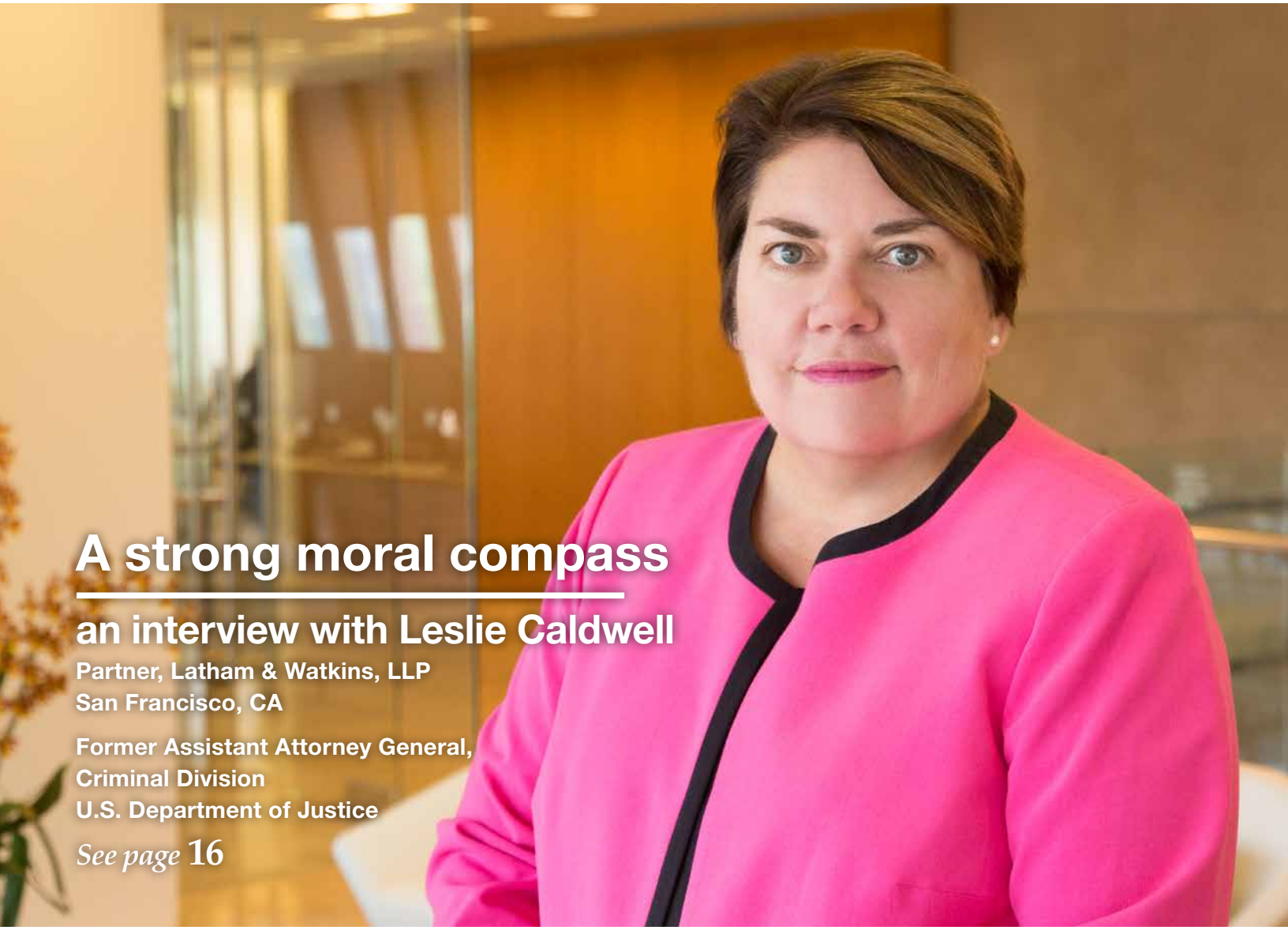
HCCA HEALTH CARE COMPLIANCE ASSOCIATION

Compliance TODAY

November 2017

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

WWW.HCCA-INFO.ORG



A strong moral compass

an interview with Leslie Caldwell

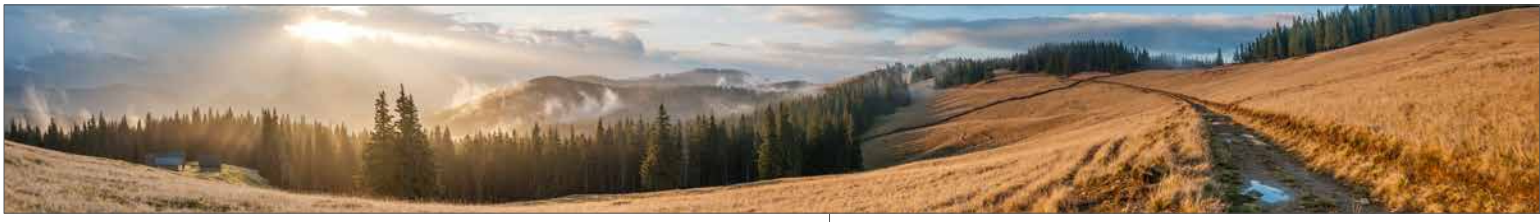
Partner, Latham & Watkins, LLP
San Francisco, CA

Former Assistant Attorney General,
Criminal Division
U.S. Department of Justice

See page 16

Contents

November 2017



FEATURES

Compliance Today is printed with 100% soy-based, water-soluable inks on recycled paper, which includes 10% post-consumer waste. The remaining fiber comes from responsibly managed forests. The energy used to produce the paper is Green-e® certified renewable energy. Certifications for the paper include Forest Stewardship Council (FSC), Sustainable Forestry Initiative (SFI), and Programme for the Endorsement of Forest Certification (PEFC).

COLUMNS

DEPARTMENTS

by Eric Lowy, CIA and Divya Moolchandani, MHA, CHC

Monitoring and auditing the quality reporting process

» Risk-based reimbursement, dependent on a variety of quality measures reported to external registries, is part of provider organizations' quality outcomes and financial and operational strategies.

» The Compliance department should incorporate quality reporting into monitoring and auditing activities with an annual refresh of different quality measures and registries included in internal work plans.

» Compliance-driven reviews of quality reporting will help engage leadership and the board in the importance of compliance to reporting requirements and their related impact on financial reimbursement.

» Audits of quality reporting should assess and document the processes and technologies in place for data collection, validation, and submission to comply with regulatory requirements of quality measures.

» A quality reporting review should also account for the additional elements of roles/responsibilities, governance, and ongoing monitoring efforts that drive corrective action and performance improvement.

Eric Lowy *(elowy@kpmg.com) is a Director at KPMG in Baltimore and* ***Divya Moolchandani*** *(dmoolchandani@kpmg.com) is a Senior Associate at KPMG in Washington DC.* *bit.ly/in-EricLow* */in/divyamool*

