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April 3, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-4190-P

Dear Ms. Verma:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) notice of proposed rulemaking entitled “Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,” published in the *Federal Register*, vol. 85, no. 32, pages 9002 to 9260. We appreciate your staff’s work on the notice, particularly considering the competing demands on the agency.

This proposed rule includes several provisions that would revise regulations for the Medicare Advantage (MA) program (Part C) and the Prescription Drug Benefit program (Part D). Our comments focus on the following provisions:

- Contracting standards for dual-eligible special needs plan (D–SNP) look-alikes
- Out-of-network telehealth at plan option
- MA and Part D prescription drug program quality rating system
- Permitting a second, “preferred,” specialty tier in Part D
- Beneficiary real time benefit tool (RTBT)
- MA and cost plan network adequacy

Contracting standards for D–SNP look-alikes

D–SNPs are specialized MA plans that limit their enrollment to beneficiaries who are dually eligible for both Medicare and Medicaid. These plans are subject to additional requirements that do not apply to traditional MA plans. For example, D–SNPs must develop and follow an evidence-based model of care that is designed to meet the specialized needs of their enrollees and have a state Medicaid contract that meets certain minimum standards for integrating Medicare and Medicaid benefits.

In our June 2018 and June 2019 reports, we discussed the growing use of “look-alike” plans, which are traditional MA plans that have some of the same features as D–SNPs (such as richer coverage of supplemental dental, hearing, and vision benefits) but do not have to meet the extra requirements that apply to D–SNPs. We expressed concern that look-alike plans would undermine states’ efforts to develop more highly integrated D–SNPs or other types of integrated plans such as Medicare–Medicaid Plans (MMPs).

The proposed rule would require traditional MA plans to meet new contract standards aimed at limiting the use of look-alike plans. CMS would not renew the contracts for existing plans where 80 percent or more of the enrollees are dual eligibles and would not approve any new plans that expect to exceed the 80-percent threshold. These new standards would not apply to plans in states that do not have D–SNPs or MMPs. The sponsors of look-alike plans could transfer the enrollees in those plans to a D–SNP (for enrollees who are dual eligibles) or another traditional MA plan that meets certain requirements, such as charging no premium for beneficiaries who receive the full Part D low-income subsidy. These changes would apply starting with the 2022 plan year.

Comment

The Commission continues to maintain that look-alike plans undermine efforts to integrate care for dual eligibles and supports the new contract standards in the proposed rule. As CMS implements these new standards, it should monitor MA plan offerings and enrollment patterns to ensure that the 80-percent threshold is sufficient to largely eliminate the use of look-alike plans.

Out-of-network telehealth at plan option

The regulation proposes a revision to newly promulgated regulations (from April of 2019) pertaining to the additional telehealth benefits (ATBs) authorized under section 50323 of the Bipartisan Budget Act of 2018. The ATBs are services that are not covered under Medicare fee-for-service rules for coverage of telehealth but which plans are permitted to cover and treat as Medicare-covered services. As such, plans would include ATBs in the plan bid, and the benefit would be financed in the manner of a covered Medicare Part A or Part B benefit. (If ATBs had to be financed like other non-Medicare-covered benefits, they would have to be financed by (1) rebate dollars that Medicare pays the plan, which are “discounted” in that rebates are a maximum of 70 percent of the difference between the benchmark and the plan bid below the benchmark, or (2) member premiums and cost sharing. ATBs financed through the bid are paid at 100 percent of their bid amount.)

The April 2019 final rule (42 CFR § 422.135(d)) required that plans use contracted providers to provide the ATBs, except that preferred provider organizations (PPOs) would be permitted to cover ATBs provided through non-contracted providers and in such a case the benefits could not be financed through the bid. The stated rationale for requiring the use of contracted providers was similar to the Commission’s previous comment on ATBs. Our December 19, 2018, comment letter stated that “CMS should require all MA plans to have a contract with telehealth providers, and to use the contract to enforce provider selection and credentialing requirements, as well as state

licensing requirements. Without a contract, it is unclear exactly how these requirements could be enforced or how a plan could ensure that an enrollee receives appropriate care through out-of-network telehealth.”

The proposed modification to ATB rules would allow any MA plan type to offer ATBs through non-contracted providers and treat them as basic benefits included in the bid. The proposal argues that this should be permissible as long as contracted and non-contracted providers meet the basic ATB requirements of the regulations, which include the credentialing requirements of §422.204 (the requirements for plans to have a credentialing and verification of licensure process, and a recredentialing process at least every three years). Because plans would no longer have contracts with the ATB providers, the proposal relies on CMS monitoring activities to detect any issues arising as a consequence of this approach. The proposed regulation states that:

CMS would leverage existing oversight programs, which include monitoring beneficiary complaints, organization determinations, and appeals related to MA ATBs. CMS has regularly scheduled meetings with the Part C Independent Review Entity (IRE) contractor; during these meetings, CMS and the IRE contractor identify and evaluate systemic problems with coverage decisions that rise to the level of the IRE. We would continue to hold plans accountable for ensuring sufficient oversight of medically necessary Medicare covered items and services such as MA ATBs through CMS’s oversight activities and believe that we have the means to do that through these monitoring and oversight policies.

