CMS Proposed Rule on 2024 Policy and Technical Changes to Medicare Advantage and Medicare Part D

On December 14, 2022, CMS released their annual Medicare Advantage (MA) and Part D Proposed Rule for 2024 (fact sheet) which governs requirements for MA and Part D plans. Among its provisions, the rule includes stricter prior authorization requirements, increases beneficiary marketing protections, better incorporates health equity into Star Ratings, provider directories, and quality improvement programs, improves access to behavioral health, and expands access to the Medication Therapy Management (MTM) program. Comments are due February 13, 2023. Details on key provisions of the proposed rule are provided below. **The summary below does not reflect a complete summary of the provisions of the rule. Rather, it includes a chosen subset of sections potentially considered 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. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018, the Consolidated Appropriations Act, 2021, and the Inflation Reduction Act of 2022

A. Applying D-SNP Look-Alike Requirements to PBP Segments (section II.A, pgs. 24-29)

1. Applying Contracting Limitations for D-SNP Look-Alikes to Plan Benefit Package Segments

Proposed Changes

CMS proposes to add a new paragraph at 42 CFR 422.514(g) to provide that § 422.514(d) through (f), which stipulate contracting limitations for D-SNP look-alikes, apply to segments of the MA plan in the same way that those provisions apply to MA plans. This means that CMS will not contract or renew contracts with a plan segment where the MA plan or segment is not a D-SNP and the enrollment thresholds in paragraph (d)(1) or (d)(2) are met.

CMS proposes to amend § 422.503(e) to allow for CMS to sever a segment from an MA plan and allow the remaining segments of that MA plan to continue along with any other MA plans offered under the same contract.

CMS proposes to amend § 422.504(a)(19) to adopt a new contract term that MA organizations agree not to segment an MA plan in a way that results in a D-SNP look-alike.

Background/Rationale

The proposal to allow § 422.514(d) through (f) to apply to segments of the MA plan would make CMS' annual review process of MA plan bids and Medicaid cost-sharing more consistent. CMS will separately evaluate MA plan segments for compliance with MA requirements.

Currently, CMS does not currently have regulatory authority to sever a segment from an MA plan to terminate a contract that has only a segment of an MA plan. The amendment of amendment of § 422.503(e) would allow CMS to sever parts of an MA plan that does not meet contracting requirements without affecting the rest of the MA plan.

By combining the proposed amendment to § 422.514(g) to apply the prohibitions on contracting with D-SNP lookalikes to segments of an MA plan, the amendments to § 422.503(e) would allow CMS to eliminate existing D-SNP look-alike segments and the amendments to § 422.504(a)(19) would allow CMS to prevent new D-SNP look-alikes. D-SNP look-alikes create beneficiary confusion due to

misleading marketing practices by brokers and agents that misrepresent D-SNP look-alike plans to dually eligible individuals.

2. Applying Contracting Limitations for D-SNP Look-Alikes to Existing MA Plans

Proposed Changes

CMS proposes to amend § 422.514(d)(1) to apply it to both new and existing (that is, renewing) MA plans that are not DSNPs and submit bids with projected enrollment of 80 percent or more enrollees of the plan's total enrollment that are dually eligible for Medicare and Medicaid. This means that CMS will not enter or renew contracts for CY 2024 and thereafter with MA plans that are not DSNPs and submit bids with projected enrollment of 80 percent or more enrollees of the plan's total enrollment that are dually eligible for Medicare and Medicaid.

Background/Rationale

CMS is correcting a loophole that identifies MA plans that meet the contract limitations of § 422.514(d)(1). Because contracts for 2022 and 2023 have already been awarded, the earliest the proposed revision can take effect is 2024.

3. Contract Limitations for D-SNP Look-Alikes as a Basis for MA Contract Termination

Proposed Changes

CMS proposes to amend § 422.510(a)(4), which outlines the bases for termination of an MA contract. CMS will add a new paragraph (a)(4)(xvi) that permits CMS to terminate an MA contract when the MA organization meets the criteria in § 422.514(d)(1) or (d)(2).

Background/Rationale

The proposed amendment is consistent with § 422.514(d), which provides limitations on MA contracts. CMS believes § 422.514(d) is sufficient cause for termination of MA contracts when § 422.514(d) applies, but they are adding this amendment to be explicit.

B. Part D Special Enrollment Period Change Based on CAA Medicare Enrollment Changes (section II.B, pgs. 30-32)

Proposed Changes

CMS proposes to amend § 423.38(c)(16) to provide that on or after January 1, 2023, an individual who is not entitled to premium-free Part A and who enrolls in Part B during the GEP is eligible to use the SEP for Individuals Who Enroll in Part B During the Part B GEP to request enrollment in a Part D plan. This SEP will begin when the individual submits the application for Part B and will continue for the first 2 months of enrollment in Part B.

CMS proposes to amend § 438.38(c)(16) to provide that where an individual uses Part D SEP for Individuals Who Enroll in Part B During the Part B GEP to request enrollment in a Part D plan, the Part D plan enrollment would be effective the first of the month following the month the Part D plan sponsor receives the enrollment request.

Background/Rationale

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established a Part D – Voluntary Prescription Drug Benefit program for Medicare beneficiaries. Section 1860D–1(b)(3)(C) of the Act authorized the Secretary to establish Part D special enrollment periods (SEP) for Medicare-eligible individuals to enroll in a Part D plan based on exceptional circumstances – that is, an individual may elect a plan or change his or her current plan election when the individual meets an exceptional condition as determined by the Secretary. CMS codified several SEPs in 2020.

CMS states the proposed changes in enrollment and effective dates through this Part D SEP should simplify the enrollment process and reduce potential for prescription drug coverage gaps and make it easier for beneficiaries to understand effective dates of their Medicare coverage. This amendment will align the start date to the first of the month following the month the beneficiary submits an enrollment request, similar to most Part D enrollment and SEP timeframes.

C. Alignment of Part C and D Special Enrollment Periods with Medicare Exceptional Condition Enrollment (section II.C, pgs. 33 – 37)

Proposed Changes

CMS proposes adding two exceptional condition SEPs for MA and Part D enrollment:

- MA Exception Condition SEP: At § 422.62(b), CMS is proposing to provide an SEP for individuals to enroll in a MA plan or MA plan that includes Part D benefits (MA-PD plan), when they use a Medicare exceptional condition SEP to enroll in premium Part A and/or Part B. The SEP would begin when the individual submits the application for premium Part A and Part B, or only Part B, and would continue for the first two months of enrollment in Part A and B.
- Part D Exceptional Condition SEP: At § 423.38(c), CMS is proposing to provide an SEP for individuals to enroll in a stand-alone Part D prescription drug plan (PDP) when they use a Medicare exceptional condition SEP to enroll in premium Part A or Part B. The SEP would begin when the individual submits their premium Part A or Part B application and would continue for the first 2 months of enrollment in premium Part A or Part B.

Background/Rationale

Under the Consolidated Appropriations Act of 2021, CMS has authority to create SEPs based on exceptional conditions for Medicare Parts A and B enrollment. The ability to grant SEPs for exceptional conditions allows CMS to provide relief to individuals who missed an opportunity to enroll in Medicare due to circumstances that were outside of their control, ensure continuous health coverage, and avoid late enrollment penalties on the premium Part A or Part B premiums.

These proposed SEPs align with the new Medicare premium Part and B exceptional condition SEPs that CMS has finalized in 42 CFR 406.27 and 407.23.

- MA Exception Condition SEP: This SEP allows beneficiaries enrolled in premium Part A and in Part B to receive their healthcare from an MA plan instead of Original Medicare as soon as the individual is enrolled in both Parts A and B, without waiting for the annual coordinated election period
- Part D Exceptional Condition SEP: This SEP provides an opportunity for Part D and helps ensure people will have timely access to Part D drugs, within the timeframe of 63 days established in regulation at § 423.46(a), to prevent a Part D late enrollment penalty from occurring.

D. Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LI NET) Program (section II.D, pgs. 38-70)

1. Eligibility and Enrollment

Proposed Changes

CMS proposes to make LI NET a permanent program through § 423.2500. The program would begin January 1, 2024, where eligible individuals would be provided transitional coverage for Part D drugs. CMS also proposes eligibility, enrollment, and sponsorship requirement for LI NET beneficiaries and sponsors.

CMS means to codify at Subpart Y the LI NET eligibility requirements set forth in section 1860D–14(e)(2) of the Act. CMS proposes two categories of individuals eligible to enroll in LI NET that encompass the previously noted categories of low-income individuals recognized by Part D in § 423.2504. The first category, "LIS-eligible," would consist of individuals whose low-income status has been confirmed through CMS' records or demonstration of the individual's low-income status. The second category, "immediate need," would consist of individuals whose low-income status has not been confirmed, because CMS' data do not yet reflect the individual's low-income status, but the individual has indicated that they are eligible for the LIS (although absence of documentation should not be a barrier to LI NET eligibility).

CMS proposes to grant immediate access to covered Part D drugs at the point-of-sale for individuals whose eligibility as defined at § 423.773 cannot be confirmed at the point-of-sale in § 423.2504(a)(2).

Under proposed paragraph (a)(2)(i), immediate need individuals may provide documentation to the LI NET sponsor to confirm LIS eligibility. If an immediate need individual's LIS status cannot be confirmed within two months, then the individual will not be automatically enrolled into a Part D plan. Documentation could include, but would not be limited to:

- A copy of the beneficiary's Medicaid card that includes their name and eligibility date
- A copy of a letter from the State or SSA showing LIS status
- The date that a verification call was made to the State Medicaid Agency, the name and telephone number of the State staff person who verified the Medicaid period, and the Medicaid eligibility dates confirmed on the call
- A copy of a State document that confirms active Medicaid status
- A screen-print from the State's Medicaid systems showing Medicaid status
- Evidence at point-of-sale of recent Medicaid billing and payment in the pharmacy's patient profile.

CMS proposes that immediate need beneficiaries whose eligibility cannot be confirmed can continue to fill prescriptions throughout their 2-month enrollment in LI NET in § 423.2504(a)(2)(i).

CMS proposes to codify LI NET enrollment, including autoenrollment, point-of-sale for immediate need individuals, direct reimbursement, and LI NET enrollment form in § 423.2504(b). CMS also proposes to automatically enroll those that are LIS-eligible and whose auto-enrollment into a Part D plan has not taken effect into the LI NET program unless they have actively declined enrollment by notifying CMS' systems. Therefore, when a beneficiary declines Part D enrollment, they are also opting out of LI NET enrollment. CMS also proposes to allow retroactive LI NET coverage beginning the date an individual is identified as full-benefit dual or an SSI benefit recipient, or 36 months before the individual enrolls in (or opts out of) Part D coverage, whichever is later. Under CMS proposal, LI NET enrollment ends once Part D coverage takes effect, consistent with section 1860D-14(e)(3) of the Act.

Background/Rationale

The LI NET demonstration provides temporary, transitional Part D prescription drug coverage for LIS-eligible beneficiaries, including beneficiaries who are eligible for the Part D LIS but who are not yet enrolled in a Part D drug plan, or are enrolled in a plan but for whom coverage has not yet taken effect. CMS plans to align sunsetting the demonstration seamlessly with the start of the permanent LI NET program. CMS sees the LI NET demonstration has become a reliable, stable program that has been successful in providing transitional and retroactive Part D coverage to millions of beneficiaries from Medicaid to Medicare.

Eligibility: CMS does not believe absence of documentation in hand at the point-of-sale should be a barrier to entry to LI NET for immediate need individuals, as 80% of immediate need individuals do have their eligibility ultimately confirmed. CMS sees continued prescriptions for 2 months provides an administratively simple approach as compared with alternative ideas, such as the approach under the demonstration of keeping immediate need beneficiaries with uncertain eligibility enrolled in LI NET but unable to fill prescriptions.

CMS plans to codify the various LI NET demonstration enrollment options in establishing a permanent LI NET program. Beneficiaries may opt out of Part D enrollment if they have other insurance or do not want to participate. LI NET retroactive enrollment and the last day for enrollment are also modified to provide more robust transitional coverage.

Comments

CMS is soliciting comments on the proposal to align the two months of enrollment with the ability to fill prescriptions for these immediate need beneficiaries.

CMS also seeks comment on whether revised or additional regulations are required to achieve accurate, streamlined, and beneficiary friendly eligibility determinations and enrollment into the LI NET program.

2. Benefits and Beneficiary Protections

Proposed Changes

CMS proposes to codify the requirement that the LI NET program provide access to all Part D drugs under an open formulary in § 423.2508(a). CMS will require the LI NET sponsor to permit all pharmacies that CMS determines to be in good standing to process claims under the program, regardless of whether the pharmacy is a network or out-of-network (OON) pharmacy for the LI NET sponsor.

CMS proposes that a pharmacy is deemed to be in good standing if it is licensed, has not been revoked from Medicare under § 424.535, does not appear on the Office of Inspector General's list of entities excluded from Federally funded health care programs (unless the OIG waives the exclusion, which the OIG has authority to do in certain specified circumstances), and does not appear on the preclusion list as defined in § 423.100. A pharmacy will appear on the preclusion list if it:

- Is currently revoked from Medicare, is under an active reenrollment bar, and CMS has determined that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program, including LI NET;
- Has engaged in behavior for which CMS could have revoked the entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program, including LI NET;
- Has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program, including LI NET.

CMS proposes to apply the following patient safety and appropriate medication dispensing regulations to the LI NET program and LI NET sponsor:

- § 423.153(b) and (c) for dispensing and point-of-sale safety edits.
- § 423.154 for appropriate dispensing of prescription drugs in long-term care facilities.
- § 423.159, requiring an electronic prescription drug program.

- § 423.160, excepting the requirements pertaining to formulary standards in § 423.160(b)(5), setting forth standards for electronic prescribing.
- § 423.162, for quality improvement organization (QIO) activities.
- § 423.165, regarding compliance deemed on the basis of accreditation.

CMS proposes that beneficiaries whose LIS-eligibility is established and who have not yet enrolled in a prescription drug plan or MA-PD plan, or who have enrolled in a prescription drug or MA-PD plan but coverage under such plan has not yet taken effect, would pay the applicable cost sharing for their low-income category as established in the yearly Announcement of Calendar Year Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. Immediate need beneficiaries would by default pay the cost-sharing for non-institutionalized FBDE individuals with incomes greater than 100 percent of the federal poverty line.

CMS proposes that LI NET enrollees have rights with respect to Part D grievances, coverage determinations, and appeals processes set out in subpart M of the Part D regulations.

Background/Rationale

The CMS proposal codifies current LI NET program beneficiaries' access to all Part D drugs under an open formulary.

Pharmacies in good standing limit fraud, waste, discrimination, and abuse. These standards are more detailed than existing standards for pharmacies under the demonstration.

CMS is proposing these requirements to ensure patient safety and appropriate dispensing of medication consistent with Part D regulations. Existing Part D requirements related to appropriate dispensing, patient safety, electronic dispensing, quality improvement organization (QIO) activities, compliance, and accreditation would improve patient safety and appropriate dispensing.

Under the demonstration, LI NET beneficiaries pay the reduced cost-sharing aligned with the LIS categories defined in the Part D program. Because there is already the existing statutory requirement for CMS to update the parameters for the LIS benefit each year using statutory indexing methods, and because CMS and pharmacy systems are already set up to reflect the appropriate cost-sharing based on the LIS category of the individual, CMS sees it as reasonable to calculate and charge cost-sharing in alignment with the Part D LIS categories. Immediate need beneficiaries pay the cost-sharing for non-institutionalized FBDE rates as it allows for the least government liability for individuals whose LIS eligibility is unable to be confirmed while still allowing prescription drug access for immediate need individuals.

CMS sees an established appeals process would adequately adjudicate LI NET beneficiary concerns. This approach of using existing processes avoids needing to devote resources to establishing separate grievance, coverage determinations. Furthermore, consistency with other Part D contracts as it relates to grievances, coverage determinations, and appeals would be simplest for LI NET sponsors.

Comments

CMS solicits comments on whether the provisions on patient safety and medication dispensing regulations would be compatible with the LI NET program proposed.

