ROPES & GRAY

ALERT

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The Centers for Medicare & Medicaid Services Proposes Changes to the Medicare Advantage and Medicare Part D Programs

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Introduction

On December 27, 2022, the Centers for Medicare & Medicaid Services ("CMS") released proposed changes and clarifications concerning the Medicare Advantage ("MA") and the Medicare Prescription Drug ("Part D") programs through a Notice of Proposed Rulemaking (the "Proposed Rule"). The Proposed Rule focuses on changes designed to improve beneficiary transparency around prior authorization, offer additional formulary flexibility, increase health equity, and clarify CMS's position on when an overpayment is "identified" by an MA Organization ("MAOs") for purposes of triggering the False Claims Act's ("FCA") "60 day rule."

In particular, the Proposed Rule includes a new requirement that prior authorization approvals by MAOs remain valid for the duration of a beneficiary's course of treatment; introduction of a health equity index ("HEI") reward for Star Rating calculations, which includes contract performance monitoring for enrollees with certain social risk factors, as well as additional Star Rating changes; imposition of new and enhanced marketing requirements for Medicare and Part D to prevent misleading advertising; codification of CMS's processes for review and approval of negative formulary changes by Part D sponsors; and the agency's adoption of UnitedHealthcare's position on MAO FCA liability amidst developing case law.[1]

This Alert summarizes the above key changes in the Proposed Rule and discusses potential implications and considerations for stakeholders.

Summary of Key Changes to Proposed Rule

- **The Proposed Rule would clarify coverage criteria for basic benefits, conditions of MAO use of prior authorization, and would impose additional utilization management requirements, including establishment of a utilization management committee ("UM Committee").**

  Under current MA rules, MAOs that offer coordinated care plans are required to ensure continuity of care and integration of services with their contracted provider networks.[2] In furtherance of ensuring continuous care, and as a response to stakeholder comments that the prior authorization process may restrict access to care and limit options for ongoing treatment, the Proposed Rule would require that an MAO's prior authorization approval remain valid for the duration of the approved course of treatment and that an MAO provide a minimum 90-day transition period when an enrollee who is currently undergoing treatment switches to a new MA coordinated care plan. Except in cases of emergency, urgently needed, and stabilization services, current regulations require that all services covered by MA coordinated care plans require prior authorization.[3] The Proposed Rule would permit a coordinated care plan to impose prior authorization restrictions only for purposes of confirming the presence of diagnoses or other medical criteria and ensuring that a service or benefit is medically necessary or clinically appropriate based on standards specified in § 422.101(c)(1).[4] Further, during an enrollee's initial 90 days with a new MA coordinated care plan or when an enrollee is new to Medicare, the MA coordinated care plan would not be permitted to subject any active course of treatment to additional prior authorization requirements, even if a service would be furnished by an out-of-network provider,[5] so that treatment is not interrupted. Note that, under the rule proposed last month by CMS related to interoperability and patient access ("Interoperability and Patient Access Proposed Rule"), impacted MAOs would be required to send prior authorization decisions within 72 hours for expedited requests and within seven calendar days for standard requests[6]. Additionally, under the Interoperability and Patient Access Proposed Rule, CMS proposed new electronic prior authorization measures to streamline review and approvals, and the creation of policies to make the MA prior authorization process more

transparent and efficient.[7] These changes come in response to feedback from stakeholders and findings from an Office of the Inspector General ("OIG") report, which identified certain strict MAO prior authorization practices as barriers to care (the "OIG Report").[8]