Healthcare organizations are submitting an increasing number of quality measures to the Centers for Medicare & Medicaid Services (CMS), commercial insurance companies, clinical registries, federal regulatory agencies, state Departments of Health, and registries used by the public. A variety of stakeholders, including CMS, commercial plans, and consumers, are now relying on performance data about quality measures to make decisions. Following CMS's approach to the Hospital Value Based Purchasing (HVBP) Program and the Hospital Readmissions Reduction Program (HRRP), health plans are introducing quality-driven contracts that tie quality performance to reimbursement. Outside of financial implications, quality measures are now being presented and used by the public at a growing rate. Consumers use these evaluations of performance to make decisions about where they seek care.

Lowy

Moolchandani

The number of measures and agencies to which providers report quality data are complex; a health system may report more than 500 measures to a multitude of registries. Additionally, quality reporting is also required for providers participating in the Quality Payment Program created by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) for both the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) tracks. With 2017 as the first performance year, these measures will impact an organization's incentive reimbursement up to 5% depending on the track, increasing annually.

Fortunately, there is a constructive and impactful role for the Compliance department to play in working with Quality and Risk Management departments to monitor,

assess, and audit the quality reporting functions across the organization. The purpose of an audit of quality reporting is to evaluate the processes in place to help ensure the accuracy and completeness of quality data reported either to or from external agencies, such as CMS or the National Health Safety Network, as well as for internal performance improvement. A quality reporting audit can:

- improve the reliability of data reported externally,
- strengthen internal performance and the organization culture of quality,
- expand the role of technology to limit manual errors, and
- increase financial performance, reputation, and brand recognition.

