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Lessons and Tools for Successfully Navigating Medicare Risk Adjustment

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Agenda

- Overview of Medicare Advantage risk adjustment regulatory framework and history
- Discussion of False Claims Act liability and recent litigation
- Status of affirmative litigation
- Developing an effective compliance program that addresses risk adjustment
- Internal audit strategies to consider

Payments to Medicare Advantage Organizations

- Capitated payments to MAOs are adjusted by
  - Normalization Adjustment
  - National per capita growth percentage
  - Coding Intensity Adjustment
  - Risk Adjustment Factors

Statutory Authority

Pre-MMA

1997: The **Balanced Budget Act** establishes Medicare + Choice and Risk Adjustment Payments

1999: The **Balanced Budget Refinement Act** adopted a phased-in approach to Risk-Adjusted payments based on health status

2000: The **Benefits and Improvements Protection Act** expanded the allowable data sources from which M+C plans could collect diagnosis data to include inpatient hospital and ambulatory settings

The MMA and Beyond

2003: The **Medicare Modernization Act** established a bidding process that requires MAOs to submit monthly bids "for the provision of all items and services under the plan, which amount shall be based on the average revenue requirements … *for an enrollee with a national average risk profile*."

2010: The **Patient Protection and Affordable Care Act** requires CMS to periodically evaluate the risk adjustment system "to … account for higher medical and care coordination costs associated with frailty, individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness, and also to account for costs that may be associated with higher concentrations of beneficiaries with those condition…."

Regulatory Authority

Key Regulations	
42 C.F.R. § 422.308- Adjustments to capitation rates, benchmarks, bids and payments	• Clarifies that CMS will adjust payment amounts to account for health status • Adjustments are intended to "improve the determination of actuarial equivalence"
42 C.F.R. § 422.310- Risk Adjustment data	Governs risk adjustment data submitted by MAOs • includes all data that are used in the risk adjustment payment model • must conform to CMS' requirements for Medicare fee-for-service data, when appropriate • Data comes from the provider, supplier, physician, or other practitioner that furnished the item or service. • Permits MAOs to impose financial penalties for failure to complete data used for risk adjustment in contracts with providers • Authorizes RADV audits
42 C.F.R. § 422.311 – RADV audit dispute and appeals processes	MAOs may appeal • Medical record review determinations • RADV payment error calculation Level 1: Request for Reconsideration Level 2: Request for CMS Hearing Official Review Level 3: Request for CMS Administrator Review
42 C.F.R. §422.504 (l)(2) – Payment Data Certification	Requires that data submitted to support payment must be accurate, complete and truthful

Subregulatory Guidance

Examples:

- Medicare Managed Care Manual, Chapter 7
- CMS Website: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.html
- CMS Notices and Memoranda
  - 45- Day Advance Notice
  - Annual Announcement and Call Letter
  - HPMS Memos
- Bid Pricing Tool
- Risk Adjustment Data Technical Assistance for Medicare Advantage Organizations Participant Guide and Related Training (CSS Operations)

Risk Adjusted Payments - HCCs

Prospective Model

- Medical conditions from a given year are used to predict expenditures in the next year
- Diagnoses from hospital inpatient, hospital outpatient and physician offices support diagnoses
- Risk factors are additive when the diseases are not closely related
- Groups may be in hierarchies when related
  - An enrollee assigned the most severe manifestations among related diseases

Hierarchical Condition Categories

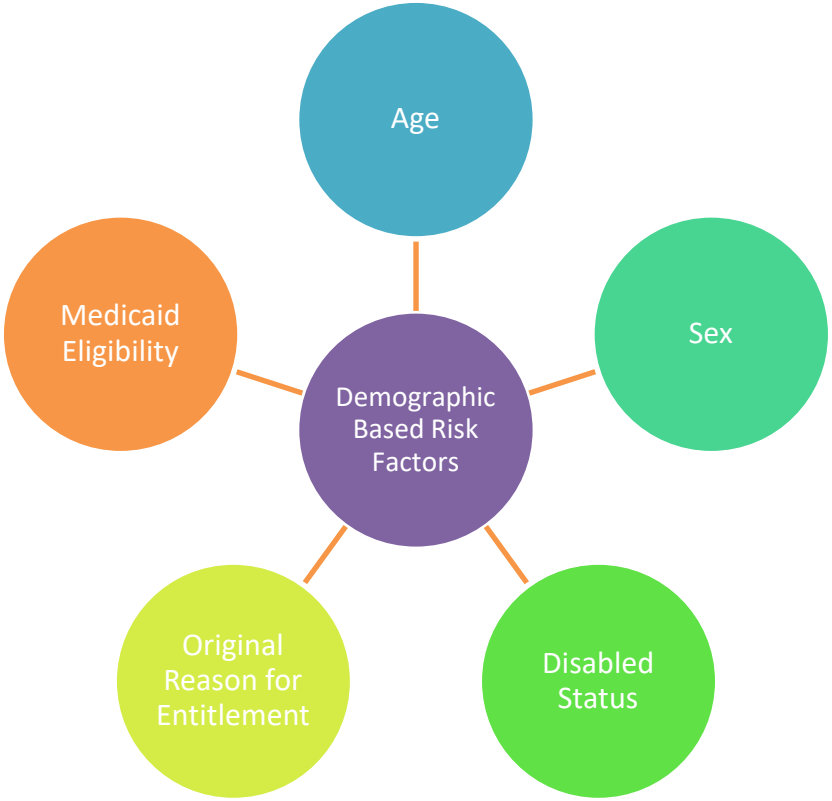
Disease groups are referred to as Hierarchical Condition Categories (HCCs).