The Proposed Rule would further codify CMS standards restricting use of MAOs' internal coverage criteria to limit care. CMS maintains a long-standing policy requiring that MAOs make medical necessity determinations based on internal policies, which include coverage rules[9] that are no more restrictive than traditional Medicare's[10] national coverage determinations ("NCDs")[11] and local coverage determinations ("LCDs")[12] and are approved by an MAO's medical director.[13] The OIG Report was particularly critical of MAOs imposing prior authorization requirements that were more restrictive than those under traditional Medicare, noting that MAOs imposed additional burdens on beneficiaries seeking care through evidence-based clinical criteria that, while non-existent in traditional Medicare, do not expressly contradict Medicare coverage rules.[14] The OIG Report highlighted the ambiguity between "more restrictive" requirements and requirements that are not "contradictory" to Medicare coverage rules. The Proposed Rule would codify the requirement that MAOs make medical necessity determinations based on express coverage and benefit designs approved by HHS, and would clarify that an MAO must adhere to all traditional Medicare coverage and benefit guidelines (i.e., those established in NCDs, LCDs, and general coverage and benefit conditions under Medicare rules). Under the Proposed Rule, an MAO may create its own internal access criteria (such as prior authorization requirements) that do not contravene the traditional Medicare coverage criteria, but these access criteria must be transparent and informed by current evidence in widely used treatment guidelines or clinical literature.

The Proposed Rule also would impose greater transparency around internal MAO medical necessity determinations. Specifically, under the Proposed Rule, MAOs would be required to provide a publicly accessible summary to CMS, enrollees, and providers, and a list of sources of evidence that they considered when developing internal coverage criteria related to medical necessity determinations, as well as their rationale for the coverage criteria. CMS reasons that this proposed change would protect beneficiaries by ensuring that coverage criteria are supported by current and widely used treatment guidelines and ensuring that MAOs are developing criteria that are consistent with traditional Medicare requirements. A similar requirement is proposed under the Interoperability and Patient Access Proposed Rule, which would require impacted payors to post certain prior authorization metrics publicly on their website or via a publicly accessible hyperlink on an annual basis.[15]

Finally, the Proposed Rule would impose additional obligations upon utilization management ("UM") in order to promote access to care. Specifically, the Proposed Rule specifies that MAOs would have to establish a UM Committee that works to ensure that the prior authorization policies are consistent with current Medicare NCDs and LCDs, guidance, statutes, and regulations, and are updated as needed. The Proposed Rule would require the UM Committee to annually review all medical services that require prior authorization and other utilization management policies, and document its findings. The Proposed Rule would establish specific composition and qualification standards for the UM Committee and implement standards related to Committee members' disclosed financial interests and conflicts of interest. The UM Committee would be responsible for developing, revising and updating the MA plan's utilization management policies on an as-needed basis, and documenting the reasons underlying its UM policy decisions.

- **CMS seeks to provide greater flexibility around certain midyear formulary changes for Part D sponsors**. Currently, Part D sponsors are allowed to immediately remove from its formulary[16] a brand name drug and substitute its newly released generic equivalent. When this immediate substitution policy was first adopted, it did not apply to biological products. Now that there is at least one interchangeable biologic product on the market, CMS proposes allowing Part D plan sponsors greater flexibility to make certain immediate substitutions in the formulary, such as for interchangeable biologic products, when immediate substitution would not disrupt existing therapy. Specifically, under the Proposed Rule, CMS would permit sponsors to immediately substitute (i) a new interchangeable biological product for its corresponding reference product; (ii) a new unbranded biological product for its corresponding brand name biological product; and (iii) a new authorized generic for its

corresponding brand name equivalent. CMS is not, however, proposing that Part D sponsors could immediately substitute biosimilar products[17] because biosimilar products have not met the requirements to support a demonstration of interchangeability.[18] In proposing to permit immediate generic substitutions of biological drugs, CMS likely believes that such substitutions present minimal risk because the therapeutically equivalent generics of the affected brand name drug are the same as an existing approved brand-name drug in dosage form, safety, strength, route of administration, and quality.[19]

CMS proposes to codify guidance and terminology related to when and how Part D Sponsors make negative formulary changes and to whom these changes would apply. For example, the rule would codify CMS's existing practice regarding review and approval of negative formulary changes.[20] Specifically, under the Proposed Rule, Part D sponsors may not make any negative formulary changes to the CMS-approved formulary except in cases where the sponsor submits a negative formulary request. Part D sponsors are not required to make a change request for immediate substitutions or market withdrawals. The proposed regulation would specify that Part D sponsors must provide notice to CMS and other specified entities[21] at least 30 days prior to the date such change becomes effective, and must either: (i) provide written notice to affected enrollees at least 30 days prior to the date the change becomes effective; or (ii) when an affected enrollee requests a refill of the Part D drug, provide the enrollee with an approved month's supply of the Part D drug under the same terms as previously allowed, as well as written notice of the formulary change.