Related risks and the role of compliance

Incorporating compliance monitoring and auditing with quality reporting is an opportunity to be ahead of the game, as the OIG, CMS, and commercial payers increase scrutiny over the submission of quality measures tied to reimbursement. Annually, CMS selects hospitals that report quality data to undergo validation audits and compares quality data against claims when performing its review. Therefore, accurate and complete information is crucial to limiting regulatory scrutiny and penalties. Hospitals that fail validation testing receive reduced Medicare payments and are excluded from receiving incentive payments for the following year.[1] Additionally, payer and provider partners who are making financial decisions based on quality performance, such as for value-based contracts or joint ventures, may seek to review and validate quality performance and data submissions.

As quality becomes an increasingly important variable in reimbursement, external assessments of reported quality data will increase. The OIG's Office of Audit Services has planned active work around reviewing quality measures submitted to Medicare Shared Savings Plans, indicating that increased scrutiny over reported quality data is now on the rise.[2] The Department of Justice (DOJ) has also filed quality measure-related suits in the past year against payers and an electronic health record (EHR) vendor. With rising financial implications tied to reported quality data, providers may likely be the DOJ and OIG's next target. The following examples demonstrate recent activity tied to penalties for submission of incorrect quality data:

- **Penalties and exclusions**: Of the 449 hospitals in CMS's hospital quality data validation audit for 2016, six hospitals failed validation. CMS reduced the Medicare payment for these six hospitals by 0.6% and also excluded them from the HVBP Program, rendering them ineligible for incentives made under that program for the following year. The hospitals cannot appeal this action.[3]
- **Meaningful Use non-compliance**: One EHR company submitted incorrect quality data for Meaningful Use requirements, resulting in incorrect incentive payments made to the physicians by the government. The company settled with a $155 million penalty payment.[4]
- **Inflated risk-adjustment lawsuits**: The DOJ filed suit in May 2017 against one major health plan and is investigating others about incorrectly submitted health status data about beneficiaries, apparently made to obtain inflated risk-adjustment payments under Medicare Advantage plans. Because inpatient acute care facilities are receiving quality-based reimbursements based on risk-adjusted data, increased scrutiny over how an organization documents and codes severity of illness for risk adjustments

related to quality measures will become increasingly important.[5]

Given the increasing number of regulatory requirements related to reporting of quality-related measures, healthcare organizations will benefit from expanding the scope of compliance monitoring and increasing audit activity over the quality reporting process. Although an audit of quality reporting does not typically assess the underlying quality of care provided, the information learned can help support ongoing performance improvement activities and the reliability of data that is externally reported. Compliance's involvement also adds value by providing a reimbursement-based lens over this high-risk area, especially with MACRA and other CMS quality-based programs playing an increasing role in reimbursement. Active auditing and monitoring of quality reporting facilitates leadership engagement and enhances the feedback loop to drive improvement from reporting to documentation and back to clinical care.

A compliance-focused approach

By assessing the steps for collecting, validating, and submitting quality data, Compliance departments are able to reduce the risk of submitting incorrect information to the government, registries, or payers for financial incentives, and also help to drive performance improvement.

The quality reporting process begins the same as the revenue cycle process, starting with patient registration and going through point of service, documentation, and coding. From here, the quality reporting cycle replicates the process of financial reporting, though performed by quality and clinical personnel rather than accounting and finance. The quality reporting process can be broken down into seven steps:

1. Patient registration
2. Documentation at point of service
3. Coding and Clinical Documentation Integrity (CDI)
4. Quality case identification
5. Measure review and calculation
6. Submission to registry
7. Internal monitoring and performance improvement

However, unlike financial reporting, which has a rigorous review process, controls over quality reporting are often informal or inconsistently performed. Processes may vary from department to department for quality case identification, measures and data collection, document review and retention, and submission to registries. Many organizations also use quality reporting software, applications, and technology to enable identification, calculation, and submission.

Through the seven quality reporting process steps above, there are five major themes or core components in performing a compliance audit of quality reporting, described in more detail below.

1. Roles and responsibilities

Ownership throughout the quality reporting cycle is essential to data integrity, collection, submission, and performance monitoring. Provider organizations typically have decentralized ownership of registries and measures by department. Defining process ownership is key to a successful quality reporting program and helps promote accountability, increase communication, and facilitate corrective action activity based on identified documentation and care gaps. Roles and responsibilities are enhanced by well-defined expectations, detailed job descriptions, and clear feedback provided downstream.

As you audit roles and responsibilities, consider the following:

- Are owners of measures/registries identified and held accountable for data accuracy and completeness?
- How are reporting relationships structured?
- What lines of communication are established? Is there a feedback loop back to documentation, coding, and clinical care?
- How are quality reporting goals and targets reviewed and monitored by committees, senior leadership, and the board?

