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Medicare Advantage Risk Adjustment Data Validation (RADV) Final Rule

On February 1, 2023, the Centers for Medicare and Medicaid Services (CMS) published a final rule (Final Rule) to "outline [its] audit methodology and related policies for the contract-level MA Risk Adjustment Data Validation (RADV) program."[i] In announcing publication of the rule, HHS Secretary, Xavier Becerra, said that the department was "taking long overdue steps to conduct audits and recoup funds."[ii] The rule, which finalizes policies related to extrapolation for audits and without a fee-for-service (FFS) Adjuster, is the latest round in a more than decade-long conflict between the health insurance industry and HHS over how Medicare Advantage (MA) plan risk adjustment should be audited and how overpayments to those plans should be "clawed back." In this brief, we summarize the history of the RADV program, policies in the Final Rule, and early industry reactions and next steps.

A Brief History of Medicare Risk Adjustment and RADV

When the Medicare+Choice program, later revised and renamed the Medicare Advantage program, was established in the Balanced Budget Act of 1997, the legislation required CMS to make risk-adjusted payments to Medicare Advantage Organizations (MAOs) in order to strengthen the program and "ensure that accurate payments are made to MAOs based on the health status and demographic characteristics of their enrolled beneficiaries, and that MAOs are paid appropriately for their plan enrollees (that is, less for healthier enrollees who are expected to incur lower health care costs, and more for less healthy enrollees who are expected to incur higher health care costs)." In other words, the purpose of risk adjustment is to better align health plan prospective payments with the actual costs of enrollee healthcare treatment. CMS would later create the RADV program, with audits first initiated with Plan Year (PY) 2007, pursuant to a requirement in the Improper Payments Information Act of 2002 (later amended by the Improper Payments Elimination and Recovery Act of 2010) that "government agencies… identify, report, and reduce erroneous payments in the government's programs and activities."[iii] The RADV program is designed to address the incentive for MAOs to potentially over-code diagnoses to increase payments. More specifically, contract-level RADV post-payment audits ensure that diagnosis data submitted by a selection of MAOs are supported by enrollees' actual treatment and reflected in the diagnoses recorded by treating physicians in their medical records.

Lack of sufficient documentation in treatment records to support risk scores has been extensively reviewed by the HHS Office of the Inspector General (OIG), including the lack of treatment records reflecting diagnoses collected instead using chart reviews and health risk assessments by MAOs. Such diagnoses are seen as inflating risk adjustment calculations. In an analysis of chart reviews, OIG found that 41% of charts (corresponding to 4.5 million beneficiaries) did not include service records of visits, procedures, tests, or supplies that contained the diagnosis reported on the chart review. As a result, OIG estimated that CMS paid MAOs $6.7 billion in payments in 2017 based on diagnoses found only on chart reviews and not on any service records—only 0.7 percent of chart reviews deleted diagnoses, while 99.3% added diagnoses. Meanwhile, OIG found that MAOs reported diagnoses on health risk assessments for 3.5 million beneficiaries with no other encounter records of visits, procedures, tests, or supplies that contained the diagnosis reported

in the assessment. These diagnoses resulted in an estimated $2.6 billion in risk-adjustment payments for 2017.[iv]

Although RADV audits are the "main corrective action for overpayments made to MAOs," formal audits have not been conducted since 2007 when CMS conducted limited reviews of 37 Medicare Advantage plans and recouped $13.7 million. CMS paused RADV audits for PY 2008, 2009, and 2010 to "continue refining the methodology for the RADV audits, including the consideration of statistical methods to calculate extrapolated improper payments based on the individual errors identified." Extrapolation involves finding a representative sample of up to 201 people in a selected Medicare Advantage plan, seeing how many erroneous codes there are, and then applying that error rate to the entire contract to see how much money will get recouped.