Additionally, the Proposed Rule would define formulary "maintenance changes"[22] (i.e., those changes that the agency has said will generally be approved) and "non-maintenance changes" (i.e., those changes subject to more strict agency limits). The rule would codify the existing practice under which Part D sponsors making maintenance changes can assume, 30 days after submitting a negative maintenance change request form, that their request has been approved. For non-maintenance changes, CMS clarifies that sponsors should wait until they receive notice from CMS before implementing any changes. The Proposed Rule also would introduce a third category to capture negative formulary changes that may be made immediately. "Immediate negative formulary changes" are those that meet the requirements as either an immediate substitution or market withdrawal under 42 CFR § 423.120(e)(2)(i) or (ii), respectively. Under the Proposed Rule, Part D sponsors that meet all the requirements for immediate negative formulary changes may choose to make these changes immediately and provide notice afterward, or submit a negative change request and provide specific notice of change 30 days before they occur.

- **In line with President Biden's Executive Order "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," the Proposed Rule aims to address health disparities among MA and Part D beneficiaries.**[23]

  CMS proposes replacing the current reward factor with an HEI reward that encourages MA and Part D plans to reduce disparities in care by performing well with enrollees with certain social risk factors ("SRFs"). The current reward factor is a rating-specific factor added to the MA plan's summary or overall ratings (or both) if an MA plan has both high and stable relative performance. This current reward factor was included in the MA and Part D Star Ratings program beginning in 2009. The Proposed Rule proposes to remove the current reward factor and instead implement the HEI reward not as a separate stand-alone measure, but rather as a methodical enhancement to MA and Part D Star Rating programs. The HEI reward would aim to improve care delivery for beneficiaries with certain SRFs (e.g., dual eligibility, low-income subsidies, and disability) by incentivizing MA and Part D plans to focus on providing quality, equitable care to enrollees and help reduce disparities. Further, the SRFs included in the HEI of this Proposed Rule may be expanded over time. In order to qualify for the HEI reward, the contracts would need to have a minimum HEI score of greater than zero and have a certain percentage of enrollees with certain SRFs. The HEI would include a performance threshold below which contracts would not be able to qualify for the HEI reward so that MA and Part D plans that see increased positive health outcome in enrollees with SRFs, but ultimately enroll fewer patients with SRFs, would not be rewarded. The new HEI

reward would be implemented for the 2027 Star Ratings, covering primarily the 2024 and 2025 measurement years. The existing reward factor would continue to be calculated through the 2026 Star Ratings.

Further, the Proposed Rule aims to improve health equity by expanding the list of populations to which MAOs must provide services in a culturally competent manner. Currently, the regulation provides a list of examples of populations that may require specific attention, including populations with limited English proficiency or reading skills, and those with diverse cultural and ethnic backgrounds.[24] The Proposed Rule would expand the list to include persons (i) with disabilities; (ii) of diverse sexual orientations; (iii) of diverse gender identities or people who were born intersex; (iv) who live in rural areas and other areas with high levels of deprivation; and (iv) who are otherwise adversely affected by persistent poverty or inequality. CMS notes that although this change expands the mandatory requirements for MAOs to deliver services to specific demographics, MAOs should nonetheless strive to provide accommodations to all enrollees. CMS notes that it believes these clarifications are consistent with, and bolster, the Biden Administration's goal of ensuring equity across Federal programs.