3. LI NET Sponsor Requirements

Proposed Changes

CMS proposes to establish requirements the LI NET sponsor must meet when administering the LI NET program:

- The sponsor(s) would be selected from among the Part D sponsors with a national presence, with an established contracted pharmacy network in all geographic areas of the United States in which LIS is available. Because LIS is not available in the territories, CMS would not require the LI NET sponsor to have network pharmacies in territories.
- The sponsor(s) should have a minimum of 2 consecutive years contracting with CMS as a Part D sponsor.
- The sponsor(s) must have the technical capability and the infrastructure to provide immediate, current, and retroactive coverage for LI NET enrollees and the technical capability to develop the infrastructure necessary for verifying Medicaid dual eligibility status for presumed eligible LI NET enrollees. The LI NET sponsor must identify, develop, and implement outreach plans in consultation with CMS targeting key stakeholders to inform them about the LI NET program.
- The sponsor must establish and manage a toll-free customer service telephone line and fax line that can be accessed by pharmacy providers and beneficiaries, or others acting on their behalf.
- The sponsor(s) must adhere to the deadlines established by the LI NET demonstration related to direct reimbursement to beneficiaries with retroactive coverage.
- The sponsor(s) should adjudicate claims from out-of-network pharmacies according to the LI NET sponsor's standard reimbursement for their network pharmacies.

Background/Rationale

Because LI NET may enroll beneficiaries from across the nation, the sponsor(s) would need to have a well-networked, national presence with strong technical capabilities.

Under the demonstration, CMS enrolls over 90 percent of LI NET beneficiaries into the LI NET plan and will likely continue to be responsible for most enrollees in a permanent LI NET program. For the beneficiaries who are not auto-enrolled, outreach is important so that stakeholders like the states, SHIPs, and pharmacies have awareness and knowledge about the LI NET program. Under the demonstration, the LI NET sponsor routinely conducts outreach in consultation with CMS to inform stakeholders about the program.

The toll-free customer service line was proposed to handle inquiries about services under the LI NET program, provide eligibility or claims statuses, and accept documentation for evidence of eligibility.

CMS plans to codify retroactive reimbursement timelines, as set in the demonstration, in the permanent LI NET program.

Because the sponsor must provide access to all Part D drugs under an open formulary, CMS believes there is the need for some protection against unreasonably high drug costs for OON claims in LI NET. Other Part D sponsors have the option to deny such claims, or to pay OON claims according to their standard reimbursement for their network pharmacies (with beneficiaries paying any difference between the cost of the OON claim the negotiated price).

4. Selection of LI NET Sponsor and Contracting Provisions

Proposed Changes

CMS proposes to follow the contracting approach set forth in proposed § 423.2516 to select the LI NET sponsor for the 2024 plan year and onwards. CMS would appoint a Part D sponsor that meets the requirements at § 423.2512. To determine this appointment, CMS proposes to conduct discussions with potentially eligible entities to establish mutual interest and ability to administer the program.

CMS proposes to use the following criteria in appointing an LI NET sponsor based on some features of the LI NET program that are related to a Part D sponsor's ability to successfully administer the program.

- Experience covering low-income beneficiaries, including but not limited to enrolling and providing coverage to low-income subsidy individuals as defined in § 423.3
- Pharmacy access as outlined in § 423.120
- Past performance consistent with § 423.503(b), including Star Ratings (as detailed in § 423.186), and previous intermediate sanctions (as detailed in § 423.750)
- Ability to meet the requirements listed in § 423.505 that are not waived under § 423.2536. The waived requirement is sponsor certification to data for price comparison purposes.

CMS proposes § 423.505 to apply to LI NET, with the exception of § 423.505(k)(6), which CMS proposes to waive.

CMS proposes that the term of the appointment will be ongoing provided mutual agreement between CMS and the selected party, subject to an annual contracting and bid process (per proposed § 423.2524(c)) to determine payment rates for the upcoming year.

CMS proposes to impose intermediate sanctions as outlined in subpart O of the Part D regulations if LI NET sponsor violates its contract.

CMS proposes that if the LI NET sponsor decides for any reason to non-renew its existing contract, it must notify CMS by January 1 of the year before the next contract year. Except as provided in paragraph (c) of this section, if CMS decides for any reason to non-renew the existing contract with the incumbent LI NET sponsor, CMS would notify the LI NET sponsor by January 1 of the year before the next contract year.

CMS proposes waiving the appeals requirement in § 423.2536(e) except for those relevant to a contract termination. This gives CMS the authority to non-renew for any reason, without cause, and the LI NET sponsor would not have a right to appeal the non-renewal.

CMS proposes to select a successor LI NET sponsor from among the other eligible entities in § 423.2520(b). CMS requires the outgoing LI NET sponsor to coordinate with the successor LI NET sponsor appointed by CMS for a period of no less than 3 months to ensure seamless transition for LI NET enrollees, including timely transfer of any data or files. All data, files, written materials, and LI NET work products would be considered CMS' property. During the transition period, the outgoing and incoming LI NET sponsors would work together to develop a transition plan, including setting up a training schedule and a schedule of events for a smooth changeover.

CMS proposes immediate termination authority in § 423.2520(d) if:

- CMS determines that a delay in termination, resulting from non-compliance prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the LI NET sponsor
- The LI NET sponsor has experienced financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to beneficiary health, or otherwise fails to make services available to the extent that such a risk to health exists
- The LI NET sponsor has had one or more of the issues enumerated in paragraphs (a)(4)(i) and (xii) of § 423.509.

Background/Rationale

The sponsor selection process is set up such that CMS can collect needed information on the Part D sponsor's ability to administer the LI NET program.

CMS sees it as appropriate to bring the LI NET contractor into closer alignment with other contracts in the Part D program by executing an LI NET contract with a Part D plan sponsor each plan year that contains, among other information, payment information for that year to establish a permanent LI NET program.

CMS intends to align the LI NET program with the demonstration model and require the LI NET sponsor to submit relevant certifications of data that determine payment as applicable, such as enrollment and payment information, claims data, bid submission information, DIR data, and overpayments.

The demonstration annual contracting and bid process worked well and CMS saw no reason to propose a different approach for the permanent program.

As there has only been a single LI NET sponsor for the duration of the demonstration, and CMS is anticipating a single LI NET sponsor for the permanent LI NET program, CMS does not want to assume the risk of the appeals process not providing finality by the time an LI NET sponsor would need to begin preparing the LI NET bid. Even if CMS required the appeals process to be complete by the April timeframe and while the appeal was pending moved forward with selection process, CMS would be cutting into or needing to forgo entirely the transition time of 3 months proposed in § 423.2520(b) to ensure seamless transition of the LI NET program.

CMS aims to ensure seamless transition between different sponsors.

5. Bidding and Payments to LI NET Sponsor

Proposed Changes

CMS proposes to establish the methodology and formulas used to determine the amounts paid to the LI NET sponsor under the contract. CMS also proposes payments for the LI NET program be made from the Medicare Prescription Drug Account, as payments are made to other Part D sponsors. CMS also proposes providing advance monthly LI NET payments, on a per-member, per-month (PMPM) basis, equal to the sum of Payment Rates A and B as established in the LI NET sponsor's approved bid submitted annually under paragraph (b) of this proposed section. Payment Rate A is proposed to be a monthly payment for projected administrative costs and estimated costs to pay pharmacy claims for prescriptions filled by immediate need individuals. Payment Rate B is proposed to be the projected net costs of the Part D drugs dispensed to individuals who receive the LI NET benefit.

CMS proposes requiring the sponsor to submit a bid and supplemental information in a format specified by CMS, with the same deadline as other Part D bids of no later than the first Monday of June each year.

CMS proposes specific provisions (§ 423.272(a), (b)(1), and (b)(4) regarding the review, negotiation, and approval of the LI NET bid.

Background/Rationale

Paying on a PMPM basis would align with other Part D payments and with CMS operations under the LI NET demonstration in which CMS provides a capitated PMPM amount established by the bid for each beneficiary enrolled in the demonstration. Unlike typical Part D monthly payments, the monthly LI NET payment under the demonstration is a PMPM amount that represents the sum of Payment Rates A and B, as determined by the LI NET bid.

The submission process gives CMS the ability to request additional information from the LI NET sponsor to support bid amounts, and the ability to require revisions to the submitted LI NET bid before it is accepted. As with other Part D bids, a qualified actuary, whether internal or external to the plan sponsor, would certify the LI NET sponsor's actuarial valuation (which may be prepared by others under the qualified actuary's direction or review). The qualified actuary would need to be a member of the American Academy of Actuaries.

CMS could review the LI NET bid, conduct negotiations regarding the terms and conditions of the proposed bid, and approve it only if the bidding LI NET sponsor and the LI NET plan comply with all applicable CMS Part D requirements. As in typical Part D bid reviews, CMS would be able to decline the LI NET bid if it proposes significant increases in cost sharing.

6. Part D Program Waivers

Proposed Changes

For LI NET, CMS proposes to waive formulary requirements in §§ 423.120(b), 423.128(e)(5), and 423.128(e)(6) and MTM program requirements in § 423.153.

CMS proposes to waive for LI NET some of the cost control and quality improvement requirements in Part 423 Subpart D, except for the provisions CMS explicitly adopts in § 423.2508(d)(1) through (d)(5) that relate to appropriate dispensing, patient safety, electronic dispensing, QIO activities, compliance, and accreditation.

CMS proposes not to subject LI NET to coverage gap discount requirements under subpart W of Part 423.

CMS proposes that the LI NET sponsor not be required to meet the minimum medical loss ratio (MLR) requirement or to report the MLR for the LI NET contract as it does for other contracts.

CMS proposes waiving the Recovery Audit Contractors (RACs) requirements that cover MA and Part D programs.

Background/Rationale

Regulation requirements relating to dissemination of general information and the provision of formulary information, formulary requirements, and medication therapy management (MTM) program requirements do not apply to the LI NET program.

CMS would waive requirements that do not make sense in the context of temporary coverage with access to an open formulary. The requirements CMS proposes to waive pertain to drug utilization management programs, medication therapy management programs, and consumer satisfaction surveys.

Part D beneficiaries receiving a low-income subsidy are not eligible for the coverage gap discount program, and under the demonstration LI NET was not subject to coverage gap discount requirements under subpart W of Part 423. Therefore, subpart W does not apply to LI NET.

The minimum MLR requirement is intended to create incentives for Part D sponsors to reduce administrative costs such as marketing costs, profits, and other such uses of plan revenues, and to help ensure that taxpayers and enrolled beneficiaries receive value from Medicare health plans. Because of the limits CMS is proposing to place on how much administrative costs in LI NET under Payment Rate A can increase year over year and because of the differing payment structure, CMS does not see MLR reporting as applicable to LI NET.

Because the LI NET sponsor must enroll every eligible LI NET beneficiary, and because LI NET does not receive reinsurance, a Part D RAC's review or examination of LI NET claims would likely be extremely limited in scope. As other audit, oversight, and compliance requirements would continue to apply to the LI NET program, the other program integrity safeguards CMS has proposed for the LI NET program would be adequate.

Comments

CMS is soliciting comments on whether they should waive any additional regulatory provisions related to paragraphs (1) and (3)(B) of section 1860D-4(a) of the Act and subparagraphs (A) and (B) of section 1860D-4(b)(3) of the Act.

CMS is soliciting comments on whether there are additional provisions in Part 423 for the Voluntary Medicare Prescription Drug Benefit that they have not mentioned in this proposed rule and should address for LI NET.

E. Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program (section II.E, pgs 70-72)

Proposed Changes

CMS proposes to amend § 423.773(b)(1) to add that to be eligible for the full subsidy for plan years beginning on or after January 1, 2024, an individual must have an income below 150 percent of the FPL. To coordinate with this change, CMS is also proposing to amend § 423.773(d) to specify that the requirement that an individual have an income below 150 percent of the FPL to be eligible for the partial subsidy applies only to plan years beginning before January 1, 2024. This latter change will effectively sunset the partial subsidy income requirements after 2023.

CMS proposes to amend § 423.773 to state that the current resource limits applicable for the full subsidy at paragraph (b)(2)(ii) apply to years 2007 through 2023. CMS also proposes that for years beginning on or after January 1, 2024, the resource limits at paragraph (d)(2) of § 423.773 – the resource standards currently applicable for the partial subsidy – would apply to full subsidy eligible individuals.

CMS proposes that the sliding scale premium amounts currently applicable for individuals with the partial subsidy apply with respect to plan years beginning before January 1, 2024. These individuals who have incomes between 135 and 150 percent of the FPL and who meet the resource requirements will now qualify for the full subsidy beginning in 2024, and will be entitled to a premium subsidy of 100 percent of the premium subsidy amount, as outlined in § 423.780(a).

Background/Rationale

To currently be eligible for the full LIS subsidy, individuals must have countable income below 135 percent of the Federal poverty level (FPL) for the individual's family size. In addition, individuals must have resources that do not exceed three times the resource limit under section 1613 for applicants for Supplemental Security Income (SSI) under title XVI. The resource limit increases annually by the percentage increase in the Consumer Price Index as of September for the year before and is rounded to the nearest multiple of $10. The Inflation Reduction Act expanded eligibility for the full LIS subsidy group.

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

A. Health Equity in Medicare Advantage (MA) (section III.A, pgs 73-100)

1. Ensuring Equitable Access to Medicare Advantage Services

Proposed Changes

CMS proposes to update the heading at § 422.112(a)(8) from "Cultural considerations" to "Ensuring Equitable Access to Medicare Advantage (MA) Services" and replacing the language after "including" with the following populations:

- (i) people with limited English proficiency or reading skills;
- (ii) people of ethnic, cultural, racial, or religious minorities;
- (iii) people with disabilities;
- (iv) people who identify as lesbian, gay, bisexual, or other diverse sexual orientations;
- (v) people who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex;
- (vi) people who live in rural areas and other areas with high levels of deprivation; and
- (vii) people otherwise adversely affected by persistent poverty or inequality.

However, CMS notes that this list is not exhaustive, and MA organizations are responsible for ensuring that all beneficiaries receive accommodations to equitably access services.

Background/Rationale

CMS established requirements for the Medicare program to ensure that all enrollees receive services that are provided in a culturally competent manner in the Medicare Program; Medicare+Choice Program final rule, published in June 2000. The rule specified program requirements to ensure that enrollees with limited English proficiency, limited education, or other socio-economic disadvantages have equitable access to the health care services they are entitled to.

While these existing regulations also apply to Medicare Advantage (MA) organizations, CMS believes the proposed amendments would clarify the requirements for MA organizations and better reflect the increasingly diverse populations they serve.

Comments

CMS solicits comments on the proposed clarifications.

2. Medicare Advantage (MA) Provider Directories

Proposed Changes

CMS proposes to require organizations to identify non-English languages spoken by each provider and provider/location accessibility for people with physical disabilities. To codify the change, CMS proposes adding the phrase "each provider's cultural and linguistic capabilities, including languages (including

American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office" to § 422.111(b)(3)(i).

CMS also proposes requiring organizations to identify providers in their directories who offer medications for opioid use disorder (MOUD). Specifically, the agency proposes including the new regulatory requirement at § 422.111(b)(3)(i) by adding the phrase "notations for MOUD-Waivered Providers as defined in § 422.116(b)(1)(xxx) who are listed on the Substance Abuse and Mental Health Services Administration's Buprenorphine Practitioner Locator" to paragraph (i). § 422.116(b)(1)(xxx) MOUD-Waivered Providers as "providers who are waived by the Substance Abuse and Mental Health Services Administration and the Drug Enforcement Agency to administer, dispense, or prescribe narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment for opioid use disorder in accordance with section 303(g)(2) of the Controlled Substances Act." The proposal would require organizations to identify these providers by including notations next to the providers' directory listings indicating that the providers are able to treat patients with MOUD.

Background/Rationale

Currently, CMS guidance includes these proposed provider directory requirements as best practices. The proposed change would mirror the Medicaid provider directory requirements at § 438.10(h)(1)(vii), improving the alignment of program requirements in Medicaid and Medicare. The proposed changes would advance the agency's health equity objectives outlined in the 2022 CMS Strategic Plan and provide enrollees with a fair opportunity to access health care services regardless of their preferred language. Research has demonstrated that language concordance between providers and patients is associated with better health outcomes and can improve the quality of care. CMS believes that the change would enhance the usability of provider directories, particularly for non-English speaking enrollees or those who use ASL.

CMS is proposing this new data element to ensure access to behavioral health services for MA enrollees. The proposed requirements would help MA enrollees with OUD to find providers who can help them receive MOUD treatment and move toward long-term recovery. The agency provides the rationale that it supports CMS' efforts related to behavioral health priorities.

Comments

CMS solicits general comment on both proposed requirements to the MA provider directories.