Comment

We continue to believe that without a contract, it is unclear exactly how credentialing and licensing requirements could be effectively enforced or how a plan could ensure that an enrollee receives appropriate care through out-of-network telehealth. What is of particular concern is how the state licensure requirement would be enforced or monitored, given that the distant telehealth services provider can be in any location, and the provider/practitioner may not be licensed in the state where the beneficiary using the services resides. A situation could arise in which a plan is required to deny payment for an ATB because it was provided by a practitioner not licensed in the beneficiary’s state.¹ This could result in the appeal that CMS alludes to and which would enable CMS to discover the problem. Beneficiaries should not be put in such a position. There should be a means of preventing the provision of inappropriate care rather than addressing an issue after the fact. Plans should continue to be required to contract with ATB providers to ensure that credentialing requirements are met. This is inherently a plan function, not a function CMS should indirectly assume or which would involve beneficiaries having to determine the status of an ATB provider.

More broadly, we believe that because the BBA has essentially established an equivalence between ATBs and Medicare-covered services (in establishing that the Medicare program is willing to pay for such services through the bid), the rules that MA plans must follow in providing Medicare-covered services should also apply to ATBs. For HMOs, this means that ATBs must be

¹ See section 190.7 of chapter 12 of the Medicare Claims Processing Manual.

available through contracted network providers, and for PPOs it means that beneficiaries should have access to network providers to obtain all ATBs and would not have to use a non-network provider because there is no network provider offering the service.

MA and Part D prescription drug program quality rating system

Each year CMS evaluates the quality of care and contract performance of the private plans participating in MA (Part C) and the Part D prescription drug program. Star ratings, ranging from a low of 1 to a maximum of 5, are assigned to a set of Part C and Part D clinical quality measures, patient experience and access measures, and contract performance measures. The different measure categories have different weights that are used to compute overall star ratings for Part C and Part D, and an overall combined rating for MA–PD contracts (MA contracts that include Part D). The lowest weight (a weight of 1) is assigned to process measures, and currently outcome measures have the highest weight (3). CMS also computes Part C and Part D improvement measures (two separate measures, each weighted 5) and makes other adjustments to arrive at the star rating that determines whether an MA plan receives a bonus under the MA quality bonus program (QBP). Contracts with an average applicable (MA–PD or MA-only) overall star rating of 4 stars or higher receive a bonus in the form of an increase in the MA benchmark (which is the maximum level of Medicare program payment to a plan for covering the Medicare Part A and Part B benefit package). The star ratings also determine the level of rebates an MA plan will offer when a bid is below the benchmark.

There is not a similar quality bonus program in Part D, but for both Part D and MA, the star ratings are publicly announced through the Medicare Plan Finder at Medicare.gov. The published star ratings, and details about the individual measures included in the star ratings, are intended to enable beneficiaries to compare the level of quality of the contracts available in their geographic area.

The rule contains a proposal to make certain changes to the star rating program, the most significant of which is to increase the weight of measures classified as “patient experience and access” measures from 1.5 (in 2020) or 2 in 2021 to 4 beginning in 2023. Following some general comments, we have specific comments on:

- The proposed change in the weighting of measures,
- The disenrollment rate measure and its weighting,
- The complaints about the drug plan measure and its weighting,
- Star ratings for new contracts, and
- Organizations leaving and immediately re-entering service areas.

Comment

Over the past decade, the Commission has been studying the question of how best to evaluate quality in MA and in comparison to fee-for-service quality.² For the past several years, we have

² Medicare Payment Advisory Commission. 2010. *Report the Congress: Medicare payment policy*. Washington, DC: MedPAC.

been examining specific issues related to the star rating system and the quality bonus program with a view toward aligning the MA quality incentive program with the Commission's principles for the design of each of Medicare's quality incentive programs for plans and providers.³

One concern with the QBP is the large number of measures included, which now number nearly 50. The Commission's principles call for the use of a small set of measures emphasizing outcome measures and patient experience measures of relevance to the program and to beneficiaries. Other concerns with the current QBP arise because of the use of the MA contract as the reporting unit for measures that determine star ratings. MA contracts cover wide, disparate geographic areas across many states. This is so for a variety of reasons, including because companies have consolidated contracts to have bonus-level star ratings apply to absorbed contracts not in bonus status in order to receive unwarranted bonus payments.⁴ With the star ratings assigned at the contract level, given the degree of geographic variation in MA quality results (see the Commission's March 2018 report to the Congress, for example), the Commission does not believe the Medicare program currently has reliable information about MA quality. In addition, the star ratings that beneficiaries can access on the Plan Finder often do not give an accurate picture of the quality of care a plan provides in the beneficiary's geographic area.

The Commission laid out the broad parameters of an MA value incentive program to replace the QBP in its June 2019 report to the Congress, and in fact voted to recommend such to the Congress at its April 2020 meeting.⁵

Below are specific comments on elements of the proposed regulation.

Changing the weight of patient experience and access measures. The proposed rule would increase the weight of the set of measures of patient experience, complaints, and "measures capturing access" to care. While the Commission believes that patient experience measures are an important component of health plan evaluations, the proposal would give disproportionate weight to patient experience measures relative to outcome measures. The set of measures proposed for increased weighting also includes measures that we refer to as administrative or insurance function measures but which CMS classifies as access measures (such as making timely decisions about appeals) (Table 1).

³ Medicare Payment Advisory Commission. 2019. *Report the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

⁴ Medicare Payment Advisory Commission. 2018. *Report the Congress: Medicare payment policy*. Washington, DC: MedPAC.

