Quality Reporting: What Do Compliance Professionals Need to Know?

January 26, 2024

PRESENTED BY

Rebecca Gittelson
Regulatory Counsel, athenahealth

Lauren Gennett
Counsel, King & Spalding

1

Goals for today's presentation

Provide the tools for you to understand quality programs and/or deepen your understanding of quality programs

Help you understand why quality programs matter for your work and/or how you can enhance your existing compliance programs for quality

2

2

Agenda

Introduction to Quality Reporting

The Mechanics

Enforcement Trends and Compliance Risks

Practical Compliance Strategies to Mitigate Risk

Introduction to Quality Reporting

Why should you care about quality programs?

Significance for HC organizations and compliance professionals

Healthcare organizations that are engaged in quality management generally participate in at least one quality program

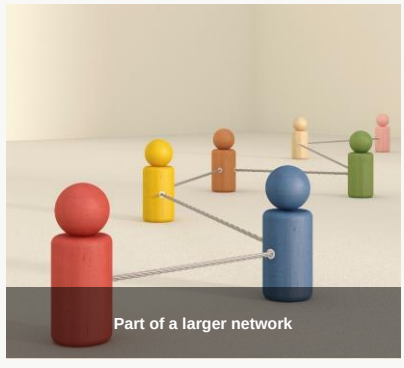
This means that your organization likely participates in 1+ quality program(s)

It's about the money…and the enforcement risk

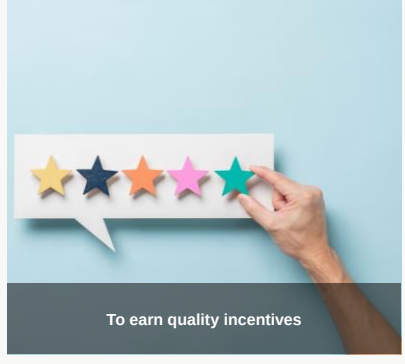
5

Why do healthcare organizations participate?

Required by payers



Part of a larger network



To earn quality incentives

6

Why do quality reporting programs exist?

- Increase quality of care
- Drive value-based care
- Decrease cost

7

Why do quality reporting programs exist?

CMS.gov Centers for Medicare & Medicaid Services

What are the value-based programs?

Value-based programs reward health care providers with incentive payments for the quality of care they give to people with Medicare. These programs are part of our larger quality strategy to reform how health care is delivered and paid for. Value-based programs also support our three-part aim:

- Better care for individuals
- Better health for populations
- Lower cost

Why are value-based programs important?

Our value-based programs are important because they're helping us move toward paying providers based on the quality, rather than the quantity of care they give patients.

8

The Mechanics: Measures and Management

9

What is a clinical quality measure (CQM)?

- Created by a commercial or government payer
- Identifies what care should be provided

