854 of the Act and establish minimum requirement related to SSBCI under section 1852 of the Act. However, they believe this additional provision establishes a clear connection between SSBCI and the most current evidence, to ensure sound use of Medicare funding.

Comments

CMS solicits comments on the proposed requirement that an MA organization that includes an item or service as SSBCI in its bid must, by the date on which it submits its bid to CMS, establish in writing a bibliography of all relevant acceptable evidence concerning the impact that the item or service has on the health or overall function of its recipient.

CMS also solicit comments on the definition of "relevant acceptable evidence," including the specific parameters or features of studies or other resources that would be most appropriate to include in CMS' definition.

CMS also solicit comments on the proposal that, for each citation in the written bibliography, the MA organization would be required to include a working hyperlink to or a document containing the entire source cited.

Additionally, CMS solicit comments on whether they should apply this requirement to all items or services offered as SSBCI, or whether there are certain types or categories of SSBCI for which this requirement should not apply.

CMS solicits comments on whether CMS should permit changes in SSBCI eligibility policies during the coverage year, and, if so, the limitations or flexibilities that CMS should implement that would still allow CMS to provide effective oversight over SSBCI offerings.

CMS solicits comments on the proposal to require an MA plan to document its findings that a chronically ill enrollee is ineligible, rather than eligible, for an SSBCI.

CMS solicits comment on the proposal to codify CMS's authority to decline to approve an MA organization's bid if the MA organization fails to demonstrate, through relevant acceptable evidence, that

an SSBCI included in the bid has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting.

C. Mid-Year Notice of Unused Supplemental Benefits (§§ 422.111(l) and 422.2267(e)(42)) (section IV.C, pgs 189-194)

Proposed Changes

CMS proposes that beginning January 1, 2026, MAOs must mail a mid-year notice annually, between June 30 and July 31st to each enrollee with information on each supplemental benefit available that plan year that the enrollee has not begun to use. MAOs must use as up-to-date information as possible to identify eligible enrollees, including but not limited to claims data. Supplemental benefits that have been accessed but not exhausted are excluded from this requirement.

These notices must include information about each benefit the enrollee has not accessed including an explanation of the SSCBI covered under the plan (i.e. eligibility criteria, limitations, scope of covered items/services). Plans must also list a point of contact either via the customer service line or a separate dedicated line, which trained staff who enrollees can contact to inquire or begin the SSBCI eligibility determination process and address any other questions enrollees may have about the availability of SSBCI under their plan. The notice must also include the specific SSBCI disclaimers for marketing and communications materials. Each notice must detail the scope of the supplemental benefit(s), applicable cost sharing, instructions on how to access the benefit(s), applicable information on the use of network providers for each benefit, list benefits consistent with the Evidence of Coverage (EOC), a toll-free customer service number, and as required a corresponding TTY number to call if additional help is needed.

Background/Rationale

CMS notes that MAOs are not required to provide information or outreach to enrollees to encourage the utilization of supplemental benefits, beyond more general care coordination requirements. While beneficiaries may make enrollment decisions based on supplemental benefits marketed by plans during the annual election period, they may not fully or at all utilize those benefits, leading to underutilization that may negate any potential health value offered by these benefits. CMS is also concerned that supplemental benefits are being primarily used as marketing tools, and plans are not ensuring enrollees are utilizing or benefiting from these services.

Additionally, section 1854(b)(1)(C) requires that MA plans offer the value of MA rebates back to enrollees in the form of payment for supplemental benefits, cost sharing reductions, or payment of Part B or D premiums. Consequently, CMS asserts they have an interest in ensuring that MA rebates are provided to enrollees in a way that they can benefit from the value of these rebate dollars.

CMS believes targeted communications on the utilization of supplemental benefits can ensure that covered benefits are used by enrollees during the plan year. Targeted outreach specific to the utilization of supplemental benefits may also serve to further ensure more equitable utilization of these benefits. This outreach, in conjunction with the improved collection of utilization data for these supplemental benefits

through MLR and CMS' proposed collection through Part C reporting, should help inform whether future rulemaking is warranted.

Comments

CMS requests comment on their proposal to require MA plans to provide enrollees with midyear notification of covered mandatory and optional supplemental benefits (if elected) that have not been at least partially accessed by that enrollee, particularly the appropriate timing (if any) of the notice for MA enrollees who enroll in the plan mid-year.

They also solicit comments on the required content, and timing of the notice for beneficiaries with enrollment effective data after January 1st.

One possible approach they are considering is to require the notice to be sent six months after the effective date of the enrollment for the first year of enrollment, and then for subsequent years, revert to mailing the notice between the proposed delivery dates of June 30 and July 31. Another option CMS is considering is to not require the notice to be mailed for the first year of enrollment for those beneficiaries with an effective date of May 1 or later, as they would be receiving their EOC at around this same time but will not have had significant time in which to access these benefits.

D. Annual Health Equity Analysis of Utilization Management Policies and Procedures (section IV.D, pgs 195-200)

Proposed Changes

Health Equity Representation on UM Committee

CMS proposes to add health equity-related requirements to § 422.137. First, the Agency proposes to require that beginning January 1, 2025, the Utilization Management (UM) committee must include at least one member with expertise in health equity. They are proposing that health equity expertise include educational degrees or credentials with an emphasis on health equity, experience conducting studies identifying disparities amongst different population groups, experience leading organization-wide policies, programs, or services to achieve health equity, or experience leading advocacy efforts to achieve health equity.

Health Equity Analysis of the Use of Prior Authorization

CMS also proposes to add a requirement at § 422.137(d)(6) that the UM committee must conduct an annual health equity analysis of the use of prior authorization. CMS proposes that the member of the UM committee, who has health equity expertise, must approve the final report of the analysis before it is posted on the plan's publicly available website. The proposed analysis would examine the impact of prior authorization at the plan level, on enrollees with one or more of the following social risk factors (SRF): (1) receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE); or (2) having a disability. Disability status is determined using the variable original reason for entitlement code (OREC) for Medicare using the information from the Social Security Administration and Railroad

Retirement Board record systems. CMS proposes that this analysis must be posted on the plan's publicly available website and easily accessible to the general public.

The proposed analysis must use the following metrics, calculated for enrollees with the specified SRFs, and for enrollees without the specified SRFs, from the prior contract year, to conduct the analysis:

- The percentage of standard prior authorization requests that were approved, aggregated for all items and services.
- The percentage of standard prior authorization requests that were denied, aggregated for all items and services.
- The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, aggregated for all items and services.

Background/Rationale

Health Equity Representation on UM Committee

CMS believes that reviewing and analyzing these policies from a health equity perspective is an important beneficiary protection. In addition, such an analysis may assist in ensuring that MA plan designs do not deny, limit, or condition the coverage or provision of benefits on a prohibited basis (such as a disability) and are not likely to substantially discourage enrollment by certain MA eligible individuals with the organization.

Health Equity Analysis of the Use of Prior Authorization

CMS notes that they chose these SRFs because they mirror the SRFs that will be used to measure the Heath Equity Index reward for the 2027 Star Ratings (see § 422.166(f)(3)), and they believe it is important to align expectations and metrics across the program. Moreover, CMS is requiring this analysis to take place at the MA plan level because the relevant information regarding enrollees with the specified SRFs is available at the plan level, and they believe this level of analysis is important to discern the actual impact of the use of utilization management on enrollees that may be particularly subject to health disparities.

CMS believes that by making this information more easily accessible to automated searches and data pulls, it will help third parties develop tools and researchers conduct studies that further aid the public in understanding the information and capturing it in a meaningful way across MA plans.

Comments

CMS is seeking comments the following:

- Additional populations CMS should consider including in the health equity analysis, including but not limited to: Members of racial and ethnic communities, members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency; members of rural communities; and persons otherwise adversely affected by persistent poverty or inequality.
- If there should be further definition for what constitutes "expertise in health equity," and if so, what other qualifications to include in a definition of "expertise in health equity."
- The proposed requirements for publicly posting the results on the plan's website under § 422.137(d)(7) to ensure the data will be easily accessible to both the public and researchers.
- Alternatives to the July 1, 2025, deadline for the initial analysis to be posted to the plan's publicly available website.
- Any specific items or services, or groups of items or services, subject to prior authorization that CMS should consider also disaggregating in the analysis to consider for future rulemaking. If further disaggregation of a group of items or services is requested, CMS will solicit comment on what specific items or services would be included within the group.