2. Data integrity

The data required for quality measures is identified and documented as patients enter the organization and receive care. Demographic information and key dates are identified during patient access and registration through insurance verification, patient intake, and care scheduling. As providers document patient care, they should consider inclusion of specific information that meets quality measure definitions for identification of reportable cases. For example, this may include documenting clinical conditions as being present on admission to avoid confusion with clinical conditions that were hospital acquired and may result in a reportable case. Clinicians may not fully understand the correlation between their medical record documentation and the measure definitions related to reportable quality cases. Documentation should include diagnostic evidence and be clear enough to support the treatment provided and monitoring recommended. CDI should further support this effort by incorporating quality measure definitions into their queries and review of clinical documentation.

After information is documented, coders should keep in mind that the accuracy of coding also drives quality reporting, because quality cases are flagged by procedure and diagnosis codes. Quality measure definitions are often complicated with specific requirements and exclusionary criteria, so documentation and coding accuracy are critical. Furthermore, definitions can be revised or updated annually or on an ad hoc basis. As such, CDI and coding staff should receive sufficient, ongoing training and education regarding quality-related language, coding requirements, and definition changes to accurately identify quality-related information that must be reported.

As you audit data integrity, consider the following:

- How are measure definition updates and exclusions tracked and communicated throughout the organization?
- What training and continuing education is provided to quality, coding, CDI, and clinical staff about quality measure definitions, exclusions, and documentation requirements?
- Does CDI review the documentation based on quality measure definitions and communicate common omissions or insufficiencies to clinicians?

3. Technology enablement and system interfaces

As the correlation between quality measures and financial reimbursement continues to grow, organizations are enabling technology to assist in data integrity, case identification, data collection, submission, and monitoring. Quality data may be required to be supplemented by additional documentation sources outside of patients' medical records in EHRs. Application programming interface (API) and integration technologies may be enabled to compile lab results and tests outside of the core EHR. Additionally, vendors may provide technology or additional services to aid in documentation and coding accuracy, as well as in detection and abstraction of quality cases. Systems may also be used to produce

dashboards and reports of key quality measures to inform performance improvement. As quality-related data is interfaced between systems across the organization, data batch error logs and case fall-out reports must be reviewed and resolved promptly.

As you audit technology enablement and system interfaces, consider the following:

- Which systems perform and support quality surveillance, collection, and reporting?
- How are data uploads and failures monitored and corrected? By whom?
- How are automated processes designed and tested (e.g., workflow or automated aggregation and calculation capabilities)?
- How are IT queries and scripts reviewed and updated for accuracy and compliance with measure definitions and changes?

4. Data collection and submission

Data may be collected from various sources, such as lab results, patient charts, and operation notes, and is typically aggregated prior to review. The collection process may also be manually tracked in paper line lists and spreadsheets, or through the use of third-party systems that receive data from an EHR. After cases are collected and aggregated, they are abstracted and reviewed to determine if the cases are reportable. Cases should be reviewed for measure definitions and for exclusionary criteria prior to reporting. A secondary review or positive confirmation of cases is often performed to help confirm the accuracy and completeness of reportable and excluded cases.

After cases are collected and reviewed, they are submitted to registries either through manual data entry, upload and transmission of files, or directly by the vendor on the organization's behalf. Although there are error thresholds for data submissions, assessing the process to validate and confirm the accuracy and completeness of submissions will minimize the risk of keystroke errors, failed data transmissions, and incorrect data submissions.

As you audit data collection and submission, consider the following:

- What sources of data provide inputs to quality reporting?
- Do the individuals who review quality cases directly reference measure specifications?
- What are the communication channels into and out of the Quality department?
- Is there a documented review of quality cases, exclusion decisions, and measure calculations prior to submission?

5. Monitoring

To drive ongoing process improvement, active monitoring efforts should be employed. Dashboards, quality metrics, and trend analysis should be routinely prepared for leadership review. Workgroups, subcommittees, and committees should meet regularly to discuss data issues, high-risk cases, root causes of errors, and potential remediation to resolve care gaps. These groups may also identify areas for additional quality-related education throughout the organization, including technicians, nurses, and physicians, as well as coders, registration staff, and CDI. Monitoring of quality performance and communicating gaps in documentation, reporting, and clinical care to key players provides feedback that reinforces an organizational culture of quality.