Telehealth has become critical to closing gaps in health care access and health equity. The Proposed Rule would, for the first time, require that MAOs develop and maintain procedures to offer digital health education to enrollees to improve access to medically necessary covered telehealth benefits and expand health literacy. CMS does not currently have requirements for MAOs related to digital health literacy. Under the Proposed Rule, MAOs would have to adopt a screening program to identify enrollees with low digital health literacy rates, and then implement a digital health education program. CMS does not propose explicit parameters for the screening and educational programs[25], but instead, affords the MAO discretion to design and implement these programs, subject to CMS oversight. CMS would require that MAOs make information about their digital health literacy screening and digital health education program available to CMS upon request.[26] Additionally, the Proposed Rule would require that MAOs include, within provider directories, descriptions of providers' cultural and linguistic capabilities (including skills in American Sign Language ("ASL")) – an agency move that would codify existing best practices. CMS hopes this change will improve the quality and usability of provider directories, particularly for non- English speakers, limited English proficient individuals, and enrollees who use ASL.

- **CMS seeks to bolster MA and Part D marketing rules to help prevent misleading marketing.**[27] Although CMS currently prohibits inaccurate or misleading information in marketing materials,[28] the Proposed Rule would prohibit advertisements that do not mention a specific plan name, as well as the use in marketing materials of the term "Medicare," the CMS logo, or other products or information issued by the federal government in a way that is misleading, confusing, or misrepresents the plan. Further, the Proposed Rule would ban sales presentations that immediately follow an educational event, ban sales agents from conducting a sales or enrollment meeting with a beneficiary within 48 hours after a beneficiary's consent to a meeting, require annual written notification to enrollees of the ability to opt out of plan business calls, and require plan oversight to monitor agent/broker activities and identify and report to CMS non-compliance. Finally, the Proposed Rule would limit use of previously permitted superlatives in marketing materials. In particular, the Proposed Rule would prohibit all superlatives, including those used in logos and taglines, unless substantiating supporting data were provided with the material.

- **CMS further adjusts Star Ratings system measures.** Medicare currently uses the Star Rating system to measure how well MA and Part D plans are performing across a range of measures including customer satisfaction, care coordination, and health care quality. The Medicare Star Ratings aim to allow prospective Medicare enrollees to compare plans so they can make a more informed enrollment decision. For MAOs, the Star Ratings determine the quality bonus payments made to them under the quality bonus program.[29] MAOs that receive Star Ratings of at least four stars receive a quality bonus payment that can be used to offer additional benefits or lower premiums (they also receive the implicit "bonus" of the prospect of expanded future enrollment based on their high rating). In recent years, the Medicare Payment Advisory Commission has raised concerns

about the Star Ratings program, specifically noting a lack of sufficient focus on SRFs, too many measures being included and scored, and plans being scored against moving, rather than preset, targets.[30] The Proposed Rule attempts to address these concerns by replacing the current reward factor[31] with the HEI reward described above.

The Proposed Rule would reduce the weight of patient experience/complaints and access measures beginning with the 2026 Star Ratings. CMS had previously increased the weight of these measures – from two to four – in the June 2020 final rule in order to align with the agency's goal of listening to patient voices to improve care delivery. In the Proposed Rule, CMS said it reevaluated the weight of these measures in response to stakeholder concerns surrounding overweighing patient experience measures to the detriment of other measures (e.g., patient outcomes, screenings, and preventive care) and creating an imbalance between clinical excellence and patient experience. CMS reasons that the reduced weight – a proposed reduction from four to two – balances the need to value the patient experience without diminishing clinical care outcomes and better align with other quality reporting programs.