Disease groups contain major diseases and are broadly organized into body systems

HCC assigned to a disease is determined by the ICD-10-CM diagnosis codes submitted during a data collection period

Only selected diagnoses are included in the risk adjustment models

Risk Adjustment Payments – Demographic Factors

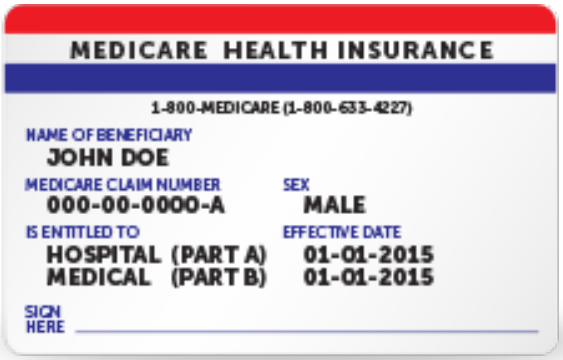


Risk Adjustment Payments – HCCs

- HCC Model groups medical conditions with similar costs of treatment to establish a risk score for each enrollee
  - Developed using Medicare Fee-For-Service claims data
  - Classifies over 70,000 ICD-10 codes into 805 diagnostic categories
  - The 805 diagnostic categories are aggregated into 189 Condition Categories
  - Hierarchies are then imposed among related Condition Categories, creating 87 HCCs
- Each HCC has an assigned coefficient, which represents the incremental predicted expenditures

Risk Adjustment Payments – HCCs

- A 1.0 risk score represents average annual Medicare costs for an individual based on FFS data.
- A risk score ***higher*** than 1.0 means the individual is likely to incur costs higher than average.
- A risk score ***less*** than 1.0 means the individual will incur costs less than average.



ICD-10 – HCC Mapping

John Doe visits his physician and is diagnosed with diabetes mellitus due to underlying condition with other diabetic kidney complication (E0829). The provider submits diagnosis code E0829 to the MAO.

The MAO submits the diagnosis code to EDS on an encounter data record. Upon applying the filtering methodology, CMS determines that E0829 is a risk adjustment eligible diagnosis code and, in risk score calculation, is mapped to HCC-18.

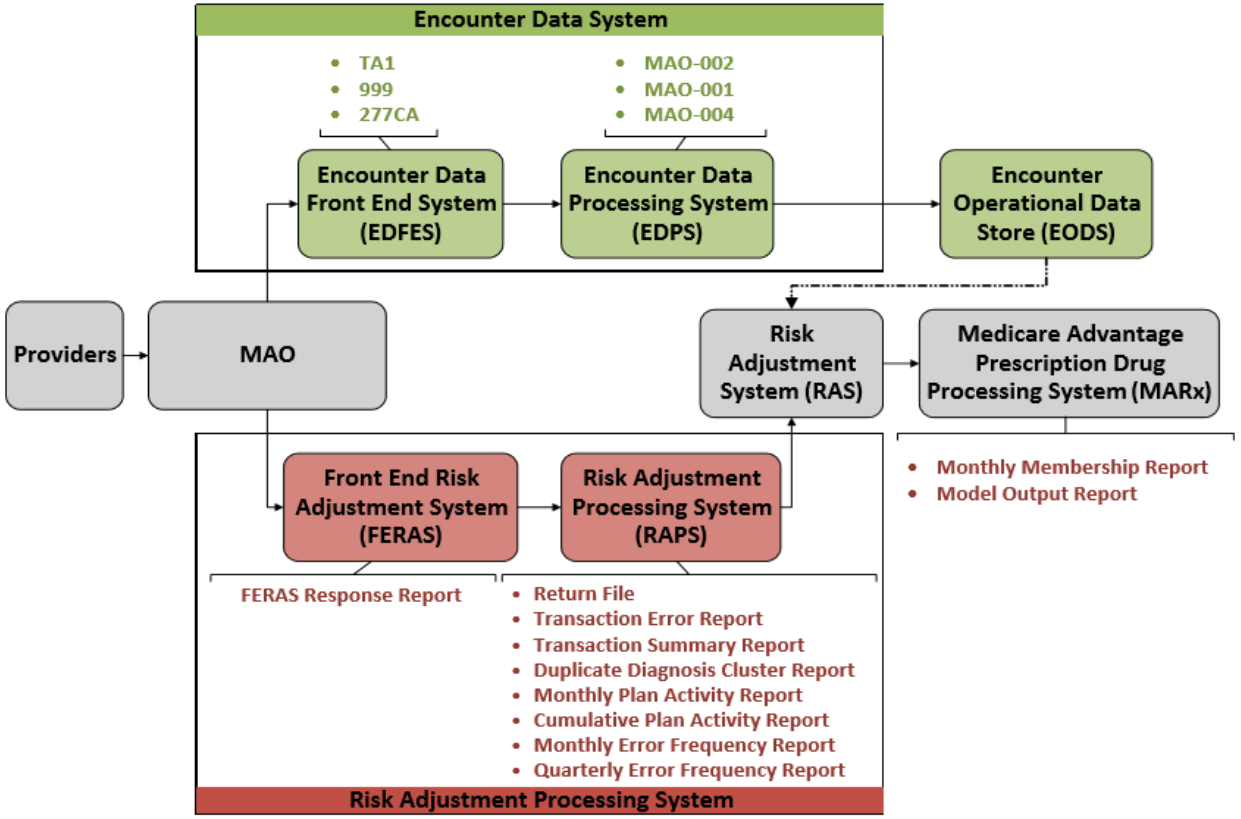
Source: Risk Adjustment for EDS & RAPS User Group, November 17, 2016