IV. Enrollment and Appeals

A. Revise Initial Coverage Election Period Timeframe to Coordinate with A/B Enrollment (§ 422.62) (section V.A, pgs 202-206)

Proposed Changes

CMS proposes to revise the end date for the initial coverage election period (ICEP) for those who cannot use their ICEP during their initial enrollment period (IEP). Specifically, CMS proposes that an individual would have 2 months after the month in which they are first entitled to Part A and enrolled in Part B to use their ICEP. The individual's ICEP would begin 3 months prior to the month the individual is first entitled to Part A and enrolled in Part B and would end on the last day of the second month after the month in which the individual is first entitled to Part A and enrolled in Part B.

Background/Rationale

The intent of the existing provision was to provide beneficiaries who enroll in both Part A and Part B for the first time with the opportunity to elect an MA plan at the time that both their Part A and B coverage were effective. However, in practice, individuals who do not enroll in Part B during their IEP, do not have an opportunity to elect to receive their coverage through an MA plan after their Part A and B coverage goes into effect. When an individual enrolls in both Part A and B for the first time using an SEP or the GEP, they have to determine, prior to the start of their coverage, if they want to receive their coverage through Original Medicare or an MA plan prior to the effective date of their Part A and B coverage. If they do not use their ICEP to enroll in an MA plan prior to when their Part A and B coverage becomes

effective, they lose the opportunity to enroll in an MA plan to receive their Medicare coverage and will generally have to wait until the next enrollment period that is available to them to choose an MA plan.

CMS believes that extending the timeframe for the ICEP under would provide beneficiaries that are new to Medicare additional time to decide if they want to receive their coverage through an MA plan. CMS also believes that extending this timeframe would help those new to Medicare to explore their options and select coverage that best suits their needs and reduce the number of instances where an individual inadvertently missed their ICEP and has to wait until the next open enrollment period to enroll in MA or MA-PD plan.

B. Enhance Enrollees' Right to Appeal an MA Plan's Decision to Terminate Coverage for Non-Hospital Provider Services (§ 422.626) (section V.B, pgs 207-209)

Proposed Changes

CMS proposes to modify the existing regulations regarding fast-track appeals for enrollees when they untimely request an appeal to the quality improvement organization (QIO), or still wish to appeal after they end services on or before the planned termination date. The proposed changes would bring the MA program further into alignment with Original Medicare regulations and procedures for the parallel appeals process. Specifically, CMS proposes to revise the regulation to specify that if an enrollee makes an untimely request for a fast-track appeal, the QIO will accept the request and perform the appeal. CMS would also specify that the IRE decision timeframe and the financial liability provision would not apply.

Secondly, CMS proposes removing the provision that prevents enrollees from appealing to the QIO if they end their covered services on or before the date on their termination notice, even in instances of timely requests for fast-track appeals. Removal of this provision preserves the appeal rights of MA enrollees who receive a termination notice, regardless of whether they decide to leave a provider or stop receiving their services.

Background/Rationale

MA enrollees have the right to a fast-track appeal by an Independent Review Entity (IRE) when their covered skilled nursing facility (SNF), home health, or comprehensive outpatient rehabilitation facility (CORF) services are being terminated. The Notice of Medicare Non-Coverage (NOMNC), must be furnished to the enrollee before services from the providers are terminated. Presently, if an MA enrollee misses the deadline to appeal as stated on the NOMNC, the appeal is considered untimely, and the enrollee loses their right to a fast-track appeal to the QIO. Enrollees may, instead, request an expedited reconsideration by their MA plan. The QIO is unable to accept untimely requests from MA enrollees but does perform appeals for untimely requests from Medicare beneficiaries in Original Medicare as described at § 405.1202(b)(4). This proposed expedited coverage appeals process would afford enrollees in MA plans access to similar procedures for fast-track appeals as for beneficiaries in Original Medicare in the parallel process. Untimely enrollee fast-track appeals would be absorbed into the existing process for timely appeals and thus, would not necessitate additional changes to the existing fast-track process.

C. Amendments to Part C and Part D Reporting Requirements (§§ 422.516 and 423.514) (section V.C, pgs 209-212)

Proposed Changes

CMS proposes revisions to update section 422.516 which currently reads, "Each MA organization must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information." CMS proposes to strike the term "statistics," as well as the words "and other," with the understanding that the broader term "information" includes statistics, Part C data, and information on plan administration. In a conforming proposal CMS proposes to strike the term "statistics" and add "information." CMS does not interpret these regulations to limit data collection to statistical or aggregated data and CMS is using this rulemaking as an opportunity to ensure that CMS is clear and consistent with its interpretation of these rules.

Additionally, CMS proposes to make an affirmative change regarding CMS's collection of information related to what occurs from beginning to end when beneficiaries seek to get coverage from their health and drug plans for specific services. In other words, under the existing requirements CMS has the ability to collect information related to all plan activities regarding adjudicating requests for coverage and plan procedures related to making service utilization decisions, and CMS aims to make this more transparent through this proposal.

Lastly, current regulation requires plans to report "The patterns of utilization of services." CMS proposes to amend said language to read, "The procedures related to and utilization of its services and items" to be clear that these regulations authorize reporting and data collection about MA and Part D plan procedures related to coverage, utilization in the aggregate, and beneficiary-level utilization, including the steps beneficiaries may need to take to access covered benefits.

Background/Rationale

CMS is not proposing to change specific current data collection efforts through this rulemaking, instead the proposed revisions simply ensure clarity and consistency with existing rules. Any future information collection would be addressed through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) process, which would provide advance notice to interested parties and provides both a 60- and 30-day public comment period on drafts of the proposed collection. CMS does not believe the proposed changes have either paperwork burden or impact on the Medicare Trust Fund at this time. These proposed changes allow CMS, in the future, to add new burden to plans in collection efforts; however, any such new burden associated with a new data collection would be estimated through the PRA process.

D. Amending Amendments to Establish Consistency in Part C and Part D Timeframes for Filing an Appeal Based on Receipt of the Written Decision (§§ 422.582, 422.584, 422.633, 423.582, 423.584, and 423.600) (section V.D, pgs 213-217)

Proposed Changes

Based on general feedback CMS has received from interested parties regarding a variance in the regulatory timeframe for beneficiaries to file an appeal with an MA organization or Part D plan sponsor, CMS proposes regulatory amendments with respect to how long an enrollee has to file an appeal with a plan or the Part D Independent Review Entity (IRE).

CMS proposes to revise the regulations to state that a request for a Part C reconsideration, Part D redetermination, Part D at-risk redeterminations and Part D IRE reconsiderations must be filed within 60 calendar days after receipt of the written determination notice. The proposal also includes adding new regulations that would provide that the date of receipt of the organization determination, integrated organization determination, coverage determination, or at-risk determination is presumed to be 5 calendar days after the date of the written organization determination, integrated organization determination, coverage determination or at-risk determination, unless there is evidence to the contrary.

In addition to the aforementioned proposals related to when an organization determination, integrated organization determination, coverage determination, or at-risk determination is presumed to be received by an enrollee of other appropriate party, CMS also proposes to add language that specifies when an appeal is considered filed with a plan and the Part D IRE. Specifically, CMS proposes to add new language to provide that for purposes of meeting the 60 calendar day filing deadline, the appeal request is considered filed on the date it is received by the plan, plan-delegated entity or Part D IRE specified in the written organization determination, integrated organization determination, coverage determination, at-risk determination, or redetermination.

CMS also proposes clarifications to explicitly state the timeframe in which an enrollee must file an expedited plan appeal for it to be timely. The current text does not include the 60-calendar day timeframe for filing an expedited appeal request, but CMS manual guidance for Part C and Part D appeals has long reflected this 60-calendar day timeframe. In proposing new language, CMS also proposes to add the procedure and timeframe for filing expedited organization determinations and coverage determinations.

Background/Rationale

If finalized, CMS believe these proposals would enhance consistency in the administrative appeals process and provide greater clarity on the timeframe for requesting an appeal and when an appeal request is considered received by the plan. Theoretically, the proposed amendments may result in a small increase in the number of appeals from allowing 65 versus 60 days to appeal an organization determination, integrated organization determination, coverage determination or at-risk determination. However, CMS believes, based on the low level of dismissals at the plan level due to untimely filing, that most enrollees who wish to appeal a denial do so immediately, thereby mitigating the impact of 5 additional days for a plan to accept an appeal request if this proposal is finalized. Consequently, CMS is not associating impact to the Medicare Trust Fund.

Comments

CMS solicits comments from stakeholders on the accuracy of the assumption above.

E. Defining Authorized Representatives for Parts C/D Elections (§§ 422.60 and 423.32) (section V.E, pgs 218-221)

Proposed Changes

CMS proposes to codify longstanding guidance on authorized representatives making Parts C and D elections on behalf of beneficiaries. Current regulation acknowledges that an "authorized representative" may assist a beneficiary in completing an enrollment form, but it does not define who an "authorized representative" is. A similar term, "representative," is currently defined; however, that definition is used only in the appeals context and applies only to subpart M of the MA and Part D regulations. Therefore, CMS is defining the term "authorized representative" for subpart B (eligibility, election, and enrollment).