CMS published a final methodology in February 2012[v] for RADV contract-level payment error calculation which described "techniques and a statistical calculation to extrapolate from the sample selected, as well as the use of a [Medicare fee-for-service] FFS Adjuster." A September 2018 ruling by the United States District Court for the District of Columbia supported the use of the FFS Adjuster by vacating a 2014 Overpayments Rule[vi] requiring MAOs to report and return within 60 days any overpayments it received from CMS. Specifically, the court ruled that the Overpayments Rule violated Medicare's "actuarial equivalence" requirement[vii] that CMS pay MAOs the same amount it would pay if all its beneficiaries were instead enrolled in FFS Medicare.

However, a follow-up CMS study in October 2018 found that "diagnosis error in FFS claims data does not lead to systematic payment error in the MA program" and concluded that it is no longer "appropriate to include a FFS Adjuster in any RADV extrapolated audit methodology."[viii] CMS subsequently issued a proposed rule in November 2018[ix] to codify in regulation its methodology for RADV audits that would apply to all payment year audits that had not yet been finalized. CMS proposed to extrapolate contract-level RADV audit findings using statistically valid random sampling techniques without the application of the FFS Adjuster previously described in the 2012 methodology. CMS also appealed several aspects of the District Court ruling.

In August 2021, the United States Court of Appeals for the District of Columbia Circuit overturned the lower court's Overpayments Rule decision and ruled that the "actuarial equivalence" statutory provision does not apply to overpayments, there was no evidence that the Overpayment Rule would inevitably result in underpayments to MAOs, and the "same methodology" requirement was not related to the process of calculating how much MAOs are paid or subsequent overpayment refunds.[x] The Supreme Court of the United States declined in June 2022 to hear an appeal of the ruling, effectively ending the challenge.[xi] As a result, CMS proceeded with not including the FFS Adjuster in the RADV audit methodology.

Through a series of Federal Register notices, most recently in November 2022, CMS extended comment periods on the 2018 proposed rule and delayed publication of a final rule until February 1, 2023.

Summary of the Final Rule

CMS states that the Final Rule aims to "help [the agency] ensure that people with Medicare are able to access the benefits and services they need, including in Medicare Advantage, while responsibly protecting the fiscal sustainability of Medicare and aligning CMS's oversight of the Traditional Medicare and MA programs." Most notably, the Final Rule finalized policies related to extrapolation and the FFS Adjuster.

Extrapolation

CMS finalized its proposal to apply extrapolation to RADV audits, but will now begin extrapolation with PY 2018 rather than PY 2011. The Final Rule states that extrapolation will not occur for PY 2011 through PY 2017 RADV audits "due to certain operational considerations and public comments on the timeliness of RADV audits."

- Although several commenters questioned the statistical validity of using extrapolation, CMS notes that it will "employ statistical methods to determine statistically valid sample sizes, accurately identify payment error, and extrapolate to the universe of enrollees from which the sample is selected" and that these methods "may include applying one or more RADV audit methodologies for any given RADV audit."
- In response to commenter concerns that the audits will increase administrative burden on providers, CMS noted that the policies "do not impose new documentation requirements on providers" and there "will be no additional audit impact on providers that contract with MAOs to provide services to MA plan enrollees."

- Finally, CMS emphasized that the use of sampling and extrapolation for prior payment years "is not retroactive [policy] because the substantive requirement of proper medical record documentation of all diagnoses submitted for payment remains unchanged, whether we calculate audit recoveries on an enrollee-by-enrollee basis or use a statistically valid sample of enrollees to extrapolate."

FFS Adjuster

CMS finalized its proposal to "not apply an FFS Adjuster to RADV audits because the "actuarial equivalence" and "same methodology" provisions do not apply to the obligation of an MAO to report and return improper payments for diagnoses lacking medical record support, including those improper payments identified during a RADV audit."