HCC18 is Diabetes with Chronic complications, and its coefficient depends on community model:

Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual Aged	Community, PBDual Aged	Community, PBDual, Disabled	Institutional
0.318	0.371	0.346	0.431	0.354	0.423	0.441

Source: Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter

Risk Adjustment EDS & RAPS Processing Flow



Source: Risk Adjustment for EDS & RAPS User Group Call, August 17, 2017

Risk Adjustment EDS & RAPS Processing Flow

Risk Adjustment Processing System

- ✓ MAOs filter diagnosis codes from providers and submit to CMS
- ✓ CMS checks for duplicates and errors
- ✓ CMS validates accuracy of codes through Risk Adjustment Data Validation Audits

Encounter Data System

- ✓ All unfiltered data is submitted to CMS
- ✓ CMS applies filtering logic to identify valid diagnosis codes
- ✓ CMS then uses these diagnosis codes to determine risk scores

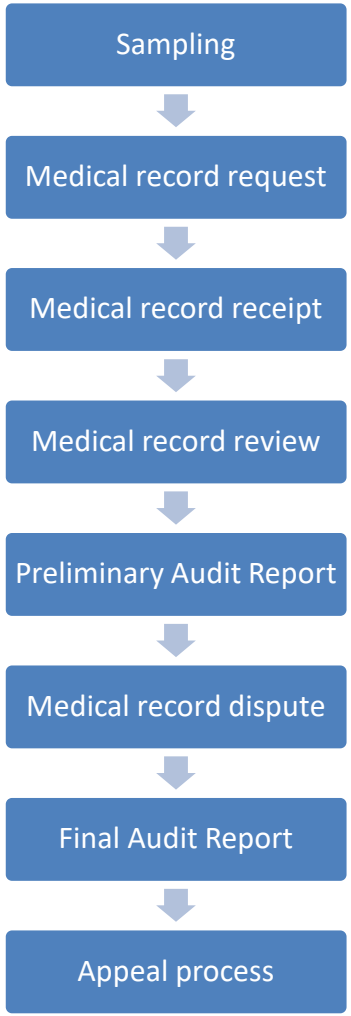
Data Submission

Diagnosis codes submitted to CMS for risk adjustment must:

- Be documented in the medical record
- Be documented as a result of a face-to-face visit
- Come from an acceptable data source (inpatient, outpatient, physician, etc.)
- Be submitted at least once during the risk adjustment data period
- Be coded according to ICD Guidelines

RADV Audits

- ✓ RADV Audits designed to ensure accuracy and integrity of risk adjustment data
- ✓ CMS selects a subset of MA plan contracts to audit
- ✓ RADV Audits review medical record documentation to verify diagnosis submitted to support HCCs
- ✓ Beginning in 2011, CMS used sample results to extrapolate overpayment estimates



RADV Audits

2007 Pilot and Targeted RADV Audits: $13.7 million in overpayments associated with sampled beneficiaries, appeals ongoing

2011 RADV Audits: 30 MA contracts audited

2012 RADV Audits: 30 MA contracts audited

2013 RADV Audits: 30 MA contracts audited

Source: GAO Report, Fundamental Improvements Needed in CMS's Efforts Medicare Advantage Risk Adjustment Data Validation Audits Fact Sheet (updated June 1, 2017)

Risk Adjustment and Key Issues

- RAPS → EDS implementation issues
- RADV extrapolation challenges
- Regulatory updates?
  - Chapter 7 last updated in 2014
  - CMS released RFI for RADV auditor in late 2015
  - CMS was supposed to release FFS adjuster in 2016
- Litigation
- Additional compliance program obligations

Risk Adjustment Litigation






The False Claims Act

- Treble damages, fines and penalties for:
  - Presenting a false claim for payment to the government with knowledge of its falsity;
  - Falsely certifying information that was material to a claim or payment; or
  - Reverse false claim – "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government."

  31 U.S.C. Section 3729
- "Whistleblowers" or "relators" bring the lawsuits on behalf of the government.
- The Department of Justice (DOJ) may elect to intervene.
- Lawsuits are initially sealed to the public.

Overpayment Rule

- 2010 amendment to Medicare/Medicaid program integrity provisions clarifies obligations upon "identification" of an overpayment. 42 U.S.C. § 1320a-7k(d)
- Must report and return an overpayment to HHS, the state, an intermediary, a carrier or a contractor by the later of . . .
  1. 60 days from the date when the overpayment was "identified" or
  2. The date "any corresponding cost report is due"
- Report must state the "reason for the overpayment"
- Retained overpayments are "obligations" under the False Claims Act → subject to treble damages, fines and penalties

False Claims Act Liability for Risk Adjustment "Overpayments"

1. **Failure to Oversee/Monitor**
   - Certification under MA regs and duty to implement compliance program
   - Purported "red flags"
   - *United States ex rel. Graves v. Plaza Med. Ctrs.*, 1:10-cv-23382 (S.D. Fla.)
2. **One-Sided Retro Reviews**
   - Reviews designed to find "adds" while ignoring "deletes"
   - *United States ex rel. Swoben v. Scan Health Plan et al.*, 2:09-cv-05013-JFW-JEM (C.D. Cal.)
   - *United States ex rel. Poehling v. UnitedHealth Group Inc.*, 2:16-cv-08697-MWF-SS (C.D. Cal.).