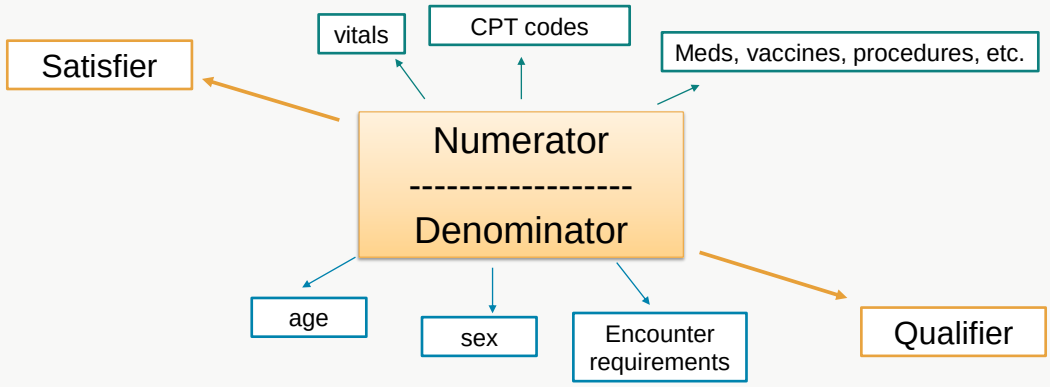
King & Spalding

athenahealth 10

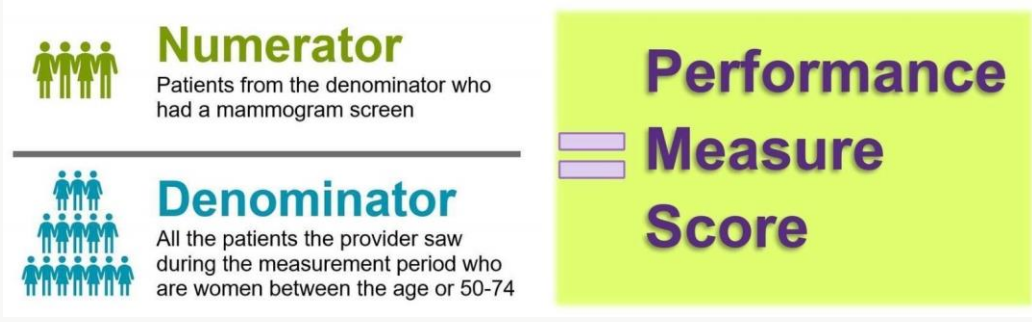
10

Where do measures come from?

How are clinical quality measures calculated?



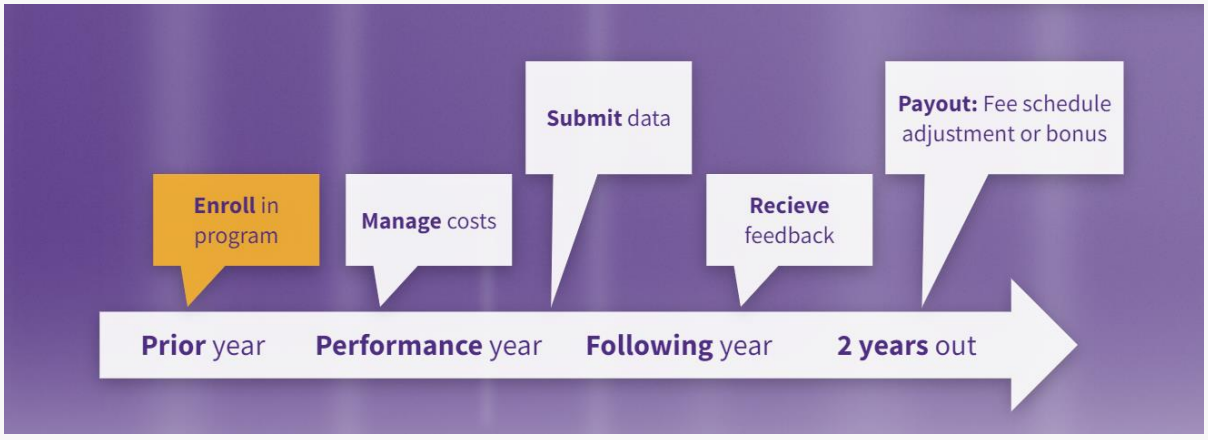
So how do clinical quality measures work?



What is the general process for quality programs?

- Review measures
- Enroll in programs
- Monitor and submit measure results at end of performance year
- Incentive payout

What is the timeline for quality programs?



15

How do payouts work?

16

The Mechanics: Key Quality Programs

17

What are the key CMS quality programs?

CMS Quality Reporting and Value-Based Programs & Initiatives

As the largest payer of health care services in the United States, CMS continuously seeks ways to improve the quality of health care. CMS manages quality programs that address many different areas of health care. These programs encourage improvement of quality through payment incentives, payment reductions, and reporting information on health care quality on government websites.

Here are examples of quality reporting and value-based payment programs and initiatives.