⁵ Medicare Payment Advisory Commission. 2019. *Report the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

| Table 1. Only half of the 16 measures proposed for increased weighting are survey-based patient experience measures, and 7 of the 8 remaining measures are administrative measures | |
|---|--|
| CAHPS® measures | Administrative/other measures |
| C22: Getting needed care | C28/D04: Complaints about the health/drug plan |
| C23: Getting appointments and care quickly | C29/D05: Members choosing to leave the plan (disenrollments) |
| C24: Customer service | C31: Plan makes timely decisions about appeals |
| C25: Rating of health care quality | C32: Reviewing appeals decisions |
| C26: Rating of health plan | C33: Call Center – foreign language interpreter and TTY availability |
| C27: Care coordination | D01: Call center – foreign language interpreter and TTY availability |
| D07: Rating of drug plan | D02: Appeals auto-forward |
| D08: Getting needed prescription drugs | D03: Appeals upheld |

Note: CAHPS (Consumer Assessment of Healthcare Providers and Systems®), a registered trademark of the Agency for Healthcare Research and Quality). The measuring number indicates Part C measures (e.g., C22) or Part D measures (D07). The complaint and disenrollment measures count only once for Medicare Advantage prescription drug (MA–PD) plans. The disenrollment measure can be classified as a patient experience measure.

Source: CMS technical notes on 2020 star ratings.

We believe the administrative measures should not be a component of a rating system measuring clinical quality and patient experience. Health plans should be held accountable for their administrative responsibilities and insurance functions through compliance standards and plan monitoring.

With regard to the effect of the proposed weighting on overall star ratings, the proposed weighting creates an imbalance between the two most important measure groupings—outcomes and patient experience. Table 2 shows the relative weighted shares of each of the CMS-defined measure categories (excluding the two improvement measures). Increasing the weights of the patient experience, access, and complaints measures to 4 would result in this category of measures constituting 61 percent of the weight of measures for an MA–PD reporting all measures. Outcome measures, arguably the most important set of measures, would have a weight of 9 percent. Even if the “administrative/other” measures of Table 1 were excluded from the star system, there would still be an imbalance in the weighting: Outcome measures would have a weight of 12 percent and patient experience measures would have a weight of 44 percent (data not shown in table).

| Table 2. Under the proposed changes, patient experience measures would far outweigh other measures, including outcomes | | | | |
|---|----------------------------------|--------------------|------------------|------------------|
| Measure category | Number of measures (2020 weight) | PE/A weight of 1.5 | PE/A weight of 2 | PE/A weight of 4 |
| Process | 20 (1) | 31% | 27% | 19% |
| Intermediate outcomes | 4 (3) | 18 | 16 | 11 |
| Outcomes | 3 (3) | 14 | 12 | 9 |
| Patient experience/access | 16 (1.5) | 37 | 44 | 61 |

Note: PE/A (patient experience, access, and complaints measures). “Intermediate outcomes” include measures such as control of blood sugar among diabetics, and adherence to medications. The three current outcome measures are hospital readmission rates and the two Health Outcomes Survey measures for improvement in physical health and mental health. Figures are based on the current measures and their distribution; there will be other changes to the measures over the coming years (such as the temporary withdrawal of the readmission measure). The current weight for PE/A is 1.5, to increase to 2 in the 2021 star ratings.

Source: MedPAC analysis of star measures and weights.

Because plans are less likely to report all outcomes measures, the proposed weighting system will create an even greater imbalance between the weight given to patient experience versus patient outcomes. Table 2 shows the weighting effect for contracts able to report all measures; however, a contract need only report half of all measures to receive a star rating for bonus purposes. Many plans do not report all measures. For example, the Health Outcomes Survey (HOS) measures of improvement in mental and physical health are among measures less likely to be included in determining an overall star rating. In the 2020 star results, of 401 contracts with an overall star rating, 53 did not have a star rating for the HOS results (which are results from a two-year survey period). The lack of HOS results would reduce to one the number of outcome measures that the 53 contracts would be able to report. With the proposal (included in this proposed regulation) to increase the minimum denominator for reportable HOS results from 30 to 100, even fewer contracts may have reportable HOS results. (In our analysis of HOS results for the 2015–2017 survey cohort, 40 of 356 contracts had a denominator of 30 or more but less than 100.)

Finally, a factor that CMS may wish to consider in determining whether Consumer Assessment of Healthcare Providers and Systems® (CAHPS) results can be used to determine star ratings is the response rate for the CAHPS surveys. CMS has reported median response rates in the 40 percent range for MA.⁶ If it is not already the case, CMS should have a minimum required response rate for the survey results to be included in star ratings.

The disenrollment rate measure and its weighting. We have specific comments on one of the “patient experience, access, and complaints” measures, which is the disenrollment rate measure. The measure is the percentage of enrollees disenrolling from a contract in a given year. However, the dissatisfaction is not necessarily with the quality of care in a given plan. The dissatisfaction is often with the cost associated with a plan (premiums and cost sharing), and the costs of a given plan as they compare with other plans when beneficiaries are choosing among plans during the annual election and open enrollment periods. Our analysis of MA disenrollments found premium

⁶ https://ma-pdpcahps.org/globalassets/ma-pdp/historic-data/historic_mapdp_response_rates.pdf

changes to be a major factor affecting beneficiary disenrollment decisions.⁷ Thus, it may be inappropriate to include disenrollment rates in a star system measuring quality. Instead, disenrollment rates can be viewed as a monitoring tool for CMS to examine plans with unusually high disenrollment rates to determine whether there are issues such as poor access to needed care that are prompting higher disenrollment rates.

