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ALERT

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Extrapolation Has Arrived: CMS Finalizes Medicare Advantage Risk Adjustment Rule

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Introduction

On February 1, 2023, the Centers for Medicare & Medicaid Services ("CMS") published a long-awaited and controversial final rule that implements technical changes to the Medicare Advantage ("MA") contract-level Risk Adjustment Data Validation ("RADV") program (the "RADV Final Rule").[1]

Following years of proposed rules, public comment, and litigation, the RADV Final Rule contains three key takeaways that will impact MA stakeholders:

1. It implements extrapolation of RADV audit findings commencing payment year ("PY") 2018;[2]
2. It rejects a Fee-For-Service ("FFS") adjuster for MA risk adjustment that would have limited the financial impact of the RADV Final Rule for Medicare Advantage Organizations ("MAOs"); and
3. It clarifies that MA overpayment self-reporting and repayment requirements for MAOs will be forthcoming from CMS.

The RADV Final Rule's changes are scheduled to go into effect on April 3, 2023 but will likely be subject to forthcoming stakeholder litigation.[3]

Background and History

The significance of the RADV Final Rule is reflected by the history of CMS's rulemaking efforts around RADV, which dates back almost 20 years. Under federal law dating back to the enactment of MA, CMS is required to risk adjust payments made to MAOs based on each MAO plan's enrollees' existing medical conditions and other demographic factors.[4] CMS first implemented RADV audits in Medicare PY 2004 and limited improper payment recovery to enrollee-level adjustments only for records sampled in the audits, which were not extrapolated[5] across an applicable MAO's MA contract to determine payment adjustments. Recovery of improper payments through the initial RADV program was paused beginning with PY 2008 as CMS sought to develop and finalize an updated RADV audit and recovery methodology, soliciting public comments in 2010 and 2012.

1. 2010 Proposal and the Introduction of the FFS Adjuster. In 2010, CMS published an informal proposal on its website outlining its intended RADV methodology for sampling enrollees and extrapolating from such sample to the whole contract.[6] MAOs first suggested the need for an FFS adjuster ("FFS Adjuster") in response to the 2010 proposal and argued that its use was necessary to account for flawed use of generally unaudited Medicare FFS claims data to recalibrate the CMS hierarchical condition category ("HCC") model reviewed and calculated in a RADV audit. The FFS Adjuster would account for the adverse impact of using potentially flawed FFS data in MA rate reconciliation by offsetting portions of preliminary RADV audit recovery amount calculations.
2. 2012 RADV Methodology Published. In 2012, CMS published a final RADV methodology (known as the "2012 Methodology") for contract-level RADV payment error calculations that was set to begin with PY 2011 RADV audits.[7] The PY 2011 RADV audits were to be the first in which CMS would conduct payment recovery based on extrapolated estimates. The 2012 Methodology implemented the use of an FFS Adjuster that responded to stakeholder feedback on the 2010 rule and could eliminate recovery if the FFS Adjuster amount exceeded the preliminary RADV audit recovery amount.[8] CMS reasoned that the FFS Adjuster was necessary to account "for the fact that the documentation standard used in RADV audits . . . is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims)" and that the actual amount of the FFS Adjuster would be forthcoming.[9] In order to calculate the FFS Adjuster, CMS proposed to review the impact of errors in

Medicare FFS claims data on the CMS-HHC model. As further discussed below, however, this review ultimately found that Medicare FFS claims data did not, in fact, have a systematic impact on the risk scores calculated using the CMS-HCC model.