- The Final Rule refutes several claims made by commenters in support of the FFS Adjuster, including most notably, that "unaudited" Medicare FFS data used to calculate MAO payments "understate the cost of treating various conditions." As noted previously, an October 2018 study (and June 2019 follow-up study[xii]) found that errors in FFS claims data do not lead to systematic payment error in the MA program. Although CMS does not "rely on the empirical findings of the study as the basis" for its decision, the Final Rule states that the (1) "magnitude of over-coding… in the Medicare FFS data is much smaller than some commenters have suggested;" (2) "FFS data contains significant under-coding…, which would likely offset the effects of FFS over-coding;" (3) the "effects of Medicare FFS over-coding are also offset by the increased costs associated with that over-coding;" and, (4) counter-studies in favor of the FFS Adjuster "employed widely differing methodologies and arrived at widely varying estimates for their FFS Adjuster."
- In response to claims that the MMA requires "actuarial equivalence" and the "same methodology" between payments to MA and payments under FFS, thus requiring use of an Adjuster, CMS concluded that the statute "applies only to how CMS risk adjusts the payments it makes to MAOs, and not to the obligation to return improper payments for diagnosis codes submitted by MAOs to CMS lacking medical record support." In support of this argument, the Final Rule cites the 2021 Court of Appeals ruling that upheld CMS' Overpayment Rule to impose voluntary refund obligations for MAOs.
- In addition, CMS notes that "even if there was evidence of systematic payment error, it would be inequitable to only correct payment errors [through the FFS Adjuster] made to audited contracts."

The Final Rule also codifies in regulation the requirement that MAOs remit improper payments identified during RADV audits in a manner specified by CMS.

Impacts of the Final Rule

CMS estimates extrapolated improper payment recoveries of approximately $479.4 million for the PY 2018 audit. Factoring in the annual cost of the RADV program ($51 million), net recoveries would total $428.4 million for PY 2018. These recoveries are expected to be received beginning in FY 2025. Improper payment recoveries are estimated to increase in later years based on growth in MA spending. Additionally, in 2023 and 2024, CMS estimates receiving approximately $13.1 million and $28.0 million, respectively, in non-extrapolated recoveries from PY 2011-2013 and PY 2014 and 2015 audits. In total, estimated recovery amounts over ten years (2023 to 2032) would be $4.7 billion.

Industry Reaction

Although policies in the Final Rule were slightly more favorable to insurers than the 2018 proposed rule (i.e., using extrapolation back to only 2018, rather than 2011), insurance industry stakeholders fiercely criticized the Final Rule. Matt Eyles, CEO of America's Health Insurance Plans, said the "rule is unlawful and fatally flawed, and it should have been withdrawn instead of finalized," while claiming it will "raise prices for seniors and taxpayers, reduce benefits for those who choose MA, and yield fewer plan options in the future."[xiii] Ceci Connolly, CEO of the Alliance for Community Health Plans, argued the rule "comes with enormous costs and fails to target the most egregious diagnosis coding violations."[xiv] Further, she hopes "CMS reconsiders more targeted approaches to meaningfully address compliance in the MA program and protect the taxpayer dollar." Additionally, some provider stakeholders are concerned about other possible downstream impacts, such as increased scrutiny of patient codes submitted by providers, more common or intensified disputes between providers and plans, and further challenges with finalizing risk-contracting arrangements[xv]

Next Steps

MAOs, and perhaps industry groups, seem nearly certain to take legal action attempting to slow or prevent implementation of the Final Rule. Humana's Chief Financial Officer recently said at the JP Morgan healthcare conference that litigation from the industry is likely if the FFS Adjuster was removed.[xvi] In response to questions about likely litigation, HHS Secretary Becerra said that the department believes it "put together a rule that is not just balanced and measured and fair, but one that is ready for primetime."[xvii]

Even if the RADV Final Rule is fully implemented as written and helps hold MAOs more accountable for accurate coding, it fails to address many of the underlying issues with the MA risk adjustment process identified by the OIG, MedPAC and other stakeholders. Most notably, clawing back payments from MAOs for overpayments in previous years does not prevent them from continuing to up-code in future years. Additionally, at least two aspects of the RADV audit will continue to impact the quality and efficiency of the audit:

1) RADV response timeline and burden: The time given for MAOs to respond to a RADV audit is nearly half a year. MAOs selected for audit are typically granted 25 weeks to request and obtain medical records from providers (often in manual, burdensome ways), review those records for best representation of audited HCCs, prepare the chart in a PDF format file with a cover sheet identifying the HCCs, and submit to a secure system such as the centralized data abstraction tool (CDAT).[xviii]

2) MAOs as middlemen: MAOs are given the responsibility of demonstrating the linkage between risk adjustment diagnosis data and encounter data in the medical record. Since MAOs have a clear financial interest in selecting and submitting coding that maximizes reimbursement, their role in curating the diagnosis data received by CMS creates some level of bias.