Another concern with the disenrollment rate measure is that the current specification removes beneficiaries enrolled under an employer-group waiver plan (EGWP) from the numerator but not the denominator. EGWP removal from the numerator is a logical exclusion because the movement of EGWP enrollees among MA plans is often as the result of changes in contracts between employers/unions and MA plan sponsors. Such movement among plans is not similar to an individual Medicare beneficiary's decision to change from one plan to another during the annual election period. On an individual basis, an EGWP enrollee of an MA plan is unlikely to leave the plan if it means that the person no longer has subsidized retiree coverage from an employer or union. By the same logic that is the basis for removing EGWP enrollees from the numerator, EGWP enrollees should also be removed from the denominator in determining a disenrollment rate. To cite a specific example, in the star ratings for 2019 and 2020, contract number H7917 had a 0 percent disenrollment rate, thereby earning a 5-star rating on the measure. However, in 2018, H7917 enrollment consisted almost exclusively of EGWP members. Only 21 enrollees were in a non-EGWP plan under the contract, and 59,000 enrollees were EGWP enrollees. If all 21 of the non-EGWP enrollees disenrolled, the disenrollment rate for the contract would be computed as 21 divided by 59,021, which rounds to 0 percent. However, it is more appropriate to determine a rate among non-EGWP enrollees; that is, the EGWP members should be removed from both the numerator and the denominator. So in the example, if 21 non-EGWP enrollees disenrolled from the H7917 contract, the disenrollment rate would be computed as 21 out of 21, or 100 percent rather than 0 percent (though a denominator of 21 is probably too small a denominator for computing a disenrollment rate).

The complaints about the drug plan measure and its weighting. The Part D measure of complaints about the drug plan is derived from the rate of complaints to CMS's Complaints Tracking Module (CTM) about each plan per 1,000 members. Many categories of complaints are included in this measure such as allegations of inappropriate marketing, issues with premium billing and cost sharing, and concerns about protection of privacy. Two other subcategories of complaints that contribute to this measure are:

- Beneficiary has difficulty securing Part D prescriptions, and
- Beneficiary has concerns about a denied claim.

We do not know from available data the extent to which these two subcategories contribute toward plans' overall complaints measure. Nevertheless, we note that such complaints can have ambiguous interpretations. On the one hand, a plan sponsor may have inappropriately denied a

⁷ Medicare Payment Advisory Commission. 2015. *Report the Congress: Medicare payment policy*. Washington, DC: MedPAC.

patient's claim or otherwise impeded his or her ability to fill their prescription promptly. On the other hand, a plan sponsor may have applied utilization management tools such as prior authorization to determine whether a prescription was safe and appropriate for the patient. If these two subcategories account for a considerable proportion of drug plan complaints, increasing the weight of this measure to four could potentially penalize plan sponsors for managing prescription drug benefits in the way that the Part D program intended.

QBP ratings for new contracts under existing parent organizations. Under the QBP, the statute provides higher benchmarks (a 3.5 percent benchmark increase) for new entrants in the MA market for a company without any current MA contract. The proposed regulation clarifies how CMS assigns ratings when there is a new contract offered by a company that is participating in MA. The policy in such a case is to assign the new contract the enrollment-weighted average star rating across all of the company's existing contracts.

We would also note that this policy has been applied to an organization that at the end of 2016 consolidated three regional contracts into one contract to obtain unwarranted bonuses (as described in our March 2017 report to the Congress regarding this specific consolidation). The company is now de-consolidating the contract to revert to the original configuration, and for the 2020 bidding cycle, the bid data indicate that two of the company's contracts are classified as being in 4-star status because they are new contracts and the organization's average star rating is used to determine their bonus eligibility.

We believe that this method of assigning a star rating to a new contract for an existing organization is both (1) inappropriate and (2) unfair for contracts competing with a new entrant offered by a participating company. A new entrant sponsored by an existing organization could immediately receive a star rating of 5 under this approach and a 5 percent benchmark increase. Given how much regional variation there is in MA quality results (as we have noted), and given how much variation companies have in their contract stars across the country, it is more appropriate to use the statutory provision as a guide and provide a 3.5 percent benchmark for both types of new contracts—those sponsored by a company new to MA and those sponsored by currently participating MA organizations.

Organizations leaving and immediately re-entering a service area. A concern related to how star ratings are assigned to new contracts is what appears to be a practice that organizations may be undertaking to ensure higher star ratings. There appears to have been at least one instance of a company reducing its service area under a contract at the end of a year—which plans can do on a county-by-county basis—and then immediately re-entering the same counties with a new contract number even though the old contract number continues for other counties. The new contract will be designated as new for two years for QBP purposes and will have the company-level average star rating (of 4 stars in this case) until the contract can collect and report data on its quality results as a new contract. In such a case, because there was a service area reduction, if the company wishes to continue to cover the individuals affected by the reduction, the enrollees have to re-enroll in the plan individually during the annual election period. In the one instance where this appears to have happened at the end of 2019, the company appears to have retained most of its enrollment.

There is a statutory provision that guards against contracts leaving and then immediately re-entering the MA program. Section 1857(c)(4) of the Social Security Act provides that the “Secretary may not enter into a contract with a Medicare+Choice [MA] organization if a previous contract with that organization under this section was terminated at the request of the organization within the preceding 2-year period,” except in special circumstances. We believe that a large service area reduction has the same effect as a contract termination that the statutory provision addresses, and that the practice of leaving and immediately re-entering a service area should not be permitted.

Permitting a second, “preferred,” specialty tier in Part D

CMS allows Part D sponsors to use a specialty tier for drugs with a negotiated price that exceeds a minimum dollar threshold amount currently set at \$670 per month. CMS sets the amount to capture about 1 percent of prescriptions with the highest prices. Under current guidance, sponsors may set specialty tier coinsurance to no higher than 25 percent after the standard deductible and before the initial coverage limit (ICL), or up to 33 percent for plans that use no deductible or one that is lower than the standard deductible. Drugs placed on a specialty tier are exempt from tiering exceptions, under which beneficiaries may appeal to the plan to obtain nonpreferred drugs at preferred (lower) cost sharing.

