Medicare Part C and Part D - Part II

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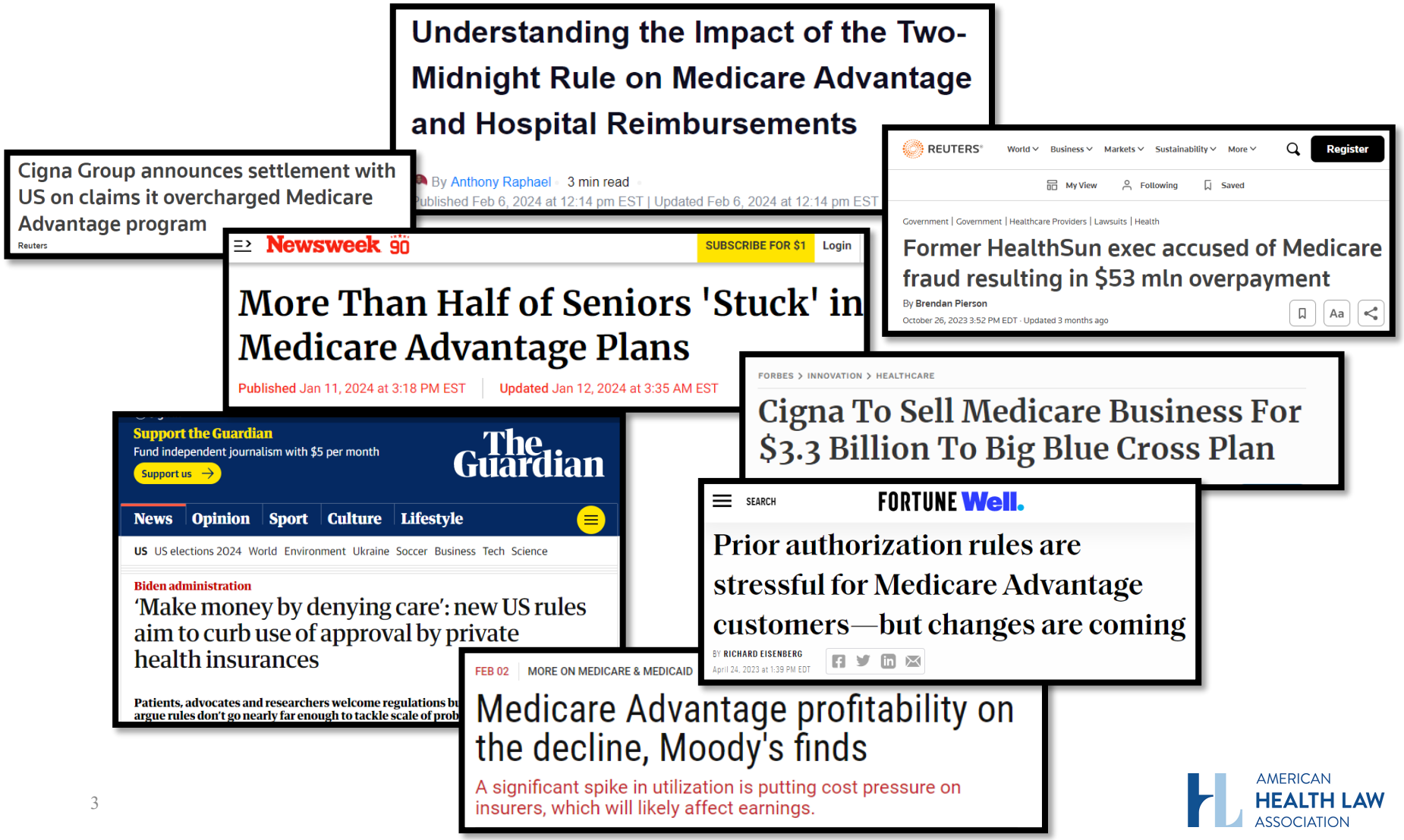
Agenda

- Background –Spotlight on MA Growth
- Recent Intensification of Regulatory Requirements and Operational Challenges for Medicare Plans
  - Changes to coverage criteria and prior authorization requirements
  - Translation requirements
  - Behavioral health network adequacy
  - Forecast of challenges ahead for 2025
- Medicare Part C and Part D oversight and enforcement trends
  - Program audits
  - Prior authorization audits
  - Brief overview of risk adjustment landscape
  - Plans in the policy and enforcement crosshairs: Congress, DOJ, OIG, CMS, and Federal Courts