Alleged Failure to Oversee /Monitor Provider

***United States ex rel. Graves v. Plaza Med. Ctrs.*, 1:10-cv-23382 (S.D. Fla.)**

- Complaint Withstood Motion to Dismiss (July 6, 2016)
  - Capitated arrangement + statistical evidence and/or other data + audit obligations = sufficient allegations that payor turned a "blind eye" or engaged in "reckless disregard" of truth or falsity of submissions to CMS.
- Survived Summary Judgment (Feb. 27, 2017).
  1. Compliance Program Lacking: Lack of "***good faith efforts***" to certify accuracy of data and maintain an "***effective***" compliance program.
  2. Ignoring Red Flags.

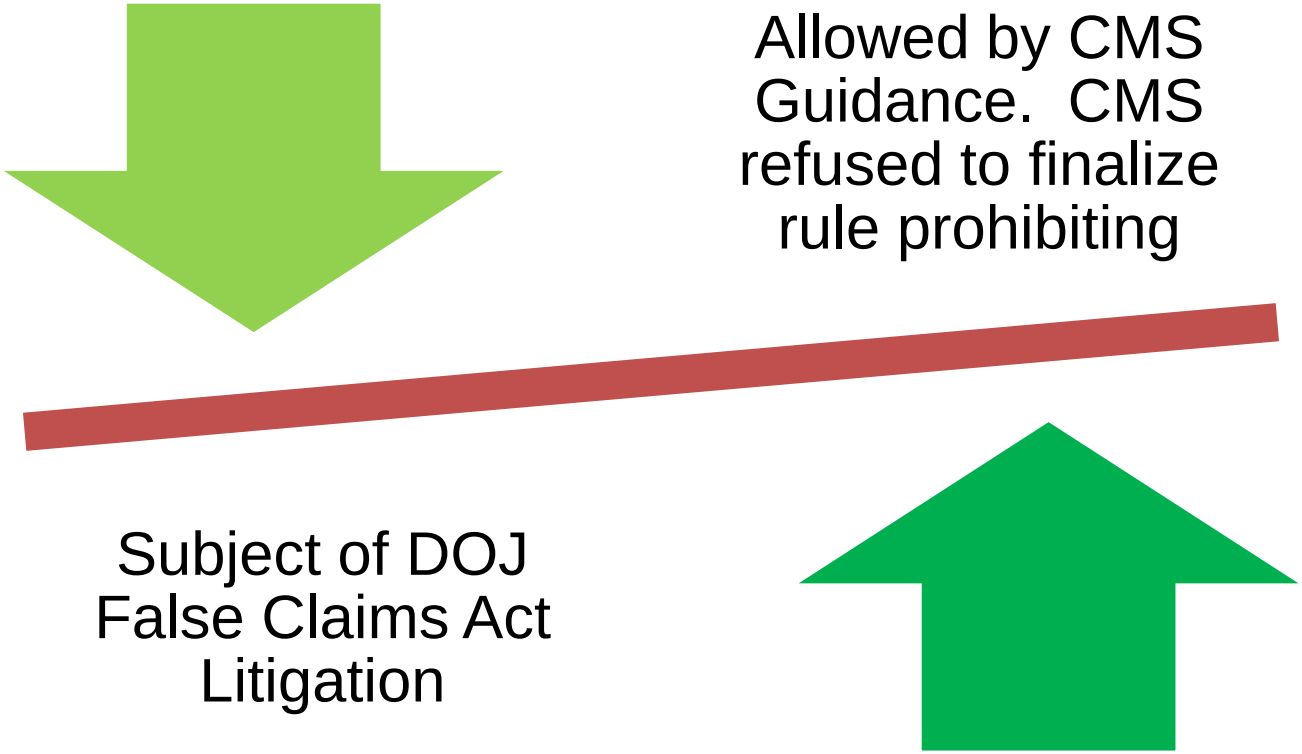
One-Sided Retro Reviews: *Swoben v. UHC*

- 9th Circuit (Aug. 2016) – error for trial court to deny leave to amend complaint alleging FCA liability for one-sided retro review of diagnosis coding.
- Applied certification standard under MA regulations and False Claims Act.
- **BUT**, complaint dismissed again on remand on Oct. 5, 2017:
  - Lacked sufficient allegations of "knowledge"
  - Lacked sufficient allegations of "materiality"
  - Lacked details as to roles of UHC defendants.
- DOJ declined to amend and voluntarily dismissed the complaint w/o prejudice.

One-Sided Retro Reviews: *Poehling v. UHC*

- Allegations that UHC's national chart review program favored "adds" over "deletes".
- Transferred from Western District of New York to Central District of California.
- DOJ Complaint in intervention filed 5/16/17.
- DOJ motion to consolidate with *Swoben* denied.
- UHC motion to transfer to D.C. denied.
- Amended Complaint-In-Partial-Intervention due November 17, 2017.

One-Sided Retrospective Reviews



Affirmative Litigation by UHC Challenging Overpayment Rule

UnitedHealthcare Insurance Company, et al. v. Hargan, et al. No. 16-cv-157 (D.D.C.)

1. **Rule Imposes a Negligence Standard on MAOs:**
   - "Reasonable diligence" and "proactive compliance activities"
   - While statutory language requires knowledge
2. **Rule Results in underpayment to MAOs**
   - Violates requirement of "actuarial equivalence" in Medicare Act.
   - FFS claims data is not subject to a document verification requirement.

ERROR HAPPENS!