3. Digital Health Education for Medicare Advantage (MA) Enrollees Using Telehealth

Proposed Changes

CMS proposes to improve health equity in telehealth by adding requirements for MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered telehealth benefits. Specifically, CMS is proposing amending current continuity of care requirements for MA organizations offering coordinated care plans by adding the proposed requirement as a new paragraph (9) in §

422.112(b). The proposal would also be relevant for all types of covered telehealth benefits including supplemental telehealth benefits. To meet the requirements, MA organizations would need to introduce a digital health literacy screening program to identify current enrollees with low digital health literacy.

CMS proposes to amend § 422.112(a)(8) to better reflect the broad scope of potentially underserved populations and to emphasize how MA plans must ensure equitable access to services. To ensure that CMS can monitor the impact of the proposals, CMS is proposing to require MA organizations to make information about digital health literacy screening and digital health education programs available to CMS upon request.

Background/Rationale

CMS' rationale is that although the supply and demand of telehealth have grown in recent years, there are barriers to accessing telehealth, resulting in health inequitable access. Low digital health literacy can impact an individual's access to or quality of telehealth visits, and evidence shows that individuals with low digital health literacy tend to be older, lower income, less educated, and Black or Hispanic. CMS does not currently have requirements for MA organizations in digital health literacy. The proposed changes are also consistent with both E.O. 13985 and its first strategic pillar "Advance Equity" under the 2022 CMS Strategic Plan. CMS' proposals would enable the agency to monitor the impact of the proposed requirements and identify best practices for improving digital health literacy amongst MA enrollees.

Comments

CMS is specifically soliciting comment on whether to amend § 422.100 instead of § 422.112(b) to apply the requirement to all MA plans and not just coordinated care plans.

B. Behavioral Health in Medicare Advantage (MA) (section III.B, pgs 100-114)

1. Behavioral Health Specialties in Medicare Advantage (MA) Networks

Proposed Changes

CMS proposes to add three provider specialty types to the § 422.116(b)(1) list subject to network adequacy evaluations:

- Clinical psychology (as defined in § 410.71(d)),
- Clinical social work (as defined in section 1861(hh) of the Social Security Act),
- Prescribers of Medication for Opioid Use Disorder, which includes:
    - Opioid Treatment Programs (as defined in Section 1861(jjj)(2) of the Social Security Act), and
    - Providers with a waiver under section 3030(g)(2) of the Controlled Substances Act.

CMS proposes the following maximum time and distance standards and minimum ratios for each new provider specialty types:

Maximum Time and Distance Standards:

Provider/ Facility type	Large Metro		Metro		Micro		Rural		CEAC	
	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance
Clinical Psychology	20	10	45	30	60	45	75	60	145	130
Clinical Social Work	20	10	30	20	50	35	75	60	125	110
Prescribers of Medication for Opioid Use Disorder (including MOUD Waivered Providers and/or OTPs)	20	10	30	20	50	35	75	60	110	100

Minimum Ratios:

Minimum Ratio	Large Metro	Metro	Micro	Rural	CEAC
Clinical Psychology	0.15	0.15	0.13	0.13	0.13
Clinical Social Work	0.25	0.25	0.22	0.22	0.22
Prescribers of Medication for Opioid Use Disorder (including MOUD Waivered Providers and/or OTPs)	0.03	0.03	0.03	0.03	0.03

CMS is proposing to amend § 422.112(a)(1)(i) to include the requirement for MA plans to include providers that specialize in behavioral health services in among those listed with existing access to services standards.

CMS is proposing to add all of the new behavioral health specialty types to the § 422.116(d)(5) list of provider types eligible to receive a 10% credit if the MA plan's network includes one or more telehealth benefits, as defined in § 422.135 for covered services.

Background/Rationale

The Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program" final rule published on June 2, 2020 (85 FR 33796), codified, at § 422.116(b), the list of 27 provider specialty types and 13 facility specialty types subject to CMS network adequacy standards. Currently, MA organizations must meet network adequacy requirements for two behavioral health specialty types: psychiatry and inpatient psychiatric facility services.

CMS received many responses to the January 2022 RFI stressing the importance of network adequacy and access to behavioral health providers, particularly those that provide outpatient or substance use disorder (SUD) services, through MA plans. CMS also highlighted Medicare FFS data showing that clinical social workers and clinical psychologists were among the top outpatient behavioral health

provider specialty types, and that less than 20% of Medicare beneficiaries with an opioid use disorder receive treatment, generally provided through an OTP or physician with a SAMHSA waiver.

CMS calculated the time and distance standards by mapping practices (via NPPES NPI file) to Medicare beneficiary location from enrollment data, and using average driving speeds, the same process that is used for existing specialty types.

Similarly, the minimum ratio is calculated according to the process outlined in § 422.116(e)(2)(i) and (e)(3); by dividing the number of beneficiaries required to cover by 1,000, as informed by Medicare FFS data and other workforce and population data sources and rounding to the next whole number. For the proposed behavioral health provider types, CMS also incorporated projected need and available workforce data to estimate the potential supply and demand of the behavioral health services from Medicare FFS claims, Medicare-enrolled providers, HRSA Health Workforce Simulation Model, and SAMHSA's list of physicians with OUD waivers.

CMS has previously received stakeholder comments emphasizing the importance of access to telehealth for behavioral health services. Further, they noted that of 2020 Medicare FFS claims with a primary behavioral health diagnosis, telehealth was the second more common place of service.

Comments

CMS seeks comments on all of these proposed changes.

2. Behavioral Health Services in Medicare Advantage (MA)

Proposed Changes

CMS is proposing to expand the list of service types MA organizations must ensure continuity of care and care coordination for beneficiaries by adding "behavioral health services" after "community-based services" at § 422.112(b)(3).

CMS is proposing to clarify that the definition of "emergency medical condition" in § 422.113(b)(1)(i) applies to both physical and mental conditions, thereby prohibiting the use of prior authorization and guaranteeing MA coverage of emergency mental health conditions.

Background/Rationale

CMS believes the proposed changes would ensure that behavioral health services are included in MA organizations' care coordination programs for enrollees and ensure access to services. They note several situations in which beneficiaries may need assistance with finding another behavioral health provider, and that the information included in provider directories may not be sufficient to connect them to the services they are entitled to in a timely manner.

The current definition of an emergency medical condition under § 422.113(b)(1)(i) does not specify that the criteria may be applied to mental health conditions and may result in MA beneficiaries not receiving the coverage protections described in the section. Section 1852(d)(1)(E) of the Social Security Act has

been interpreted by CMS to include both physical and behavioral health conditions, so CMS believes this proposal clarifies this interpretation for MA organizations.

Comments

CMS solicits comments on both proposed changes.

C. Medicare Advantage (MA) Network Adequacy: Access to Services (section III.C, pgs 114-117)

Proposed Changes

CMS proposes to amend § 422.112(a)(1) and (a)(3) to more clearly state the scope of the MA organization's obligation to ensure adequate access to medically necessary covered benefits and reflect longstanding policy. Specifically, CMS requires MA organizations offering coordinated care plans to arrange for any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs.

CMS has not been made aware of any issues of MA organization non-compliance with this policy and, as such, believes that MA organizations have been complying with this longstanding guidance. Therefore, the proposed amendment to § 422.112 would not impose new information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements), and CMS has not provided burden estimates in the Collection of Information section of this proposed rule. In addition, this provision is not expected to have any economic impact on the Medicare Trust Fund.

Background/Rationale

Historically, CMS has interpreted MA statutory and regulatory requirements to mean that in the event an in-network provider or service is unavailable or inadequate to meet an enrollee's medical needs, the MA organization must arrange for any medically necessary covered benefit outside of the plan provider network at in-network cost sharing for the enrollee. Consequently, CMS believes that furnishing access out of network with higher cost sharing when the MA plan's network is inadequate or otherwise does not address the medically necessary benefit required by an enrollee is not consistent with section 1852(d)(1) of the Act.

Currently, the regulation text at § 422.112(a)(3) does not fully account for the scope of an MA organization's obligations when medically necessary benefits are only accessible out of network in two key ways. First, the regulation text refers to specialty care only, not all medically necessary covered benefits. Second, the aspect of maintaining in-network cost sharing when the MA organization arranges for the benefit outside of the network is not clearly stated in § 422.112(a)(3).

Comments

CMS solicits comment on this proposal, including on the accuracy of their assumptions regarding information collection requirements and regulatory impact.

D. Enrollee Notification Requirements for Medicare Advantage (MA) Contract Terminations (section III.D, pgs 117-129)

Proposed Changes

CMS proposes to remove "good faith effort" beneficiary notification requirements for no-cause provider contract terminations and requiring MA organizations to provide notice to beneficiaries at least 30 days before the termination effective date, as required under § 422.111(e).

CMS is proposing to add behavioral health providers to the notification requirements § 422.111(e) and adding new requirements for notifications related to behavioral health and primary care providers:

- § 422.111 (e)(1)(i) would create a new requirement for MA organizations to provide both written and telephonic notice to beneficiaries for terminations that involve their primary care or behavioral health providers.
- § 422.111 (e)(1)(ii) would require MA organizations to provide enrollees with telephonic notice of contract terminations that involve a primary care or behavioral health provider at least 45 days before the effective date. The first attempt to provide telephonic notice must also be provided at least 45 days in advance, and MA organizations will be required to continue attempting to reach the enrollee a reasonable number of times.
- § 422.111 (e)(1)(iii) would require that notice be sent to all enrollees who have ever been patients of the terminating primary care or behavioral health provider.

CMS is proposing to codify the § 422.111(e)(2)(iii) definition of enrollees who are patients seen on a regular basis by the provider whose contract is terminating as enrollees who are assigned to, currently receiving care from, or have received care within the past three months from a provider or facility being terminated, also called "affected enrollees".

CMS is proposing to clarify the existing notification requirements for all other specialty types (besides primary care and behavioral health providers) in a new section § 422.111(e)(2). For these provider types, notifications will continue to be required to be provided at least 30 days in advance, through written notice only, and only to affected enrollees.

CMS is proposing to codify the best practices for provider termination notices at § 422.2267(e)(12) by adding:

- § 422.2267(e)(12)(ii)(A) requires informing the enrollee the provider will no longer be in network, and the date when they will leave.
- § 422.2267(e)(12)(ii)(B) requires including name and phone numbers of in-network providers the enrollee may access for continued care, and optionally include information on how to access the current provider directory online and by direct mail.
- § 422.2267(e)(12)(ii)(C) requires including information on how the enrollee may request a continuation of ongoing medical treatment or therapies with their current provider.
- § 422.2267(e)(12)(ii)(D) requires including information about the Annual Coordinated Election Period (AEP) and the MA Open Election Period (MA-OEP), explain that impacted enrollees may

contact 1-800-MEDICARE to request assistance is switching to other coverage or consideration for a special election period (SEP) based on the existing parameters in § 422.62(b)(26).

- § 422.2267(e)(12)(ii)(E) requires including the MA organization's call center telephone number, TTY number, and hours and days of operation.
- § 422.2267(e)(12)(iii) requires that telephonic notice of provider termination must relay the same information as the written notice, described above.

Background/Rationale

MA organizations and contracted providers are required by § 422.202(d)(4) to provide at least 60-day notice before terminating their contract without cause. Consequently, CMS believes the MA organization should be aware of the termination in time to provide the required notice to beneficiaries. For-cause terminations may occur with little or no advanced notice, so CMS will preserve the "good faith effort" flexibility to allow plans to notify beneficiaries of the change as they are able within the proposed timeline. CMS emphasizes that all MA organizations must provide beneficiaries with provider termination notices, so they can determine how to continue their care.

CMS notes that both primary care and behavioral health providers have ongoing provider/patient relationships. The mutual trust developed in these relationships is essential for promoting positive health outcomes, and there are potentially significant negative consequences for ending a patient's relationship with their primary care or behavioral health provider. Therefore, CMS believes that continuity of care is essential, and warrants additional protections to ensure they can make informed decisions about the future of their care.

CMS defined affected enrollees and best practices related to provider termination notices in section 110.1.2.3 of Chapter 4 of the MMCM in 2016, and they believe most MA organizations have adopted and routinely utilize this definition already. CMS also noted that MA organizations are responsible for accurately providing the required information to beneficiaries in the order CMS specifies, but do not need to follow model material exactly. CMS notes they intend to create a model document, following these requirements if this proposal is finalized. CMS also expects to continue current oversight of MA organizations' compliance with the regulation, such as approval, modification, or discontinuation of communication of materials.

Comments

CMS solicits comments from MA organizations on their experiences in providing enrollees with telephonic notice of primary care and behavioral health provider contract terminations, as well as how many contact attempts are reasonable for organizations to undertake.

CMS also solicits comments on the proposal to consider enrollees impacted by provider contract terminations to be experiencing an exceptional condition and eligible for a SEP under § 422.62(b)(26). They also seek feedback on alternative approaches, such as the adoption of a new SEP for this type of provider contract termination with explicit standards.

Additionally, CMS solicits feedback generally on the proposed changes to the enrollee notification requirements and content requirements about provider contract terminations.

E. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (section III.E, pgs 129-164)

1. Coverage Criteria for Basic Benefits

Proposed Changes

CMS proposes to remove the reference to "original Medicare manuals and instructions" and clarify that MA organizations must comply with general coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans, when making coverage decisions.

CMS also proposes that MA organizations must make medical necessity determinations based on coverage and benefit criteria and may not deny coverage for basic benefits based on coverage criteria. This means that when an MA organization is making a coverage determination on a Medicare covered item or service, the MA organization cannot deny coverage of the item or service based on internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies.

CMS proposes that when coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD, an MA plan may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available. In creating these internal policies, CMS proposes that MA organizations must follow similar rules that CMS and MACs must follow when creating NCDs or LCDs. Specifically, MA organizations must provide publicly available information that discusses the factors the MA organization considered in making coverage criteria for medical necessity determinations.

CMS proposes that MA organizations must follow a somewhat similar process when creating internal plan coverage criteria by providing a publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations, a list of the sources of such evidence, and include an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. CMS proposes a requirement that an MA organization's internal clinical criteria must be based on current evidence in widely used treatment guidelines or clinical literature.

CMS proposes that MA organizations' medical directors be involved in ensuring the clinical accuracy of medical necessity decisions where appropriate.

CMS proposes a narrower policy that permits MA organizations to continue to choose who provides Part A and Part B benefits through the creation of their contracted networks, but limits MA organizations' ability to limit when and how covered benefits are furnished when Traditional Medicare will cover different provider types or settings. MA organizations may not deny authorization based on internal MA organization clinical criteria that go beyond Medicare coverage rules or addressing standards for when MA internal coverage rules are permissible.

CMS proposes to provide that a coordinated care plan may use prior authorization processes for basic benefits and supplemental benefits only when the prior authorization processes are consistent. They are also proposing to limit the use of prior authorization processes only to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service, to ensure basic benefits are medically necessary, or to ensure that the furnishing of supplemental benefits is clinically appropriate.

Background/Rationale

CMS states their proposal is designed to prohibit MA organizations from limiting or denying coverage when the item or service would be covered under Traditional Medicare and continue the existing policies that permit MA organizations to cover items and services more broadly than original Medicare by using supplemental benefits. It clarifies that statutes and regulations that set the scope of coverage in the Traditional Medicare program are applicable to MA organizations in setting the scope of basic benefits that must be covered by MA plans.

CMS notes that it is their interpretation that certain utilization management processes, such as clinical treatment guidelines that require another item or service be furnished prior to receiving the requested item or service, would violate the proposed requirements and thus, would be prohibited under this proposal unless it is specified within the applicable NCD or LCD or Medicare statute or regulation.

CMS recognizes that there are some Part A or Part B benefits that do not have applicable Medicare NCDs, LCDs, or specific traditional Medicare coverage criteria in regulation for MA plans to follow when making medical necessity determinations.

CMS states that providing a publicly accessible summary of the evidence, a list of the sources of evidence, and an explanation of the rationale for the internal coverage criteria will protect beneficiaries by ensuring that coverage criteria are rational and supportable by current, widely used treatment guidelines and clinical literature. This requirement provides further transparency into MA organizations' medical necessity decision making and is consistent with CMS' expectation that MA organizations develop and use coverage criteria in a way that aligns with Traditional Medicare.

CMS notes that appropriate prior authorization should only be used to confirm the presence of diagnoses or other medical criteria and to ensure that the furnishing of a service or benefit is medically necessary or, for supplemental benefits, clinically appropriate and should not function to delay or discourage care.

Comments

CMS solicits comment about the specificity of the coverage conditions in Traditional Medicare regulations and whether they should consider, and under what circumstances, allowing MA organizations to have internal coverage criteria in addition to requirements in current regulations.