The Headlines



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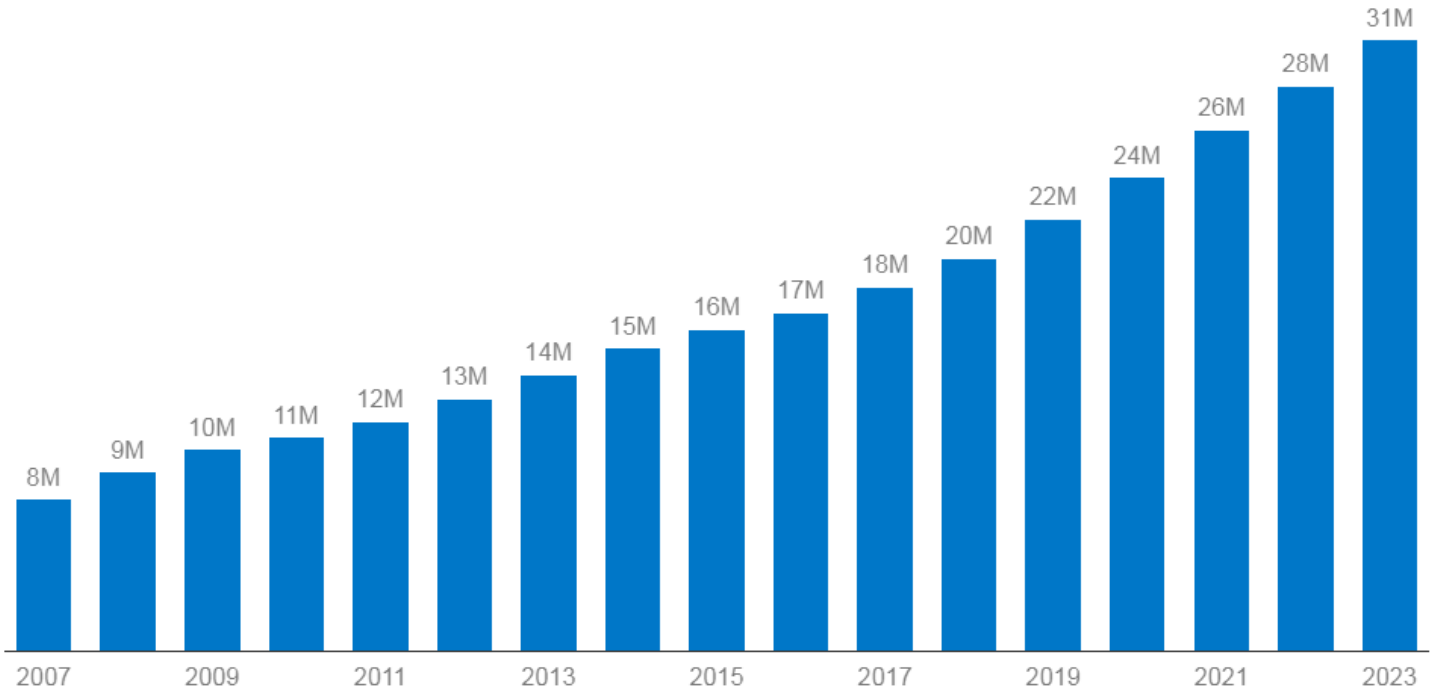
Medicare Advantage Enrollment

Figure 1

Total Medicare Advantage Enrollment, 2007-2023

Medicare Advantage Penetration | **Medicare Advantage Enrollment**



NOTE: Enrollment data are from March of each year. Includes Medicare Advantage plans: HMOs, PPOs (local and regional), PFFS, and MSAs. About 60.0 million people are enrolled in Medicare Parts A and B in 2023.

SOURCE: KFF analysis of CMS Medicare Advantage Enrollment Files, 2010-2023; Medicare Chronic Conditions (CCW) Data Warehouse from 5 percent of beneficiaries, 2010-2016; CCW data from 20 percent of beneficiaries, 2017-2020; and Medicare Enrollment Dashboard 2021-2023. •