Encounter Data in MA Risk Adjustment Coding

Provider renders clinical diagnosis

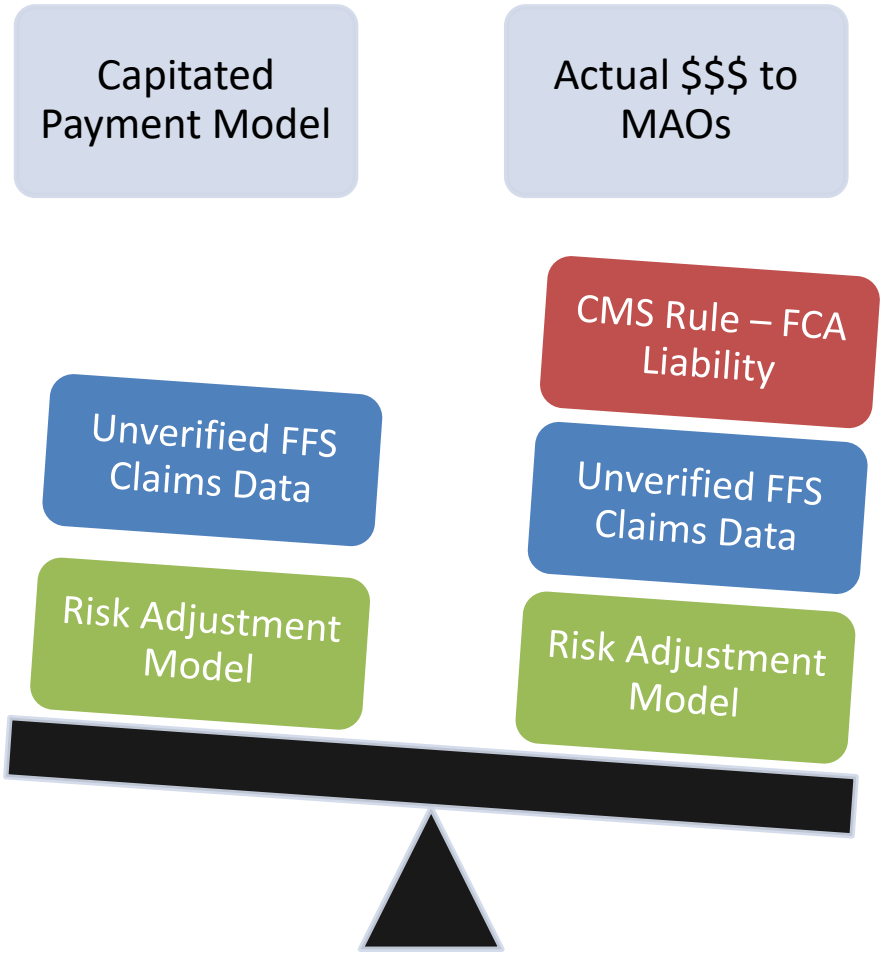
Provider documents diagnosis in medical records

Provider or “coder” translates diagnosis into ICD-9/10 codes

Provider submits codes to MAO

MAO submits codes to CMS

UHC v. Hargan: Alleges Actuarial (In)Equivalence



Example: Calculate How Much CMS Pays for Beneficiary with a Particular Diagnosis

Assume CMS observes $9K in total claims costs based on FFS data.

Calculated per-beneficiary cost

No Medical Record Validation

$900 ($9K / 10 beneficiaries)

With Medical Record Validation

$1,000 ($9K / 9 beneficiaries)

Payment to MAO: CMS Subject to Document Validation Requirement ...

With Medical Record Validation

CMS calculated per-beneficiary cost of $1,000

MAO paid $10K ($1K x 10)

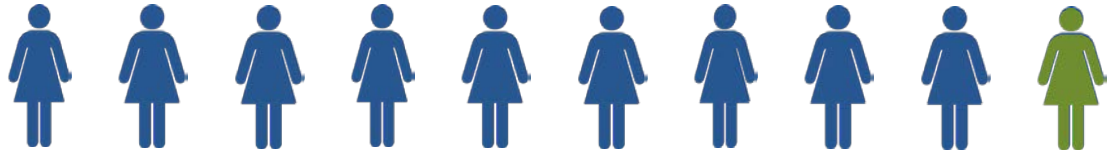
MOAs subject to CMS Rule – FCA Liability

MAO returns $1,000 for

Actuarial Equivalence Achieved

MAO paid $9,000: (10 x $1K) - $1K

Current State: MAOs Subject to CMS Overpayment Rule With No Equivalent Requirement of CMS



No Medical Record Validation

CMS calculated per-beneficiary cost of $900

MAO paid $9K ($900 x 10)

MOAs subject to CMS Rule – FCA Liability

MAO returns $900 for

Lack of Actuarial Equivalence

MAO is paid $8,100: (10 x $900) - $900.

UHC v. Hargan: Proceedings on the "Administrative Record"

- January 29, 2016: Complaint challenging the CMS' 2014 Overpayment Rule.
- March 31, 2017: Court denied Defendants' Motion to Dismiss.
- June 14, 2017: Court denied Defendants' Motion to Stay.
- July 14, 2017: Service of Administrative Record.
- October 2, 2017: Motion to Supplement Administrative Record to include FFS Adjuster Docs.
- October 17, 2017 - January 19, 2018 : Summary Judgment briefing.

UHC v. Hargan: Early Rulings Favorable to MAOs

- Found CMS Rule imposes new obligations*:*

"In essence, the Secretary would have the Court find that the CMS Rule's insistence on 'proactive compliance activities,' under pain of a False Claims Act suit provable by negligence alone, is meaningless. It is not; it imposes (for good reason or not) new obligations."

- Limits 9th Cir. decision in *Swoben*
- Noted "industry wide implications" in denying motion to stay.
- *Poehling* Court denied motion to transfer to D.C. to be coordinated with *UHC v. Hargan*

Scope of Administrative Record

- Created by the Government agency.
- The full administrative record that was before the agency official at the time he or she made the decision to promulgate the final rule at issue.
- CMS has included UHC affiliate RADV error rates.
- UHC seeks to include internal CMS documents concerning the FFS Adjustor in the RADV process

  * Compelling evidence that CMS understood how the lack of a document verification process in the FFS data results in underpayments to MAOs

Building Risk Adjustment Oversight into an Effective Compliance Program



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CMS Requirements

"The implementation of an ***effective compliance program*** is a prerequisite to an MA Organization's obtaining and retaining payments under both Parts C and D of the Medicare program."