- Ambulatory Surgical Center Quality Reporting (ASCQR)
- Appropriate Use Criteria Program
- Comprehensive Primary Care Plus (CPC+)
- End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
- Health Insurance Marketplace Quality Initiatives
- Home Health Quality Reporting Program
- Home Health Value-Based Purchasing (HHVBP)
- Hospice Quality Reporting
- Hospital Acquired Condition Reduction Program (HACRP)
- Hospital Inpatient Quality Reporting (IQR)
- Hospital Outpatient Quality Reporting (OQR)
- Hospital Readmissions Reduction Program (HRRP)
- Hospital Value-Based Purchasing (VBP) Program
- Innovation Center (CMMI) Models
- Inpatient Psychiatric Facility Quality Reporting (IPFQR)
- Inpatient Rehabilitation Facility (IRF) Quality Reporting
- Long-Term Care Hospital Quality Reporting (LTCHQR)
- Medicaid-related programs
- Medicare Advantage Quality Improvement Program
- Medicare Parts C and D
- Medicare Promoting Interoperability: Eligible Hospitals and Critical Access Hospitals
- Medicare Shared Savings Program
- Nursing Home Quality Initiative
- Program of All-Inclusive Care for the Elderly (PACE)
- Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR)
- Quality Improvement Organizations
- Quality Payment Program (QPP)

18

What are the key CMS quality programs?

MIPS

Medicare PI

Primary Care First (PCF)

ACOs

King & Spalding

athenahealth 19

19

What other federal* programs are in this space?

- Patient-Centered Medical Home (PCMH): *National Committee for Quality Assurance (NCQA)**
- Patient Centered Specialty Practice (PCSP): *National Committee for Quality Assurance (NCQA)**
- Uniform Data Systems (UDS): *Health Resources and Service Administration (HRSA)*

* Note: NCQA programs can be federal, local, state, and public/private payer initiatives

King & Spalding

athenahealth 20

20

What are the key commercial quality programs?

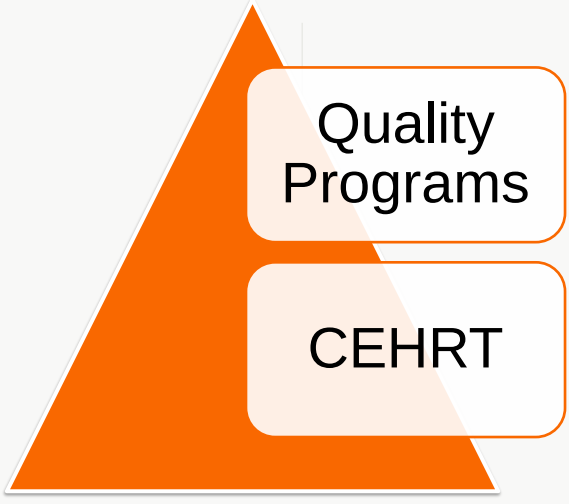
- Healthcare Effectiveness Data and Information Set (HEDIS)
- ACOs

The Mechanics: Certified EHR Technology (CEHRT) + Quality

What is a Certified Electronic Health Record?

CEHRT = EHR that has demonstrated adherence to technical requirements established by the government through a testing process

Why does CEHRT matter for quality programs?



CEHRT and MIPS PI

What do you need to know?

- MIPS=most adopted quality program under CMS's QPP
- Meaningful Use → CEHRT
- 4 Categories:
  - Quality
  - **Promoting Interoperability (PI)**
  - Improvement activities (IA)
  - Cost

25

Enforcement Trends and Compliance Risks

26

Payment Risks Related to Quality and Payment Incentives

- Failure to comply with reporting requirements can result in downward payment adjustments or lack of reimbursement increases
- CMS conducts audits of quality program submissions (e.g., MIPS data validation and audits).

Payment Risks Related to Quality and Payment Incentives

CMS Audits

- MIPS Data Validation and Audits (DVA) conducted by Guidehouse
- MIPS participants will be selected randomly for DVA

State Medicaid Audits

- Promoting Interoperability Program for Medicaid audits

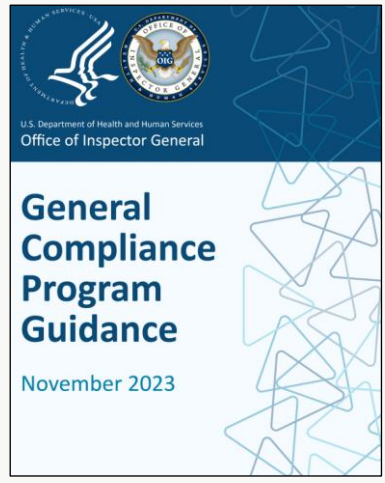
Enforcement Risks Related to Quality and Payment Incentives

- Quality programs and payment incentives are an area of enforcement focus for many government agencies.
- Government agencies are increasingly relying on data analytics to identify enforcement targets and investigate potential fraud.
- False Claims Act enforcement has historically been focused on EHR incentive payments and whether EHR companies meet applicable requirements for meaningful use.
- Looking to the future, provider quality data submission and payment incentives are a risk area ripe for potential scrutiny.