CMS proposes modifications to an existing rule that aims to adjust certain Star Ratings measures for emergency circumstances. Currently, the Star Rating for each non-Consumer Assessment of Healthcare Providers and Systems ("CAHPS") measure score is determined by applying a clustering algorithm to the numeric value scores. CMS has had in place, for some time, a rule that removes a plan from the cut point decisions if the plan has 60 percent or more of its enrollees located in Federal Emergency Management Agency-designated Individual Assistance areas (the so-called "60 percent rule"). The 60 percent rule was intended to remove outlier plans from the cut point decisions so that those plans do not distort the cut point determinations. However, in light of the COVID-19 public health emergency, CMS experienced firsthand how extreme and uncontrollable circumstances can affect nearly all contracts in the program. CMS therefore proposes to simplify the methodology to account for such uncontrollable circumstances and, instead of the existing 60 percent rule, remove from the non-CAPHS measures what CMS deems to be "extreme outliers."[32] Under this proposal, the 60 percent rule would be phased out over time, ultimately sunsetting with the 2026 Star Ratings for non-CAHPS measures, including the Health Outcomes Survey measures.[33]

The Proposed Rule also would codify long-standing guidance pertaining to the Medicare final settlement process, as well as clarify aspects of the administrative review process to align with how CMS has historically administered the process. The final settlement process is used to determine the final payment, or final settlement amount, paid to MAOs and Part D sponsors, adjudicate disputes, and receive or remit payments when an MAO contract consolidates, is not renewed or is otherwise terminated. Once a contract is terminated, CMS must complete reconciliation activities to determine retroactive payment adjustments for a year that would have been made had the contract remained in effect, which are then either paid out or the MAO or Part D sponsor is charged. Under the Proposed Rule, in addition to codifying the existing final settlement process described above, CMS proposes to add a new appeals process for MAOs and Part D sponsors that disagree with the final settlement amount. Specifically, an MAO or Part D sponsor that submits a request for appeal, within 15 days of issuance of a final settlement amount, would have to specify what calculations they disagree with and provide evidence that CMS's calculation of the notice of final settlement is incorrect. Additionally, the Proposed Rule would add two additional levels of appeal (i) an informal hearing conducted by the CMS Office of Hearings to review CMS's initial determination, following a request for appeal of the reconsideration of CMS's initial determination; and (ii) a review by the CMS Administrator of the hearing officer's determination if there is an appeal of said determination.

Generally, the appeals process is limited to data sets that have not been previously subject to independent validation.[34] The Proposed Rule would clarify that administrative review cannot be requested based on the accuracy of the following data sources: Healthcare Effectiveness Data and Information Set, Consumer Assessment of Healthcare Providers and Systems, Health Outcomes Survey, Part C and D Reporting Requirements, Prescription Drug Event, Medicare Plan Finder pricing files, data from the Medicare Beneficiary Database Suite of Systems, MARx system, and other Federal data sources. Further, the rule would provide that

MAOs cannot appeal measures that are based on feedback or surveys that come directly from MA or Part D plan enrollees. CMS reasoned that because the data has already been validated or audited, it would be inappropriate to use the appeals process to challenge the accuracy of the data.

- **As part of CMS's many cross-cutting strategies, CMS is focusing on improving access to behavioral health services and outcomes for people with behavioral health care needs.** As a complement to CMS's Behavioral Health Strategy,[35] CMS proposes enhancing network adequacy requirements and behavioral health protections. In a June 2020 final rule, CMS finalized a list of 27 provider specialty types and 13 facility specialty types subject to CMS network adequacy standards.[36] Later, in a January 2022 proposed rule,[37] CMS solicited comments from stakeholders about the MA-specific challenges and potential solutions related to building adequate behavioral health networks and allowing for appropriate access to behavioral health providers. CMS proposes: (i) adding "Clinical Psychology Licensed Clinical Social Worker" and "Prescribers of Medication for Opioid Use Disorder," as provider specialty types that will be evaluated using the time, distance[38] and minimum provider standards in CMS's network adequacy reviews;[39] (ii) amending CMS general access-to-services standards to include behavioral health services; (iii) codifying minimum access wait time standards that apply to both primary care and behavioral health services; (iv) clarifying that behavioral health services may qualify as emergency services not subject to prior authorization when delivered as emergency services; and (v) extending requirements for MAOs to establish programs to coordinate covered services with community and social services to close equity gaps in behavioral health treatment.