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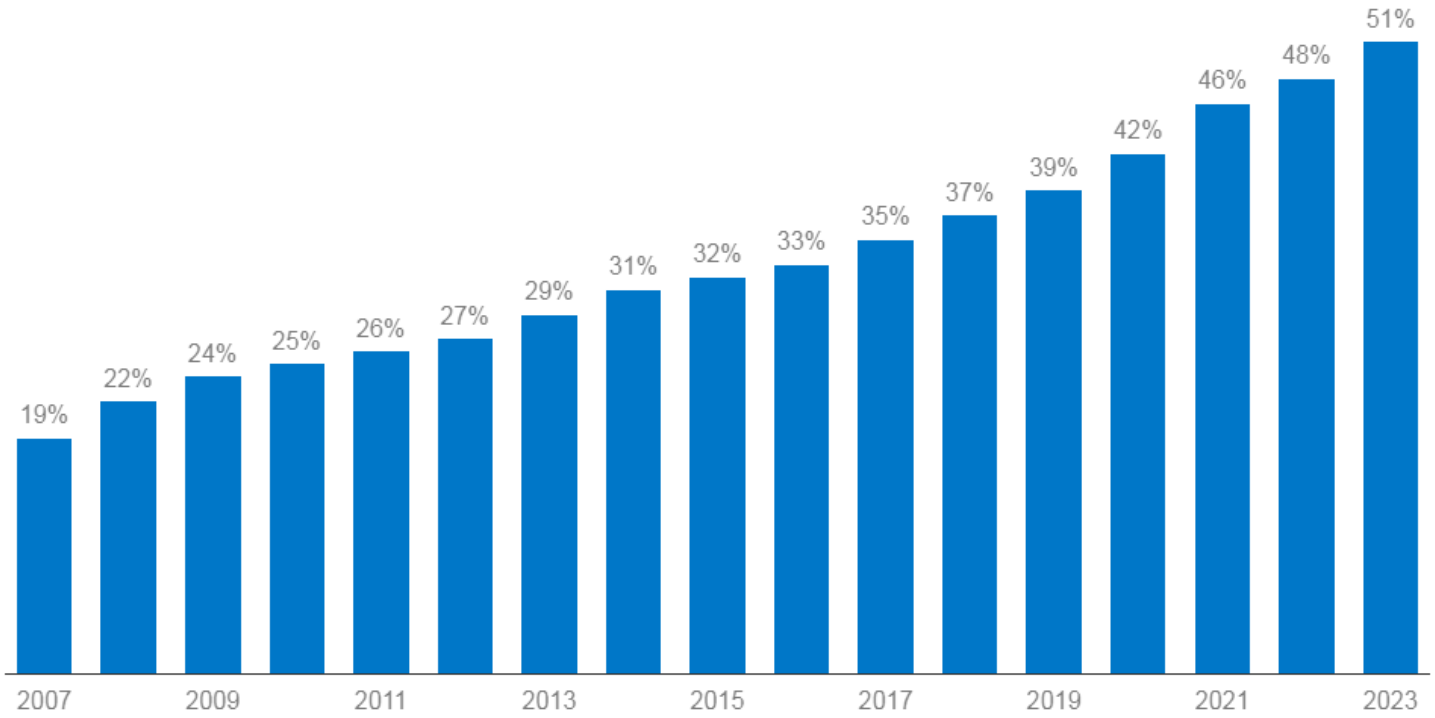

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Recent Intensification of Regulatory Requirements and Operational Challenges for Medicare Plans

MA Coverage Criteria
CMS Interpretation in CY 2024 Final Rule
(Issued 4/12/23,CMS-4201-F)

- **Follow Parts A and B / Original Medicare (OM)** by complying with
  - National Coverage Determinations (NCDs)
  - General coverage and benefit conditions included in OM laws, unless superseded by laws applicable to MA plans
    - Includes criteria for determining whether an item or service is a benefit available under OM
    - Examples: Payment criteria for inpatient admissions (2-midnight rule), Skilled Nursing Facility Care and Home Health Services, and Inpatient Rehabilitation Facilities
  - Local Coverage Determinations (LCDs)
  - 42 CFR § 422.101(b)
- **Broadened Interpretation**: Regulations classified as "payment rules" under OM may be coverage criteria for MA, as payment for an item or service is one way that MAOs provide coverage for benefits. 88 Fed. Reg. 22120, 22188, 22191.

When MA Plans May Create Their Own Coverage Criteria

- When coverage criteria are not fully established in Original Medicare (incl. NCDs and LCDs), an MA plan may create internal coverage criteria
  - Must be based on current evidence in widely used treatment guidelines or clinical literature
- Coverage criteria are not fully established when:
  - Additional, unspecified criteria are needed to interpret or supplement general provisions.
  - NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the listed specific indications
  - There is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria.