3. 2014 Proposed Rule and Subsequent Litigation. In 2014, CMS published a proposed rule (the "2014 Proposed Rule") requiring MAOs to refund payments received under Medicare Part C that are unsupported by sufficient patient medical records—deeming such amounts overpayments—within 60 days of identifying such overpayments. The 2014 Proposed Rule was ultimately challenged and invalidated in the seminal case of *UnitedHealthCare Insurance Co. v. Azar,* 330 F. Supp. 3d (D.D.C. 2018), *rev'd sub nom; UnitedHealthCare Insurance Co. v. Becerra,* 16 F.4th 867 (D.C. Cir. August 13, 2021, reissued November 1, 2021), cert denied, 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21-1140).[10] In these cases, UnitedHealthCare argued that the overpayment refund calculations and related requirements promulgated in the 2014 Proposed Rule violated the statutory requirement of "actuarial equivalence"[11] of payment rates between Medicare FFS and MA and established a mere negligence standard for an MAO's False Claims Act liability, regardless of knowledge of falsity or reckless disregard. The District Court agreed with UnitedHealthCare, finding also that CMS recognized actuarial equivalence requirements when it included an FFS Adjuster in the 2012 Methodology. In August 2021, the U.S. Court of Appeals for the D.C. Circuit reversed the district court's 2018 decision in *UnitedHealthCare v. Azar,* reasoning that the actuarial equivalence standard applied to prospective MA rate-setting but not for determining repayments from RADV audits. Consequently, the D.C. Circuit found that "CMS [has] no obligation to consider an FFS Adjuster or similar correction in the overpayment-refund context."[12]

4. 2018 Proposed Rule. While *UnitedHealthCare v. Azar* was being appealed by CMS to the D.C. Circuit, CMS published a 2018 notice of proposed rulemaking that proposed to codify in regulation its methodology for RADV audits (the "2018 Proposed Rule") as further discussed below, but final rulemaking was delayed as CMS focused on the COVID-19 public health emergency, and early-stage litigation regarding the 2014 Proposed Rule remained ongoing.[13]

Summary of RADV Final Rule

With this historical and procedural context, the RADV Final Rule addresses the following areas that have been subject to multi-year rulemaking by CMS.

1. Extrapolation. In the 2018 Proposed Rule, CMS sought to extrapolate RADV audit findings beginning with PY 2011. Taking into consideration the comments it received regarding the administrative burden and payment delays arising from appeals if extrapolation were applied beginning in PY 2011, CMS announced in the RADV Final Rule that extrapolation would instead begin with PY 2018 RADV audits.[14] CMS declined to adopt any specific sampling or extrapolation methodology in the RADV Final Rule but retained discretion to apply one or more statistically valid methods for a particular RADV audit.[15] Thus, under the RADV Final Rule, CMS is not restricted in setting how it will establish the scope of its review and recovery, whether contract-wide, cohort-by-cohort, or otherwise.[16]

   Furthermore, CMS states in the RADV Final Rule that the RADV program has shifted away from its prior randomized approach for sampling to a more tailored approach focusing on MAO contracts that through "statistical modeling and/or data analytics" would be considered more "high risk" for improper payments.[17] The RADV Final Rule adopted the Government Accountability Office's ("GAO") recommended approach for identifying MAOs most likely to have high rates of improper payments: "contracts with the highest coding intensity scores; . . . contracts with high rates of unsupported diagnoses in prior contract-level RADV audits; . . . contracts with high enrollment that also have either high rates of unsupported diagnoses in prior contract-level RADV audits or high coding intensity scores."[18] Accordingly, MAOs that are not identified as high risk may be less likely to receive notice of initial RADV audits from CMS.

In calendar year 2025, the year in which CMS projects that it will receive improper payments for PY 2018 RADV audits, CMS estimates that it will receive $428.4 million in net recovery (subtracting the annual costs associated with audit activities). Between calendar years 2023 and 2032, CMS estimates that it will recover approximately $4.7 billion.[19]

2. Fee-for-Service Adjuster. In the 2018 Proposed Rule, citing the study described above that demonstrated that errors in Medicare FFS claims data did not have a systematic impact on the risk scores calculated by the CMS-HCC model, CMS declined to implement the FFS Adjuster. On June 28, 2019, CMS published a notice stating that it had replicated this study on a more complete set of data with results that "were broadly consistent with the initial implementation of the study."[20] In the RADV Final Rule, CMS clarified three additional bases for again rejecting its adoption: first, citing the D.C. Circuit's 2021 decision in *UnitedHealthCare v. Becerra,* CMS states that the actuarial equivalence statutory provision only applies to the prospective risk adjustment of MAO payments, not to the obligation to remit improper payments under MA. Second, CMS reasons that it would be contradictory to loosen medical record documentation requirements via an FFS Adjuster while also systematically reducing MAO payments consistent with the "minimum coding pattern adjustment" requirements under Section 1853(a)(1)(C)(ii) of the Act.[21] Finally, CMS states that it would be inequitable to apply an FFS Adjuster to only audited contracts, even if systematic error existed.