- **The Proposed Rule would clarify CMS's position on what constitutes an identified overpayment by MAOs under the FCA.** Currently, Medicare requires the reporting and returning of an overpayment to CMS within 60 days of identification.[40] In 2016, UnitedHealthcare challenged a CMS overpayment rule requiring that MAOs conduct "reasonable diligence" in order to identify overpayments, which, UnitedHealthcare argued, imposed a greater FCA act standard upon MAOs than other payors.[41] The District Court agreed with UnitedHealthcare, ruling that CMS lacked authority, under the Administrative Procedure Act, to hold MAOs to a heightened FCA standard for identifying overpayments.[42] However, the DC Court of Appeals reversed and upheld the overpayment rule, although it did not vacate the District Court's holding regarding the agency's lack of authority to adopt the reasonable diligence standard.[43] This DC Court of Appeals ruling left open the door for CMS to require MAOs to maintain more robust compliance apparatuses than commercial payors in order to mitigate FCA risk as a condition of program participation.

  The Proposed Rule would codify that an MAO or Part D sponsor has "identified" an overpayment only if it has actual knowledge of the overpayment's existence or acts in reckless disregard or deliberate ignorance of the overpayment. This proposed regulation expressly excludes a requirement of "reasonable diligence" to identify an overpayment. The adoption of the FCA "knowingly" standard would apply to Medicare Parts A, B, and D, as well as Part C. Accordingly, whistleblowers and governmental investigations are likely to focus on intentionally deficient or reckless compliance oversight in order to allege FCA liability for MAOs, rather than lack of internal processes "reasonably" intended to identify overpayments.

  Although CMS aims to bring clarity to what does *not* constitute an identified overpayment under the FCA, questions remain regarding reporting obligations. For instance, CMS failed to address whether the quantifiable amount of the overpayment must be reported within the 60 days in order to meet this standard and how to report an overpayment within 60 days if the amount of the overpayment is unknown.

Looking Ahead

Comments on the Proposed Rule are due by February 13, 2023. The Proposed Rule, if finalized, would not take effect until 2024, with some provisions taking effect later; however, stakeholders would likely need time to implement various changes contemplated under the Proposed Rule. MAOs and providers should consider the cost and infrastructure implications of implementing the changes contemplated by the Proposed Rule—in particular, the prior authorization and

marketing requirements—and consider conducting a gap assessment to determine what they would need to do to comply with the Proposed Rule.

Separately, the Proposed Rule does not address the anticipated and stricter guidelines related to the Risk Adjustment Validation program. Those guidelines are likely to be addressed through a separate rulemaking, and Ropes & Gray will continue to monitor any updates on this and other related matters.

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If you have any questions concerning the Proposed Rule, please do not hesitate to contact one of the authors or your regular Ropes & Gray advisor.

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1. *See* UnitedHealthcare Ins. Co. v. Azar, 330 F. Supp. 3d 173, 191 (D.D.C. 2018), rev'd in part on other grounds sub nom.; UnitedHealthcare Ins. Co. v. Becerra, 16 F.4th 867 (D.C. Cir. 2021), cert. denied, 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21-1140).
2. 42 CFR § 422.112(b).
3. 42 CFR § 422.113(a); Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, 87 Fed. Reg. 76238, 79504 (proposed Dec. 13, 2022) (to be codified at 42 CFR 422).
4. CMS proposes to use the term "processes" to include prior authorization policies and procedures that address any and all aspects of how prior authorization is used by an MAO in a coordinated care plan.
5. Under proposed § 422.112(b)(8)(ii)(B), "active course of treatment" means a course of treatment in which a patient is actively seeing the provider and following the course of treatment.
6. Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, 87 Fed. Reg. 76238, 76307 (proposed Dec. 13, 2022) (to be codified at 42 CFR 422).
7. *Id.* at 76243. These proposed changes include, but are not limited to, requiring impacted payors to build and maintain prior authorization requirements, documentation, and decision programming interface; include a specific reason when denying a prior authorization request; send prior authorization decisions within 72 hours for expedited requests and seven days for standard requests, and publicly report certain prior authorization metrics by annually posting them directly on their website or via publicly accessible hyperlink.
8. OFF. OF INSPECTOR GEN., OEI-09-18-00260, SOME MEDICARE ADVANTAGE ORGANIZATION DENIALS OF PRIOR AUTHORIZATION REQUESTS RAISE CONCERNS ABOUT BENEFICIARY ACCESS TO MEDICALLY NECESSARY CARE (2022). The report summarized the results of a study by OIG of MA plan denials of requests for prior authorization of services. OIG recommended that CMS (1) issue new guidance on the appropriate use of MAO clinical criteria in medical necessity reviews; (2) update its audit protocols to address the issues related to MAOs' use of clinical criteria and/or examining particular service types; and (3) direct MAOs to take steps to identify and address vulnerabilities that can lead to manual review errors and system errors. *Id.* at 3.
9. Medicare coverage rules are outlined in NCDs, LCDs in the geographic area in which the MAO operates; the Medicare Benefit Policy Manual; the Medicare Managed Care Manual; legislative changes in benefits applied through notice-and-comments rulemaking, and other coverage guidelines and instructions issued by CMS. Coverage rules can include administrative and clinical requirements. *See* Medicare Managed Care Manual, Ch. 4, § 90.2 and 90.3.
10. Traditional Medicare means the Medicare Fee-For-Service program. See OFF. OF INSPECTOR GEN., OEI-09-18-00260, PG. 13.