Continuity of Care for New Enrollees

- **Duration of Authorization** - Prior authorization approvals for a course of treatment must be valid for as long as medically necessary to avoid disruptions in care.
  - Course of Treatment: a prescribed or ordered course of treatment for a specific individual with a specific condition, as outlined and decided upon ahead of time, with the patient and provider
- **For coordinated care plans**: minimum **90-day transition period** for any ongoing, active course of treatment when an enrollee has enrolled in an MA coordinated care plan after starting a course of treatment.
  - Active Course of Treatment: a course of treatment in which a patient is actively seeing a provider and following the prescribed or ordered course of treatment as outlined by the provider for a particular medical condition.
  - Applies even if the course of treatment was for a service with an out-of-network provider, including use of a physician-administered drug covered under Part B.

CY2025 Prior Authorization Proposals

- Changes to Prior Authorization Timeframes in Interoperability and Prior Authorization Final Rule (CMS-0057-F) finalized Jan. 17, 2024
  - 72 hours for urgent requests
  - 7 calendar days for non-urgent requests
    - Halves the current timeline for non-urgent requests
    - These changes will become effective Jan. 1, 2026
- Proposed Rule (CMS-4205-P) published Nov. 6, 2023
  - New UM Committee requirements:
    - The UM committee must conduct an annual health equity analysis of prior authorization policies
    - A member of the UM committee must have expertise in health equity
    - MAOs must make the results of the analysis publicly available on their website.

Translation Requirements

- Plans must provide materials on a **standing basis** in any non-English languages that are the primary language of at least 5 percent of the individuals in a plan benefit package service area.
- Materials in other languages or accessible formats upon learning of the enrollee's need
  - Can be a request by the enrollee or otherwise learning of the enrollee's need for alternate materials.
  - Includes both accessible formats for enrollees with disabilities and alternate languages.
  - Includes materials in both an identified non-English primary language and accessible format when needed (for example Spanish braille).
- Translation requirements also apply to cost plans and individualized plans of care for special needs plan enrollees.

Behavioral Health Network Adequacy

- Addition of behavioral health providers to access to services requirements
  - Time and distance standards for new behavioral health specialties
    - Clinical Psychology
    - Licensed Clinical Social Work
  - Specialty types that will be evaluated as part of the network adequacy reviews.
  - Eligible for the 10-percentage point telehealth credit
- Behavioral health services that qualify as emergency services must not be subject to prior authorization

Medicare Part C and Part D Oversight and Enforcement Trends

CMS Oversight of Utilization Management

- Audits: Both routine program audit and targeted audits to assess compliance with the coverage and UM requirements of the Final Rule.
  - Routine Audits: special focus on the new UM requirements during the Part C Organization Determinations, Appeals, and Grievances (ODAG) review and the Compliance Program Effectiveness (CPE) review.
    - 2023 Program areas for audits:
      - Part D Coverage Determinations, Appeals, and Grievances
      - Compliance Program Effectiveness
      - Part D Formulary and Benefit Administration
      - Medicare-Medicaid Plan Service Authorization Requests, Appeals, and Grievance
      - Medicare-Medicaid Plan Care Coordination
      - Part C Organization Determinations, Appeals, and Grievances
      - Special Needs Plans Care Coordination
  - Focused Audits: limited to ODAG and CPE and designed specifically to target compliance with the coverage and UM policies in the Final Rule.

What is a CMS Program Audit?

- CMS annual audit plan ensures CMS evaluates Sponsoring organizations' compliance with Medicare Parts C & D program requirements by conducting program audits that focus on high-risk areas that have the greatest potential for beneficiary harm:
  - Compliance Program Effectiveness (CPE)
  - Part D Formulary & Benefit Administration (FA)
  - Part D Coverage Determinations, Appeals, & Grievances (CDAG)
  - Part C Organization Determinations, Appeals, & Grievances (ODAG)
  - Special Needs Plans Care Coordination (SNPCC)
- Each year, CMS conducts program audits of a subset of Sponsoring organizations at the parent organization level.
  - In general, CMS attempts to audit coverage for at least 95% of MA & PD covered enrollees within a given audit cycle.
  - Each audit cycle averages 4 years in duration, and organizations with the most MA & PD enrollees tend to be audited at the beginning of each audit cycle.
  - Organizations with less MA & PD enrollees, or organizations that have never been subject to a program audit, tend to be scheduled in the latter half of the cycle.
- In addition, CMS conducts annual timeliness monitoring of Part C organization determinations and appeals.

