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2021 Medicare Parts C and D Final Rule: Enhancing Coverage for ESRD and Easing Network and MLR Standards

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On May 22, 2020, the Centers for Medicare & Medicaid Services ("CMS") released the Contract Year ("CY") 2021 Medicare Advantage ("MA") and Part D Final Rule ("Final Rule"). Important areas addressed include a new program intended to expand enrollment of End Stage Renal Disease ("ESRD") beneficiaries in MA plans and otherwise improve coverage and payment for kidney transplants, and generally more relaxed standards for calculating the medical loss ratio, network coverage and telehealth. The Final Rule's ESRD provisions may be regarded as the Administration's latest step to implement President Trump's July 2019 Executive Order on Advancing American Kidney Health ("Kidney Health EO"), along with the recent announcement of high levels of participation by Part D plans in a new program for capping insulin costs to certain Part D plan beneficiaries.

This Alert summarizes key provisions of the Final Rule. If you have questions, please do not hesitate to contact one of the authors or your usual Ropes & Gray Advisor.

The Final Rule acknowledges that CMS's response to the COVID-19 public health emergency caused it to leave unaddressed many other policy changes from the February 2020 proposed rule, including provisions relating to prescription drug pricing. CMS intends to address these in subsequent rulemaking, which shall be effective (or finalized) on or before January 1, 2021, and be applicable, i.e., impose obligations, no earlier than January 1, 2022. This indicates that any policies finalized from the balance of the proposed rulemaking will only be applicable to CY 2022.

Expanding Access to MA Plans for ESRD Patients

Following the policies suggested in the Kidney Health EO, the Final Rule codifies and explains several changes ordered by the 21st Century Cures Act (the "Cures Act") that open new opportunities for ESRD providers for plan years beginning January 1, 2021:

- *Allowing ESRD enrollment.* Removal of the general prohibition of individuals with ESRD from enrolling in MA plans will expand the population eligible for MA.[i]
- *Reducing plan costs for ESRD patients to make enrollment more attractive to MA plans.*
    - Expansion of Medicare Fee-for-Service ("FFS") coverage of costs associated with organ acquisition for kidney transplants for MA beneficiaries will push those costs onto the FFS program, encouraging plans to accept ESRD patients.[ii]
    - Implementing the Cures Act provisions that exclude kidney acquisition costs from the MA benchmarks and capitation rates used in determining payments to MA plans should have a similar effect.[iii]

Eased Outpatient Dialysis Network Adequacy Requirements May Advantage In-Home Dialysis Providers

CMS also has made it easier for MA plans to meet network participation requirements for dialysis, by removing outpatient dialysis facilities from the list of specialty providers subject to Medicare's network adequacy evaluation.

- *No CMS evaluation of MA plan time and distance standards for outpatient ESRD facilities.* Although the proposed rule would have treated outpatient dialysis facilities as one of 14 facility-specialty types that must be evaluated for each MA plan to ensure the plan meets specific time and distance standards, the Final Rule removed them from the list.iv

- *Self-attestation of network adequacy by plans to include in-home dialysis.* Instead of assessing whether an MA plan has contracted with an adequate number of outpatient dialysis facilities, CMS will now only require MA plans to self-attest that they have an adequate network for providing dialysis services, including access to in-home dialysis.[v]
- *Improved leverage for in-home dialysis providers.* The reduced level of scrutiny could disadvantage outpatient dialysis providers' bargaining power when negotiating with MA plans, and improve the leverage of in-home dialysis providers, which seems to be in line with CMS's stated position that "home-based dialysis may offer advantages over in-center hemodialysis."[vi]

Relationship to Other Kidney Care Initiatives

Stakeholders will also note that these ESRD changes follow other favorable treatment of the Administration's Kidney Care Initiative.