CMS solicits comment on the definition of widely used treatment guidelines and clinical literature that would justify internal coverage criteria used in the absence of NCDs, LCDs, or Traditional Medicare statutes or regulations along with the other requirements proposed.

CMS solicits comments on when it would be appropriate for the MA organization's medical director to be involved, in light of how statute requires the medical director to be responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity.

CMS is unable to quantify or predict how many MA organizations are currently operating in a manner that conforms with their proposal. They are soliciting comments from stakeholders on the full scope of this burden.

2. Continuity of Care

Proposed Changes

CMS proposes that MA coordinated care plans must have, as part of their arrangements with contracted providers, policies for using prior authorization for basic benefits. These prior authorization policies must reflect that all approved prior authorizations must be valid for the duration of the entire approved prescribed or ordered course of treatment or service.

CMS proposes that MA organizations offering coordinated care plans must have, as part of their arrangements with contracted providers, policies for using prior authorization that provide for a minimum 90-day transition period for any ongoing course(s) of treatment when an enrollee has enrolled in an MA coordinated care plan after starting a course of treatment, even if the course of treatment was for a service that commenced with an out-of-network provider.

Background/Rationale

CMS expects any active course of treatment to be documented in the enrollee's medical records so that the enrollee, provider, and MA plan can track an active course of treatment and avoid disputes over the scope of this proposed new requirement.

CMS notes their experience with oversight and monitoring of the Part D program indicates that the transition policy has proved effective in ensuring continuity of care for Part D beneficiaries. Based on this experience, they believe it is appropriate to incorporate a similar beneficiary protection and coverage requirement in the MA program.

Comments

CMS solicits comments on whether the prior authorization should be required to be valid for the duration of the prescribed order or ordered course of treatment provided that the criteria are met.

CMS solicits comments on alternative timeframes for transition periods of ongoing treatment, including the clinical and economic justification for alternative proposals.

3. Mandate Annual Review of Utilization Management (UM) Policies by a UM Committee

Proposed Changes

CMS proposes to require MA organizations to establish a Utilization Management (UM) committee to operate similar to a Pharmacy and Therapeutics, or P&T, committee. An MA organization that uses UM policies, such as prior authorization, must establish a UM committee that is led by an MA plan's medical director.

CMS proposes that an MA plan may not use any UM policies for basic or supplemental benefits on or after January 1, 2024, unless those policies and procedures have been reviewed and approved by the UM committee.

CMS proposes the committee responsibilities, which would include that the UM committee, at least annually, review the policies and procedures for all utilization management, including prior authorization, used by the MA plan. The review must consider:

- The services to which the utilization management applies
- Coverage decisions and guidelines for original Medicare, including NCDs, LCDs, and
- laws
- Relevant current clinical guidelines.

CMS proposes though the committee approve only utilization management policies and procedures that:

- Use or impose coverage criteria that comply with the requirements and standards
- Comply with requirements and standards
- Apply and rely on medical necessity criteria that comply

CMS proposes that the committee must revise UM policies and procedures as necessary, and at least annually, to comply with the standards in the regulation, including removing requirements for UM for services and items that no longer warrant UM so that UM policies and procedures remain in compliance with current clinical guidelines.

CMS proposes that the UM committee must include a majority of members who are practicing physicians; include at least one practicing physician who is independent and free of conflict relative to the MA organization and MA plan; include at least one practicing physician who is an expert regarding care of elderly or disabled individuals; and include members representing various clinical specialties (for example, primary care, behavioral health) to ensure that a wide range conditions are adequately considered in the development of the MA plan's utilization management policies.

CMS proposes that the UM committee must clearly articulate and document processes to determine that the requirements have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts. They also propose that the UM committee must document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request.

Background/Rationale

CMS notes that these proposals would ensure that plan policies and procedures meet the standards set forth in this proposed rule beginning with the contract year after the finalization of this proposed rule. They anticipate that there will be sufficient time between their issuance of a final rule and January 1, 2024, for each MA organization to engage in the necessary administrative activity to establish the UM committee and have its existing UM policies reviewed and, if they meet the standards in this proposed regulation, approved for use.

CMS states that mandating annual review of utilization management policies using these standards will help ensure that medically necessary services are accessible to all enrollees.

CMS notes they received feedback from the provider community that UM policies for specific services or items are often not reviewed by providers with the expertise appropriate for the service.

CMS believes these proposals are designed to require review and approval of utilization management policies, including utilization management policies that use or impose coverage criteria, to ensure that these policies and procedures are medically appropriate, consistent with Medicare coverage rules, and do not negatively impact access to medically necessary services.

Comments

CMS solicits comment on whether they should also require the UM committee to ensure that the UM policies and procedures are developed in consultation with contracted providers; whether the UM committee should ensure that MA organization communicates information about practice guidelines and UM policies to providers and, when appropriate, to enrollees; and whether the UM committee should have an ongoing or active oversight role in ensuring that decisions made by an MA plan throughout the year are consistent with the final, approved practice guidelines and UM policies.

CMS solicits comments on the extent to which the proposed regulation text sufficiently and clearly establishes the standards and requirements discussed in the proposed rule.

CMS solicits comments on whether to require the UM Committee to review all internal coverage criteria used by the MA plan.

CMS requests comments on recommendations for other types of providers, practitioners, or other health care professionals that should also be included on the UM committee and whether additional standards for composition of the UM committee are necessary with regard to expertise, freedom of conflicts of interest, or representation by an enrollee representative.

CMS solicits comment on whether they should include a requirement, that when the proposed UM committee reviews UM policies applicable to an item or service, that the review must be conducted with the participation of at least one UM committee member who has expertise in the use or medical need for that specific item or service.

CMS requests comments on whether an MA plan should be permitted to utilize the proposed UM committee to also meet the existing P&T committee requirements, provided that elements and requirements of all applicable regulations governing the committees and their functions are met.

CMS also solicits comment on whether to explicitly permit an MA organization, or the parent organization of one or more MA organizations, to use one UM committee to serve multiple MA plans, including whether that should be limited to MA plans that are offered under the same contract.

4. Additional Areas for Consideration and Comment

Comments

CMS has received complaints about potential quality of care issues regarding early termination of services in post-acute care settings by MA organizations. They are soliciting feedback from stakeholders that have information related to this situation, and investigating internally, in order to get a more thorough understanding on the issue.

CMS is soliciting comments on potential changes they could make to existing rules or in adopting new rules to better manage incentives between MA organizations and post-acute care providers to deliver the best possible care for Medicare beneficiaries. Some topics include:

- How MA organizations preauthorize treatment in discrete increments and the extent to which CMS' proposals may address or limit these practices.
- Whether enrollees should have additional time to file appeals or be able to file late appeals to the QIO regarding terminations of services.
- Whether enrollees should receive information from the MA plan regarding the basis for termination of services (for example, the clinical rationale for termination of services) as part of the termination notice and without the enrollee having to request an appeal to the QIO.
- When coverage is reinstated based on a QIO decision, whether the enrollee should have more than the 2-day period from the date of a new termination of services notice before coverage can be terminated again by the MA organization, taking into account any medical necessity determinations made by the QIO.

CMS solicits comments on whether and how existing requirements may be adjusted to better account for these medical review and system errors. In addition, they solicit comment whether they should include a provision for the UM committee to develop, implement and oversee activities by MA organizations related to utilization policies and procedures.

F. Request for Comment on the Rewards and Incentives Program Regulations for Part C Enrollees (section III.F, pgs 165-167)

Proposed Changes

CMS is not proposing a new provision solicits comment on a potential revision to regulation governing MA Reward and Incentive (R&I) programs.

Background/Rationale

Through R&I programs, MA plans have the option to offer enrollees rewards in exchange for participation in health-related activities. Based on this Sections 1851(h)(4) and 1854(d)(1) of the Act, CMS prohibits a reward item consisting of cash or cash equivalents at 42 CFR 422.134(d)(2)(i). In 2021, CMS issued a final rule including a provision (§ 422.134(d)(3)(ii)) permitting MA organization's R&I programs to offer gift cards that can only be redeemed at specific retailers or category of items. In December 2020, the OIG issued a rule (85 FR 77684) that explained that cash equivalents include gift cards offered by large retailers or online vendors that sell a wide variety of items (e.g., big-box stores). CMS has received inquiries from stakeholders requesting a definition of 'big-box stores' and clarification on the types of stores that would not be permissible under regulation, and, as a result, CMS wanted to solicit stakeholder comment.

Comments

CMS is soliciting comment on whether it should

- further clarify the definition of "cash equivalent" as that term is used in § 422.134
- revise its MA R&I program regulation to include parameters for permissible gift cards
- issue more specific guidance on permissible gift card reward items

G. Section 1876 Cost Contract Plans and Cost-Sharing for the COVID-19 Vaccine and its Administration (section III.G, pgs 167-169)

Proposed Changes

CMS proposes to require 1876 cost plans, coordinated care plans with features like MA plans but separate statutory authority, to cover the COVID–19 vaccine and its administration without cost sharing as described in section 1861(s)(10)(A) of the Act. Specifically, CMS is proposing to replace the provision adopted at § 417.454(e)(4) in the November 2020 interim final rule (Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency) with the new proposed requirement.

Background/Rationale

The Coronavirus Aid, Relief, and Economic Security (CARES) Act revised section 1861(s)(10)(A) of the Act to require COVID-19 vaccine and its administration at zero cost-sharing for Traditional Medicare and MA enrollees. In November 2020, CMS issued an interim final rule requiring cost plans to cover COVID-19 vaccine and its administration without cost sharing through the end of the pandemic public health emergency (PHE). The CARES act requirement did not include an end date. CMS states that requiring cost plans to comply the same cost-sharing protections as in Traditional Medicare and MA would ensure equitable access to care and remove cost barriers for beneficiaries of cost plans to receive the COVID-19 vaccine.

Comments

CMS solicits general comment on this proposal.

H. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional with Expertise in the Field of Medicine Appropriate to the Requested Service and Technical Correction to Effectuation Requirements for Standard Payment Reconsiderations (section III.H, pgs 169-174)

Proposed Changes

CMS proposes to modify the requirement with respect to the expertise of the physician or other appropriate health care professional who must review an organization determination if the MA organization or applicable integrated plan (AIP) expects to issue an adverse decision based on the initial review of the request.

CMS is proposing that the existing regulation text with the more general requirement that the physician or other appropriate health care professional have sufficient medical and other expertise be replaced by a requirement linking the requisite expertise of the reviewer to the specific service that is the subject of the organization determination request. The physician or other appropriate health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider.

Background/Rationale

CMS notes this proposal is based on general feedback CMS has received from provider associations regarding the use of prior authorization (PA) by MA organizations and the submission and review of clinical documentation to support a request for coverage of a service subject to PA.

CMS notes the standard of requiring a reviewing physician's expertise to be appropriate for the specific service at issue is long-standing policy with respect to plan reconsiderations and they believe it is appropriate as well as practical to adopt this standard for the review of organization determinations by physicians and other appropriate health professionals. Specifically, this proposed approach would strengthen clinical review in the organization determination process, while continuing to afford plans maximum flexibility in leveraging reviewer resources.

Comments

CMS welcomes comments on these proposals.

I. Part C and Part D Midyear Benefit Changes and Part D Incorrect Collections of Premiums and Cost Sharing (section III.M, pgs 185-201)

1. Medicare Advantage Prohibition on Midyear Benefit Changes

Proposed Changes

CMS proposes to use the term "midyear benefit changes" in regulatory text as opposed to midyear benefit enhancements (MYBEs) for MA and Part D plans. CMS also proposes to add regulatory text prohibiting changes to non-drug benefits, premiums, and cost sharing by an MA organization starting after plans are permitted to begin marketing prospective contract year offerings on October 1 of each year for the following contract year and until the end of the applicable contract year.

Background/Rationale

CMS' rationale is that the term "midyear benefit changes" would better clarify that all changes (enhancements or reductions) to non-prescription drug benefits, premiums, and cost sharing are prohibited for MA plans. Prohibition on these changes has been a longstanding CMS policy. CMS explains that allowing MYBCs undermines the integrity of the bidding process as it allows MA organizations alter their benefit packages after the bidding process is complete and misrepresent their actual costs. The proposed time frame prohibiting changes to benefits enables MA organizations to make changes during the bidding process when permitted by CMS to remain in compliance with the requirements set forth at § 422.254(b), while also maintaining the integrity of the bidding process. CMS states that this policy should be codified because MYBC's can also violate the uniformity requirements set forth at § 422.100(d)(ii), which requires that MA plans offer their plan to all beneficiaries in a service area at a uniform premium, with uniform benefits and level of cost sharing throughout the plan's service area.

Comments

CMS solicits general comment on this proposal.

2. Part D Prohibition on Midyear Benefit Changes

Proposed Changes

Similarly, CMS proposes to codify into regulation its longstanding policy at new paragraph § 423.265(b)(5) which would prohibit Part D sponsors from making midyear changes to the benefit design or waiving or reducing premiums, bid-level cost sharing, or cost sharing for some or all of a Part D plan's enrollees starting after plans are permitted to begin marketing prospective contract year offerings on October 1 of each year for the following contract year and until the end of the applicable contract year. Part D plans would have to provide the benefits described in its CMS-approved plan benefit package (PBP) for the contract year without modification, except where a modification in benefits is required by law.

Background/Rationale

CMS states that, since the beginning of the part D program, it has declined to permit Part D sponsors from changing their benefit designs or waive or reduce premiums, "bid-level" cost sharing (for example, or cost sharing once plans are permitted to market for the following contract year on the grounds that such activities would be inconsistent with the CMS-approved Bid. Even if the plan changed the benefit midyear for all the plan's enrollees, this change would still violate the uniform benefits provision

according to CMS because some of the plan's enrollees would still have paid for benefits prior to the change.

Comments

CMS is soliciting general comment on this proposal.

3. Failure to Collect and Incorrect Collections of Part D Premiums and Cost Sharing Amounts Proposed Changes

CMS proposes to amend § 423.293(a)(4) by replacing "Medicare Advantage organization" with "Part D sponsor" to be consistent terminology used in the rest of § 423.293.

CMS also proposes to add new § 423.294 to codify the below requirements related to failure to collect, and incorrect collections of enrollee premiums and cost sharing for Part D sponsors:

- Specify in proposed § 423.294(a) that Part D sponsors' incorrect collection of or failure to collect premiums and cost sharing violates the uniform benefit provisions at § 423.104(b);
- At proposed § 423.294(b)(2) and (4) and § 423.294(c)(2), respectively, clarify that the 3-year lookback period established in § 423.466(b) for coordination of benefits applies to retroactive claim or premium adjustments that result in refunds and recoveries;
- At proposed § 423.294(b)(2) and (4) and § 423.294(c)(2), respectively, clarify that the 45-day timeframe in § 423.466(a) applies to the processing of refunds and recoveries for both claims and premium adjustments;
- At proposed § 423.294(b)(3), specify the refund methods for amounts incorrectly collected and other amounts due; and
- At proposed § 423.294(b) and (c)(1), specify a de minimis amount, calculated per Prescription Drug Event (PDE) transaction or, for premium adjustments, per month, for these refunds and recoveries.

Background/Rationale

CMS states that although the MA program adopted language at § 422.270 to address incorrect collections of premiums and cost sharing in the January 2005 MA final rule, the regulations in Part 423 do not address the same requirements in Part D. The proposed changes would align Part D requirements with the existing MA requirements for incorrect collections. CMS states that the proposed changes would go further by establishing new requirements regarding failure to collect premiums and cost sharing amounts.

CMS justifies the proposed 3-year lookback period by explaining that there is currently no limit in the regulation for how far back retroactive premium adjustments or claims adjustments unrelated to coordination of benefits must be made. The proposed change would align the timeframe established in § 423.466(b) for coordination of benefits with the timeframe for premium adjustments and claims adjustments unrelated to coordination of benefits. CMS states that 3-year lookback period and de minimis

amount would remove administrative burden on plan sponsors and the government, particularly when the refunded amount is less than the postage required to provide a refund notice.

Comments

CMS is soliciting general comments on these proposals.

CMS is also specifically soliciting comment on adding new requirements (adding a de minimis amount and lookback period) for MAOs regarding failure to collect premiums and cost sharing in § 422.270 to align with the proposed changes for Part D sponsors described in this section of the proposed rule.