For those with State legal authority to act and make health care decisions on behalf of a beneficiary, the proposal would codify that authorized representatives will constitute the "beneficiary" or the "enrollee" for the purposes of making an election, meaning that CMS, MA organizations, and Part D sponsors will consider the authorized representative to be the beneficiary/enrollee during the election process. Any mention of beneficiary/enrollee in the enrollment and eligibility regulations would be considered to also include "authorized representative," where applicable. The proposal clarifies that authorized representatives under State law may include court-appointed legal guardians, durable powers of attorney for health care decisions and State surrogate consent laws as examples of those State law concepts that allow the authorized representative to make health care decisions on behalf of the individual.

Background/Rationale

Codifying this longstanding guidance provides plans, beneficiaries and their caregivers, and other interested parties clarity and transparency on the requirements when those purporting to be the representatives of the beneficiary attempt to make election decisions on their behalf. CMS proposes to codify this longstanding guidance in order to clarify policy regarding the role of authorized representatives in the MA and Part D enrollment process, including the applicability of State law in this context. This proposal represents the codification of longstanding MA and Part D sub-regulatory guidance.

Based on questions from plans and beneficiaries related to current guidance, CMS concludes that the guidance has been previously implemented and is currently being followed by plans. Therefore, there is no additional paperwork burden associated with codifying this longstanding sub-regulatory policy, and there is also no impact to the Medicare Trust Fund. All information impacts related to the current process for determining a beneficiary's eligibility for an election period and processing election requests have already been accounted for.

F. Definition Open Enrollment Period for Institutionalized Individuals (OEPI) End Date (§ 422.62(a)(4)) (section V.F, pgs 222-223)

Proposed Changes

To provide transparency and stability for plans, beneficiaries and their caregivers, and other interested parties about this aspect of MA enrollment, CMS proposes to codify current sub-regulatory guidance that defines when the OEPI ends. Specifically, CMS proposes to codify that the OEPI ends on the last day of the second month after the month the individual ceases to reside in one of the long-term care facility settings described in the definition of "institutionalized".

Background/Rationale

CMS published a final rule with comment period in June 2000 establishing a new continuous open enrollment period for institutionalized individuals (OEPI). This proposal would define when the OEPI ends and would not result in a new or additional paperwork burden since MA organizations are currently implementing the policy related to the OEPI end date as part of existing enrollment processes. All burden impacts related to an applicant's eligibility for an election period have already been accounted for. Similarly, CMS does not believe the proposed changes would have any impact to the Medicare Trust Fund.

G. Beneficiary Choice of C/D Effective Date if Eligible for More Than One Election Period (§§ 422.68 and 423.40) (section V.G, pgs 224-227)

Proposed Changes

To provide transparency and stability about the MA and Part D program for plans, beneficiaries, and other interested parties, CMs proposes that if the MA organization or Part D plan sponsor receives an enrollment or disenrollment request, determines the beneficiary is eligible for more than one election period and the election periods allow for more than one effective date, the MA organization or Part D plan sponsor must allow the beneficiary to choose the election period that results in the desired effective date. CMS also proposes that the MA organization or Part D plan sponsor must attempt to contact the beneficiary, and must document its attempt(s), to determine the beneficiary's choice.

In addition, CMS proposes to require that the MA organization or Part D plan sponsor must use the proposed ranking of election periods to assign an election period if the beneficiary does not make a choice. With the exception of the SEP EGHP noted earlier, if a beneficiary is simultaneously eligible for more than one SEP and they do not make a choice, and the MA organization or PDP sponsor is unable to obtain the beneficiary's desired enrollment effective date, the MA organization or PDP sponsor should assign the SEP that results in an effective date of the first of the month after the enrollment request is received by the plan. Finally, CMS proposes to require that if the MA organization or Part D plan sponsor is unable to obtain the beneficiary's desired disenrollment effective date, they must assign an election period that results in the earliest disenrollment.

Background/Rationale

Existing regulations do not address what the MA organization or Part D plan sponsor should do when a beneficiary is eligible for more than one election period, thus resulting in more than one possible effective date for their election choice. Because a beneficiary must be entitled to Medicare Part A and enrolled in Medicare Part B in order to be eligible to receive coverage under a MA or MA-PD plan, CMS's sub-regulatory guidance explains that if one of the election periods for which the beneficiary is eligible is the ICEP, the beneficiary may not choose an effective date any earlier than the month of entitlement to Part A and enrollment in Part B. Furthermore, sub-regulatory guidance provides that if a beneficiary is eligible for more than one election period and does not choose which election period to use, and the MA organization or Part D plan sponsor is unable to contact the beneficiary, the MA organization or Part D plan sponsor assigns an election period for the beneficiary using the following ranking of election periods (1 = Highest, 5 = Lowest): (1) ICEP/Part D IEP, (2) MA-OEP, (3) SEP, (4) AEP, and (5) OEPI. The election period with the highest rank generally determines the effective date of enrollment.

This new proposal represents the codification of longstanding MA and Part D sub-regulatory guidance. Based on infrequent complaints and questions from plans and beneficiaries related to current guidance, CMS concludes that the guidance has been previously implemented and is currently being followed by plans. There is no additional paperwork burden associated with codifying this longstanding sub-regulatory policy, and there is also no impact to the Medicare Trust Fund.

V. Medicare Advantage/Part C and Part D Prescription Drug Plan Marketing and Communications

A. Involuntary Marketing and Communications Requirements for Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.2267) (section VI.A, pgs 228-235)

Proposed Changes

CMS proposes to expand the current required SSBCI disclaimer to include more specific requirements, with the intention of increasing transparency for beneficiaries and decreasing misleading advertising by MA organizations. This expansion would clarify what must occur for an enrollee to be eligible for the SSBCI; per § 422.102(f), the enrollee must first have the required chronic condition(s), then they must meet the definition of a "chronically ill enrollee" at § 422.102(f)(1)(i)(A), and finally the MA organization must determine that the enrollee is eligible to receive a particular SSBCI under the plan's coverage criteria. Notably, this proposal aims to amend the required SSBCI disclaimer content to clearly communicate the eligibility parameters to beneficiaries without misleading them.

Specifically, CMS proposes to redesignate current paragraph (e)(34)(ii) as paragraph (e)(34)(iii) and add a new paragraph (e)(34)(ii), in which they propose to require MA organizations offering SSBCI to list, in their SSBCI disclaimer, the chronic condition or conditions the enrollee must have to be eligible for the SSBCI offered by the MA organization. A "chronically ill enrollee" must have one or more comorbid and medically complex chronic conditions to be eligible for SSBCI; CMS proposes that if the number of condition(s) is five or fewer, than the SSBCI disclaimer must list all condition(s), and if the number of

conditions if more than five, than the SSBCI disclaimer must list the top five conditions, as determined by the MA organization.

CMS proposes to expand the provision that states MA organizations that offer SSBCI must convey that not all members will qualify to require MA organizations to convey in its SSBCI disclaimer that even if the enrollee has a listed chronic condition, the enrollee may not be eligible to receive the relevant SSBCI, as other criteria need to be met.

CMS proposes specific formatting requirements for MA organizations' SSBCI disclaimers in ads, related to font and reading pace. For print ads, they reiterate existing requirements and for television, online, social media, outdoor, radio, or other voice-based ads, CMS proposes that MA organizations either read the disclaimer at the same pace as the organization does for the phone number or other contact information mentioned in the ad or display the disclaimer in the same font size as the phone number or other contact information mentioned in the ad.

Background/Rationale

This proposal would expand upon the current SSBCI disclaimer requirements at § 422.2267(e)(34) in several ways. Requiring a more robust disclaimer with specific conditions listed would provide beneficiaries with more information to determine whether a particular plan with SSBCI is appropriate for their needs. CMS believes the revised disclaimer would diminish the ambiguity of when SSBCI are covered and reduce the potential for misleading information or advertising. This aligns with their goal to ensure beneficiaries enrolling in MA choose a plan that best meets their needs.

Pertaining to the eligibility of a "chronically ill enrollee" CMS believes five is a reasonable number of comorbid or medically complex chronic conditions for the MA organization to list, so that a beneficiary may have an idea of the types of conditions that may be consideration for eligibility for SSBCI, without listing so many conditions that a beneficiary ignores the information.