CMS proposes to allow Part D sponsors to establish up to two specialty tiers—one preferred and one nonpreferred. Under the proposal, CMS would codify the current 25/33 percent maximum allowable cost sharing to apply to both specialty tiers and require the second, “preferred,” specialty tier to have lower cost sharing than the nonpreferred specialty tier. Part D sponsors would have the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the dollar-per-month cost threshold. Beneficiaries could not apply for a tiering exception to nonspecialty-tier levels of cost sharing. However, under the proposal, a beneficiary taking a nonpreferred specialty-tier drug could apply for a tiering exception to the preferred specialty-tier cost sharing.

Comment

The Commission shares CMS’s goals of improving Part D enrollee access to needed drugs while lowering drug costs for enrollees and the taxpayers who finance the program. The rapid growth in spending for specialty-tier drugs has been a concern of the Commission for several years. Between 2007 and 2017, spending for specialty-tier drugs has grown more than 10-fold—from \$3.4 billion to \$37.1 billion—and made up nearly a quarter of gross Part D spending by the end of that period.⁸ As the agency noted in its proposed rule, one component of the Commission’s 2016 recommendations would have provided plan sponsors with greater flexibility to manage their enrollees’ spending for specialty drugs.⁹ As an example of such flexibility, the Commission discussed allowing sponsors to use two specialty tiers, including a preferred tier that offered lower

⁸ Medicare Payment Advisory Commission. 2019. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

⁹ Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

cost sharing to encourage the use of lower cost biosimilars, and recommended that the Secretary implement such a tiering structure in its April 2020 meeting.

Allowing sponsors to have two specialty tiers could encourage price competition among existing specialty drugs that are therapeutic substitutes and improve the ability of plan sponsors to negotiate with pharmaceutical manufacturers for rebates. In turn, patients may see lower cost sharing. This tier structure could also encourage beneficiaries to consider using biosimilar products when they become available. Because more expensive or less clinically effective therapies could be placed on the nonpreferred tier, rather than excluded from the formulary, this tier structure could reduce the need for nonformulary exceptions.

While we are generally supportive of the proposal, we are concerned that maintaining the current 25/33 percent maximum allowable amount for both specialty tiers may be too constraining. Plan sponsors would be able to encourage use of preferred specialty drugs more effectively if they could establish differential rates of coinsurance between the preferred and nonpreferred specialty tiers. Greater flexibility over this differential would, in turn, give plan sponsors greater leverage with manufacturers over rebates.

In addition, because the benefits must be actuarially equivalent to the defined standard benefit, requiring plan sponsors to use a coinsurance below the 25/33 percent maximum for the preferred tier without the ability to set a coinsurance rate above the maximum amount for the nonpreferred specialty tier would necessitate increasing cost sharing on nonspecialty tiers. Spending for specialty-tier drugs already accounts for about a quarter of gross Part D spending and is likely to continue to grow. As a result, to maintain actuarial equivalence, constraining coinsurance on both specialty tiers to the proposed rates means that, in the future, plan sponsors would have to increase cost sharing for nonspecialty tiers by a larger amount than they would today.

For these reasons, we encourage CMS to consider giving plan sponsors more flexibility in setting the appropriate coinsurance for the two specialty tiers. For example, CMS could allow plan sponsors to set a coinsurance that is higher than 25 percent as long as the cost sharing on the two specialty tiers averages to 25 percent. As with other (nonspecialty) tiers, CMS could set a maximum coinsurance rate (e.g., 50 percent) for all specialty tiers.

We believe CMS could strike an appropriate balance between plan flexibility and Part D enrollees' access to drugs placed on specialty tiers by continuing to use its formulary review process to prevent discriminatory formulary structure. In addition, CMS could require plan sponsors that use two specialty tiers to establish a process to request a tiering exception to obtain drugs placed on the nonpreferred specialty tier at the lower cost sharing that is applied to drugs on the preferred specialty tier when clinically warranted.

Beneficiary real-time benefit tool (RTBT)

This rule proposes to require that Part D plan sponsors implement an electronic RTBT for beneficiaries by January 1, 2022. The tool would give beneficiaries access to patient-specific formulary and benefit information including cost-sharing amounts for prescription drugs and

clinically appropriate formulary alternatives on computers, mobile devices, or through plan call centers. Under this proposed rule, plan sponsors would be permitted to offer rewards and incentives to beneficiaries who access RTBT information using the plan's portal, application, or call center. CMS intends for this proposal to complement its May 2019 final rule that requires Part D plan sponsors to implement an electronic RTBT capable of integrating with at least one prescriber's e-prescribing and electronic medical record (EMR) system by January 1, 2021.

Comment

The Commission supports CMS's goal of encouraging beneficiaries to consider potential cost differences when selecting among medications. As cohorts of Medicare beneficiaries become increasingly comfortable using electronic tools, plans' RTBT applications and portals could help enrollees take a more active role in decisions about the prescriptions they use. While we support providing beneficiaries with personalized information about prescription drug cost sharing, we encourage CMS to monitor the effectiveness of plans' use of rewards and incentives and their impact on Part D administrative costs.

At the same time, the Commission believes that the potential benefits of RTBTs—facilitating better-informed choice of drugs, streamlining the prior authorization process, and helping to avoid lengthy and costly exceptions and appeals processes—would be best achieved if clinicians used prescriber RTBTs and electronic prior authorization within their EMR workflow. As we noted in our previous comment letter, the Commission supports CMS's May 2019 requirement that plans set up a prescriber RTBT as a means of improving informed choice, efficiency, and patient safety. However, the extent to which that requirement (which applies to plan sponsors) increases the use of RTBTs in Medicare Part D will depend on the degree to which clinicians—who face no requirement—adopt them when prescribing for their Medicare patients.