J. Updating Translation Standards for Required Materials and Content (section III.O, pgs 207-216)

Proposed Changes

CMS proposes to require MA organizations and Part D sponsors to provide materials to enrollees on a standing basis in any non-English languages that is the primary language of at least 5 percent of the individuals in a plan benefit package service area and in any accessible formats using auxiliary aids and services upon receiving a request for the materials in another language or using auxiliary aids and services or otherwise learning of the enrollee's preferred language or need for an accessible format using auxiliary aids and services.

CMS also proposes to extend this requirement to the individualized plans of care described in § 422.101(f)(1)(ii) for SNP enrollees. The proposed requirement would allow enrollees to avoid having to submit a request to receive required materials in a preferred language and/or using auxiliary aids and services each time the MA or Part D plan distributes a required material.

Lastly, CMS is proposing to require FIDE SNPs, HIDE SNPs, and Applicable Integrated Plans to Translate Materials into the Medicare Translation Standard Plus Additional Medicaid Language.

Background/Rationale

The U.S. Census Bureau's 2019 American Community Survey (ACS) 1-year estimates show that 12.2 percent of individuals 65 years of age and older speak a language other than English in the home. Nearly 8 percent of Medicare beneficiaries are individuals with limited English proficiency, many of whom need an interpreter or other language assistance to communicate effectively. The U.S. Census Bureau's 2019 American Community Survey 1 year estimate also finds that 2.3 percent of the population is blind or low vision and 3.6 percent are deaf or have hearing loss, with 13.7 percent of adults over 65 reporting hearing loss or deafness, and 6 percent of adults over age 65 reporting blindness or low-vision. Communication and language barriers are associated with decreased quality of care and poorer health outcomes. In addition, individuals with limited English proficiency are less likely to have routine health visits, more likely to defer needed health care, and more likely to leave the hospital against medical advice. Effective communication is critical to providing high-quality care. Reliance on unqualified individuals to interpret medical information can lead to misunderstandings, poor outcomes, or even death.

Comments

CMS understand their proposal would require some FIDE SNPs, HIDE SNPs, and AIPs to translate the Medicare materials listed in §§ 422.2267(e) and 423.2267(e) into additional languages. CMS believes that the benefit gained by the ability for more enrollees to receive all materials in their preferred language outweighs this burden. As a result, CMS welcomes comments on their proposal and the potential alternatives they are considering.

K. Medicare Advantage (MA) and Part D Marketing (section III.P, pgs 216-255)

Proposed Changes

CMS proposes several changes to the Medicare Advantage (MA) and Part D Marketing materials to better protect Medicare beneficiaries, their privacy rights, and their personal data from bad actors. Proposed changes would be made to Subpart V of both 422 and 423 regulations and include the following:

- Prohibit all superlatives unless substantiating supporting data or documentation is also provided with the material. This proposal would apply to all superlatives, including those used in logos and taglines.
- Add a requirement that the supportive documentation and/or data be based on current data. CMS' proposed regulation text requires that the supportive documentation or data must reflect data, reports, studies, or other documentation to have been published either in the existing contract year or the prior contract year.
- MA organizations and Part D sponsors may not engage in marketing that advertises benefits that are not available to beneficiaries in the service area where the marketing appears unless unavoidable in a local market.
- Prohibit marketing unless the names of the MA organizations or Part D sponsors that offer the benefits are being advertised or are clearly identified.
- Require website provider directories be searchable by all required elements (for example, name, phone number, address); add "effect on current coverage" to the Pre-enrollment Checklist (PECL), as well as require agents to discuss the PECL during an enrollment call.
- Request plans to list benefits at the beginning of the Summary of Benefits and in a specified order.
- Label the non-renewal notice as standardized rather than a model, consistent with CMS' guidance instructions; limit the requirement to record calls between third-party marketing organizations (TPMOs) and beneficiaries to marketing (sales) and enrollment calls
- Clarify that contacting a beneficiary at his or her home is door-to-door solicitation unless an appointment at the beneficiary's home at the applicable date and time was previously scheduled.
- Prohibit marketing of benefits in a service area where those benefits are not available.
- Prohibit MA organizations and Part D sponsors from including information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary.

- Require each MA organization and Part D sponsor to provide the opt-out information to all its enrollees, regardless of plan intention to contact, at least annually in writing, instead of just one time.
- Reinstate the prohibition on accepting SOA cards or the collection of beneficiary contact information at educational events.
- Prohibit marketing events from taking place within 12 hours of the educational event in the same location.
- Codify previous marketing (MCMG) guidance by prohibiting personal marketing appointments from taking place until after 48 hours have passed since the time the SOA was completed by the beneficiary.
- Add "At least 48 hours" before the word "Prior" to §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) to read, "At least 48 hours prior to the personal marketing appointment beginning, the MA plan (or agent or broker) must agree upon and record the Scope of Appointment with the beneficiaries."
- Limit the validity of the SOAs and BRCs to six months from the beneficiary's signature date or the beneficiary's request for more information.
- Require TPMOs to list or mention all the MA organizations or Part D sponsors that they sell.
- Modify the pre-enrollment checklist (PECL) requirements, including adding new paragraphs at §§ 422.2267(e)(4)(viii) and 423.2267(e)(4)(viii), to add "Effect on current coverage" to the list of references currently provided within §§ 422.2267(e)(4)(i) – (vii) and 423.2267(e)(4)(i) – (vii).
- Require that plans review the PECL with the prospective enrollee during telephonic enrollments.
- Require a Summary of Benefits medical benefits be listed in the top half of the first page and in the order currently listed.
- Specify that the non-renewal notice is a "standardized communications material" so that it is clear these materials must be used without modifications except where noted.
- Require MA organizations and Part D sponsors to have an oversight plan that monitors agent/broker activities and reports agent/broker non-compliance to CMS.
- Modify the TPMO disclaimer to add State Health Insurance Programs (SHIPs) as an option for beneficiaries to obtain additional help.
- Require TPMOs to disclose the names of the MA organizations or Part D sponsors with which they contract.
- Clarify the requirement to record calls between TPMOs and beneficiaries such that the requirement includes virtual connections such as Zoom and Facetime.
- Prohibit TPMOs distributing beneficiary contact information to multiple entities, in any manner, including selling this information.

Background/Rationale

CMS believes the changes proposed to marketing materials strengthen CMS' ability to ensure MA and Part D marketing to beneficiaries is not misleading, inaccurate, or confusing—a top priority. Over the past few years, CMS has seen a significant increase in national marketing promoting benefits such as dental, vision, and money back on a beneficiary's Social Security check. While many of these benefits are available to many beneficiaries, they are not available in all service areas or to all Medicare beneficiaries in the amounts often advertised, which is misleading in CMS' opinion. CMS believes beneficiaries should only receive marketing that advertises benefits available to the beneficiary where the beneficiary resides.

Furthermore, Sections 1851 and 1852 of the Act — which addresses Medicare Part C—provide CMS with the authority to review marketing materials, develop marketing standards, and ensure that marketing materials are accurate and not misleading. These provisions also give CMS the authority to prohibit certain marketing activities and to add additional standards to the MA program that the Secretary determines are necessary for CMS to carry out the program. These statutory provisions help ensure Medicare beneficiaries are informed and protected when deciding to enroll in an MA or a Part D plan.

Comments

CMS is soliciting comments on these marketing and communications proposals and whether the proposed regulatory changes will sufficiently achieve the goals CMS has outlined of protecting beneficiaries.

L. Changes to an Approved Formulary (section III.Q, pgs 255-277)

1. Approval of Changes to Approved Formularies

Proposed Changes

CMS proposes to codify longstanding sub-regulatory guidance and terminology (such as classification of changes as either maintenance or non-maintenance) that specify when and how Part D sponsors obtain approval to make negative formulary changes and the enrollees to whom these changes would apply.

CMS proposes to permit Part D sponsors that meet certain requirements to immediately substitute a new interchangeable biological product for its corresponding reference product; a new unbranded biological product for its corresponding brand name biological product; or a new authorized generic for its corresponding brand name equivalent.

CMS proposes a third category of negative formulary changes defined as immediate negative formulary changes, which would exempt Part D sponsors making any immediate negative formulary changes (that is, all types of immediate substitutions and also market withdrawals) from providing transition supplies.

Background/Rationale

CMS realizes that implementing new developments may require formulary changes, and as such they support formulary changes that would allow enrollees to quickly benefit from the latest clinical research, new potentially lower-cost options, or possibly result in better health outcomes. For instance, § 423.120(b)(5)(iii) permits Part D sponsors to immediately remove drugs from their formularies when Food & Drug Administration (FDA) deems them unsafe and drug manufacturers remove them from the market. Similarly, § 423.120(b)(5)(iv) permits a Part D sponsor that adds an equivalent generic drug, and otherwise meets requirements, to immediately remove a brand name drug or change its preferred or tiered cost-sharing status.

Formulary stability is extremely important so that enrollees maintain access to the benefit they chose. Moving too often from one drug to a different drug for non-clinical reasons could also pose undue threats

to enrollee health. Indeed, the current regulation, § 423.120(b)(6), prohibits Part D sponsors from removing drugs or making changes to preferred or tiered cost-sharing status between open enrollment up through the first 60 days of the contract year except as specified. To balance the need for a rigorously vetted, stable formulary against the need to permit formulary changes that respond to developments such as new drug therapies and knowledge, CMS has, since the start of the program, permitted certain drug-specific changes to approved formularies.

2. Notice Requirements

Proposed Changes

CMS proposes in § 423.120(f)(1) to specify that only maintenance and non-maintenance negative formulary changes would require 30 days' advance notice to CMS and other specified entities, and in writing to affected enrollees.

CMS also proposes to retain at § 423.120(f)(1) an alternative option for Part D sponsors to provide an affected enrollee who requests a refill an approved month's supply of the Part D drug under the same terms as previously allowed, as well as written notice of the change.

CMS further proposes in § 423.120(f)(5)(i) to require Part D sponsors to provide advance general notice of other formulary changes to all current and prospective enrollees and other specified entities, in formulary and other applicable beneficiary communication materials advising that the formulary may change subject to CMS requirements; providing information about how to access the plan's online formulary and contact the plan; and stating that the written notice of any change made when provided would describe the specific drugs involved.

CMS proposes in § 423.120(f)(5)(i) to require Part D sponsors to provide advance general notice of other formulary changes to all current and prospective enrollees and other specified entities, in formulary and other applicable beneficiary communication materials advising that the formulary may change subject to CMS requirements; providing information about how to access the plan's online formulary and contact the plan; and stating that the written notice of any change made when provided would describe the specific drugs involved.

CMS proposes to update § 423.128(d)(2)(iii), to require online notice of negative formulary changes.

Consistent with their existing requirements for immediate generic substitutions, CMS proposes to require advance general notice of immediate substitutions and market withdrawals at § 423.120(f)(2), followed by written notice to affected enrollees as soon as possible under § 423.120(f)(3), but by no later than the end of the month following any month in which a change takes effect.

CMS also proposes at § 423.120(f)(4) to maintain their current requirements for the contents of the direct written notice but reorganize and renumber them for clarity.

CMS further proposes to revise the regulation at § 423.120(f)(4)(iv) to require information on appropriate alternative drugs that treat the same condition in the same or a lower cost-sharing tier in addition to retaining the long-standing requirement for information on expected cost-sharing.

CMS proposes that the contents of the written notice should be the same regardless of when the notice must be provided. That is, for notices of maintenance and non-maintenance changes, which must be provided to affected enrollees at least 30 days in advance per § 423.120(f)(1), and for notices of negative immediate changes, which can be provided after the changes take effect per § 423.120(f)(3), the content of the written notice would remain largely the same. Consistent with existing requirements, the notice proposed in § 423.120(f)(4) would contain the name of the affected drug, the type of negative formulary change being made and why, alternatives and expected cost sharing, and for immediate substitutions, how an affected enrollee can obtain a coverage determination or exception.

Background/Rationale

Section 1860D-4(b)(3)(E) of the Act requires Part D sponsors to provide "appropriate notice" to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists before removing a Part D drug from a formulary or changing the preferred or tiered cost-sharing status of such a drug. CMS implemented this statute in regulations issued at the start of the program in January 2005 Part D final rule and updated it in the April 2018 final rule. CMS considered various forms of advance notice to be appropriate in different situations, and in some cases their current regulations reflect these distinctions, such as in the case of permitted immediate generic substitutions, where advance general notice is appropriate so long as direct notice is provided later.

M. Part D Medication Therapy Management (MTM) Program (section III.R, pgs 278-296)

1. MTM Eligibility Criteria

Proposed Changes

CMS proposes to modify the main MTM eligibility criteria at § 423.153(d)(2). Specifically, the changes focus on one of the two main groups of eligible patients that Part D plans can choose to focus their MTM efforts on. That group is defined at § 423.153(d)(2)(i) and currently requires that in order to be eligible for MTM, the beneficiaries must have multiple chronic diseases (up to a maximum of three), take multiple Part D drugs (with a maximum amount of 8), *and* are likely to incur a certain amount of Part D drug costs (greater than or equal to $3,000 increased by an annual percentage). The other main group of beneficiaries eligible for MTM - "at risk" beneficiaries (generally understood to be individuals at risk of substance use disorders) – is defined at § 423.153(d)(2)(ii) and is left unchanged.

The specific changes CMS proposes for § 423.153(d)(2)(i) are:

- Require plan sponsors that choose to target beneficiaries with specific chronic diseases to target *all* core chronic disease identified by CMS. Previous MTM guidance from CMS identifies 9 core chronic diseases and required that plans that do not target all chronic disease should target at least

5 of the 9 core diseases. CMS proposes to codify the 9 core chronic diseases into regulation and add HIV AIDS to that list for a new total of 10. Plans would remain free to target beneficiaries beyond the core list *or* to include all diseases in their targeting criteria.

- Lower the maximum number of covered Part D drugs beneficiaries be prescribed to be eligible from 8 to 5 drugs. The changes make explicit that the definition of Part D drug for purposes of MTM eligibility includes all Part D maintenance drugs (as identified in "widely accepted, commercially or publicly available drug information databases" such as Medi-Span or First Databank). Plans would no longer be allowed to target only specific Part D drug classes.
- Revise the methodology for calculating cost threshold to be commensurate with the average annual cost of 5 generic drugs (thereby lowering the cost threshold criteria significantly). The current 2023 threshold is $4,935. The proposed methodology would result in a $1,004 threshold for 2024. CMS states the cost threshold requirement prevented 65-70% of otherwise-eligible MTM beneficiaries from participating.

Background/Rationale

CMS primary rationale behind these changes is to increase the amount of beneficiaries eligible for MTM services. It was CMS' original goal to achieve a 25% beneficiary participation rate in MTM. Currently, the program only serves 8% of all Part D beneficiaries. CMS states that it identified 6 million beneficiaries who have 3 or more chronic conditions and use 8 or more drugs that were nevertheless ineligible for MTM due to their Part D plans' chosen coverage. The proposed changes are intended to increase the total participation level to an estimated 23% by expanding the criteria themselves and mandating Part D plans focus on an increased subset of beneficiaries.

Comments

CMS seeks comment on all of these changes. Specifically:

- Comments on whether additional diseases should be added to the core chronic diseases at 423.153(d)(2)(iii), such as cancer (generally or specific diagnoses). CMS seeks feedback on the impact of including any additional diseases may have on whether MTM services furnished under Part D MTM program are effective for care management

2. <u>Define "unable to accept an offer to participate" in a comprehensive medication review (CMR)</u>

Proposed Changes

CMS is codifying at § 423.153(d)(1)(vii)(B)(2) longstanding guidance that a beneficiary who is "unable to accept the offer to participate" in the MTM program can receive the benefit of the required comprehensive medication review (CMR) by performing the CMR with the beneficiaries' prescriber, caregiver, or other authorized individuals.

CMS considers a person unable to accept an offer to participate only when the beneficiary is cognitively impaired and cannot make decisions regarding their medical needs.

Background/Rationale

Under the current MTM program, residents in long-term care facilities eligible for MTM services must still receive the comprehensive medication review (CMR) required under the program. However, CMS recognizes that many of these individuals may be "unable to accept the offer to participate" in the program due to the prevalence of higher-than-average cognitive and capacity-limiting conditions in LTC settings. As a result, CMS permits the CMR to be performed with an enrollee's prescriber, caregiver, or other authorized individual if the enrollee is "unable to accept the offer to participate."

NOTE: This exception is not intended to be limited to just LTC facilities / LTC eligible individuals. It merely originated from considerations of the unique circumstances of patients in those delivery settings.

Comments

CMS seeks general comments on these proposals.