Pertaining to the proposal to require MA organizations to communicate that not all members will qualify for SSBCI, CMS highlights that the SSBCI disclaimer is model content so each MA organization may tailor the language as they see fit. While CMS does not propose to specify the order of content for the SSBCI disclaimer, they ensure that the disclaimer must be clear, accurate, and comply with all applicable rules on marketing, communications, and the standards for required materials and content at § 422.2267(a).

Comments

CMS welcomes comment on their proposed amendments to § 422.2267(e)(34).

B. Agent Broker Compensation (section VI.B, pgs 236-252)

1. Limitation on Contract Terms

Proposed Changes

CMS proposes to add at § 422.2274(c)(13) that, beginning in contract year 2025, MA organizations must ensure that no provision of a contract with an agent, broker, or TPMO has the direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent's or broker's ability to objectively assess and recommend which plan best meets the health care needs of a beneficiary.

Background/Rationale

CMS has received numerous complaints from a variety of stakeholders that agents and brokers are being paid, typically through various purported administrative and other add-on payments, amounts that cumulatively exceed the maximum compensation allowed under the current regulations, and these payments amount to questionable financial incentives that influences which MA plan(s) agents encourage beneficiaries to select. CMS believes this proposal gives plans further direction as to the types of incentives and outcomes that must be avoided without being overly prescriptive as to how the plans should structure these arrangements.

Comments

CMS seeks comment on this proposal and on how CMS can further ensure that payments made by MA plans to FMOs do not undercut the intended outcome of these agent and broker compensation proposals.

2. Compensation Rates

Proposed Changes

CMS proposes to amend their regulations to require that all payments to agents or brokers that are tied to enrollment, related to an enrollment in an MA plan or product, or are for services conducted as part of the relationship associated with the enrollment into an MA plan or product must be included under compensation, as defined at § 422.2274(a). CMS also proposes to make confirming amendment to the regulations at § 422.2274(e)(2) to clarify that all administrative payments are included in the calculation of enrollment-based compensation.

CMS proposes to change the caps on compensation payments that are currently provided in § 422.2274 to set rates that would be paid by all plans across the board.

Background/Rationale

CMS believes this proposal would level the playing field for all plans represented by an agent or broker and promote competition. Further, by explicitly saying that compensation extends to additional activities as a part of the relationship between the agent and the beneficiary, CMS aim to reinforce their understanding that the initial and renewal compensation amounts are based on the fact that additional work may be done by an agent or broker throughout the plan year, including fielding follow-up questions from the beneficiary.

MA organizations are currently required to report to CMS on an annual basis the specific rates and range of rates they will be payment independent agents and brokers. CMS proposes to remove the reporting requirements as all agents and brokers would be paid the same compensation rate in a given year under their proposal.

Comments

CMS seeks comment on this proposal.

3. Administrative Payments

Proposed Changes

CMS proposes that all payments to an agent or broker relating to the initial enrollment, renewal, or services related to a plan product would be included in the definition of compensation. To remain consistent, they propose to remove the separate regulatory authority regarding "administrative payments" currently at § 422.2274(e)(1), and to amend § 422.2274(e)(2) to clarify that the portion of an agent's compensation for an enrollment may be calculated and updated independently.

CMS proposes to add, beginning in 2025, that Fair Market Value (FMV) will be increased by $31 to account for administrative payments included under the compensation rate, and to be updated annually in compliance with the requirements for FMV updates.

Background/Rationale

CMS believes removing the separate regulatory authority regarding "administrative payments" is necessary to ensure that MA organizations cannot utilize the existing regulatory framework allowing for separate payment for administrative services to effectively circumvent the FMV caps on agent and broker compensation. They use the example of instances in which an agent or broker enrolls a beneficiary into a plan, asks the enrollee to complete a health risk assessment (HRA), and then is compensated at a rate inconsistent with market value. They highlight a CDC study that recommends HRAs be tied closely with clinician practice and that agents and brokers lack the necessary health care knowledge to link HRAs in the recommended way. Thus, CMS believes HRAs completed by agents and brokers do not have the same value as those performed and interpreted by health care providers.

By eliminating separate payment for administrative services, CMS expects this proposal would eliminate a significant method which some plans have used to circumvent the regulatory limits on enrollment compensation. They believe that ensuring a fixed payment rate for agents will result in compensation greater than what is currently provided through typical contractual arrangements with FMOs. CMS recognizes that their proposal would leave agents and brokers unable to directly recoup administrative costs, however, given the high volume of enrollees that use an agent or broker for enrollment services, they do not believe there would be a large risk of agents or brokers failing to cross that initial threshold to recoup their administrative costs.

CMS believes it is necessary to increase the rate for compensation by $31, based on the estimated costs for training, testing, and call recording that would need to be covered by this single enrollment-based payment. They note that they are not proposing a proportionate increase to compensation for renewals and they considered this in determining the amount by which they are proposing to increase the rate for compensation for enrollments.

Comments

CMS seeks comment on their proposal to include all payments to an agent or broker relating to the initial enrollment, renewal, or services related to a plan product in the definition of compensation.

CMS seeks comment on their proposal to increase the rate for compensation to account for necessary administrative costs that would be incorporated into this rate under their previous proposal. Specifically, CMS requests comment on the administrative costs that should be considered, and how else they might determine their value, as we consider the future of the compensation structure.

4. Agent Broker Compensation for Part D Plans

Proposed Changes

CMS proposes to apply each of the proposals described above to the sale of PDP plans by agents and brokers, as codified at § 423.2274.

Background/Rationale

Because the same agents and brokers are often licensed to sell both MA plans and PDPs, CMS believes it's necessary under their statutory authority to apply the same compensation rules to the same of both MA plans and PDPs in order to ensure that both plan types are being held to the same standards and are on a "level playing field" when it comes to incentives faced by agents and brokers. CMS also believes it is necessary to extend the regulations to the sale of PDPs to avoid shifting the incentives they discussed in the previous sections.

Comments

CMS seeks comment on this proposal, and specifically whether and to what extend modifications to these proposals should be made to account for differences between MA and Part D plan types.

VI. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System

A. Adding, Updating, and Removing Measures (§§ 422.164 and 423.184) (section VII.B, pgs 255-260)

Proposed Changes

CMS proposes changes to the Comprehensive Medication Review (CMR) completion rate measure, effective the 2027 measurement year. This change will modify cost, medication, and disease thresholds for eligibility for the Medication Therapy Management (MTM) services as outlined in December 2022 proposed rule. Specifically, these include – targeting more chronic diseases, including HIV/AIDS,

lowering the number of maximum chronic medications for MTM eligibility from 8 to 5, and revising the method for calculating cost-threshold, effectively reducing it.

Background/Rationale

The MTM eligibility requirement changes proposed in December 2022 proposed rule were not subsequently finalized. In April 2023 final rule, CMS noted that because the denominator would change considerably, this change would be considered a substantial change, and must be part of the display measures for two years. In the December 2022 rule, CMS had justified proposing modifications to the eligibility by stating its intention to make the MTM program more accessible to a greater proportion of beneficiaries.

B. Data Integrity (§§ 422.164(g) and 423.184(g)) (section VII.C, pgs 260-265)

Proposed Changes

References to Data Completeness

CMS proposes to revise the introductory language in § 422.164(g)(1)(iii) to remove references to the timeliness monitoring study and audits and replace them with references to data from MA organizations, the Independent Review Entity (IRE), or CMS administrative sources. They are also proposing to modify § 422.164(g)(1)(iii)(A) to use data from MA organizations, the IRE, or CMS administrative sources to determine the completeness of the data at the IRE for the Part C appeals measures starting with the 2025 measurement year and 2027 Star Ratings.

Appeals to the IRE

CMS proposes to compare the total number of appeals received by the IRE, including all appeals regardless of their disposition (for example, including appeals that are dismissed for reasons other than the plan's agreement to cover the disputed services and withdrawn appeals), to the total number of appeals that were supposed to go to the IRE.

CMS also proposes to modify the calculation of the error rate at § 422.164(g)(1)(iii)(H) by taking 1 minus the quotient of the total number of cases received by the IRE and the total number of cases that were supposed to be sent to the IRE (Equation 1). The total number of appeals that were supposed to be sent to the IRE in Equation 2 would be calculated from the data described in the proposed revisions to § 422.164(g)(1)(iii)(A):

Equation (1)

$$\text{Part C Calculated Error Rate} = 1 - \frac{\text{Total number of cases received by the IRE}}{\text{Total number of cases that should have been forwarded to the IRE}}$$

Equation (2)

$$\begin{aligned}\text{Total Number of Cases that should have been forwarded to the IRE} \\ = \text{Number of partially favorable reconsiderations} \\ + \text{Number of unfavorable reconsiderations}\end{aligned}$$

CMS proposes to remove and reserve § 422.164(g)(1)(iii)(J) because they intend to calculate the Part C error rate based on 12 months rather than a projected number of cases not forwarded to the IRE in a 3-

month period as has historically been done with the TMP data. CMS also proposes to modify § 422.164(g)(1)(iii)(K)(2) so that the number of cases not forwarded to the IRE is at least 10 for the measurement year (that is, total number of cases that should have been forwarded to the IRE minus the total number of cases received by the IRE is at least 10 for the measurement year).