MA and cost plan network adequacy

CMS maintains network adequacy standards to ensure that MA plans establish a network of providers that is sufficient to make all Medicare-covered services available and accessible to all plan enrollees with reasonable promptness. Network adequacy standards are applied to each provider specialty and facility type and generally require that plans contract (1) with a minimum number of providers or facilities within a geographic area and (2) with a sufficient number of providers and facilities such that 90 percent of Medicare beneficiaries have access to at least one provider of each specialty and one facility of each type within a maximum time and distance standard.

To establish time and distance standards, CMS uses a common process across all provider specialties and facility types. For each provider specialty and facility type, CMS establishes network adequacy standards by using the location of all providers (or facilities) and the location of Medicare beneficiaries to determine a standard that is feasible and practical for the majority of counties of a given type. Estimates are established uniformly for counties in each category: large metropolitan, metropolitan, micropolitan, rural, and county with extreme access consideration (CEAC). In areas with a shortage of supply of a certain provider specialty or facility type such that

it is not possible to meet time and distance standards, CMS uses a customization process to relax the time and distance standards for individual counties so that standards are attainable. (The list of provider specialties and facility types subject to network adequacy standards is broad, but our comments focus on dialysis facilities and nephrologists.)

For the minimum number standard, CMS requires each plan’s network to include at least one dialysis facility in each county in a plan’s service area. For nephrologists, CMS requires a minimum number per 1,000 Medicare beneficiaries, but never less than one nephrologist per county in a plan’s service area.¹⁰ For time and distance standards, CMS requires that 90 percent of beneficiaries have access to a dialysis facility and a nephrologist within the maximum times and distances shown in Table 3.

Table 3. MA network adequacy time and distance standards for dialysis facilities and nephrologists, 2020

| | Maximum time (minutes) | | | | | Maximum distance (miles) | | | | |
|-------------------|------------------------|-------|-------|-------|------|--------------------------|-------|-------|-------|------|
| | Large Metro | Metro | Micro | Rural | CEAC | Large Metro | Metro | Micro | Rural | CEAC |
| Dialysis facility | 20 | 45 | 65 | 55 | 100 | 10 | 30 | 50 | 50 | 90 |
| Nephrologist | 30 | 45 | 80 | 90 | 125 | 15 | 30 | 60 | 75 | 110 |

Note: County with extreme access consideration (CEAC). Definitions of large metropolitan, metropolitan, micropolitan, rural, and CEAC counties are based on total population and population density in each county and are included in the proposed rule.

Source: CMS health services delivery (HSD) reference file (2020-01-14).

Since the beginning of the MA program, statutory provisions excluded individuals with end-stage renal disease (ESRD) from enrolling in MA plans, except in limited circumstances (e.g., Medicare beneficiaries with ESRD could enroll in a special needs plan, and individuals who develop ESRD while enrolled in an MA plan or in a health plan offered by an MA organization can remain in that MA plan or can elect to enroll in another health plan offered by that organization). The 21st Century Cures Act expanded enrollment options for individuals with ESRD by removing the prohibition on MA enrollment starting on January 1, 2021. Because of this change, the CMS Office of the Actuary expects that ESRD enrollment in MA plans (131,000 in 2020) will increase by 83,000 over six years, with half of the increase in enrollment occurring in 2021.

In this rule, CMS proposes changes to network adequacy requirements:

- To encourage more MA plan offerings in rural areas, CMS proposes to reduce the percentage of beneficiaries for which a plan must meet time and distance criteria to 85 percent for micropolitan, rural, and CEAC counties. CMS states that there is evidence of a lower supply of physicians and specialists in these counties compared to urban areas, and

¹⁰ Minimum nephrologist thresholds are 0.09 per 1,000 Medicare beneficiaries (or 1 per 11,111 Medicare beneficiaries) for metropolitan counties and 0.08 per 1,000 Medicare beneficiaries (or 1 nephrologist per 12,500 Medicare beneficiaries) for micropolitan, rural, and CEAC counties. MedPAC analysis of CMS health service delivery (HSD) reference file (2020-01-14). Accessed 3/4/20. <https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/index>.

that plans failing to meet the 90 percent standard often have met the standard for 80 to 89 percent of beneficiaries.

- In addition, CMS solicits comment on eliminating or altering time and distance standards for dialysis facilities. CMS received comments from providers and physician groups identifying limitations in current network adequacy policies for dialysis treatments, and comments from stakeholders noting that providers in concentrated areas may leverage network adequacy requirements in order to negotiate prices well above Medicare fee-for-service (FFS) rates. Furthermore, CMS cites research suggesting that home dialysis offers advantages over in-center hemodialysis and encourages plans to exercise all options, with respect to accessing medically necessary dialysis care, to best meet beneficiaries' health care needs. CMS proposes the following options for altering dialysis facility time and distance standards:
 - Eliminating time and distance standards for outpatient dialysis facilities,
 - Allowing plans to attest to providing medically necessary dialysis services in its contract application instead of requiring plans to meet time and distance standards for providers of those services,
 - Allowing exceptions to time and distance standards if a plan covers home dialysis for all enrollees who need those services, and
 - Customizing time and distance standards for dialysis facilities.