   Notably, throughout the RADV Final Rule, CMS emphasizes the D.C. Circuit's holding in *UnitedHealthCare Ins. Co. v. Becerra* that a diagnosis code that is not supported by documentation in a patient's medical record is not a valid HCC code for purposes of a member's risk-adjustment score.[22] CMS uses the RADV Final Rule as an opportunity to remind stakeholders that only when medical records "comply with all CMS data and documentation requirements, . . . described in current agency policy documents, including the Medicare Managed Care Manual," do they properly support a reported diagnosis for MA documentation purposes.[23]

3. Remittance of Improper Payments. While the Office of Inspector General for the United States Department of Health and Human Services ("OIG-HHS") is responsible for conducting RADV audits, CMS collects the improper payments identified in such audits. In the 2018 Proposed Rule, CMS proposed that improper payments must be remitted through CMS's payment system, the Medicare Advantage Prescription Drug System ("MARx"), to offset MA plans' monthly capitation payments. While the RADV Final Rule codifies in regulation that MAOs must remit improper payments based on RADV audit findings in accordance with a manner specified by CMS, the RADV Final Rule does not state the manner in which such improper payments must be remitted. Instead, the manner in which improper payments must be remitted will be specified by CMS at a later date. Before CMS finalizes a remittance method, MAOs should follow CMS's voluntary repayment and self-disclosure protocol under 42 C.F.R. § 422.326.[24]

Conclusion

The RADV Final Rule will have material implications not just for MAOs, but also for contracted and at-risk providers who complete the clinical documentation to support risk adjustment and vendors who support accurate HCC capture. While litigation concerning the RADV Final Rule appears imminent, unless a preliminary injunction is granted, contract-wide extrapolation is on the immediate horizon. MA stakeholders would be well advised to begin preparing for the impact of the RADV Final Rule's changes.