11. NCDs are Department of Health and Human Services determinations on whether a particular item or service is covered under Medicare. See OFF. OF INSPECTOR GEN., OEI-09-18-00260, PG. 7.
12. LCDs are written coverage decisions of local Medicare Administrative Contractors with jurisdiction for claims in a particular geographic area. *Id.* at 7.
13. These guidelines are discussed in further detail in § 10.16 of Chapter 4 of the Medicare Managed Care Manual.
14. *See* OFF. OF INSPECTOR GEN., OEI-09-18-00260, PG. 9-12.
15. *Id.* at 76304.
16. "Formulary" is a list of pharmaceutical drugs.
17. A biosimilar is a biologic that is highly similar to, and has no clinically meaningful differences from, another biologic that is already U.S. Food & Drug Administration ("FDA") approved (referred to as the reference product or original biologic).
18. "Interchangeable" in this context "may be substituted for the reference product without the intervention of the health care professional who prescribed the reference product." PHSA § 351(i)(3) (42 U.S.C. 262(i)(3)).
19. The FDA noted on a webpage for consumers that interchangeable biologics are similar to how generic drugs are routinely substituted for brand-name drugs. *See* https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices. Accessed January 16, 2023.
20. CMS defines "negative formulary changes" as the following changes with respect to a Part D drug: (1) removing the drug from a formulary; (2) moving the drug to a higher cost-sharing tier; or (3) adding or making more restrictive prior authorization, step therapy ("ST"), or quantity limit ("QL") requirements for the drug. Safety-based claim edits are not included in the negative formulary changes.
21. Under the proposed regulation, "Other specified entities" means State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists. 42 CFR § 423.100.
22. A "maintenance change" is defined as (1) making any negative formulary changes to a drug and adding a corresponding drug at the same or lower cost-sharing tier and with the same or less restrictive prior authorization, ST, or QL requirements (other than those meeting the requirements of immediate substitutions currently permitted); (2) removing a non-Part D drug; (3) adding or making more restrictive prior authorization, ST, or QL requirements based upon a new FDA-mandated boxed warning; (4) removing a drug deemed unsafe by FDA or withdrawn from sale by the manufacturer if the Part D sponsor chooses not to treat it as an immediate negative formulary change; (5) removing a drug based on long-term shortage and market availability; (6) making negative formulary changes based upon new clinical guidelines or information or to promote safe utilization; or (7) adding PA to help determine Part B versus Part D coverage.
23. Exec. Order No. 13985, 86 Fed. Reg. 7009 (2021).
24. 42 CFR § 422.112(a)(8).
25. In the Proposed Rule, CMS list some examples of digital health education designs, which include: distributing educational materials about how to access certain telehealth technologies in multiple languages including sign language, and in alternative formats; holding digital health literacy workshops; integrating digital health coaching; offering enrollees in-person digital health navigators; and partnering with local libraries and/or community centers that offer digital health education services and supports.
26. CMS proposes that this requested information may include, but is not limited to, statistics on the number of enrollees identified with low digital health literacy and receiving digital health education, manner(s) or method of digital health literacy screening and digital health education, financial impact of the programs on the MA organization, evaluations of effectiveness of digital health literacy interventions, and demonstration of compliance with the requirements of § 422.112(b)(9).
27. The Medicare Communications and Marketing Guidelines (MCMG), updated Feb. 09, 2022, provide the marketing and communication requirements for MA and Part D plans and are used in conjunction with regulatory requirements set forth in 42 CFR 422 Subpart V and 42 CFR 423 Subpart V to regulate marketing by these plans.
28. 42 CFR §§ 422.2262(a)(1)(i) and 423.2262(a)(1)(i).

29. Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111–148, 124 Stat. 449, 450 (2010).
30. MEDPAC, REDESIGNING THE MEDICARE ADVANTAGE QUALITY BONUS PROGRAM (July 2019).
31. 42 C.F.R. § 422.166(f)(1).
32. CMS states that extreme outliers will be removed through what's called Tukey outlier deletion, which is a standard statistical method to remove extreme outliers prior to applying the clustering methodology to determine the cut points. *See* 42 C.F.R. §§ 422.166(a)(2) and 423.186(a)(a)(i).
33. The Medicare Health Outcomes Survey is the first patient-reported outcomes measure used in Medicare managed care. The goal of the Medicare Health Outcomes Survey is to gather valid, reliable, and clinically meaningful health status data from the MA program to use in quality improvement activities, pay for performance, program oversight, public reporting, and to improve health. All managed care organizations with Medicare contracts must participate.
34. Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes, 76 FR 21431, 21490 (finalized June 6, 2011).
35. The CMS Behavioral Health Strategy covers multiple elements including access to prevention and treatment services for substance use disorders, mental health services, crisis intervention and pain care; and further enables care that is well coordinated and effectively integrated. The CMS Behavioral Health Strategy also seeks to remove barriers to care and services, and to adopt a data-informed approach to evaluate our behavioral health programs and policies. The CMS Behavioral Health Strategy will strive to support a person's whole emotional and mental well-being and promotes person-centered behavioral health care. *See* https://www.cms.gov/cms-behavioral-health-strategy.
36. 42 CFR § 422.116(b).
37. Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 FR 1842 (proposed Jan. 12, 2022, and finalized May 9, 2022) (codified at 42 CFR 417, 422, and 423).
38. MAOs receive a 10 percent credit towards the percentage of beneficiaries that must reside within required time and distance standards for the applicable provider specialty type and county when the plan includes one or more telehealth providers that provide additional telehealth benefits, as defined in § 422.135, in its contracted networks for the following provider specialty types: Dermatology, Psychiatry, Cardiology, Otolaryngology, Neurology, Ophthalmology, Allergy and Immunology, Nephrology, Primary Care, Gynecology/OB/GYN, Endocrinology, and Infectious Diseases. *See* 42 CFR 422.116(d)(5).
39. Network adequacy reviews are used by CMS to evaluate whether an MAO maintains a network of appropriate providers and facilities, and sufficiently provides adequate access to covered services based on the needs of the population served.
40. 42 C.F.R. § 422.326(d).
41. UnitedHealthcare Ins. Co. v. Azar, 330 F. Supp. 3d 173, 191 (D.D.C. 2018); 42 C.F.R. § 422.326(c).
42. *Id.*
43. UnitedHealthcare Ins. Co. v. Azar, 330 F. Supp. 3d 173, 191 (D.D.C. 2018), rev'd in part on other grounds sub nom.; UnitedHealthcare Ins. Co. v. Becerra, 16 F.4th 867 (D.C. Cir. 2021), cert. denied, 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21-1140).