- United States' Complaint-In-Partial-Intervention, *United States ex rel. Poehling v. UnitedHealth Group, Inc., et al.*, No. CV-16-08697 (C.D. Cal. May 16, 2017) at ¶67 (citing 42 C.F.R. §§ 422.503(a) & 423.504(b)(4)(vi)).

CMS Requirements

"[E]ach MA Organization must '[a]dopt and implement an effective compliance program, which must include ***measures that prevent, detect, and correct non-compliance*** with CMS' program requirements as well as measures that ***prevent, detect, and correct fraud, waste, and abuse***."

- United States' Complaint-In-Partial-Intervention, *United States ex rel. Poehling v. UnitedHealth Group, Inc., et al.*, No. CV-16-08697 (C.D. Cal. May 16, 2017) at ¶68 (citing 42 C.F.R. §§ 422.503(b)(4)(vi) & 423.504(b)(4)(vi)).

CMS Requirements

The compliance program must include, at a minimum:

- Routine monitoring and identification of compliance risks, including internal monitoring and audits and external audits to evaluate First Tier Entities' compliance
  - An MA Organization maintains responsibility for compliance with the terms of its contract with CMS
- A system for promptly responding to compliance issues as they are raised or identified

- United States' Complaint-In-Partial-Intervention, *United States ex rel. Poehling v. UnitedHealth Group, Inc., et al.*, No. CV-16-08697 (C.D. Cal. May 16, 2017) at ¶68 (citing 42 C.F.R. §§ 422.503(a) & 423.504(b)(4)(vi)).

Poehling Examples

- In its complaint in Poehling, the DOJ alleged that United failed to oversee its First Tier, Downstream and Related Entities and to resolve identified issues:
  - "[O]ne of United's own actuarial consulting subsidiaries . . . identified unsupported diagnosis codes as a 'Potential Compliance Risk Area' …"
  - "United, however, took over three years to develop its [risk adjustment chart audit service]. Furthermore, the manner in which United developed and then implemented its [chart audits] shows that United was never committed to honoring its obligation to undertake good faith efforts to ensure the validity of the risk adjustment data ..."
  - "United effectively terminated the [Risk Adjustment Coding and Compliance Reviews] Program and deliberately avoided identifying and, thus, deleting invalid diagnoses reported by its financially-incentivized providers …"

- United States' Complaint-In-Partial-Intervention, United States ex rel. Poehling v. UnitedHealth Group, Inc., et al., No. CV-16-08697 (C.D. Cal. May 16, 2017) at ¶¶ 102, 158, & 229.

THE ROLE OF COMPLIANCE IN RISK ADJUSTMENT

Broad Evaluation of Process

Risk adjustment evaluation may begin with coding assessments, but data submission and population health processes should also be included.

Coding & Documentation

- Process begins with patient care and Provider recording Face to Face Encounter
- To assist Providers, profiling (e.g. prescriptions w/o corresponding dx) and,
- Provider outreach and education opportunities (e.g. scorecards)