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

1. Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 88 Fed. Reg. 6643 (Feb. 1, 2023).
2. "Payment year" refers to the year in which risk-adjustment payments are made. RADV audits are not conducted immediately after a payment year—final RADV audits have not been issued for PY 2011 or any subsequent year, but CMS projects that it will complete PY 2018 RADV audits in calendar year 2025.
3. 88 Fed. Reg. at 6645, footnote 6. The Final Rule only applies to the MA *contract-level* RADV program, which focuses on sampled MAO contracts to determine improper payments. Of note, the Final Rule is not applicable to the Medicare Part C Improper Payment Measurement more commonly referred to as the "national RADV" or to the U.S. Department of Health and Human Services ("HHS") RADV program, which oversees the integrity of the Affordable Care Act Marketplace. The Medicare Part C Improper Payment Measurement is an annual program that estimates improper payments made under Medicare Part C, also known as "MA," due to unsubstantiated risk-adjustment data. Payment error estimates are made on a sample of MA beneficiaries, which are then extrapolated to the entire Medicare Part C population. These results are reported each fiscal year. Ctrs. for Medicare & Medicaid Servs., Medicare Part C Improper Payment Measurement (IPM), https://www.cms.gov/research-statistics-data-systems/improper-payment-measurement-programs/medicare-part-c. The HHS-RADV program validates the accuracy of data provided by health insurance issuers that are used to calculate the funds transferred to the issuers based on the risk level of beneficiaries from a healthcare cost perspective.
4. The CMS-HCC model is the model used to risk adjust capitated payments to MAOs. Recalibration of the CMS-HCC model uses claims data from beneficiaries enrolled in FFS Medicare (also known as "Original Medicare" or Medicare Parts A and B), not beneficiaries enrolled in MA.
5. Extrapolation has long been an option in Medicare FFS auditing and involves the auditor reviewing a statistical sample of claims. If the auditor finds that there is a sustained or high level of payment errors or documentation that educational intervention has failed to correct, the auditor may make a statistical estimation as to the prevalence of the error throughout all claims in a defined universe. *See* Ctrs. for Medicare & Medicaid Servs., Medicare Program Integrity Manual § 8.4, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c08.pdf.
6. Ctrs. for Medicare & Medicaid Servs., Medicare Advantage Risk Adjustment Data Validation (RADV) Notice of Payment Error Calculation Methodology for Part C Organizations Selected for RADV Audit – Request for Comment (December 21, 2010).
7. Ctrs. for Medicare & Medicaid Servs., Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation (RADV) Contract-Level Audits (Feb. 24, 2012), https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf. As CMS has not issued final RADV audits for PY 2011 audits or any subsequent year, the 2012 Methodology has never been applied.
8. Ctrs. for Medicare & Medicaid Servs., Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits (Oct. 26, 2018), https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/FFS-Adjuster-Excecutive-Summary.pdf.
9. Ctrs. for Medicare & Medicaid Servs., *supra* note vii.
10. *See* Stephanie A. Webster et al., *D.C. Circuit Overturns 2018 D.D.C. Decision Invalidating Medicare Advantage Overpayment Rule: Changed Compliance and Legal Landscape for Medicare Advantage*, Ropes & Gray (August 30, 2021), https://www.ropesgray.com/en/newsroom/alerts/2021/august/dc-circuit-overturns-2018-ddc-decision-invalidating-medicare-advantage-overpayment-rule.
11. Section 1853(a)(1)(C)(i) of the Social Security Act states that "the Secretary shall adjust the payment amount . . . for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status . . . , so as to ensure *actual equivalence*." 42 U.S.C. § 1395w-23(a)(1)(C)(i) (emphasis added).
12. *UnitedHealthCare Ins. Co. v. Becerra*, 16 F.4th 867, 892 (D.C. Cir. 2021).

13. Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54982 (Nov. 1, 2018).
14. Only enrollee-level overpayments will be collected for those identified in RADV audits for PYs prior to PY 2018.
15. In the commentary of the RADV Final Rule, CMS has stated that it will provide guidance on RADV audit methodology through the Health Plan Management System ("HPMS"), through memoranda and other means. 88 Fed. Reg. at 6649.
16. In the 2018 Proposed Rule, CMS sought public feedback on different audit methodologies. The cohort-by-cohort methodology, for example, would identify a particular sub-cohort in an MA contract (*e.g.*, enrollees for whom a particular HCC was reported), select a statistically significant sample of enrollees in the sub-cohort, and then extrapolate improper payments to the sub-cohort in that payment year. *See* 88 Fed. Reg. at 6649.
17. For example, "high-risk" contracts may include those that had high rates of unsupported diagnoses in prior contract-level RADV audits.
18. 88 Fed. Reg. at 6652.
19. 88 Fed. Reg. at 6663.
20. Ctrs. for Medicare & Medicaid Servs., RADV Provision CMS 4185-N4 Data Release June 2019, (June 27, 2019), https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources. *See also* Medicare and Medicaid Programs; Risk Adjustment Data Validation, 84 Fed. Reg. 30983 (June 28, 2019).
21. Under Section 1853(a)(1)(C)(ii) of the Act, a minimum coding pattern adjustment is applied to reduce the risk scores of all MA beneficiaries in order to account for MA and FFS coding differences.
22. *UnitedHealthCare Ins. Co. v. Becerra*, at 869, 877.
23. 88 Fed. Reg. at 6646–47.
24. Under 42 C.F.R. § 422.316, the regulation governing MAO overpayments ("any funds that an [MAO] has received or retained under title XIII of the Act to which the [MAO], after applicable reconciliation, is not entitled under such title"), MAOs must report and return the identified overpayments in the manner specified by CMS.