Comment

The Commission strongly opposes the proposals to eliminate or alter time and distance standards for dialysis facilities. Network adequacy for ESRD beneficiaries is critical for ensuring access to MA plan options at a level that is equal to the level of access for other Medicare beneficiaries. Proximity to a dialysis facility is an important factor in dialysis care. Current distance standards vastly exceed typical travel times for ESRD beneficiaries in FFS Medicare and distances considered relevant under FFS Medicare's low-volume payment adjustment. Finally, a large share of Medicare ESRD beneficiaries is already enrolled in MA, and it is unclear what problem is being addressed by eliminating or altering time and distance standards. In the rest of this comment, we explain our general concerns, followed by additional concerns about the specific proposals, and one final consideration for network adequacy of dialysis treatment.

CMS should identify a specific concern and explain the goal it is trying to achieve. Currently, a large number of ESRD beneficiaries are enrolled in MA (131,000, about 25 percent of all ESRD beneficiaries). CMS cited comments from providers and physician groups about the limitations of the current network adequacy policies on dialysis treatment, but it did not state that plans have had trouble meeting existing network adequacy requirements for their current ESRD enrollees. Although CMS projects ESRD enrollment in MA to increase as a result of 21st Century Cures Act provisions, it is unclear why additional enrollees would add strain to current network adequacy standards. The time and distance standards are based on beneficiary and facility locations and are unaffected by actual MA enrollment (e.g., standards do not address the capacity of those facilities, to ensure a sufficient number of dialysis stations in a plan's network of dialysis facilities).

CMS did cite comments from stakeholders that “providers in concentrated areas may leverage network adequacy requirements in order to negotiate prices well above Medicare FFS rates.” We recognize that the dialysis sector is highly concentrated—in 2018, 74 percent of dialysis facilities were owned by two organizations—and that this level of concentration may limit the ability of MA plans to negotiate what they would view as reasonable payment rates, which may result in payments for dialysis that are higher than FFS Medicare. Although we share CMS’s concern about the impact on MA plans, we note that CMS has not identified a concern about negotiating leverage that has led to plans paying lower than FFS Medicare rates for other items and services, as in the case of skilled nursing facility services or certain physician services, labs, and durable medical equipment.^{11, 12} Furthermore, we do not know with certainty that a problem will arise for MA plan payments for dialysis. After the prohibition on ESRD beneficiaries enrolling in MA is lifted and MA has many more enrollees with ESRD, the balance of negotiating leverage and the nature of negotiations between MA plans and dialysis facilities may change, or plans may identify alternative coverage arrangements (e.g., ESRD special needs plans, or sub-capitation agreements). The Commission generally approaches policy concerns by evaluating the extent of the problem and then developing a policy remedy that addresses the identified problem directly. If CMS’s main concern is asymmetric negotiating leverage between dialysis facilities and MA plans, relaxing network adequacy requirements should not be the remedy.

MA coverage should be the same for ESRD beneficiaries as for all Medicare beneficiaries.

Access to Medicare services in MA is generally more limited than access to services in FFS Medicare. MA plans contract with a limited network of providers to cover the same set of services as FFS Medicare, but many more providers participate in FFS Medicare than with any MA plan. Within MA, network adequacy standards ensure that plans offer sufficient coverage for all Medicare services. Applying network adequacy standards equally across provider specialties and facility types is consistent with the statutory provision requiring MA plans to cover all items and services covered under Medicare Part A and Part B in a manner that “makes such benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits.”¹³

The 21st Century Cures Act provides ESRD beneficiaries with the same access to Medicare coverage through an MA plan as other Medicare beneficiaries. Given the requirement that MA plans make all items and services available and accessible to each individual electing a plan, CMS should treat MA ESRD enrollees equally with how other MA enrollees are treated and should ensure network adequacy for all provider specialties and facility types to the same degree, including dialysis facilities. Relaxing MA network adequacy standards for dialysis facilities reduces access to a necessary treatment for MA ESRD enrollees, and it creates a dichotomy within

¹¹ Medicare Payment Advisory Commission. 2020. *Report to the Congress: Medicare payment policy*. Chapter 8: Skilled nursing facility services. Washington, DC: MedPAC.

¹² Trish, E., P. Ginsburg, L. Gascue, and G. Joyce. 2017. Physician reimbursement in Medicare Advantage compared with traditional Medicare and commercial health insurance. *JAMA Internal Medicine* 177, no. 9 (September 1): 1287–1295.

¹³ Section 1852(d)(1)(A) of the Social Security Act.

MA where MA ESRD enrollees are less able than other MA enrollees to gain access to needed services.

We are concerned that CMS has proposed four options that would relax network adequacy standards for dialysis facilities, each of which would result in reduced access to dialysis services for individuals with ESRD who have elected to enroll in MA. If more lenient network adequacy standards were adopted, MA plans could construct more limited networks for dialysis services, leaving ESRD beneficiaries with unequal access to MA plans relative to other Medicare beneficiaries. Under current program rules, such practices could be considered discriminatory as defined under section 1852(b) of the Act: “the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals with the organization.” If plans are allowed to construct networks with a lesser degree of coverage for dialysis facilities than other specialties and facility types, it would effectively allow plans some ability to discriminate against ESRD beneficiaries wishing to enroll in MA.