- *Comprehensive end-stage renal disease care model.* In addition to extending the model through March 2021:
    - *Reduced downside risk.* CMS reduced participants' 2020 downside risk by:
        - reducing shared losses by the proportion of months during the public health emergency;
        - capping gross savings upside potential at 5% gross savings;
        - removing COVID-19 inpatient episodes from the performance calculation; and
        - removing the 2020 financial guarantee requirement.[vii]
- *Kidney Care Choices.* CMS also delayed this voluntary demonstration's performance period until April 202l and will create an application cycle for a second cohort in 2021 that will launch in 2022.[viii]
- *Capped Part D insulin cost-sharing.* Because of the close correlation of ESRD with chronic, uncontrolled diabetes, many of the same stakeholders will see a connection to CMS' recent announcement of widespread participation in the Part D Senior Savings Model that promises seniors with diabetes a maximum insulin copay of $35/month.
    - Plans participating in this voluntary program that reach certain higher levels of enrollment of insulin-dependent diabetics will receive additional risk-corridor protection, when meeting certain qualifying criteria.

Additional Changes Ease Other Plan Participation Requirements

The Final Rule also implements several other changes to make Parts C and D participation more appealing to plans, including:

- *MA and Part D prescription drug program quality rating system.* Changes to CMS's quality rating methodology generally give more weight to patient experience in evaluating plan performance, and decrease the importance of expensive outlier cases in rating costs of care.[ix] This latter change has delayed application until the 2022 measurement year, which coincides with the 2024 Star Ratings produced in October 2023.[x]
- *Favorable adjustments to MA plan payment calculations.* CMS finalized its proposal to amend the MA MLR regulation such that:
    - the "incurred claims" portion of the Medical loss ratio numerator includes all amounts that an MA organization pays (including under the capitation contracts) for covered services, including amounts paid to entities or individuals that do not meet the definition of "provider" under the regulations;[xi] and
    - a deductible-based adjustment is provided to MA plans that offer Medical Savings Accounts ("MSA") to account for variability of claims experience for MA MSA plans.[xii] This would reduce the likelihood that

an MA contract with a high average deductible would report a low MLR as compared with an MA contract with the same number of enrollees but with a low average deductible.[xiii]

- *Easing access to telehealth with other changes to network adequacy standards.* CMS finalized proposals relating to network adequacy, including to account for the provision of services via telehealth. This includes:
    - reducing the percentage of beneficiaries that must reside within the maximum time and distance standards in non-urban counties from 90 percent to 85 percent in order for an MA plan to comply with network adequacy standards.[xiv]
    - eligibility to receive a 10-percentage point credit toward a percentage of beneficiaries within published time and distance standards:
        - when the plan contracts with telehealth providers in certain specialty types, including dermatology, psychiatry, and cardiology (despite a solicitation of comments in the proposed rule, home dialysis providers were not included);[xv] and
        - for affected provider and facility types in states that have Certificate of Need ("CON") laws, or otherwise impose "anti-competitive restrictions" that limit the number of providers or facilities in a county or state.[xvi]
- *Special Supplemental Benefits for the Chronically Ill ("SSBCI").* As part of codifying existing guidance concerning these benefits, CMS is expanding the kind of chronic conditions an enrollee must have to be eligible under SSBCI to include autoimmune disorders, cancer, diabetes mellitus, end-stage liver disease, and ESRD requiring dialysis, among others.[xvii] As stated in recent guidance, CMS is using the non-exhaustive list of chronic conditions applicable to MA Special Needs Plans and applying it to the SSBCI.[xviii]

Drug Pricing Changes Postponed

Changes in the February 2020 proposed rule that were not included in the Final Rule, but may be included in further rulemaking later this year, include the following related to drug pricing.

- *Permitting a second, "preferred" specialty tier in Part D.* Currently, Part D plans have flexibility in how they design their formulary benefit design subject to a review and approval process; however, all drugs with a cost greater than $670 are placed in a single specialty tier.[xix] CMS proposed to allow Part D sponsors to establish a second, "preferred" specialty tier with lower cost-sharing than the current specialty tier, and make other changes to increase the leverage of plans to negotiate lower prices by tier placement.[xx]
- *Beneficiary Real-Time Benefit Tool ("RTBT").* CMS proposed requiring Part D sponsors implement a beneficiary RTBT that will allow enrollees to view plan-provided, patient-specific, real-time formulary and benefit information by January 1, 2022.[xxi] The intent of the RTBT is to allow both prescriber and patient to consider potential cost differences.[xxii]