As you audit monitoring, consider the following:

- Are quality reporting metrics routinely presented to management, senior leadership, workgroups/committees, and the board?
- Do performance improvement workgroups and committees use quality measure data to drive root cause analysis and define action items for process improvement?

- How is monitoring of quality performance and measures communicated to clinicians, CDI, and the Coding department to drive documentation and clinical care improvement?

Tips for performing a successful audit

To influence and mature your organization's quality reporting processes, compliance officers may consider the following steps to address an audit of quality reporting:

- **Perform a high-level risk assessment** to build an inventory of quality registries, measures, owners, monitoring committees, and known issues. The landscape of quality measures that a healthcare organization reports is extensive, both in terms of volume and complexity. Some measures may overlap across registries with varying definitions, which creates additional risk that requires attention. Future monitoring and auditing activities may cover different registries in an annual refresh of the internal compliance work plan.
- **Consider the roles of the board, senior leadership, related departments** (e.g., Quality, CDI, Coding, IS/IT), **and providers of care** (e.g., physician champions, nurses) throughout the organization when identifying roles, responsibilities, and governance structure related to quality. The "tone at the top" is essential to promoting a culture of quality throughout the organization. Structured communication lines enhance the feedback loop that drives performance improvement and effective use of resources to improve quality.
- **Create a mapping of governance and monitoring activities**, including subcommittees, workgroups, and committees that review and assess quality measures and quality performance. Document what is discussed in these meetings, the frequency of meetings, the data analyzed, action items, and next steps. Accurate and timely data is essential for effective performance improvement, governance, and root cause analysis.
- **Identify the data gathering and data integrity checkpoints in process flows** that clearly delineate roles and responsibilities and identify key controls. This will help to detect potential risk areas and identify quality-based controls to evaluate. As processes tend to vary by department, opportunities to streamline controls may exist.
- **Develop registry or measure-specific process flows and/or narratives for the data review and submission processes.** The processes may not be standardized across different departments or for the various registries. Finding the areas with successes and opportunities for improvement across the organization will help drive consistency and stronger internal controls over quality reporting.
- **Continue to re-evaluate the reporting processes across different registries annually**, including certain condition-specific and/or disease-specific registries that may be manually intensive, show poor quality results, are undergoing technology changes, and/or tie to commercial contracts or measures with financial reimbursement incentives and penalties.

Conclusion

Though quality reporting has been an ongoing activity well before healthcare reform, the financial implications to reimbursement continue to grow rapidly. With MACRA's MIPS, and APMs putting more 2017 and future dollars at risk based on quality performance, assessing quality reporting and data reliability will be essential to success in the shift to value over volume. Because healthcare organizations often submit data to several specialty-specific

registries (e.g., National Database of Nursing Quality Indicators, Get with the Guidelines[6]), the organization's quality reporting at large will benefit from a review by Compliance.

As you perform audit activities, consider the processes and successful controls identified and how they can be extended to other processes or departments used to submit quality data to agencies and for value-based contracts. This includes understanding the value of the data already submitted and its potential role in strategic pay-for-performance models that are condition-specific, including shared savings arrangements and payment bundles. Through an audit of quality reporting, Compliance is able to continue to provide added value that not only provides assurance over meeting regulatory requirements, but impacts the way quality care is delivered to your patients.

As this article goes to print, the suit filed by the DOJ against one large health plan in May 2017 was dismissed. However, the DOJ continues to investigate inflated risk adjustments for several health plans that are eligible to receive payments based on risk-adjusted scores.

1. DHHS Office of Inspector General: CMS Validated Hospital Inpatient Quality Reporting Program Data, But Should Use Additional Tools To Identify Gaming. April 2017. Available at http://bit.ly/2x2fLQz
2. OIG: Review of Quality Measures Data Reported by Accountable Care Organizations in the Medicare Shared Savings Program. June 2017. Available at http://bit.ly/2yyvQJM
3. Ibid, Ref #1.
4. Rachel A. Arndt: "eClinicalWorks will pay $155 million for misleading users" *Modern Healthcare*, May 31, 2017. Available at http://bit.ly/2fEofpz
5. Mara Lee: "DOJ's Medicare Advantage lawsuits, investigations likely to change insurance culture" *Modern Healthcare*, May 19, 2017. Available at http://bit.ly/2yee8zd
6. American Heart Association: Focus on Quality: Get with the Guidelines. Available at http://bit.ly/2fXiuQp