OIG Emphasis on Quality and Payment Incentives

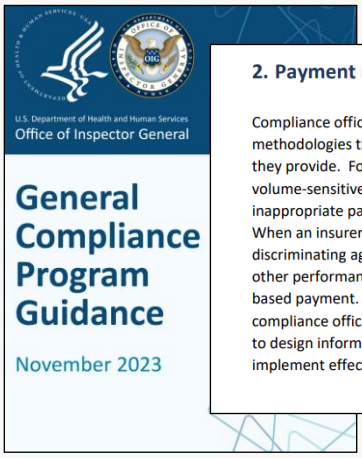
2023 Compliance Guidance contains new recommendations

- "The Compliance Committee should be comprised of the relevant leaders of both operational and supporting departments, which could include . . .**Quality** . . ."
- "When conducting risk assessments, Compliance Committees should ensure that medical necessity, patient safety, and other **quality** compliance issues are included in the risk universe"
- "The Compliance Committee may find it helpful to have compliance, audit, **quality**, and risk management functions coordinate to conduct a joint risk assessment"
- "OIG and DOJ have long emphasized the importance of **quality** and patient safety . . . Entities should incorporate **quality** and patient safety oversight into their compliance programs"



OIG Emphasis on Quality and Payment Incentives

2023 Compliance Guidance contains new recommendations



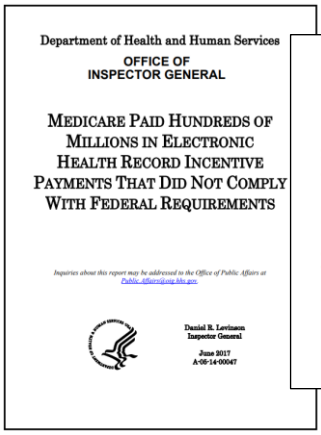
2. Payment Incentives

Compliance officers should be attuned to the varying risks associated with the payment methodologies through which health care entities are reimbursed for the items and services they provide. For example, when an insurer, including Federal health care programs, pays on a volume-sensitive or fee-for-service basis, there may be increased risks of overutilization, inappropriate patient steering, and use of more expensive items or services than needed. When an insurer pays on a capitated basis, heightened risks include stinting on care and discriminating against more costly patients. Payments that take into account quality of care or other performance measures may give rise to risk of gaming of data to qualify for performance-based payment. When payment incentives and associated risks are fully understood, compliance officers, including those at entities with private investment, are better positioned to design informed audit plans, conduct effective monitoring, detect problems early, and implement effective preventive strategies.

"Payments that take into account quality of care or other performance measures may give rise to risk of gaming of data"

31

OIG Emphasis on Quality and Payment Incentives



Department of Health and Human Services
OFFICE OF INSPECTOR GENERAL

MEDICARE PAID HUNDREDS OF MILLIONS IN ELECTRONIC HEALTH RECORD INCENTIVE PAYMENTS THAT DID NOT COMPLY WITH FEDERAL REQUIREMENTS

Inquiries about this report may be addressed to the Office of Public Affairs at Public_Affairs@oig.hhs.gov.

Daniel R. Levinson
Inspector General

June 2017
A-06-14-00047

WHAT WE FOUND

CMS did not always make EHR incentive payments to EPs in accordance with Federal requirements. On the basis of our sample of 100 EPs, we identified 14 EPs with payments totaling $291,222 that did not meet the meaningful use requirements because of insufficient attestation support, inappropriate reported meaningful use periods, or insufficiently used certified EHR technology. On the basis of our sample results, we estimated that CMS inappropriately paid $729,424,395 in incentive payments to EPs who did not meet meaningful use requirements.