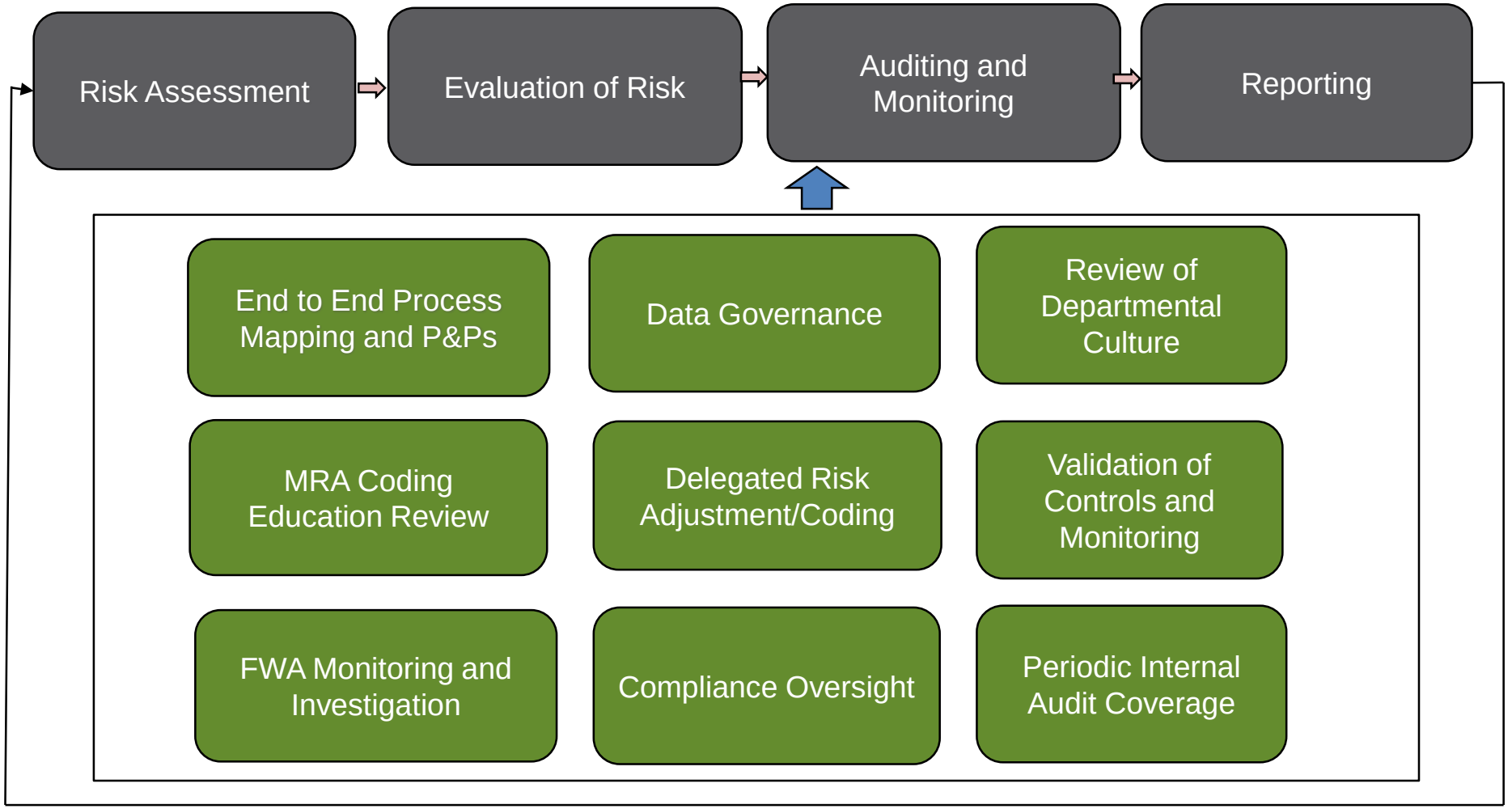
Population Health

- Population segmentation for tailored outreach
- Member outreach and education opportunities
- Gaps in care (follow-up visit scheduled, outreach w/in 2 days of discharge, etc.)

Compliance

- Accuracy of data fields for submission
- Timeline adherence with contract standards
- Controls and policies & procedures in place
- Chart reviews (random or targeted sample)

The Risk Adjustment Compliance Program



Business Process Controls and Monitoring

1. **Clinical Care Management:** Complete and accurate clinical diagnosis coding leads to earlier identification of members in need of Care Management, which in turn drives costs down.
   A. Ensure that this important follow up aspect is a part of the work that is done to identify complete and accurate diagnosis.
   B. Integration of Care Management into Risk Adjustment starts with Suspecting and Analytics and continues on through the process until they make it to Clinical Care Managers and Provider Education.

2. **Coding Quality Audit:** It's important to measure the quality of the work performed and to use those results to drive improvement in the programs through internal and external education.

3. **Vendor Management:** Vendors should be managed by the plan, not the other way around.
   A. No Black Boxes: The plan needs to understand how and what the vendor does on its behalf.
   B. Data provided by vendors must meet plan standards and be capable of augmenting plan quality and education programs.

HOW RISK ADJUSTMENT AFFECTS THE WHOLE ORGANIZATION

Risk Adjustment Processes and Oversight

1. Identifying and Collaborating with the right accountable associates throughout the organization.
   A. The Chief Medical Officer (CMO) or their Delegate
   B. Appropriate layers of your Market based Leadership
   C. Medicare Finance Leadership
   D. Medicare Compliance Leadership
   E. Legal
   F. The Special Investigation Unit
   G. Information Technology
   H. Internal Audit

2. Getting the Message Right: Risk Adjustment Compliance is about ensuring the accurate reflection of health status
   A. Internal Policies and Procedures
   B. External Contracts
   C. Educational Materials
   D. Internal and External Communication (Email and Verbal)

Multiple Areas Involved in Mitigating Risk

A. Claims & Encounter Processing

Data sources & feeds
Data validation checks
Payer data considerations

B. Clinical / Provider

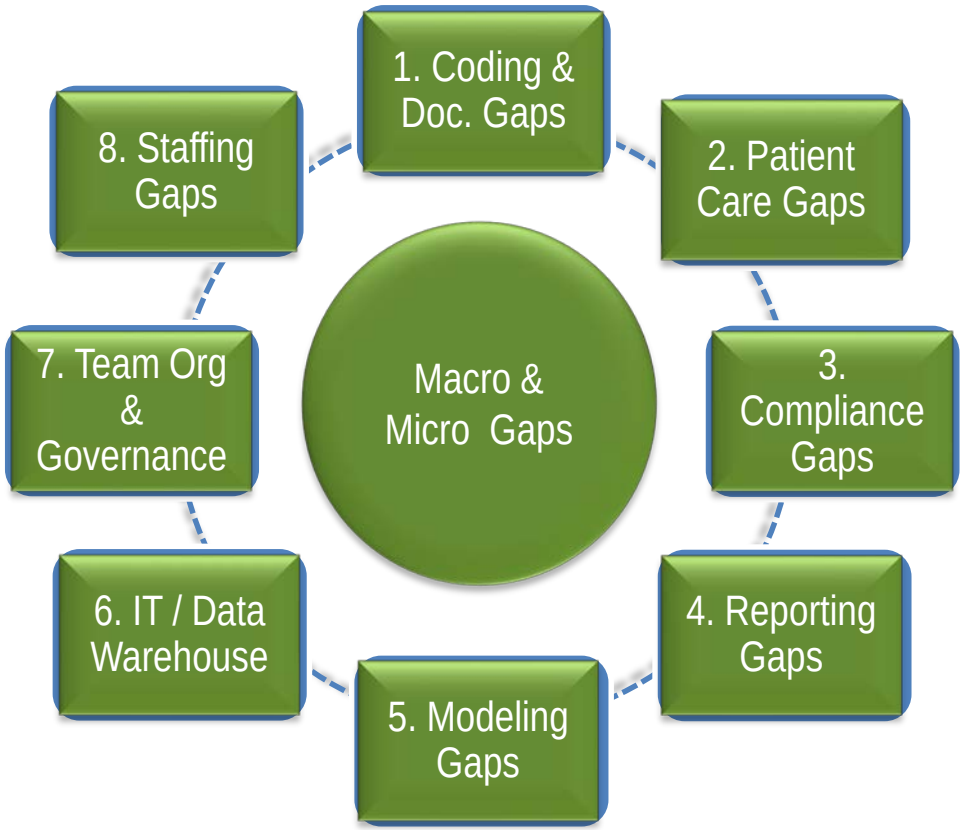
Pop. health innovation
Member outreach
Provider education