3. **Requirement for in-person or synchronous telehealth consultation**

Proposed Changes

CMS is proposing to codify the requirement that CMR be performed either in person or via synchronous telehealth. This is in keeping with longstanding CMS guidance.

Background/Rationale

Since 2011, comprehensive medication reviews (CMRs – a required component of MTM) must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider. In subsequent guidance CMS specified these interactions must occur real-time. Since then, and particularly during the COVID-19 pandemic, telehealth technologies have significantly evolved. CMS feels the need to codify and update their position that CMRs must still be performed in real-time (precluding asynchronous telehealth).

Comments

CMS seeks general comments on these proposals.

4. **MTM Program Technical Changes**

Proposed Changes

CMS proposes to include definitions of "MTM program" in regulation and include several clarifying terminological changes.

Background/Rationale

CMS' proposal is for clarification purposes.

Comments

CMS seeks general comments on these proposals.

N. Adoption of Health IT Standards (section III.T, pgs 311-324)

1. Proposal to Adopt Standards for Use by HHS

Proposed Changes

CMS and HHS Office of the National Coordinator for Health Information Technology (ONC) are proposing to adopt the current versions of the National Council for Prescription Drug Programs (NCPDP) SCRIPT and Real-Time Prescription Benefit standards under a single Code of Federal Regulations location, which will be cross-referenced across HHS programs.

To implement this, the agencies are proposing several updates:

- At 45 CFR 170.205(b)(2) replace the reference to NCPDP SCRIPT standard version 10.6 with NCPDP SCRIPT standard version 2022011 and incorporate the updated version by reference at 45 CFR 170.299.
- At 45 CFR 170.205(b)(1) set January 1, 2025 expiration date for the adoption of NCPDP SCRIPT standard version 2017071; to allow both the 2017071 and 2022011 standards during this transition period. After the expiration date only the 2022011 version would be available.
- At 45 CFR 170.205(c)(1) adopt the NCPDP Real-Time Prescription Benefit standard version 12 and incorporate by reference at 45 CFR 170.299. Further, under § 423.160(b)(7)(i), Part D plan sponsors will be required to utilize standard version 12 to fulfill the requirements for real-time benefit tools, and ONC will consider proposals to require use of this standard in future rule-making.
- Create a uniform resource locator (URL) for the standards and implementation specifications incorporated by reference above. The URL will include summaries of the proposed standards, relevant implementation specifications, and how to access the standards (i.e. links, membership or subscription requirements, etc.)

Background/Rationale

CMS and ONC have coordinated and maintained aligned policies related to Medicare Part D electronic prescribing, medication history, and electronic prior authorization for prescriptions. Prescribers are generally required to adhere to CMS' standards while Promoting Interoperability programs must follow ONC's Health IT Certification program. However, this has required HHS to update requirements across multiple regulatory vehicles, with different regulatory cycles and timelines. HHS received feedback that this has led to regulatory discrepancies and confusion for stakeholders. HHS believes that adopting these standards under a single CFR location and then cross-referencing across programs will address stakeholders' concerns about regulatory alignment.

HHS is proposing to incorporate NCPDP SCRIPT standard version 2022011 because it contains enhancements to the drug utilization review/use alerts, support for electronic prior authorization function, electronic transfer of prescriptions between pharmacies, among others. HHS is proposing to remove

NCPDP SCRIPT standard version 10.6 because it is no longer required for use in either the Part D Program or ONC Health IT Certification Program.

The Consolidated Appropriations Act of 2021 required sponsors of Medicare prescription drug plans and MA organization to implement a real-time benefit tool designated by the Secretary, and specified that qualified electronic health records must be capable of including this tool. HHS believes that NCPDP Real-Time Prescription Benefit standard version 12 includes important requirements that plan sponsors must meet to fulfill the requirements for real-time benefit tools.

The Office of the Federal Register requires that agencies make materials incorporated by reference in CFR reasonably available to interested parties and summarize the materials in the preamble of the proposed rule. HHS proposes to provide the URLs to address this requirement.

Comments

CMS is requesting comments on this approach to adopting standards in a single location for HHS use, and the proposed expiration date for the 2017071 standard and transition period, and the adoption of the Real-Time Prescription Benefit standard version 12.

2. ONC Health IT Certification Program

Proposed Changes

CMS is not proposing new or revised certification criteria based on the proposed adoption of standards within this rulemaking. Rather, ONC is proposing to adopt new or revised standards, if finalized, to align with HHS in future rulemaking.

Background/Rationale

CMS believes this will not only support alignment across HHS, but will allow for continued input from interested parties on how this standard should be incorporated into specific certification criteria for certified health IT functionality prior to any such proposals in future rulemaking.

O. Limitation on PDP Contracts Held by Subsidiaries of the Same Parent (section III.V, pgs 326-332)

Proposed Changes

CMS proposes to bar approval of bids from PDP sponsors or their parent organizations (either directly or through subsidiaries) to offer individual market PBPs under more than one PDP contract per region at § 423.272(b)(5). Sponsors or parent organizations who do not meet this requirement currently or in the future after an acquisition would be allowed two bid cycles to consolidate their PDP contracts.

This would not apply to EGWP PBPs.

Background/Rationale

CMS believes this requirement aligns with previous efforts to promote meaningful competition and level playing field for Part D sponsors as well as meaningful choice among plans for beneficiaries. CMS

currently prohibits approving applications that would lead to sponsors or parent organizations from holding multiple PDP contracts in a single region under § 423.503(a)(3). CMS has also historically encouraged PDP sponsors that have merged or acquired other sponsors to consolidate their PDP contracts to only offer one contract per region, but not all sponsors have consolidated. However, parent organizations with multiple PDP contracts that applied prior to 2014, when the prohibition was codified, and those that purchased another PDP sponsor are exempt from this requirement.

CMS believes that two subsidiaries of the same parent organization, with shared leadership, staffing, and systems to administer Part D benefits are not truly competitors. Additionally, CMS is concerned that these sponsors are segmenting risk or manipulating Part D star ratings. Therefore, they do not believe it is fair to allow the operation of multiple PDP contracts to continue.

Comments

CMS solicits comments on these proposals generally. Additionally, they seek feedback on whether sponsors that acquire new PDP contracts should have longer transition periods than those currently operating multiple contracts, due to the added difficulty of navigating a concurrent acquisition and consolidation.

P. Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (section III.V, pgs 332-335)

Proposed Changes

CMS is proposing to update the standard for an identified overpayment for Medicare Part A and B under § 401.305(a)(2), and for Medicare Advantage and Part D at §§ 422.326(c) and 423.360(c) by incorporating by reference the False Claims Act (FCA) definition of "knowing" and "knowingly." As proposed, a provider, supplier, MA organization, or Part D sponsor has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.

Background/Rationale

The Patient Protection and Affordable Care Act established requirements for overpayments to be reported and returned and incorporates the definitions of "knowing" and "knowingly" established under the FCA. HHS has since published two rules defining when providers or suppliers under Medicare Parts A and B and MAO or Part D sponsors have determined or should have determined with "reasonable diligence" that they have received an overpayment. Subsequent litigation highlighted the discrepancy between the "reasonable diligence" and "knowing" and "knowingly" established in the FCA. CMS believes that the proposal would align the regulation with an agency rule, the FCA and the Affordable Care Act.

III. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit Program Policies

A. Amending the Definition of Severe or Disabling Chronic Condition; Defining C-SNPs and Plan Types; and Codifying List of Chronic Conditions (section IV.A, pgs 336-358)

1. Amending the Definition of Severe or Disabling Chronic Condition

Proposed Changes

CMS is proposing to amend the definition of severe or disabling chronic condition to match the definition within the Bipartisan Budget Act (BBA) of 2018 and to include the specific conditions identified. Under this new definition, an eligible individual must "have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits overall health or function, have a high risk of hospitalization or other adverse health outcomes, or require intensive care coordination."

CMS proposes to codify the list of chronic conditions created by the panel of clinical advisors, taking into account changes proposed by the panel, which include:

- Removing the term "limited,"
- Renaming "Chronic alcohol and other drug dependence" to "Chronic alcohol use disorder and other substance use disorders,"
- Adding dermatomyositis, psoriatic arthritis, and scleroderma to the Autoimmune disorders chronic condition category,
- Changing title of "Cancer, excluding pre-cancer conditions or in-situ status" to "Cancer,"
- Adding valvular heart disease to the cardiovascular disorders chronic condition category,
- Adding new chronic condition category, "Overweight, Obesity, and Metabolic Syndrome,"
- Adding new chronic condition category, "Chronic gastrointestinal disease" with the following conditions: chronic liver disease, non-alcoholic fatty liver disease (NAFLD), hepatitis B, hepatitis C, pancreatitis, irritable bowel syndrome, and inflammatory bowel disease,
- Renaming the "End Stage Renal Disease (ESRD) requiring dialysis" condition category to "Chronic kidney disease (CKD)" with the following conditions: CKD requiring dialysis/end stage renal disease (ESRD), and CKD not requiring dialysis,
- Adding Cystic Fibrosis and Chronic Obstructive Pulmonary Disease (COPD) to the Chronic lung disorders chronic condition category,
- Adding post-traumatic stress disorder (PTSD), eating disorders, and anxiety disorders to the Chronic and disabling mental health conditions category,
- Adding fibromyalgia, chronic fatigue syndrome, and spinal cord injuries to the Neurologic disorders conditions category,

- Adding post-organ transplantation care and immunodeficiency and immunosuppressive disorders as new chronic condition categories,
- Creating new chronic condition category "Conditions that may cause cognitive impairment," including the following sub-conditions: Alzheimer's disease, intellectual disabilities, developmental disabilities, traumatic brain injuries, disabling mental illness associated with cognitive impairment, and mild cognitive impairment,
- Creating new chronic condition category "Conditions that may cause similar functional challenges and require similar services," including the following sub-conditions: spinal cord injuries, paralysis, limb loss, stroke, arthritis, and chronic conditions that impair vision, hearings (deafness), taste, touch, and smell,
- Creating new chronic condition category "Conditions that require continued therapy services in order for individuals to maintain or retain functioning."

Background/Rationale

Currently, CMS provides guidance on severe or disabling chronic conditions that meet the current regulatory definition of the term in the Medicare Managed Care Manual (MMCM), which includes a list of SNP-specific chronic conditions. The panel of clinical experts recommend a number of changes to the list of chronic conditions that are currently used by CMS to approve C-SNPs. CMS' proposal considers the changes recommended by the panel, notably removing the term "limited," which ensures that unlisted chronic conditions will not disqualify enrollees from plan eligibility even if the unlisted or another listed condition is not the targeted condition that qualities the beneficiary for a specific C-SNP.

Regarding the three new chronic condition categories, CMS intends for SNPs to not address the needs of enrollees who share the same disease or chronic condition, but those diagnosed with different diseases and chronic conditions that share similar impacts on health and functionality.

Comments

CMS seeks comment specifically on the proposal to limit the regulatory definition of severe or disabling chronic condition. Also, CMS is seeking comment on the proposed list of chronic conditions recommended by the 2019 panel of clinical advisors, calling attention to proposed condition number 19-22 and the potential clinical accomplishments that may be addressed through the C-SNP plan design. Lastly, they seek comment on challenges that may exist from a clinical and business standpoint

2. Chronic Condition Special Needs Plan Definition, Scope and Eligibility

Proposed Changes

CMS is proposing to codify current guidance regarding the ability of MA organizations to offer a C-SNP that focuses on single or multiple chronic conditions. Additionally, CMS is proposing to define C-SNPs as SNPs that restrict enrollment to MA special needs eligible individuals who have a severe or disabling chronic condition. CMS is proposing to limit C-SNPs that focus on multiple chronic conditions to the list of CMS-approved groups of commonly co-morbid and clinically linked conditions. In addition, they are

proposing to clarify that enrollees need only one qualifying condition for enrollment when a C-SNP focuses on multiple conditions. The current set of combinations, as detailed in section 20.1.3.1 of Chapter 16b of the MMCM, are:

- Diabetes mellitus and chronic heart failure;
- Chronic heart failure and cardiovascular disorders;
- Diabetes mellitus and cardiovascular disorders;
- Diabetes mellitus, chronic heart failure, and cardiovascular disorders; and
- Stroke and cardiovascular disorders.

CMS proposes to codify the above list and add the following pairings as permissible groupings of severe or disabling chronic conditions which were recommended by the clinical advisor panel:

- Anxiety associated with COPD
- CKD and post-renal organ transplantation
- Substance Use Disorder (SUD) and Chronic and disabling mental health conditions

Background/Rationale

In 2010, CMS adopted subregulatory guidance that a C-SNP could only offer a plan benefit package (PBP) that covered one of the fifteen SNP-specific chronic conditions identified in the guidance. Examples of such conditions include autoimmune disorders, cardiovascular disorders, severe hematologic disorders, chronic lung disorders, chronic disabling mental health conditions, and chronic disabling neurologic disorders. Currently, C-SNPs may only cover one of the fifteen qualifying chronic conditions in a single PBP, unless the C-SNP receives approval from CMS to focus on a group of severe or disabling chronic conditions. CMS believes that structuring a C-SNP to target multiple commonly co-morbid conditions that are not clinically linked in their treatment would result in a general market product, rather than an MA plan that is tailored for special needs individuals.

While the proposed policy would allow MA organizations to select new C-SNP plan type options, it would not compel them to do so or add an additional burden to sponsor a C-SNP now or in the future. CMS would monitor all C-SNP type applications for CY 2025 to inform future implementation strategies and impact on the program. CMS expects that MA organizations may be slow to create new C-SNP plan type options around the new set of chronic conditions. They anticipate changes from current plan and enrollment practices would most likely be related to ESRD, given the proposal to use the condition category “chronic kidney disease (CKD)” and to include ESRD as part of that condition category. CMS has no evidence of impact on current ESRD plans, yet expects current ESRD C-SNPs will be permitted to enroll beneficiaries with CKD stages 1-4 once the proposal is finalized.

A new definition of C-SNP would unify and streamline existing requirements as well as reduce burden. The proposals regarding the definition of severe or disabling chronic conditions and C-SNP will influence the proposed changes which include new chronic condition categorifies, relabeling of several existing categories, and new sub-conditions under chronic conditions.

Comments

CMS seeks comments on the proposals.

B. Defining Institutional Special Needs Plans and Codifying Beneficiary Protections (section IV.B, pgs 358-368)

Proposed Changes

CMS proposes to add a definition of I-SNPs to be SNPs that restrict enrollment to MA eligible individuals who meet the definition of institutionalized and institutionalized-equivalent, and to include that there are the following types: I-SNP Institutionalized, I-SNP Equivalent, and I-SNP Hybrid. These three I-SNPs correspond to CMS' current MA application process.

CMS is also proposing to define three I-SNP types that are currently used by CMS to operations MA applications and Medicare beneficiary enrollment into I-SNPs. The proposed definitions for each current I-SNP types address both enrollment limitations used by different types of I-SNPs and certain performance and contracting requirements that are specific to each type. The first proposed definition of an I-SNP type that enrolls only Medicare beneficiaries who meet the definition of institutionalized in § 422.2 would be called "Facility-based Institutional Special Needs Plan" or FI-SNPs. The second I-SNP type would be called "Institutional-Equivalent Special Needs Plan" or IE-SNP, which would be an I-SNP type that restricts enrollment to MA eligible individuals who meet the definition of institutionalized-equivalent in § 422.2. the last I-SNP type that CMS is proposing a definition for would be called "Hybrid Institutional Special Needs Plan" or HI-SNPs, which would be an I-SNP type that restricts enrollment to both MA eligible individuals who meet the definition of institutionalized and MA eligible individuals who meet the definition of institutionalized-equivalent.

In addition, they propose to codify current policies that address the need for the I-SNP to contract with the institutions where such special needs individuals reside. CMS' proposal includes tying the definitions of institutionalized and institutionalized-equivalent in § 422.2 and the list of eligible institutions set forth in that definition, to their proposed definition of I-SNP.

Background/Rationale

CMS believes that adding the three definitions will help clarify the specific standards that are applicable to I-SNPs, as distinguished from other MA plans and from other MA SNPs. Additionally, CMS' approach in tying the definitions of institutionalized and institutionalized-equivalent and the list of eligible institutions within the definition is consistent with current regulatory definitions for D-SNPs, FIDE SNPs, and HIDE SNPs. Notably, their proposed language linking I-SNP enrollment to the definitions match current subregulatory guidance and practice used by CMS during the MA application process for I-SNP. CMS notes that there are no burdens associated with either piece of their proposal, given that the creation of a definition will not engender operational or policy changes impacting MA organizations sponsoring I-SNPs nor impact enrollees. Additionally, they do not anticipate any burden associated with the continuation of existing guidance that was incorporated and implemented with the release of the 2016 update of chapter 16b of the MMCM.