CMS also proposes at § 422.164(g)(1)(iii)(O) that the two Part C appeals measure Star Ratings be reduced to 1 star if CMS does not have accurate, complete, and unbiased data to validate the completeness of the Part C appeals measures. CMS proposes to update § 422.164(g)(1)(iii)(A)(2) to change the data source in the case of contract consolidations so that the data described in paragraph (g)(1)(iii)(A)(1) are combined for consumed and surviving contracts for the first year after consolidation.

Background/Rationale

References to Data Completeness

Currently, data collected through § 422.516(a) could be used to confirm the completeness of the IRE data; however, data collected from MA organizations through other mechanisms in addition to data from the IRE or CMS administrative sources could be used in the future. The proposed amendment to § 422.164(g)(1)(iii)(A) is intended to limit the data CMS uses to conduct analyses of the completeness of the IRE data in order to adapt to changing information submissions that could be reliably used for the same purpose in the future.

Appeals to the IRE

CMS collects information at the contract level from MA organizations about the number of partially favorable reconsiderations (that is, the number of partially favorable claims and the number of partially favorable service requests by enrollees/representatives and non-contract providers) and unfavorable reconsiderations (that is, the number of partially favorable claims and the number of partially favorable service requests by enrollees/representatives and non-contract providers) over a calendar year.

These data are subject to data validation requirements, in accordance with specifications developed by CMS, under § 422.516(g), to confirm that they are reliable, valid, complete, and comparable. CMS would use this information to determine the total number of cases that should have been sent to the IRE over the measurement year (that is, number of partially favorable reconsiderations + number of unfavorable reconsiderations) to compare to information from the IRE about submissions received from each MA organization.

CMS notes that the requirement for a minimum number of cases is needed to address statistical concerns with precision and small numbers.

Comments

CMS welcomes feedback on all the provisions noted in this section.

C. Review of Sponsor's Data (§§ 422.164(h) and 423.184(h)) (section VII.D, pgs 265-267)

Proposed Changes

CMS proposes that sponsors' requests for CMS review of administrative data must be received no later than the annual deadline set by CMS. Beginning with the 2025 measurement year (2027 Star Ratings), CMS proposes at §§ 422.164(h)(3) and 423.184(h)(3) that any requests by an MA organization or Part D sponsor to review its administrative data for Patient Safety measures be made by the annual deadline set by CMS for the applicable Star Ratings year.

Background/Rationale

CMS stated that they expect sponsors to review their monthly Patient Safety reports that include measure rates along with available underlying administrative data and alert CMS of potential errors or anomalies in the rate calculations per the measure specifications in advance of CMS's plan preview periods to allow sufficient time to investigate and resolve them before the release of the Star Ratings.

CMS notes that reviewing administrative data for the Patient Safety measures is a time-consuming process. In addition, once CMS implements sociodemographic status (SDS) risk adjustment for the three Medication Adherence measures, the final measure rates, which are calculated in July after the end of the measurement period, will require increased processing time to calculate. This proposal will allow enough time for CMS to review a sponsor's administrative data and ensure the accuracy of the final calculated Patient Safety measure rates.

Comments

CMS requests comments on this proposal.

D. Categorical Adjustment Index (§§ 422.166(f)(2) and 423.186(f)(2)) (section VII.E, pgs 267-268)

Proposed Changes

CMS proposes to calculate the percentage LIS/DE enrollees and percentage disabled enrollees used to determine the Categorical Adjustment Index (CAI) adjustment factor in the case of contract consolidations based on the combined contract enrollment from all contracts in the consolidation beginning with the 2027 Star Ratings. CMS proposes to modify §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B) to calculate the percentage LIS/DE enrollees and the percentage disabled enrollees for the surviving contract for the first two years following a consolidation by combining the enrollment data for the month of December for the measurement period of the Star Ratings year across all contracts in the consolidation.

Background/Rationale

CMS notes this proposal is to reflect the membership of the surviving contract more accurately after the consolidation and to determine the percentage LIS/DE enrollees and percentage disabled enrollees for the surviving contract. CMS also highlights that they are proposing this change since §§ 422.166(b)(3) and 423.186(b)(3) do not address the calculation of enrollment for the CAI in the event of a contract consolidation; rather, they focus on the calculation of measure scores in the case of consolidations.

Comments

CMS requests comments on this proposal.

E. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3)) (section VII.F, pgs 268-269)

Proposed Changes

For the first year following a consolidation, CMS proposes to add new paragraphs §§ 422.166(f)(3)(viii)(A) and 423.186(f)(3)(viii)(A) to assign the surviving contract of a consolidation the enrollment-weighted mean of the HEI reward of the consumed and surviving contracts using enrollment from July of the most recent measurement year used in calculating the HEI reward.

CMS proposes that contracts that do not meet the minimum percentage of enrollees with the specified SRF thresholds or the minimum performance threshold described at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) would have a reward value of zero used in calculating the enrollment-weighted mean reward. For the second year following a consolidation, CMS proposes at new paragraphs §§ 422.166(f)(3)(viii)(B) and 423.186(f)(3)(viii)(B) that, when calculating the HEI score for the surviving contract, the patient-level data used in calculating the HEI score would be combined across the contracts in the consolidation prior to calculating the HEI score. The HEI score for the surviving contract would then be used to calculate the HEI reward for the surviving contract following the methodology described in §§ 422.166(f)(3)(viii) and 423.186(f)(3)(viii).

Background/Rationale

CMS notes that in calculating the HEI reward for the surviving contract of a consolidation, they want to avoid masking the scores of contracts with low performance among enrollees with the specified SRFs under higher performing contracts. CMS also wants to avoid masking contracts that serve relatively few enrollees with the specified SRFs under contracts that serve relatively many more of these enrollees.

Comments

CMS requests comments on this proposal.

F. Quality Bonus Payment Rules (QBPs) (§ 422.260) (section VII.G, pgs 269-270)

Proposed Changes

CMS proposes to revise the language at § 422.260(c)(2)(vii) to provide the CMS Administrator the opportunity to review and modify the hearing officer's decision within 10 business days of its issuance. CMS proposes that if the Administrator does not review and issue a decision within 10 business days, the hearing officer's decision is final and binding. Under this proposal, if the Administrator does review and modify the hearing officer's decision, a new decision will be issued as directed by the Administrator.

Background/Rationale

CMS notes that sections 1853(n) and 1853(o) of the Act require CMS to make QBPs to MA organizations that achieve at least 4 stars in a 5-star quality rating system. In addition, section 1854(b)(1)(C) of the Act ties the share of savings that MA organizations must provide to enrollees as the beneficiary rebate to the level of an MA organization's QBP rating.

Comments

CMS requests comment on this proposal.

VII. Improvements for Special Needs Plans

A. Verification of Eligibility for C-SNPs (§ 422.52(f)) (section VIII.A, pgs 271-276)

Proposed Changes

CMS proposes to codify existing guidance that the MA organization must contact the individual applicant's current physician to confirm that the chronic condition special needs program (C-SNP) enrollee has the specific severe or disabling chronic condition(s), as specified in § 422.52(f)(1). CMS also proposes that the physician must be the enrollee's existing provider, either a primary care physician or specialist treating their chronic condition(s) as outlined in § 422.52(f)(1)(i).

CMS proposes two new options for MA organizations to verify enrollees' conditions by either contacting the applicant's physician or office before enrollment or using a Pre-enrollment Qualification Assessment Tool (PQAT) prior to enrollment and subsequently obtain their physician's verification within the individual's first month of enrollment in the C-SNP. CMS is also proposing at new § 422.52(f)(1)(i) to require that the physician's verification must be in a form and manner authorized by CMS, such as a note or documented phone call with the physician or their office.

CMS proposes at § 422.52(f)(1)(ii)(A) that the PQAT must meet specific standards and consequently CMS is not required to review and approve plan-specific tools. Under this proposal PQATs must include a set of clinically appropriate questions relevant to the C-SNP's focus condition(s); gather information on applicant's medical history, current signs/symptoms, and current medications; include the date and time of in-person assessments or receipt date of mail/electronic assessments (if available); and a signature line for the physician to confirm the individual's eligibility.