C. Coding / ICD-10

Chart reviews
Audit readiness
ICD-10 readiness

D. Contacting

Physician incentives
Payer relations
Uniform provisions



E. Finance

Strategic initiatives
Cross collaboration
Vendor performance

F. Information Technology

Data warehouse
Data infrastructure
Data submissions

G. Decision Support

Reporting & modeling
Population segmentation
Predictive analytics

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CONTROLS AND MONITORING

Risk Adjustment Oversight

The roles of the following committees should be considered:

1. Risk Adjustment Steering/Oversight Committee
    A. This group oversees the Risk Adjustment Operations, as well as, represents the decision making body when vendors or providers do not meet the accuracy expectations of the organization.
    B. This group should drive the Provider Coding Risk Assessment and the Provider Auditing process, including but not limited to Provider based Risk Adjustment Operations and Coding Activity.
    C. This group should have direct authority to approve pilot programs, which should be fully developed and planned prior to even test implementation. Any results from these programs need to be fully run to ground.
2. Coding Compliance Committee
    A. This group should have Clinical, Legal, and Compliance Leadership, as well as appropriate ICD-10-DM coding SMEs.
    B. This function should set policy and provide educational guides on how the organization codes.
    C. This function should oversee coding reviews results, drive education materials, and ensure those are provided to the correct sources; vendors, providers, internal resources.

Risk Adjustment Oversight (cont'd)

3. Fraud Waste and Abuse (FWA)
   A. In Risk Adjustment, this is a collaborative effort among Special Investigations, Legal, Clinical Leadership, and Provider Risk Assessment/Auditing.
   B. Proper Data Governance that allows combinations of all chart review and QA results, as well as, operational data metrics is key to identifying outliers.
   C. Provider Audit results, clinical knowledge, and market based knowledge will be necessary to understand outliers.
   D. The standard plan FWA reporting methods must be appropriately informed to ensure Risk Adjustment issues can be appropriately identified and routed to the appropriate parties.

Sample Risk Adjustment Metrics

Rank	Metric	Context/Rationale
1	Risk Score by market and provider grouping. (Differentiated by clinical vs. demographic score, with and without normalization.)	Comparison and trends of risk scores by markets and provider groups can point to general coding trends. It is important to separate clinical HCCs from other components of the Risk Score (demographic and CMS normalization components) to measure what may be impacted by process and education changes.
2	HCC Prevalence Rates	Prevalence rates that are outside regional norms may indicate poor documentation or inconsistent coding patterns.
3	Coding Quality Accuracy Rates	Medical Record coders should be subject to regular quality assessments, sometimes referred to as IRRs (Inter Rater Reliability reviews). Coders are generally expected to code at a 95% or higher accuracy rate.
4	Risk Score Distribution vs. National Averages	Groups or PCPs with risk distribution outside of averages may be at risk of under- or over-coding.
5	Rate of Chronic HCCs Re-Documented by group, by PCP	HCCs are required to be re-documented each year. Low re-documentation rates of known chronic conditions may indicate inconsistent patient interaction or poor documentation.
6	Non Corroboration Rate	Rather than looking only at Non-Corroborated Codes alone and their impact to the provider look at the non corroboration rate amongst providers. Who stands out in the market compared to others.
7	RAPS and Encounter Data Error Rates, particularly provider- preventable errors such as ICD9/ICD10 coding issues.	CMS performs basic ICD9/ICD10 level edits (gender- appropriate coding, for example). Health plans should monitor these errors and correct prior to submission to the plan.
8	# of Acute Diagnosis made in an outpatient setting	Acute diagnosis in general should appear in an inpatient setting, so outliers in this area will warrant further review.
9	Percent of Members with at least one PCP visitor percent of Members with a completed annual comprehensive exam, by group, by PCP	This metric indicates which PCPs are seeing members regularly. Regular PCP visits (at least annually) provide an opportunity to re-document chronic conditions and assess members for new or worsening conditions.

Internal Audit Strategies

1. Risk Assessment
   A. Appropriate Identification of Financial, Compliance, Strategic and Operational Risk
   B. Escalation of Issues
2. Process and Controls Review and Testing
   A. Validation of the Oversight functionality and Operations
   B. Validation of Accuracy of Data Submission
   C. Audit of Vendors and supporting activity
   D. Validation of QA Methodology
   E. Baseline and Accuracy of Reporting/ Analytics
   F. Review of Market Operations to ensure consistency with Corporate Oversight expectations
3. Internal Investigatory Support

TAKE AWAYS

Take Aways

Risk Adjustment is a High Risk for every Payer.

Risk Adjustment Compliance is a team effort.

Compliance and Legal need Subject Matter Experts to help address Risk Adjustment.

View Capitated Provider Risk Adjustment Programs with the Delegation lens, similar to Claims or Utilization Management.

The integration of Risk Adjustment and Clinical Care Management programs improves compliance and financial outcomes.