Comments

CMS seeks comment on the proposed codification of chapter 16b subregulatory guidance and the proposed new definition of I-SNP. They are seeking feedback on I-SNP operationalization of the current subregulatory guidance. Lastly, they are seeking feedback from commenters who have suggestions for improving the care furnished to the special needs individuals enrolled in I-SNPs, based on parallels or lessons learned from other State or Federal programs administering services to long-term care residents or beneficiaries requiring a nursing home level of care.

C. Definition of Network-Based Plan (section IV.C, pgs 368-369)

Proposed Changes

CMS proposes to move the current definition of a network-based plan from § 422.114(a)(3)(ii) to the definitions section in § 422.2. CMS proposes to make a conforming change to reference § 422.2 within § 422.116(a)(1)(i) to be consistent with their proposal.

Background/Rationale

Private fee-for-service (PFFS) plans were established by the Balanced Budget Act of 1997 and were originally not required to have networks. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) revised the PFFs requirements to require that any PFFS plan operating in the same service areas as two or more network-based plans also have a network. For the purpose of this requirement, section 1852(d)(5)(C) of the Act and § 422.114(a)(3)(ii) define network-based plans as a coordinated care plan, a network-based MSA plan, and a section 1876 reasonable cost plan. CMS notes that a network-based plan has meaning in contexts other than in addressing specific requirements for MA PFFS plans, and in order to ensure the definition is readily accessible for those seeking requirements related to network-based plans, they are proposing to move it to the definitions section at § 422.2. The PFFS section would still include language specifying the network requirements.

D. Required Notices for Involuntary Disenrollment for Loss of Special Needs Status (section IV.D, pgs 369-372)

Proposed Changes

CMS proposes to codify current policy for MA plan notices prior to a member's disenrollment for loss of special needs status, as well as a final disenrollment notice. They propose to revise § 422.74(d) to state that the plan would be required to provide the enrollee a minimum of 30 days advance notice of disenrollment, regardless of the date of the loss of special needs status. An advance notice would be provided to the enrollee within 10 calendar days of learning of the loss of special needs status, affording the enrollee an opportunity to prove that he or she is still eligible to remain in the plan. The plan would be required to provide the enrollee a final notice of involuntary disenrollment within 3 business days following the disenrollment effective date. Lastly, they propose that the final involuntary disenrollment

notice must include an explanation of the individual's rights to file a grievance under the MA organization's grievance procedures, which are required by § 422.564.

Background/Rationale

CMS believes that given infrequent questions and complaints from MA organizations and enrollees on these notices, these notice requirements have been previously implemented and are currently being followed by plans. They do not believe the proposed changes to the regulatory text will adversely impact MA organizations or individuals enrolled in MA special needs plans who lose special needs status, other than the appropriate disenrollment from the plan due to the individual's loss of eligibility plan.

E. Involuntary Disenrollment for Individuals Enrolled in a MA Medical Savings Account (MSA) Plan (section IV.E, pgs 372-374)

Proposed Changes

CMS proposes to amend § 422.74 to add new paragraph to include the requirement that an MA MSA enrollee must be disenrolled, prospectively, due to the loss of eligibility. If an MA MSA enrollee does not provide assurances that he or she will reside in the United States for at least 183 days during the year the election if effective, is eligible for or begins receiving health benefits through Medicaid, FEHBP, DoD, or the VA or obtains other health coverage that covers all or part of the annual Medicare MSA deductible, that enrollee must be involuntarily disenrolled by the MSA plan effective the first day of the calendar month after the month in which notice by the MA organization is issued that the individual no longer meets the MA MSA's eligibility criteria. CMS is also proposing to revise § 422.74(c) to require MA MSA plans to provide a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual before the disenrollment transaction is submitted to CMS.

CMS is proposing that involuntarily disenrolled individuals will be defaulted to enrollment in Original Medicare, which will now pay claims incurred by the former MSA enrollees.

Background/Rationale

The current regulations do not specify that an individual who ceases to satisfy the eligibility criteria described in § 422.56 while already enrolled in an MA MSA plan must be involuntary disenrolled from the MSA, regardless of the time of the year. CMS notes that their proposal is consistent with their general approaches in the Medicare Managed Care Manual, in which an enrollee becomes ineligible due to a status change, such as the loss of entitlement to Medicare Part A or Part B or the inability to regain special needs status during the period deemed continued eligibility and outlined in § 422.74. CMS' proposals will address more clearly the consequences of the general loss of eligibility in an MSA plan.

F. Codification of Special Needs Plan Model of Care Scoring and Approval Policy (section IV.F, pgs 374-388)

1. Codification of Model of Care (MOC) Scoring Requirements for Special Needs Plans (SNPs)

Proposed Changes

CMS is proposing to codify certain existing guidance from Chapters 5 and 16B of the Medicare Advantage Managed Care Manual as well as separate sub regulatory guidance related to SNP MOC scoring protocols.

Specifically, CMS is proposing to codify the SNP MOC at 42 C.F.R. § 422.101(f)(3)(iii) to include the existing sub regulatory scoring protocols. This includes:

- adding the minimum overall score requirement for approval of a SNP's MOC using the same minimum standard as is currently used by NCQA (requiring a minimum benchmark score of 50% on each element and an aggregate minimum benchmark of 70%),
- codifying that C-SNP MOCs are annually reviewed and evaluated,
- codifying that I-SNP and D-SNP MOCs that receive and aggregate minimum benchmark score of 85% or greater are approved for 3 years, 75% - 85% approved for 2 years, and that 70-74% approved for 1 year.
- Codifying an opportunity for SNPs to cure deficiencies in MOC if the MOC fails to meet the minimum benchmark standards, which will be available only once per scoring cycle for each MOC. SNPs making use of this cure can only be approved for 1 year.

Background/Rationale

CMS is aiming to codify existing subregulatory guidance that currently governs the MOC scoring process. CMS views these new regulatory sections as aligned with existing practice and expectations of the MOC scoring process as governed by NCQA.

Comments

CMS welcomes feedback on the codification of existing MOC scoring requirements.

2. Amending SNP MOCs after NCQA Approval

Proposed Changes

CMS is proposing to codify existing policies and procedures for MA organizations to amend SNP MOCs after NCQA.

Specifically, CMS is proposing at 42 C.F.R. § 422.101(f)(3)(iv) to:

- Set specific times when SNPs can submit MOCs to NCQA for mid-cycle review (between June 1st and November 30th of each calendar year or anytime when CMS deems it necessary to comply with MOC standards),
- Codifying a list of reasons for when a SNP must use an off-cycle submission of a revised MO,
- Stating that NSPs may not implement changes to MOCs until NCQA has approved the changes,
- Stating that the successful revision of a MOC off-cycle does not change the MOC's original period of approval by NCQA,
- Clarifying that C-SNPs remain ineligible for off-cycle MOC modification.

Background/Rationale

CMS appreciates that SNPs may need to amend MOCs off-cycle in order to meet the needs of their beneficiaries. In other scenarios such mid-cycle change may be necessary to comply with MOC audit results. The practice has become more common among SNPs, thus CMS feels it necessary to codify the off-cycle modification process. However, CMS states clearly that they still believe off-cycle modifications should be a rare occurrence.

Comments

CMS seeks feedback on these proposals.

G. Clinical Trial-Related Provisions (section IV.G, pgs 388-394)

1. Clinical Trials Under National Coverage Determination

Proposed Changes

CMS proposes the below changes to clarify the required Medicare coverage of clinical trials covered under the Clinical Trials National Coverage Determination 310.1 (NCD):

- In § 422.109(e)(1), codify that traditional Medicare is responsible for coverage of routine costs of qualifying clinical trials for MA enrollees for clinical trials covered under NCD and all necessary services used to diagnose and treat complications from participating in clinical trials.
- In § 422.109(e)(2), codify this policy that MA enrollees participating in clinical trials are not subject to Part A and B deductibles.
- In § 422.109(e)(3), codify the requirement that MA plans pay the difference between traditional Medicare and MA plan's in-network cost sharing incurred for qualifying clinical trial items and services.
- In § 422.109(e)(4), codify that the enrollee's in-network cost-sharing portion must be included in the plan's maximum out-of-pocket (MOOP) calculation.
- In § 422.109 (e)(5), specify that MA plans may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create barriers to enrollee participation in a non-plan-sponsored clinical trial.

Background/Rationale

For clinical trials covered under NCD, CMS states that it has been longstanding policy for traditional Medicare to cover the costs of qualifying clinical trials for all Medicare enrollees who volunteer to participate in the approved trial, including those enrolled in MA plans. These proposed changes would codify and clarify this longstanding policy. CMS explains that the changes would ensure that MA enrollees have access to and coverage of clinical trials within the scope of NCD to the same extent as those enrolled in the traditional Medicare program.

Comments

CMS is not requesting comment on these proposed changes.

2. A-B Investigational Device Exemption Trials

Proposed Changes

CMS is proposing to add § 422.109(f) to specify MA plan coverage of the routine items and services, including the Category B investigational device exemption (IDE) device and related items and services in the context of a Category A and B IDE studies, that are covered by Medicare under §§ 405.211(a) and (b).

Background/Rationale

CMS states that the proposed change would clarify the scope of required coverage of Category A and Category B IDE studies and devices for MA plans and avoid any inadvertent confusion between the coverage requirements associated with clinical trials under NCD 310.1. The regulation at § 405.211 specifies Medicare coverage of Category A and B investigational device exemption (IDE) studies. MA organizations are responsible for payment of claims related to enrollees' participation in both Category A and B IDE studies that are covered under traditional Medicare. An MA plan is also responsible for coverage of CMS-approved Category B devices. CMS will not approve coverage of Category A devices themselves because they are considered experimental and excluded from coverage under § 405.211(a). As a result, MA plan may apply utilization management, including prior authorization.

3. National Coverage Determinations with Coverage with Evidence Development

Proposed Changes

CMS is not making any proposed changes to this policy; this section reiterates that MA plans must cover NCDs with "coverage with evidence development" (CED).

Background/Rationale

In this section, CMS reiterates that § 422.101(b) requires MA plans to cover NCDs, and this coverage requires that NCDs have a trial or registry component, which is referred to as "coverage with evidence development". As a result of CED, Medicare covers items and services on the condition that they are furnished in the context of CMS approved clinical studies or with the collection of additional clinical data (for example, registry).

Comments

CMS is soliciting comment on whether additional regulations are needed to address NCDs with CED or if § 422.101(b) makes this requirement clear.

H. Part D Retroactive Transactions for Employer/Union Group Health Plan (EGHP) Members (section IV.S, pgs 424-426)

Proposed Changes

CMS proposes at new §§ 423.32(i) and 423.36(e) to permit a Part D plan sponsor that has a contract with an employer or union group to arrange for the employer or union to process enrollment and disenrollment elections for Medicare-entitled group members who wish to enroll in or disenroll from an employer or union sponsored Part D plan.

Background/Rationale

CMS' intent is to align the Part D regulation with the requirements that MA organizations follow in existing Part C regulations at §§ 422.60(f) and 422.66(f) and codify existing policies in the sub-regulatory guidance in Chapter 3 of the Medicare Prescription Drug Benefit Manual.

Further, retroactive transactions may be necessary and are permitted if a delay exists between the time the individual completes the enrollment or disenrollment request through the employer's election process and when the request is received by the Part D plan sponsor. CMS states in current subregulatory guidance at section 60.5.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual that the option to submit limited EGHP retroactive enrollment and disenrollment transactions is to be used only for the purpose of submitting a retroactive enrollment into an EGHP made necessary due to the employer's delay in forwarding the completed enrollment request to the Part D plan sponsor.

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

A. Contract Ratings (section V.C, pgs 515-517)

1. Contract Type

Proposed Changes

CMS proposes to add a sentence at the end of §§ 422.162(b)(1) and 423.182(b)(1) to clarify that overall and summary Star Ratings are calculated based on the measures required to be collected and reported for the contract type being offered for the Star Ratings year.

Background/Rationale

CMS notes that this approach has been the current practice of how Star Ratings have been historically calculated. For example, if a contract offered a SNP PBP in measurement year 2021, but is no longer offering a SNP PBP in contract year 2023, the 2023 Star Ratings would exclude the SNP-only measures and the contract would be rated as "Coordinated Care Plan without SNP."

Comments

CMS welcomes any comments on the proposal.

2. Contract Consolidation

Proposed Changes

For the first year after a consolidation, CMS proposes to amend §§ 422.162(b)(3)(iv)(A)(1) and 423.182(b)(3)(ii)(A)(1) to clarify that the Part C and D improvement measures will not be calculated for the consolidated contract. For the second year after a consolidation, the improvement measure is still calculated, as scores for the current and prior year are then available.

Background/Rationale

The prior year measure-level scores only include data from the surviving contract; using those as a comparison point for a consolidated contract would not be an accurate comparison because it does not include any information about performance of the consumed contract.

Comments

CMS welcomes any comments on the proposal.

B. Adding, Updating, and Removing Measures (section V.D, pgs 517-538)

1. Proposed Measure Removal

The table below outlines measures CMS proposes to remove from Star Ratings, as well as the rationale provided.

Measure	Background/Rationale	Effective Year
Diabetes Care - Kidney Disease Monitoring (Part C)	NCQA, the measure steward, announced the retirement of the measure after measurement year 2021. NCQA will no longer be collecting data for this measure. CMS intends to replace this measure with the Kidney Health Evaluation for Patients with Diabetes measure.	2024 Star Ratings
Medication Reconciliation Post-Discharge (MRP)	CMS notes the measure would be duplicative of the MRP component of the Transitions of Care (TRC) measure to be included in the 2024 Star Ratings. The TRC measure includes four indicators; MRP, Notification of Inpatient Admission, Patient Engagement After Inpatient Discharge, and receipt of Discharge Information. The MRP measure is duplicative of a component of a TRC measure.	2026 Star Ratings

2. Proposed Measure Updates

The table below outlines measures CMS proposes to update due to substantive changes, as well as the rationale provided.

Measure	Updated Measure Description	Change/Rationale	Effective Year
Colorectal Cancer Screening (Part C)	Percent of plan members aged 45 to 75 who had appropriate screenings for colorectal cancer.	In May 2021, the U.S. Preventive Services Task Force (USPSTF) released updated guidance for the age at which colorectal cancer screenings should begin. Subsequently, NCQA, the measure steward, has updated its colorectal cancer screening measure to include a rate for adults 45-49 years of age for measurement year 2022. Therefore, CMS proposes expanding the age range for the Colorectal Cancer Screening measure to adults age 45-49, for an updated age range of 45-75	2024 Star Ratings
Care for Older Adults (COA) – Functional Status Assessment (Part C)	Percent of Special Needs Plan enrollees 66 years and older who received a functional status assessment	CMS proposes to add the measure back into the Star Ratings after it has been on the display page following a substantive measure change. Historically, the measure requires documentation of a complete functional status assessment, to include: • assessment of ADLs, • assessment of IADLs, • result or an assessment using a standardized functional tool, **or** • notation that at least three of the following four components were assessed: cognitive status, ambulation status, hearing, vision, and speech, and other functional independence.	2026 Star Ratings

		In HEDIS 2021, NCQA implemented a change in the measure, removing the fourth option. The updated measure was moved to the display page starting with 2022 Star Ratings. CMS now proposes to return the updated measure to Star Ratings, and per regulation, the measure will receive a weight of 1 for the first year and treated as a process measure in subsequent years.	
Medication Adherence for Diabetes Medication	The percentage of individuals > 18 years of age who met the Proportion of Days Covered (PDC) threshold of 80% for diabetes medications during the measurement year.	To align with PQA measure specifications, CMS proposes to implement risk adjustment based on sociodemographic status (SDS) characteristics (including age, gender, dual/LIS status, and disability status) to the three Part D medication adherence measures. Because of this change, the medication adherence measures will also be excluded from Categorical Adjustment Index, which also assesses for contract disparities in performance among beneficiaries receiving a low income subsidy, are dual eligible, or are disabled. CMS conducted a number of simulations to test how the change will impact Star Ratings, finding minimal impacts. CMS also proposes two non-substantive updates. First, CMS will apply a continuous enrollment (CE) instead of member-years (MYs) adjustment to the measures, to align with PQA measure specifications and exclude beneficiaries with more than a 1-day gap in enrollment during the treatment period. Second, CMS will discontinue adjusting for SNF and IP stays in calculating measures, to again align with PQA measure specifications.	SDS: 2028 Star Ratings
Medication Adherence for Hypertension (RAS Antagonists)	The percentage of individuals > 18 years of age who met the PDC threshold of 80% for RAS antagonists during the measurement year.		CE: 2026 Star Ratings
Medication Adherence for Cholesterol (Statins)	The percentage of individuals > 18 years of age who met the PDC threshold of 80% for statins during the measurement year.		Removal of SNF/IP stays: 2028 Star Ratings

3. Proposed Measure Additions

The table below outlines measures CMS proposes to add to Star Ratings, as well as the rationale provided.