2024 CMS Program Audit Changes

- Apply the 2022 MMP Audit Protocols and Data Requests to any audit that includes a Medicare-Medicaid Plan (MMP).
- Suspend collection of 3 universes, including:
  - *Table 3: Prescription Drug Event (PDE)* found in the Part D Formulary & Benefit Administration (FA) program audit protocol and data request.
    - CMS tested use of PDE data already collected and determined it could also be used for program audit purposes.
  - *Table 7: Comprehensive Addiction & Recovery Act (CARA) At-Risk Determination (AR)* found in the Part D Coverage Determinations, Appeals & Grievances (CDAG) program audit protocol and data request, due to low volume of data received.
    - Sponsors will continue to submit appeals of at-risk determinations in CDAG Universe Table 4: Standard & Expedited Redeterminations (RD) & at-risk determinations fully or partially overturned by the IRE, ALJ, or MAC in CDAG Universe 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D)
  - *Table 6: Dual Special Needs Plan – Applicable Integrated Plan Reductions, Suspensions, and Terminations (AIP)* found in the ODAG program audit protocol and data request.
    - CMS will continue to monitor updates to regulations applicable to SNP and will use this information to make decisions on future protocol revisions.

2024 CMS Program Audits

- Require sponsoring organizations to hire an independent auditor when there are more than 5 conditions unrelated to the CPE review that must be tested during the validation audit.
  - Once a sponsoring organization meets or exceeds the threshold and an independent audit is required, all findings (including CPE conditions) identified during the program audit must be validated by the internal auditor.
    - FA conditions classified as an *Observation Requiring Corrective Action (ORCA)* are included in the number of conditions that would require an independent auditor; however, FA ORCAs will be addressed by the CMS Account Manager when an independent auditor is required.

CMS Prior Authorization Audits 2024

- On 4/12/23, CMS issued a final rule (CMS-4201-F) that included new requirements regarding coverage criteria and the use of utilization management (UM) requirements in the MA program.
- Strategic Conversations
  - CMS Account Managers conducted strategic conversations with MAOs to ensure understanding and implementation of coverage criteria and UM requirements beginning in November 2023.
- Program Audits
  - Starting in January 2024, CMS began conducting both routine and focused audits to assess compliance with the UM requirements finalized in CMS-4201-F.
    - Routine program audits conducted as in the past.
    - Focused audits will be limited in scope (only testing CPE and ODAG program areas) and duration.
  - Organizations offering MA and MAPD may be subject to a focused audit even if the organization completed a 2021 or 2022 routine program audit.
    - Organizations audited in 2023 and will undergo a CMS-led validation may be subject to a review of the new UM requirements during the validation audit.

CMS Prior Authorization Audits 2024

- CMS will utilize physician reviewers to:
  - Review denied requests to assess whether MAOs are meeting new clinical coverage requirements, such as following coverage & benefit conditions included in Traditional Medicare laws, and,
  - Where permissible, applying internal coverage criteria only when coverage criteria are not fully established in statute, regulation, National Coverage Decisions, and Local Coverage Decisions.
- Audits will ensure that:
  - internal coverage criteria are publicly available,
  - MAOs are only using physicians (or other appropriate health care professionals) with appropriate expertise in the field of medicine for the service at issue when issuing adverse medical necessity decisions, and
  - MAOs have established UM committees in accordance with regulatory requirements, including who the members of the committee are and the responsibilities they are required to complete.

OIG Risk Adjustment Audits
CMS RADV Audits

- OIG completed evaluations of health risk assessments & chart reviews
  - 3 evaluations estimated $9.2 billion in MA risk-adjusted payments for diagnoses that have no other records of services
    - Disproportionately driven by a small number of Medicare Advantage companies
- OIG risk adjustment data validation (RADV) audits
  - Compliance audit of specific diagnosis codes (targeted)
    - Target high-risk diagnoses with a greater probability for error; specific scenarios or mis-keyed
    - 200+ enrollee years sample per plan
  - Targeted audit results to date
    - 26 audit reports issued
    - Over $209 million in overpayments identified
    - 72% of HCCs not validated in Targeted Audits