These errors occurred because sampled EPs did not maintain support for their attestations. Furthermore, CMS conducted minimal documentation reviews of self-attestations, leaving the EHR program vulnerable to abuse and misuse of Federal funds.

32

False Claims Act (FCA) Overview

Imposes liability for (among other things):

- Knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;
- Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim;
- Conspiring to commit a substantive violation;
- Knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government.

31 U.S.C. § 3729(a)(1).

DOJ Enforcement

PRESS RELEASE

Electronic Health Records Vendor to Pay $57.25 Million to Settle False Claims Act Allegations

Wednesday, February 6, 2019

Share

Greenway Health LLC (Greenway), a Tampa, Florida-based
records (EHR) software, will pay $57.25 million to resolve
United States under the False Claims Act alleging that Gr
false claims to the government by misrepresenting the ca
Suite" and providing unlawful remuneration to users to in
the Justice Department announced today.

Additionally, in order to be eligible to receive incentive payments, healthcare providers were required to meet certain targets for EHR-related activities. For example, at certain times providers were required to provide patients with clinical summaries following office visits. In its complaint, the government further alleges that Greenway was aware that an earlier version of Prime Suite, which was certified to 2011 Edition criteria, did not correctly calculate the percentage of office visits for which its users distributed clinical summaries and thereby caused certain Prime Suite users to falsely attest that they were eligible for EHR incentive payments. Greenway refrained from rectifying this error in order to ensure that its users would receive incentive payments. As a result, numerous users of this earlier version of Prime Suite falsely attested that they were eligible for EHR incentive payments when, in fact, they had not met all necessary use requirements

FCA Enforcement

United States ex rel Janssen v Lawrence Memorial Hospital (2020)

- Allegations included that LMH falsified patients' arrival times in order to increase its Medicare reimbursement under the Inpatient Quality Reporting (IQR) program, the Outpatient Quality Reporting (OQR) program, and the Hospital Value Based Purchasing (HVBP) program
- 10th Circuit affirmed District Court holding that relator failed to show allegations satisfied the Act's materiality requirement—that the alleged falsehoods influenced the Government's payment decision as required under the FCA.
- Notably, CMS became aware of the potential issue through an NCI AdvanceMed investigation and did not take any action.
- Among other things, the court noted that there is "little evidence" demonstrating the extent to which inaccurate arrival times affected the accuracy of LMH's reporting.

FCA Enforcement

- The analysis in the *Lawrence Memorial Hospital* case is fact specific.
- Contours of materiality analysis are still being litigated.
- When assessing materiality, the court emphasized that CMS had not taken any action.
- A different case with different could facts could present a higher risk that allegedly manipulative methods of collecting data could be material in an FCA case.
- As the prevalence of value based and quality programs continues to grow, Relators may bring additional enforcement actions and generate more creative theories.

The Future of Enforcement: Follow the Money

Potential enforcement theories may include:

- False attestations
- Falsified or manipulated data submissions
- Medically unnecessary services

Practical Compliance Strategies to Mitigate Risk

Compliance Strategies

- Compliance Coordination:
  - Ensure Compliance Officer coordination with quality efforts
  - Consider composition of Compliance Committee
- CEHRT:
  - Stay up to date on your EHR vendor's CEHRT status and functionality (check out ONC's Certified HealthIT Product List (CHPL))
  - Review relevant vendor contracting related to use of your CEHRT and how quality measures calculate

Compliance Strategies

- Education, Policies & Procedures
  - Develop and implement risk-based education/training
  - Develop relevant policies including regarding Fraud, waste and abuse, Quality Data Submission Readiness, and a process for the reporting of identified quality issues
  - Confirm documentation preservation policies and practices

Compliance Strategies

- Risk assessment and audits:
  - Consider quality risk areas as part of regular risk assessment
  - Consider development of targeted risk-based audits for assessing whether measure calculations are accurate

Any Questions

Thank You

athenahealth

Lauren Gennett
King & Spalding
Lgennett@kslaw.com

Rebecca Gittelson
athenahealth
rgittelson@athenahealth.com

King & Spalding

43