Measure	Measure Description	Rationale	Effective Year
Kidney Health Evaluation for Patients with Diabetes (KED) (Part C)	Percent of plan members ages 18-85 with diabetes (type 1 and type 2) who received a kidney health evaluation during the measurement year.	Aligns with recommendations from the American Diabetes Association and provides information for screening and monitoring of kidney health for patients with diabetes. This measure would replace the prior related measure, Diabetes Care – Kidney Disease Monitoring. CMS began reporting this measure on the display page for 2022 Star Ratings.	2026 Star Ratings
Concurrent Use of Opioids and	The percentage of individuals ≥18 years	CMS notes the measures are important areas of focus for the Part D population;	

Benzodiazepines (COB)	of age with concurrent use of prescription opioids and benzodiazepines	these measures will help plans identify enrollees who are at risk of respiratory depression or fatal overdoses, cognitive decline, or falls and fractures, respectively, and facilitate plans to encourage appropriate prescribing when clinically necessary.	2026 Star Ratings
Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH)	The percentage of individuals ≥65 years of age with concurrent use of ≥2 unique anticholinergic medications.		
Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (Poly-CNS)	The percentage of individuals ≥65 years of age with concurrent use of ≥3 unique central nervous system (CNS)-active medications.		

4. Revising the Rule for Non-substantive Measure Updates

Proposed Changes

CMS proposes to add collection of survey data through another mode of survey administration to the non-exhaustive list of non-substantive measure updates that can be made without rulemaking.

Background/Rationale

CMS reasons that the expansion of how data are collected is non-substantive because there would be no change to the information that is being collected; the only change would be the way in which it is collected.

Comments

CMS welcomes comments on the proposal.

5. Measure Removal

Proposed Changes

CMS proposes that when a measure steward other than CMS (for example, NCQA or PQA) retires a measure, CMS will have the authority to remove the measure from calculations of Star Ratings through the process described at §§ 422.164(e)(2) and 423.184(e)(2).

Background/Rationale

The proposal will allow CMS to respond more quickly to measure removals by external measure stewards to ensure that measures included in Star Ratings are clinically meaningful, reliable, and up-to-date. Further, measure stewards go through a process that includes extensive review by various measurement panels and they solicit public comment regarding proposed measure retirements so that stakeholders have an opportunity to weigh in on any changes.

Comments

CMS welcomes comments on the proposal.

C. Measure Weights (section V.E, pgs 538-544)

1. Patient Experience/Complaints and Access Measures

Proposed Changes

CMS proposes to lower the weight of the patient experience/complaints and access measures to 2 beginning with 2026 Star Ratings. Measures impacted include patient experience of care measures collected through CAHPS, Members Choosing to Leave the Plan, Appeals, Call Center, and Complaints measures, noted below:

Patient experience and complaints measures:

- Measure: C17 - Getting Needed Care (CAHPS)
- Measure: C18 - Getting Appointments and Care Quickly (CAHPS)
- Measure: C19 - Customer Service (CAHPS)
- Measure: C20 - Rating of Health Care Quality (CAHPS)
- Measure: C21 - Rating of Health Plan (CAHPS)
- Measure: C22 - Care Coordination (CAHPS)
- Measure: C23 - Complaints about the Health Plan (CTM)
- Measure: C24 - Members Choosing to Leave the Plan (MBDSS)
- Measure: D02 - Complaints about the Drug Plan (CAHPS)
- Measure: D03 - Members Choosing to Leave the Plan (CAHPS)
- Measure: D04 - Drug Plan Quality Improvement (CAHPS)
- Measure: D05 - Rating of Drug Plan (CAHPS)
- Measure: D06 - Getting Needed Prescription Drugs (CAHPS)

Patient access measures:

1) Measure: C26 - Plan Makes Timely Decisions about Appeals (IRE)
2) Measure: C27 - Reviewing Appeals Decisions (IRE)
3) Measure: C28 - Call Center – Foreign Language Interpreter and TTY Availability (Call Center)
4) Measure: D01 - Call Center – Foreign Language Interpreter and TTY Availability (Call Center)

Background/Rationale

CMS provides several reasons for the decreasing the weight of these measures to 2:

- Better aligns these measures with the weight of patient experience/complaints and access measures in other CMS quality measure programs, such as the hospital value-based purchasing program and the Quality Rating System for QHPs.
- Concerns from stakeholders about the disproportionate weight given to these measures and how it may devalue measures of health outcomes, encourage plans to abandon efforts to drive clinically appropriate care, devalue preventive care, and not balance clinical excellence and patient experience appropriately.
- The impact of the current weighting policy on 2023 Star Ratings.

Comments

CMS welcomes comments on the proposal.

2. **Weight of Measures with Substantive Updates**

Proposed Changes

CMS proposes to add language at §§ 422.166(e)(2) and 423.186(e)(2) to clarify that when a measure with a substantive update moves back to Star Ratings from the display page following rulemaking, it is treated as a new measure for weighting purposes and therefore would receive a weight of 1 for its first year back in the Star Ratings program

Background/Rationale

The change is consistent with CMS' current and prior practice and with the explanation provided in the January 2021 final rule.

Comments

CMS welcomes comments on the proposal.

D. Guardrails (section V.F, pgs 544-548)

Proposed Changes

CMS proposes to remove the guardrails that restrict maximum allowable movement of non-CAHPS measure cut points. The guardrails for non-CAHPS measures will only be effective through 2025 Star Ratings released in October 2024, and will not apply for 2026 Star Ratings or beyond.

Background/Rationale

The intent of the original policy was to create predictability and stability of the cut points. However, CMS notes unintended consequences of this policy, where caps on upward movement may inflate measure-level Star Ratings if true improvements in measure performance cannot be fully incorporated into the current year's ratings, and caps on downward movement can deflate Star Ratings when industry performance overall shifts downwards. These unintended consequences were especially made apparent by the COVID-19 pandemic, where unforeseen circumstances significantly shifted overall industry performance. Further, CMS reasons that the introduction of mean resampling and Tukey outlier deletion will provide sufficient predictability and stability of cut points from one year to the next. They note that it is important for cut points to be allowed to shift by more than 5 percent when there are unanticipated, large changes in industry performance.

Comments

CMS welcomes comments on the proposal.

E. Health Equity Index Reward (section V.G, pgs 548-565)

Proposed Changes

CMS proposes to replace the current reward factor described at §§ 422.166(f)(1) and 423.186(f)(1) with the new Health Equity Index (HEI) reward. Beginning with 2027 Star Ratings and using 2024/25 measurement year data, the HEI will assess contract performance among beneficiaries with certain social risk factors (SRFs). CMS proposes these factors to initially include:

1) receipt of Low-Income Subsidies (LIS) at any time during the applicable measurement period,
2) being a full-benefit or partial-benefit dually eligible individual, or
3) having a disability (based on the original reason for entitlement to the Medicare program).

The proposed HEI would assess performance across all Star Ratings measures unless the measure meets one of the following exclusion criteria:

- The focus of the measure is on the plan or provider (e.g., appeals and call center measures)
- The measure is retired, moved to display, or has a substantive specification change
- The measure is only applicable to SNPs, as these measures are not relevant for all contracts
- Measure has a reliability of .7 and meets measure denominator requirements.

CMS proposes the following steps to calculate the HEI:

1. Measure-level scores for each measure included in the HEI are calculated for each contract using data from the two most recent measurement years based on enrollees with the specified SRFs using a modeling approach that accounts for year.

2. Measures that are case-mix adjusted in the Star Ratings would employ all standard case-mix adjustors except for adjusters that are the same as the SRFs included in the HEI, are strongly correlated with the included SRFs, or are conceptually similar to the included SRFs.
3. A contract would need to meet the .7 reliability and minimum denominator criteria for at least half of the measures included in the HEI based on data from the two most recent measurement years and have at least 500 enrollees at the contract level in the most recent measurement year to have the HEI calculated.
4. For each included measure, points are awarded as follows: 1 point to those contracts that score in the top third of all contracts, 0 points to those that score in the middle third of all contracts, and 1 negative point to those that score in the bottom third of all contracts.
5. Points are added together using the weighted average of Star Ratings measure weights.
6. Separate HEIs are calculated for overall and summary ratings (e.g., an MA-PD contract would have an overall, Part C, and Part D summary rating).
7. To qualify for an award, the HEI must be greater than zero. CMS proposes a "tiered" structure to determine the amount of reward, based on the percentage of enrollees in the contract with SRFs, as noted in the table below. The award itself is based on a linear scale.

Percentage of Enrollees with Specified SRFs Threshold	**Amount of Reward**
% of enrollees in a contract with the specified SRFs < 0.5 of the median for all contracts.	Zero Reward.
% of enrollees in a contract with the specified SRFs ≥ 0.5 of the median for all contracts and < the median for all contracts.	HEI reward would vary from 0 to 0.2 on a linear scale for contracts that have an HEI score > 0.
% of enrollees in a contract with the specified SRFs ≥ the median for all contracts.	HEI reward would vary from 0 to 0.4 on a linear scale for contracts that have an HEI score > 0.

8. Once each of the HEI rewards are calculated, the HEI reward is added to the respective unrounded overall and Part C and Part D summary ratings after the addition of the Categorial Adjustment Index and the application of the improvement measures.

Background/Rationale

CMS reasons the HEI will incentivize improved performance by contracts for their enrollees with the specified SRFs and help reduce disparities. The HEI assists plan sponsors in identifying and then addressing disparities in care provided to members with a particular SRF, with the ultimate goal of reach equity in the level and quality of care provided to enrollees with SRFs. In developing the methodology for calculating the award, CMS adhered to the following goals:

- Avoiding rewarding large contracts over small contracts
- Avoiding rewarding contracts that may do well among enrollees with SRFs but serve very few enrollees with SRFs.

- Only rewarding contracts that have high relative performance among enrollees with SRFs compared to other contracts to incentivize high performance.
- Ease of use and understanding
- Minimizing the number of years of data needed
- Allowing for updates to the measure set included in the HEI
- Promoting improvement in performance and enrollment of individuals with SRFs in MA plans, cost plans, and Part D plans.
- Accurately reflecting true performance

CMS considered including the Area Deprivation Index (ADI), as proposed in ACO REACH, but decided not to due to analyses showing that ADI explains very little variation in the quality of care received beyond enrollee-level LIS/DE and disability information.

In simulating the removal of the current reward factor and the addition of the proposed new HEI reward, 7, (1.7%) MA-PD contracts gained one-half star on the overall rating and 54 (13.4%) MA-PD contracts lost one-half star on the overall rating compared to the 2021 Star Ratings. Among PDP contracts, 3 (5.3%) gained one-half star on the Part D summary rating and 7 (12.3%) lost one-half star.

Comments

CMS welcomes all comments on the proposal. CMS also mentions the below specific considerations:

Social Risk Factors: CMS is interested in feedback on potential additional ways to identify enrollees who have a disability that could be incorporated over time, and whether the same process and standards should be used for the CAI adjustment as well. In particular, CMS is interested in how they can expand the disability definition to include enrollees who develop a disability after aging into Medicare.

Health Equity Index: CMS is considered an alternative non-tiered HEI reward structure, where all contracts with percentages of enrollees with any of the specified SRF greater or equal to one-half of the contract-level median would qualify for the full HEI reward. In addition, while CMS is initially proposing to require a minimum HEI score of greater than zero to qualify for an award, they are considering increasing this minimum score over time.

F. Improvement Measure Hold Harmless (section V.H, pgs 565-566)

Proposed Changes

CMS proposes to apply the improvement measure hold harmless provision to only contracts with 5 stars for their highest rating beginning with 2026 Star Ratings. Currently, the hold harmless provision applies to contracts with 4 or more stars.

Background/Rationale

The original intent of the hold harmless provision was to recognize that higher performing contracts have less room to improve, and thus should not be penalized for it. However, CMS' experience since the 2018

policy was enacted has suggested that contracts with 4 or 4.5 stars still have room for improvement. For example, based on a review of data from the 2020 Star Ratings, MA-PD contracts with 4 stars for the overall rating received 5 stars on 42 percent of measures on average, those with 4.5 stars for the overall rating received 5 stars on 55 percent of measures on average, and those with 5 stars for the overall rating received 5 stars on 79 percent of measures on average.

Comments

CMS welcomes comments on the proposal.

G. Extreme and Uncontrollable Circumstances (section V.I, pgs 566-570)

1. 60 Percent Rule

Proposed Changes

CMS proposes to remove the 60 percent rule beginning with 2026 Star Ratings for non-CAHPS measures. The 60 percent rule excludes from the clustering algorithm and reward factor calculations contracts with 60 percent or more of their enrollees in a Federal Emergency Management Agency (FEMA) designated Individual Assistance area at the time of an extreme and uncontrollable circumstance.

Background/Rationale

CMS reasons that the combination of mean resampling (implemented with 2022 Star Ratings) and the Tukey outlier deletion will alleviate the impact of any extreme outliers. Removing the 60 percent rule will also simplify Star Ratings calculations and continue to allow measure-level Star Ratings to be calculated if all or most contracts qualify for an extreme or uncontrollable circumstance in the future (e.g., the COVID-19 pandemic).

Comments

CMS welcomes comments on the proposal.

2. Health Outcomes Survey (HOS) Measures

Proposed Changes

CMS proposes to clarify the timing for HOS measure adjustments for extreme and uncontrollable circumstances. Specifically, for Part C measures derived from HOS, the disaster adjustment is delayed an additional year, such that the adjustment occurs 3 years after the extreme and uncontrollable circumstance.

Background/Rationale

The delay is due to the timing of the HOS survey and the 1-year recall period.

Comments

CMS welcomes comments on the proposal.

H. Quality Bonus Payment Rules (section V.J, pgs 570-574)

Proposed Changes

CMS proposes to clarify in § 422.260(c)(3)(iii) some additional aspects of that administrative review process for appeals of QBP status determinations:

- Clarifying that certain data sources are not eligible for requesting an administrative review, including HEDIS, CAHPS, HOS, Part HEDIS, CAHPS, HOS, Part C and D Reporting Requirements, PDE, Medicare Plan Finder pricing files, data from the Medicare Beneficiary Database Suite of Systems, MARx system, and other Federal data sources.
- Adding additional language clarifying that the burden of proof is on the MA organization to prove an error was made in the calculation of the QBP status. The appropriate standard of proof will be the preponderance of the evidence.
- Clarifying that ratings can go up, stay the same, or go down based on an appeal of the QBP determination.
- Clarifying that a reopening of a QBP determination to address a systemic calculation issue that impacts more than the MA organization that submitted an appeal would only be updated if it results in a higher QBP rating for other MA organizations that did not appeal.

Background/Rationale

Clarifications made are how CMS has historically administered the appeals process.

The eligible data sources not eligible for administrative review have either already been validated or audited or come from the CMS system of record for that type of data such as enrollment data, which make it inappropriate to use the QBP appeal process to challenge the accuracy of the data. Plan enrollee data sources cannot be appealed because plans cannot challenge the validity of an enrollee's response since that is the enrollee's perspective.

Measures derived from Prescription Drug Event (PDE) data, Medicare Beneficiary Database Suite of Systems, enrollment data from Medicare Advantage Prescription Drug (MARx) system, and other Federal data sources (for example, FEMA disaster designations) also cannot be appealed for data accuracy because CMS is pulling data from the system of record or authoritative data source.

Comments

CMS welcomes comments on the proposal.

I. Calculation of Star Ratings (section V.H, pgs 574-575)

Proposed Changes

CMS proposes a technical change to fix a statement that was inadvertently removed from the codified regulation text in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) ("Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed.")

CMS also proposes a non-substantive technical change to move the sentence about removal of Tukey outer fence outliers earlier in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) since Tukey outlier deletion is applied prior to the other steps.

Background/Rationale

Regulation text is made clearer.

Comments

CMS welcomes comments on the proposal.