To address these two limitations, CMS may consider expanding its use of emerging standards for interoperable data exchange to streamline the RADV process. The Da Vinci Fast Healthcare Interoperability Resource (FHIR) accelerator has begun work on a Risk Adjustment use case for exchanging information on risk adjustment coding gaps between payers and providers.xix CMS might separately even consider requesting sample medical record data directly from provider certified health record technology systems using more mature FHIR standards, such as those for Clinical Data Exchange. Such an approach could streamline the medical record information collection process, reducing stakeholder burden, accelerating the timeliness of the audits, and eliminating the opportunity for biased data submission.

Whether or not CMS moves to substantially change the RADV process in the future, the RADV Final Rule is likely to prompt continued debate among stakeholders and policymakers on some of these issues. At the same time, regardless of how potential litigation is resolved, unless there are changes in how risk adjustment scores are reported, the impact of RADV policies is likely to only intensify in the years to come as MA program enrollment continues to grow beyond the current 30.2 million or roughly half of all Medicare beneficiaries in 2022.[xx]

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[i] Centers for Medicare & Medicaid Services. 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.

[ii] Department of Health and Human Services. HHS Issues Final Rule to Protect Medicare, Strengthen Medicare Advantage, and Hold Insurers Accountable. January 30, 2023.

[iii] Centers for Medicare and Medicaid Services. Payment Validation for Part C and D Programs.

[iv] Erin Bliss. Testimony Before the United States House Committee on Energy and Commerce Subcommittee on Oversight and Investigations. Protecting America's Seniors: Oversight of Private Sector Medicare Advantage Plans.

[v] Centers for Medicare & Medicaid Services. Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits

[vi] Set forth at 42 U.S.C. § 1320a-7k(d)

[vii] *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 176 (D.C. District Court 2018)

[viii] Centers for Medicare and Medicaid Services. Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits.

[ix] Centers for Medicare & Medicaid Services. 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 FR 54982-55088.

[x] *UnitedHealthcare Ins. Co. v. Becerra*, No. 18-5326, 2021 WL 3573766 (D.C. Circuit Aug. 13, 2021).
[xi] Robert King. Supreme Court declines to hear UnitedHealth's lawsuit on Medicare Advantage overpayments rule. Fierce Healthcare. June 22, 2022.
[xii] Centers for Medicare and Medicaid Services. Medicare and Medicaid Programs; Risk Adjustment Data Validation. 84 FR 30983-30984.
[xiii] AHIP Comments on Medicare Advantage RADV Final Rule. January 30, 2023.
[xiv] ACHP Disappointed by CMS Final Policies on RADV. January 30, 2023.
[xv] Nona Tepper. More MA insurer audits mean more scrutiny on providers. Modern Healthcare. January 24, 2023.
[xvi] Paige Minemyer. JPM23: Humana bounces back from poor MA enrollment showing in 2022, boosts guidance on membership growth. Fierce Healthcare. January 10, 2023.
[xvii] Robert King. Medicare Advantage plans lose out in final RADV audit rule that ditches fee-for-service adjuster. Fierce Healthcare. January 30, 2023.
[xviii] Melissa James. Seven key strategies for a successful RADV audit. Wolters Kluwer. June 13, 2022.
[xix] HL7 International. Da Vinci Risk Adjustment Implementation Guide Home Page.
[xx] Centers for Medicare and Medicaid Services. Access to Health Coverage. Updated January 31, 2023. and Medicare Payment Advisory Committee. The Medicare Advantage Program: Status Report. January 12, 2023.

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