Sampling of OIG MA Compliance Audit Findings

MAO	Report Date	Years Audited	Percent of HCCs Not Validated	Percent Disagreement with HCC Determination	Estimated Overpayment
BCBS Michigan	February 2021	2015-2016	76%	0%	$14.5M
UPMC	November 2021	2015-2016	69%	8%	$6.4M
Humana	September 2022	2016-2017	77%	5%	$34.4M
Highmark	November 2022	2015-2016	60%	1%	$6.2M
Cigna	December 2022	2016-2017	70%	7%	$5.9M
Keystone Health	May 2023	2016-2017	76%	10%	$11.3M
Excellus Health	July 2023	2017-2018	96%	1%	$3.1M
Aetna	October 2023	2015-2016	74%	2%	$25.5M
SelectCare of TX	November 2023	2015-2016	77%	1%	$5.1M

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OIG Risk Adjustment Audits
CMS RADV Audits

- OIG risk adjustment data validation (RADV) audits
  - Compliance audit of diagnoses submitted by MAOs (RADV-like)
    - Sample across plan & review all diagnoses for selected beneficiaries
    - 200 enrollees selected per plan; over 1,500 HCCs
  - Contract RADV audit results to date
    - 6 audit reports issued
    - Over $374 million in overpayments identified
    - 9% of HCCs not validated in Targeted Audits
- OIG Risk Adjustment Work Plan Items
  - Audits of at-risk diagnoses
    - Continue targeted audits
    - Nationwide audits
  - HRAs and chart reviews
    - HRA submission update
    - HRA audit
    - Unlinked chart reviews
- Medicare Advantage RADV Final Rule (CMS-4185-F2)
  - Two main provisions:
    - Extrapolation to begin with payment year 2018
    - CMS will not apply an adjustment factor (FFS adjuster)

Risk Adjustment Enforcement Recent Developments

- Increased scrutiny and pressure for more oversight
- Cigna: $172M settlement
  - FCA suit based on allegedly false diagnosis codes
  - Alleged false claims: Diagnoses based on in-home assessments of patients conducted by health care professionals who are not physicians.
- HealthSun: RA director facing prison time
  - DOJ declined prosecution of HealthSun (MAO) due to prompt voluntary self-disclosure and repayment of $53 million in overpayments
  - New risk dynamic: RA director Kenia Valle Boza indicted, faces up to 20 years in prison
    - Submission of false diagnosis codes for risk adjustment
    - Using credentials of affiliated entity providers to falsify diagnoses in electronic medical record

Medicare Risk Adjustment Litigation

Case	Government Intervention	Status
US v. Janke	Yes	Settled in 2010 for $22.6M
US ex rel. Swoben v. SCAN Health Plan	No*	Settled in 2012 for $3.8M
US ex rel. Olivia Graves v. Plaza Medical Centers Corp.	No	Settled in October 2017
US ex rel . Silingo, et al ., v. Mobile Medical Examination Services Inc.	No	Settled in 2020
US ex rel. Sewell v. Freedom Health, Inc.	Yes	Settled in 2017 for $32.5M
US ex rel Benjamin Poehling v. Unitedhealth Group Inc.	Yes	Ongoing
US ex rel. Ross v. Group Health Coop.	Yes	Settled in 2020 for $ 6.3
U.S. ex rel. Cutler v. Cigna	Yes	Settled in 2023 for $172M
U.S. ex rel. Wilbur v. Martin's Point Health Care Inc.	Yes	Settled in 2023 for $22M
U.S. v. HealthSun Health Plans Inc.	Yes	Settled in 2023 for $53M
US v. Anthem, Inc.	**Yes**	**Ongoing**
Kaiser Cases*	**Yes**	**Ongoing**

*Includes U.S. ex rel. Osinek v. Kaiser Permanente, United States ex rel. Taylor v. Kaiser Permanente, U.S. ex rel. Arefi, et al. v. Kaiser Foundation Health Plan, Inc., U.S. ex rel. Stein, et al. v. Kaiser Foundation Health Plan, Inc., U.S. ex rel. Bryant v. Kaiser Permanente, and U.S. ex rel. Bicocca v. Permanente Med. Group, Inc.

Will Medicare Advantage drift out of the spotlight? (Not likely)

RollingStone

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'DISASTROUS'

Republicans Are Planning to Totally Privatize Medicare – And Fast

The right-wing policy agenda written for a new Donald Trump presidency would "greatly accelerate" efforts to privatize Medicare

BY ANDREW PEREZ

FEBRUARY 6, 2024

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