Proximity to a facility is important for dialysis care. The vast majority of all ESRD beneficiaries receive treatment in a dialysis facility and travel to that facility three times per week, making proximity to the nearest facility an important factor in dialysis care. Studies show that increased travel time to a facility increases missed treatments and is associated with worse outcomes for patients. In particular, a longer travel time to the dialysis facility creates a substantial burden for many patients and has been linked to decreased adherence by patients to the dialysis prescription (i.e., more missed treatments) and increasing mortality.^{14, 15} Difficulty with transportation more generally is also associated with missed dialysis treatments and increased morbidity and mortality in ESRD patients.^{16, 17}

To benchmark typical travel distances to dialysis facilities, we looked at our prior analysis of the ESRD population in FFS Medicare. We calculated driving miles for new FFS dialysis beneficiaries in 2004, 2006, and 2008; we found that the median driving distance was about 6 miles, and the 25th to 75th percentile range was from about 3 miles to 13 miles. All distance estimates were roughly unchanged during this four-year period. As expected, beneficiaries residing in rural areas drove longer distances (median of about 11 miles) than beneficiaries residing in urban areas (median of about 5.5 miles).¹⁸

¹⁴ Al Salmi, I., M. Larkina, M. Wang, et al. 2018. Missed hemodialysis treatments: International variation, predictors, and outcomes in the Dialysis Outcomes and Practice Patterns Study (DOPPS). *American Journal of Kidney Diseases* 72, no. 5 (November): 634–643.

¹⁵ Moist, L. M., J. L. Bragg-Gresham, R. L. Pisoni, et al. 2008. Travel time to dialysis as a predictor of health-related quality of life, adherence, and mortality: The Dialysis Outcomes and Practice Patterns Study (DOPPS). *American Journal of Kidney Diseases* 51, no. 4 (April): 641–650.

¹⁶ Chenitz, K. B., M. Fernando, and J. A. Shea. 2014. In-center hemodialysis attendance: Patient perceptions of risks, barriers, and recommendations. *Hemodialysis International* 18, no. 2 (April): 364–73.

¹⁷ Chan, K. E., R. I. Thadhani, and F. W. Maddux. 2014. Adherence barriers to chronic dialysis in the United States. *Journal of the American Society of Nephrology* 25, no. 11 (November): 2642–2648.

¹⁸ Medicare Payment Advisory Commission. 2011. *Report to the Congress: Medicare payment policy*. Chapter 6: Outpatient dialysis services. Washington, DC: MedPAC.

The maximum distance standards applied for MA network adequacy is 10 miles for large metro areas. For all other areas, maximum distance standards range from 30 to 90 miles. Although the network adequacy distance standard is a maximum, it is worth noting that the standard for areas (other than large metro areas) vastly exceeds the range of distances commonly traveled for dialysis in FFS Medicare.

Concerns about specific proposals:

- The Commission strongly opposes the proposal to waive time and distance standards for dialysis facilities. Under the proposal, plans could avoid ESRD beneficiaries, effectively allowing the discrimination against ESRD beneficiaries wishing to enroll in MA.
- Allowing plans to attest to providing medically necessary dialysis services may ensure access to dialysis for enrolled beneficiaries, but without time and distance standards, plans would be able to discourage ESRD beneficiaries from choosing to enroll in MA because of inadequate networks.
- Covering home dialysis for all enrollees (in exchange for waiving time and distance standards) would not meet the needs of the dialysis patient population. No one modality (in-center, home hemodialysis, or home peritoneal dialysis) is best for all patients. The vast majority of dialysis patients receive dialysis in a center. Many of those patients are unable to conduct home dialysis at all, and the needs of patients currently receiving home dialysis may change over time (e.g., because of caregiver burnout, or declining health status) such that in-center dialysis is necessary. Home dialysis is not a substitute for in-center dialysis for all patients. Furthermore, home dialysis patients generally travel to a facility for training and possibly for monthly visits with their nephrologist (although two out of every three monthly visits may now be conducted via telehealth).
- Customizing time and distance standards for dialysis facilities would presumably treat ESRD beneficiaries differently from other Medicare beneficiaries. CMS uses customization to increase (never decrease) time and distance standards by using a less strict threshold when it is not possible to meet the time and distance standard with available providers. Presumably this proposal would apply a more lenient threshold when determining time and distance standards as compared to the standards for other providers and facilities. Given that the maximum distance standards are already much higher than typical travel times to dialysis facilities, such a proposal would further limit the Medicare options available to ESRD beneficiaries.

A final consideration for network adequacy of dialysis treatment. Dialysis treatment requires patients to have access to both a dialysis facility and a nephrologist to manage their treatment. We find that a significant share of nephrologists refers patients to dialysis facilities owned by the same company (perhaps due to the consolidation of dialysis facilities into a few companies, or due to the

joint ventures that nephrologist and dialysis facilities undertake). When looking at the five largest dialysis organizations in FFS Medicare, 18 percent of nephrologists referred exclusively to a single organization's dialysis facilities, and 52 percent of nephrologists referred at least 90 percent of treatments to a single organization's dialysis facilities.¹⁹ An MA plan attempting to discourage enrollment by ESRD beneficiaries could attempt to contract with nephrologists referring exclusively to one company, and then contract only with dialysis facilities owned by another company. Although such a strategy could meet network adequacy standards, such a practice should be considered discriminatory and should be barred.

Conclusion

The Commission values the ongoing cooperation and collaboration between CMS and our staff on technical policy issues. We look forward to continuing this productive relationship. If you have any questions, or require clarification of our comments, please feel free to contact James E. Mathews, the Commission's Executive Director, at 202-220-3700.

Sincerely,

A handwritten signature in black ink that reads "Francis J. Crosson M.D." The signature is written in a cursive, flowing style.

Francis J. Crosson, M.D.
Chairman

¹⁹ MedPAC analysis of FFS Medicare claims data for 2018. Our estimates are a lower bound. We analyzed dialysis treatments at all facilities, but we only assessed the share of referrals to the five largest dialysis organizations.