CMS proposes at § 422.52(f)(1)(ii)(B) to require C-SNPs to conduct a post-enrollment confirmation of enrollee's information and eligibility via medical information (e.g. medical history, current signs/symptoms, diagnostic testing, and current medications) provided by their current PCP or specialist treating their chronic condition. At § 422.52(f)(1)(ii)(C), CMS is proposing to require the C-SNP to include the information gathered in the PQAT and from the verification process in enrollee records subject to the § 422.118 confidentiality requirements.

CMS also proposes to require C-SNPs to track the total number of enrollees and the number and percent of enrollees whose post-enrollment verification matches the pre-enrollment assessment. These data and supporting documentation must be made available to CMS upon request.

CMS proposes to codify their existing guidance for MA organizations offering C-SNPs at § 422.52(f)(1)(ii)(E) that C-SNP must continue enrollment if confirmation of the qualifying condition(s) is obtained before the end of the prior to the disenrollment date, as outlined at § 422.52(f)(1)(ii)(F). Furthermore, CMS proposes to codify at § 422.52(f)(1)(iii) that the C-SNP is required to have the individual's current physician (primary care physician or specialist treating the qualifying condition) administer the PQAT directly with the enrollee or provide confirmation (with or without the presence of the enrollee) that the information in the document supports a determination that the individual is eligible for the C-SNP.

Background/Rationale

CMS does not expect this proposal to result in new or additional paperwork burden, as the policy to verify eligibility for C-SNPs has been in existence for some time. CMS intends for these proposed changes to provide transparency and stability for MA organizations offering C-SNPs and other interested parties about this aspect of the MA program. They also hope to clarify the SNP's roles and responsibilities and further assist MA organizations in meeting the requirements pertaining to verification of eligibility for C-SNPs.

CMS believes that by requiring a physician—either the applicant's primary care physician or a specialist treating the qualifying condition(s)—to provide the required verification of the applicant's condition, the accuracy and integrity of the verification process will be strengthened. By clarifying the verification process, CMS hopes that these procedures will allow the MA organization to efficiently serve special needs populations while maintaining the integrity of SNP offerings under the MA program. They specifically hope that pre-enrollment verification with the applicant's primary care physician or specialist treating the qualifying condition will allow C-SNP to process the enrollment promptly.

All burden impacts related to the SNP eligibility verification procedures have already been accounted for under OMB control number 0938–0753 (CMS-R267). These requirements have been previously implemented and are currently being followed by MA organizations. There is also no expected impact to the Medicare Trust Fund.

B. I-SNP Network Adequacy (section VIII.B, pgs 277-285)

Proposed Changes

CMS proposes to adopt a new exception for facility-based institutional special needs plans (I-SNP) from the network evaluation requirements. Currently, § 422.116(f) allows an MA plan to request an exception to network adequacy criteria when both of the following occur: 1) certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file and 2) the MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria. CMS proposes to broaden the acceptable rationales for an exception from the requirements in § 422.116(b)-(e) for facility-based I-SNPs by allowing requests for an exception when only one of the two situations described above occurs. The text will be reorganized accordingly with the original two requirements being moved to new paragraphs (f)(1)(i)(A) and (B) and the proposed rationales for an exception being added to new paragraphs (f)(1)(ii)(A) and (B).

CMS additionally proposes new considerations for determining whether to grant an exception under § 422.116(f). The first proposed new basis for an exception request is that a facility-based I-SNP is unable to contract with certain specialty types required under § 422.116(b) because of the way enrollees in facility-based I-SNPs receive care, and can submit relevant evidence. The second proposed basis is if a facility-based I-SNP provides sufficient and adequate access to basic benefits through additional telehealth benefits, and can submit relevant evidence.

CMS is proposing a new paragraph (f)(3) at § 422.116 to ensure that the exception for facility-based I-SNPs is used by and available only to facility-based I-SNPs. CMS also proposes to add, at § 422.504(a)(21), a new contract provision that MA organizations must not establish additional plans that are not facility-based I-SNPs to a contract that is within the scope of proposed § 422.116(f)(3).

Background/Rationale

The I-SNP industry has indicated through public comments and in prior correspondence to CMS that many facility-based I-SNPs have difficulty contracting with providers outside their facilities due to their model of care. This is rooted in the fact that providers know that I-SNP enrollees will not routinely seek care. Those in the business of offering facility-based ISNPs have concerns about whether CMS network standards are appropriate for the facility-based I-SNP coverage model, as it differs from other MA plan types. CMS has also received public comments regarding the challenges facility-based I-SNP plans have contracting.

CMS believes that the time and distance standards that apply to other plan types are not appropriate for I-SNP plans because enrollees in facility-based I-SNP plans do not generally travel to receive care. CMS hopes that this proposal appropriately balances the need to ensure access to covered benefits for enrollees in facility-based I-SNPs while recognizing the unique way this type of MA plan furnishes benefits and how enrollees generally receive services at the institution where the enrollee resides. CMS emphasizes that expanding this proposed exception to other I-SNPs or MA plans that do not meet the requirements of this proposal would not serve the best interests of the Medicare program or beneficiaries.

Comments

CMS seeks comments on all aspects of this proposal. They specifically solicit comments on the proposed new rationale for an exception from the network adequacy requirements in § 422.116(b) through (e) and on the type of evidence they should consider in determining whether to grant an exception. CMS also requests comment on the aspect of the proposal that ensures that the exception for facility-based I-SNPs is used by and available only to facility-based I-SNPs and whether additional guardrails are necessary.

C. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services from the Same Organization (§§ 422.503, 422.504, 422.514, 422.530, and 423.38) (section VIII.C, pgs 286-310)

1. Changes to the Special Enrollment Periods for Dually Eligible Individuals and Other LIS Eligible Individuals

Proposed Changes

CMS proposes to amend § 423.38(c)(4)(i) to replace the quarterly dual SEP with a simpler new dual/LIS SEP. The proposed dual/Low Income Subsidy (LIS) SEP would allow dually eligible and other LIS-enrolled individuals to enroll once per month into any standalone prescription drug plan. CMS also proposes to create a new integrated care SEP at § 423.38(c)(35) for dually eligible individuals. This new integrated care SEP would allow enrollment in any month into FIDE SNPs, HIDE SNPs, and AIPs for those dually eligible individuals who meet the qualifications for such plans.

In combination, these two SEP proposals would enable dually eligible beneficiaries to have a monthly election to:

- Leave an MAPD plan for Medicare FFS by enrolling in a PDP
- Switch between standalone PDPs
- Enroll in an integrated D-SNP such as a FIDE, HIDE, or AIP.

Background/Rationale

CMS notes its policies proposed in this section drive toward a longer-term vision of increasing aligned enrollment until it is the normative managed care enrollment scenario for dually eligible beneficiaries. Consequently, CMS is focused on increasing enrollment in integrated D-SNPs, including fully integrated dual eligible special needs plans (FIDE SNPs), highly integrated dual eligible special needs plans (HIDE SNPs), and applicable integrated plans (AIPs).

Currently, there is a quarterly SEP in place that enable dually eligible beneficiaries to change plans. However, CMS notes several concerns with the current SEP, including the opportunity for misleading marketing, the limited ability to enroll in integrated D-SNPs, and the complexity for states, enrollment counselors, and individuals.

CMS believes the proposed SEP changes will:

- Create more opportunity for dually eligible or LIS individuals to leave MA-PD plans if MA is not working well for them.
- Reduce the incentive for most plans to deploy aggressive sales tactics targeted at dually eligible or LIS-enrolled individuals outside of the Annual Enrollment Period.
- Increase transparency for Medicare beneficiaries and enrollment counselors
- Create more opportunities for enrollment into integrated D-SNPs
- Reduce the burden on States working to align Medicaid MCO enrollment to D-SNP enrollment
- Strengthen incentives for MA sponsors to also compete for Medicaid managed care contracts.

CMS also recognizes there are potential challenges with the SEP change, including lack of ability to change plans outside of established enrollment periods in states without integrated D-SNPs, possibility for churn hindering care coordination and case management efforts, and the limit on how the dual/LIS SEP can be used for these individuals compared to the current policy.

Comments

CMS welcomes comments on utilizing these flexibilities to establish a different enrollment effective date for the proposed integrated care SEP. CMS also welcomes comments on the proposed changes to the dual SEP, the proposed integrated care SEP, and their combined impacts.

2. Enrollment Limitations for Non-Integrated Medicare Advantage Plans

Proposed Changes

CMS proposes at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h)(1) and (2) to require the following:

- Beginning in plan year 2027, when an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization (abbreviated as "entity"), also contracts with a state as a Medicaid managed care organization (MCO) that enrolls dually eligible individuals in the same service area, the D-SNP offered by that entity must limit new enrollment to individuals enrolled in the D-SNP's affiliated Medicaid MCO.
- With certain exceptions, only one D-SNP may be offered by the entity in the same service area as the aligned Medicaid MCO.
- Beginning in 2030, such D-SNPs must only enroll individuals enrolled in the affiliated Medicaid MCO. Thus, integrated D-SNPs would be required to disenroll individuals who are not enrolled in both the D-SNP and Medicaid MCO offered under the same parent organization, except in instances of temporarily lost Medicaid coverage.