Other Proposed Changes Not Enacted

Additional changes from the proposed rule that were not finalized, but may be acted on later in the year, include mandatory implementation of drug management programs by Part D sponsors,[xxiii] permitting additional telehealth benefits to be provided by out-of-network providers by MA plans,[xxiv] implementing provisions of the SUPPORT Act regarding suspension of pharmacy payments and establishment of a website portal to enable sharing among plans regarding fraud, waste, and abuse,[xxv] and modification of the structure of the finder's fee for brokers and agents.[xxvi]

[i] 85 FR 33796.
[ii] *Id.* at 33796-7.
[iii] *Id.* at 33797.

[iv] *Id.* at 33860.
[v] *Id.*
[vi] 85 FR 9099.
[vii] Centers for Medicare & Medicaid Services, "CMS Innovation Center Models COVID-19 Related Adjustments," https://www.cms.gov/files/document/covid-innovation-model-flexibilities.pdf.
[viii] *Id.*
[ix] 85 FR 33797.
[x] *Id.*.
[xi] *Id.*
[xii] *Id.* at 33850.
[xiii] *Id.* This would also bring the Medicare MLR rules more in line with the commercial MLR rules, and encourage MA organizations to offer MSA plans, consistent with Executive Order 13890's directive to reduce barriers to obtaining Medicare MSAs. *Id.* at 33850-1.
[xiv] *Id.* at 33797.
[xv] *Id.* The full list includes dermatology, psychiatry, cardiology, otolaryngology, neurology, ophthalmology, allergy and immunology, nephrology, primary care, gynecology/OB/GYN, endocrinology and infectious diseases; 85 FR 9006.
[xvi] 85 FR 33798, 33896. CMS mentions this is in lock-step with Executive Order 13890, which provided that the Secretary of Health and Human Services would propose such a regulation adjusting network adequacy requirements for competitiveness of the health market in states in which plans operate and is implemented to take into account the administration's view that CON laws have an adverse effect on access to health care providers. 85 FR 9099.
[xvii] As noted in the Call Letter for CY 2020, "For CY 2020, CMS will consider any enrollee with a condition identified as a chronic condition in section 20.1.2 of Chapter 16b of the Medicare Managed Care Manual to meet the statutory criterion of having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee." Centers for Medicare & Medicaid Services, Medicare Managed Care Manual, Chapter 16-B, Section 20.1.2, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c16b.pdf; Centers for Medicare & Medicaid Services, "Contract Year 2021 Medicare Advantage and Part D Final Rule (CMS-4190-F1) Fact Sheet," https://www.cms.gov/newsroom/fact-sheets/contract-year-2021-medicare-advantage-and-part-d-final-rule-cms-4190-f1-fact-sheet.
[xviii] 85 FR 33802.
[xix] CMS Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (the "Call Letter"), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf ("[W]e intend to maintain the specialty tier threshold at $670 in an effort to balance plan flexibility with beneficiary access."); Centers for Medicare & Medicaid Services, "What Medicare Part D drug plans cover," https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover#:~:text=Tier%201%E2%80%94lowest%20Copayment%20%3A%20most,very%20high%20cost%20prescription%20drugs; 42 C.F.R § 423.120(b)(2).
[xx] 85 FR 9005. Specifically, the proposal would codify the maximum cost-sharing for the higher specialty tier; codify the methodology that determines and increases the specialty tier cost threshold, require sponsors to permit tiering exceptions between the two specialty tiers, and permit sponsors to determine which drugs go on either tier subject to the proposed cost threshold.
[xxi] *Id.* Centers for Medicare & Medicaid Services, "Contract Year 2021 and 2022 Medicare Advantage and Part D Proposed Rule," Fact Sheet, https://www.cms.gov/newsroom/fact-sheets/contract-year-2021-and-2022-medicare-advantage-and-part-d-proposed-rule-cms-4190-p.
[xxii] *Id.*
[xxiii] 85 FR 9003.
[xxiv] *Id.* at 9041.
[xxv] *Id.* at 9004.
[xxvi] *Id.* at 9042.