CMS also proposes certain exceptions to its one D-SNP per service area policy:

- Allows MA organizations that share a parent organization and offer D-SNPs subject to these proposed new limits to crosswalk enrollees (within the same parent organization and same D-SNP type) when the MA organization chooses to non-renew or consolidate its current D-SNPs to comply with the new rules to only operate a single D-SNP.
- If a parent organization operates both HMO and PPO D-SNPs, they are allowed to continue doing so as long as they no longer accept new full-benefit dually eligible enrollees in the same service area as the D-SNP affected by the new regulations. I.e., the parent organization is "choosing" the HMO or PPO D-SNP that will align with its Medicaid MCO and enroll full-benefit duals. The other D-SNP may no longer enroll duals.
- Allows an MA entity to offer more than one D-SNP for full-benefit dually eligible individuals in the same service area as the affiliated Medicaid MCO only when the SMAC requires it. For example, if the SMAC limits enrollment for certain groups into certain D-SNPs (e.g., by age).

Background/Rationale

CMS notes that as the number of dually eligible individuals with misaligned enrollment and sheer number of D-SNPs have grown, they now believe that Federal rulemaking is warranted to promote greater alignment of D-SNPs and Medicaid MCOs and to begin to simplify the array of choices. Overall, CMS believes that its proposals would:

- Increase the percentage of D-SNP enrollees in aligned enrollment
- Reduce number of D-SNP options overall, reducing choice overload and market complexity
- Remove some incentives for agents/brokers to target duals
- Simplify provider billing
- Promote integrated care

- Lead to more states requiring D-SNP only contracts

CMS also recognizes that there may be certain challenges to its proposals, including the following:

- Reduces number of D-SNP options
- Require changes to MPF, HPMS and other CMS public materials to explain new coverage options
- May disadvantage parent organizations that choose to offer Medicaid MCOs as well as D-SNPs given aligned enrollment requirements. CMS notes that the monthly SEP would compensate this limitation.
- May incentivize plans to participate in fewer Medicaid procurements, or exit.
- May contribute to more D-SNP look-alikes
- Result in disruption when enrollees are disenrolled in 2030

Comments

CMS welcomes comments on their overall policy direction, specific proposals, and analysis of their likely effects.

D. Comment Solicitation: Medicare Plan Finder and Information on Certain Integrated D-SNPs (section VIII.D, pgs 311-313)

Comments

CMS requests comment on the following changes to better enhance the Medicare Plan Finder (MPF):

- Adding a limited number of specific Medicaid-covered benefits (dental, non-emergency medical transportation, certain types of HCBS) to the MPF for applicable integrated plans (AIPs) if those services are available to enrollees through the D-SNP or the affiliated Medicaid MCO. This does not include any Medicaid benefits that are available but through a separate carve-out (E.g. NEMT is provided to dually eligible individuals but only through a statewide vendor separate from the AIP).
- Whether to indicate which services are Medicare supplemental benefits and which are Medicaid, as additional information may lead to more complexity for the beneficiary.

CMS is also seeking comment on the practicality of implementing a mechanism by which D-SNPs can report and AIPs can report the Medicaid benefits covered by their plans in order to populate the MPF with such information.

CMS is also interested in stakeholder comments regarding any features from the 'My Care My Choice that are helpful for individuals in making plan decisions.

Background/Rationale

CMS is considering enhancing the Medicare Plan Finder (MPF) tool located on the Medicare.gov website, which allows individuals to compare options for enrolling MA or Part D plans. CMS works to

improve the functionality of the tool each year by implementing changes geared towards creating a tool that provides accurate and easily accessible information for Medicare beneficiaries.

CMS is considering these potential updates to the MPF for several reasons. One being that currently, the MPF only displays benefits that are included in the MA plan benefit package (PBP). This includes Medicare Parts A and B benefits, Part D coverage, approved Medicare supplemental benefits and Value Based Insurance Design. For most MPF users, this illustrates the totality of their coverage, yet for AIPs (defined at § 422.561) that do not receive Medicaid benefits through the D-SNP or affiliated Medicaid managed care organization, the MPF does not reflect all the benefits available to enrollees in the D-SNP. Providing individuals with information solely about Medicare benefits offered by Medicare Advantage (MA) plans, while accurate, might not offer as comprehensive details to dually eligible users of the Medicare Plan Finder (MPF). This is because integrated Dual Eligible Special Needs Plans (D-SNPs) may offer a combination of Medicare and Medicaid benefits that surpass the Medicare benefits exclusively displayed in the MPF. Furthermore, this approach could potentially incentivize D-SNPs to promote specific supplemental benefits for Medicare marketing purposes, even if these services are already accessible to all plan enrollees through Medicaid.

E. Comment Solicitation: State Enrollment Vendors and Enrollment in Integrated D-SNPs (section VIII.E, pgs 314-319)

Comments

CMS seeks feedback on the feasibility of requiring integrated D-SNPs to contract with state enrollment brokers to effectuate enrollment. Specifically, CMS seeks comments on the following:

- What challenges do individuals face when trying to enroll in integrated D-SNPs?
- What are States' reasons for having a specific Medicaid managed care enrollment cut off date in place?
- What type of operational or systems barriers do States and Medicaid managed care plans face to making changes to their Medicaid enrollment cut-off date to align with the Medicare managed care enrollment start date?
- What potential concerns would stakeholders have about CMS using flexibilities at section 1860D-1(b)(1)(B)(iv) of the Act and § 423.40(c) to determine effective dates for Medicare enrollments that occur in the context of CMS' proposed special enrollment period for integrated care? (For example, Medicare enrollment effective dates that align with Medicaid enrollment effective dates, even if they are not the first day of the first calendar month following the date on which the election or change is made.)
- Are there operational or systems barriers for States and Medicaid managed care plans to align disenrollment dates with Medicare?
- What concerns, if any, should CMS consider with States requiring D-SNPs to route enrollment through the State enrollment vendor via the SMAC? Are there any Federal regulations, other than or in addition to the limitations on enrollment brokers under section 1903(b)(4) and §§ 438.71(c) and 438.810, that interested parties view as an impediment to this option?

- What type of technical assistance related to effectuating MA plan and D-SNP enrollment and eligibility processes would be helpful to States?
- What concerns should we consider about potential abusive enrollment practices?
- What are States' current requirements and policies related to agents and brokers?
- Are there other aspects of the integrated enrollment and disenrollment processes in FAI that should apply to D-SNPs?

A major challenge of applying FAI enrollment processes outside the demonstration context is alignment of Medicaid and Medicare managed care enrollment start and end dates. If a dually eligible individual is trying to enroll in an integrated D-SNP at the end of a month in a State with a Medicaid managed care enrollment cut-off date, there could be a monthlong lag between their Medicare managed care effective date and Medicaid managed care effective date. Because of this issue, CMS is also seeking comments regarding the reasons for implementing Medicaid managed care enrollment cut-off dates and the barriers, as well as potential solutions, to aligning Medicare and Medicaid managed care enrollment start and end dates.

Background/Rationale

CMS seeks feedback on these changes because, despite progress, technical challenges persist, such as the misalignment of Medicare and Medicaid enrollment processes and operational issues for both States and plans. In the Financial Alignment Initiative (FAI), CMS delegated eligibility and enrollment functions to states, with variations in the functions delegated to enrollment vendors. The use of State enrollment vendors in FAI serves multiple purposes, including simultaneous Medicare and Medicaid enrollment, unbiased information dissemination, and mitigating conflicts of interest. Outside FAI, dually eligible individuals enroll in MA plans, including D-SNPs, through various channels, posing challenges for D-SNPs with exclusively aligned enrollment. Some States express interest in using State enrollment vendors for these cases. The overall goal is to promote integrated D-SNP enrollment, align Medicare and Medicaid enrollment processes, protect beneficiaries from abusive practices, and streamline communication about enrollment.

F. Clarification of Restrictions on New Enrollment into D-SNPs via State Medicaid Agency Contracts (SMACs) (§§ 422.52 and 422.60) (section VIII.F, pgs 320-321)

Proposed Changes

CMS proposes to revise § 422.52(b)(2) to better emphasize that to be eligible to elect a D-SNP, an individual must meet all additional eligibility requirements established in the SMAC. Additionally, CMS proposes to revise § 422.60(a)(1) and add § 422.60(a)(3) to be more explicit that MA organizations may restrict enrollment in alignment with § 422.52(b)(2).

Background/Rationale

CMS notes that state limitation of D-SNP enrollment to certain populations has been a feature throughout the history of D-SNPs. While it has been a longstanding policy in the crafting of SMACs, CMS believes it can further clarify its regulations. CMS does not expect any new burden associated with these proposed

changes because States are already including eligibility categories and criteria in their SMACs and they are reviewing those accordingly.

G. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes (§ 422.514) (section VIII.G, pgs 322-335)

1. Reducing the Threshold for Contract Limitation on D-SNP Look-Alikes

Proposed Changes

CMS proposes significant changes to address the substantial growth in non-Special Needs Plans (SNP) Medicare Advantage (MA) plans with a high enrollment of dually eligible individuals.

Specifically, CMS proposes amending paragraph § 422.514(d)(1)(ii) such that CMS would not enter into or renew a contract for a new or existing non-SNP MA plan that projects enrollment in its bid of 80% or more dually eligible individuals for plan year 2024 (as is already the case under current regulations); 70% or more dually eligible individuals for plan year 2025; and 60% or more dually eligible individuals for plan year 2026 and subsequent years. CMS would apply the proposed changes at § 422.514(d)(1)(ii) to all bids for the next plan year, including any bids for non-SNP MA plans projected to exceed the threshold even if the actual enrollment for the current plan year is under the threshold at § 422.514(d)(1).

Similarly, CMS proposes revisions to paragraph (d)(2) to apply the lower thresholds to non-SNP MA plan enrollment. Specifically, they propose to amend paragraph (d)(2)(ii) to state that they will not renew a contract with a non-SNP MA plan that has actual enrollment, using January enrollment of the current year, in which dually eligible individuals constitute 80% or more dually eligible individuals for plan year 2024 (as is already the case under current regulations); 70% or more dually eligible individuals for plan year 2025; or 60% or more dually eligible individuals for plan year 2026 or subsequent years.

Background/Rationale

In the June 2020 final rule, titled "Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program," CMS implemented contracting limitations for D-SNP (Dual Eligible Special Needs Plan) look-alikes. These limitations, outlined in § 422.514(d) and associated procedures, prohibit CMS from entering into contracts for new non-SNP MA plans projecting 80% or more enrollment of individuals entitled to Medicaid. Additionally, for plan year 2023 and beyond, CMS will not renew contracts with existing non-SNP MA plans having actual enrollment of 80% or more dually eligible individuals unless the plan has been active for less than a year with enrollment of 200 or fewer individuals.

These contract limitations were established to address concerns arising from the proliferation of D-SNP look-alikes. The aim was to ensure the effective implementation of D-SNP requirements, including contracts with State Medicaid agencies, minimum integration of Medicare and Medicaid benefits, care coordination through health risk assessments (HRAs), and evidence-based models of care. The regulation was also designed to counteract potentially misleading marketing practices by brokers and agents

promoting D-SNP look-alikes to dually eligible individuals. The rationale for initially setting the threshold at 80 percent was based on a 2019 MedPAC analysis showing that the proportion of dually eligible individuals in most geographic areas did not exceed this threshold.

In new analyses of data from 2017 to 2023, CMS notes that the percentage of D-SNP look alikes operating under the 80% threshold has significantly increased over time. The rate of growth from 2017 to 2023 in the number of non-SNP MA plans with 50 to 60 percent (544 percent increase), 60 to 70 percent (900 percent), and 70 to 80 percent dually eligible individuals as a percent of total enrollment (1,400 percent)184 exceeded the rate of enrollment growth for all MA-PD plans (109 percent) over the same period of time. They note that these growth increases suggest that MA organizations are offering plans for duals but circumventing rules for D-SNPs, detracting from efforts to integrate care. CMS proposes lowering to a 60% threshold because it exceeds the share of dually eligible individuals in any given MA plan service area currently and, therefore, would not be the result for any plan that simply reflected the concentration of dually eligible enrollees in its service area. CMS proposes an incremental approach to minimize disruptions to dually eligible individuals and allow MA organizations and CMS to operationalize these transitions over a two-year period.

Comments

CMS invites public input on various aspects, including the impact on affected plans, potential unintended consequences, and the appropriateness of lowering the threshold to 50% as an alternative.

2. Amending the Transition Processes and Procedures for D-SNP Look-Alikes

Proposed Changes

CMS proposes changes to the transition processes and procedures outlined in Section 422.514(e). Effective for plan year 2025, the existing processes at § 422.514(e) would apply to non-SNP MA plans with 70% or more dually eligible individuals, and for plan year 2026, the threshold would be 60% or more dually eligible individuals. However, starting from plan year 2027, CMS proposes to limit the transition processes and procedures at § 422.514(e) to only D-SNPs. Thus, D-SNP look-alikes would not be able to transition enrollees into a non-D-SNP beginning in 2027.

Additionally, CMS proposes a technical edit at § 422.514(e)(1)(i) to make the term "specialized MA plan for special needs individuals" lowercase, consistent with the definition of D-SNPs at § 422.2.

Background/Rationale

CMS observes that in practice, most enrollees from D-SNP look-alikes transition to other MAPDs under the same parent organization. CMS expresses concern that if D-SNP look-alikes continue to transition enrollees into non-D-SNPs indefinitely, there would be little incentive for MA organizations to comply with the D-SNP look-alike thresholds.

Comments

CMS invites public input on specific elements of the proposed changes, particularly on the consideration of an alternative proposal that eliminates the 70% threshold for plan year 2025. Here, CMS would instead extend the 80% threshold to 2025, and apply a 60% transition limitation for 2026 and beyond. Under this alternative, CMS would permit use of transition authority into non-SNP MA plans for 2025, but limit transitions to only D-SNPs in 2026. CMS is seeking feedback on whether this alternative strikes a better balance in achieving the goals of preventing circumvention of D-SNP requirements and encouraging enrollment in integrated care plans.

H. For D-SNP PPOs, Limit Out-of-Network Cost Sharing (§ 422.100) (section VIII.H, pgs 336-346)

Proposed Changes

CMS proposes new limits on out-of-network cost-sharing under D-SNP PPOs. The proposal, outlined in § 422.100(o)(1), suggests capping out-of-network cost-sharing for professional services including primary care services, physician specialist services, partial hospitalization and rehabilitation services at the cost-sharing limits established at § 422.100(f)(6) starting in 2026.

The limits would be contingent on the catastrophic limit set at the mandatory MOOP, intermediate MOOP, or lower MOOP, with corresponding coinsurance caps. Furthermore, § 422.100(o)(1) proposes limiting cost-sharing for out-of-network acute and psychiatric inpatient services, aligning them with cost-sharing caps under § 422.100(f)(6) applicable to in-network benefits. § 422.100(o)(2) suggests applying existing in-network cost-sharing limits for specific services to out-of-network services under D-SNP PPOs, ensuring consistency and alignment. The proposal is scheduled for implementation in the 2026 plan year, with CMS anticipating minimal additional burden on MA organizations or itself, as current information collection requirements cover the proposed changes.

Background/Rationale

MA organizations provide diverse health plan options, such as MSA plans, PFFS plans, PPOs, HMOs, and HMO/POS plans (§ 422.4). The most common options are HMOs and PPOs, with HMOs typically requiring network providers and PPOs allowing both in-network and out-of-network services. D-SNP PPOs, exclusive to individuals dually eligible for Medicare and Medicaid, have seen increased enrollment, reaching around 925,000 enrollees as of May 2023. Four national MA sponsors dominate over 98 percent of D-SNP PPO enrollment. The out-of-network cost-sharing structure in D-SNP PPOs, especially for services like primary care, Part B prescription drugs, and skilled nursing facility stays, raises concerns due to its potential impact on State Medicaid costs, the financial burden on non-QMB full-benefit dually eligible individuals, and the disincentives for safety net providers. Furthermore, these cost-sharing levels may conflict with the policy goals of section 1852(a)(2) of the Act, potentially leading to inconsistent net payments for out-of-network services compared to Traditional Medicare.

Comments

CMS invites public input on various aspects of this proposal, including determining if there should be limitations on cost-sharing for additional out-of-network services, aligning with Traditional Medicare

levels. CMS is also exploring alternative approaches, such as capping Dual Eligible Special Needs Plans (D-SNP) Preferred Provider Organization (PPO) out-of-network cost-sharing at Traditional Medicare levels or setting specific limits for certain services. Additionally, CMS is considering restricting out-of-network cost-sharing for services to Qualified Medicare Beneficiaries (QMBs), as well as general comments on the proposal in its entirety.