Special Edition: Innovative Approaches to Improve Quality and Compliance

Presenters:

Janice Anderson, Partner, Foley & Lardner LLP

Cheryl Wagonhurst, Partner, Foley & Lardner LLP

Cory Flickinger, Healthcare Consultant, Quality/Patient Safety & Compliance, Huron Consulting Group

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Overview
The Quality Revolution and The Government's Three-Prong Approach to Quality of Care
– Payment Reform
– Public Reporting
– Government Enforcement
Innovative Solutions
– "Pay for Quality" – A New Approach to Aligning Physicians and Hospitals
– Assessments to Enhance Quality and Compliance
– Integrating Quality and Compliance
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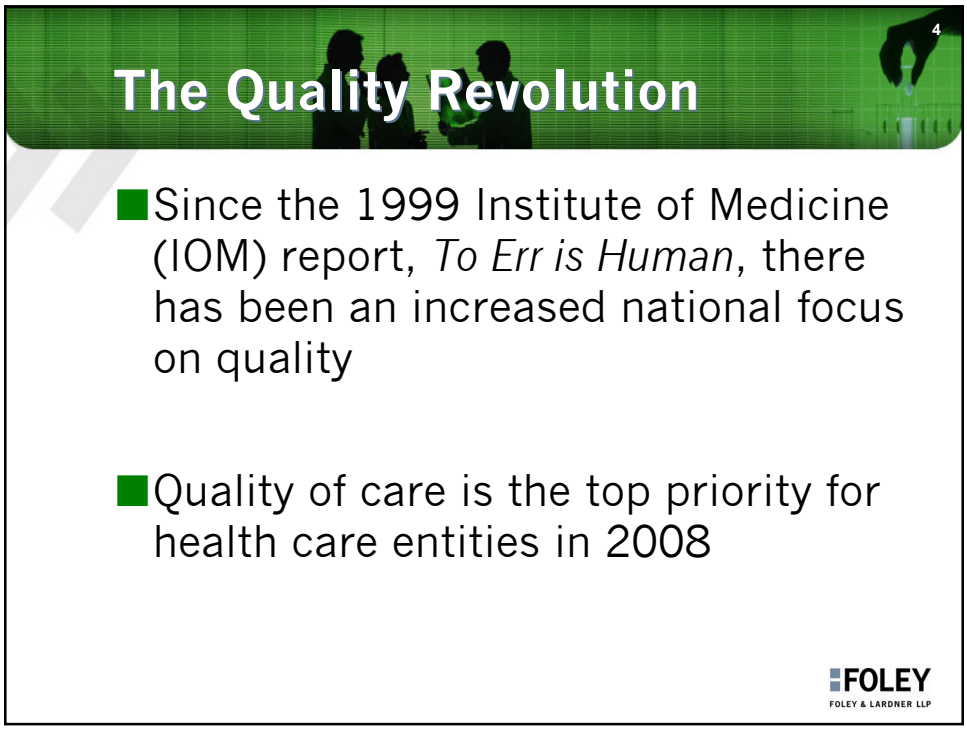
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The Quality Revolution
Since the 1999 Institute of Medicine (IOM) report, *To Err is Human*, there has been an increased national focus on quality
Quality of care is the top priority for health care entities in 2008
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Prong 1: Incentivizing Quality of Care Through Payment Reform

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- The new paradigm for reimbursement
- CMS is transforming payment policy from passive payor of services to active purchaser of high value health care
- Private payors also are changing payment policies to pay for quality

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Incentivizing Quality of Care Through Payment Reform (cont'd)

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- ***"I strongly support linking provider payment to quality care as a way to make Medicare a better purchaser of health care services. Today, Medicare rewards poor quality care. That is just plain wrong and we need to address this problem."***

  Sen. Chuck Grassley

  Budget Hearing with Michael Leavitt

  February 7, 2007

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Incentivizing Quality of Care Through Payment Reform (cont'd)

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Pay for Performance

- Financial incentives for:
  - Adhering to recommended tasks or processes
  - Adopting desired tools or infrastructure
  - Meeting or improving measured outcomes
- Sometimes includes cost savings or efficiency targets (aka "gainsharing")

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Incentivizing Quality of Care Through Payment Reform (cont'd)

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Dramatic Increase in Pay for Performance Payments

- The number of private P4P programs is increasing exponentially
- Blue Cross of California expanded its P4P programs into California market in March, 2008
- Wellpoint has hospital P4P programs in 12 states (California, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, New Hampshire, New York, Ohio and Virginia)
- In Spring, 2008, Wellpoint standardized its core quality indicators, including safety measures such as staffing ratios in intensive care units, the use of computerized physician order entry, and disease-specific standards such as the use of ACE inhibitors and angiotensin receptor blocker (ARB) medications in heart-attack patients

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Incentivizing Quality of Care Through Payment Reform (cont'd)

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No Payment for Poor Quality

- Hospitals will not be paid for 11 Hospital Acquired Conditions (HAC) unless present on admission (POA)
  - Object left in during surgery
  - Air embolism
  - Blood incompatibility
  - Catheter associated UTI
  - Pressure ulcers
  - Vascular catheter associated infection
  - Surgical site infection following CABG
  - Falls
  - Surgical site infections following certain elective procedures, including certain orthopedic surgeries, and bariatric surgery for obesity
  - Certain manifestations of poor control of blood sugar levels
  - Deep vein thrombosis or pulmonary embolism following total knee replacement and hip replacement procedures

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Incentivizing Quality of Care Through Payment Reform (cont'd)

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Medicare Value Based Purchase Plan

- Hospitals are reporting quality data to CMS under RHQDAPU program
- CMS issued final report to Congress on November 21, 2007
- VBP will build on the RHQDAPU program
- As required by the DRA, CMS has been developing a Value Based Purchasing plan

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Incentivizing Quality of Care Through Payment Reform (cont'd)

Quality FIRST Act (H.R. 7067)

- Introduced in the House Sept 25, 2008. The most substantive VBP bill to date
- VBP proposals were included in physician-based payment bills S. 3101, and S. 3118
- The Act would reward hospitals for their performance on process measures for the four specified conditions currently reported to CMS:
  - acute myocardial infarction;
  - heart failure;
  - pneumonia; and
  - surgical care improvement/surgical infection prevention.

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Incentivizing Quality of Care Through Payment Reform (cont'd)

Quality FIRST Act (H.R. 7067)

- Under the Quality FIRST Act, the VBP program would begin FY 2011 with the benchmark levels announced in FY 2009 using hospital performance data from FY 2008. Hospitals' payments would be adjusted in FY 2011 based on performance on quality measures in FY 2010
- A four-year, phased-in transition of Medicare payment bonuses would start with 0.5% for FY 2011, 1% for FY 2012, 1.5% for FY 2013, and 2% for FY 2014
- Hospitals would have the opportunity to earn up to 2% of their reimbursement payments by meeting certain performance quality benchmarks. Bonus payments would be made to high-performing hospitals from the pool of funds made available by payment reductions to hospitals that do not meet the full-incentive benchmark level.

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Prong 2: Driving Quality of Care Through Public Reporting

Reporting Hospital Quality Data for Annual Payment Update Program

- Effective October 1, 2008, hospitals are required to report 30 inpatient measures in the following sets:
  - Heart attack (MI) – 8 measures
  - Heart failure (HF) – 4 measures
  - Pneumonia (PN) – 7 measures
  - Surgical Care Improvement Project (SCIP) – 7 measures
  - Mortality – 3 measures
  - Experience of Care (HCAHPs survey) ***Published March 28, 2008!***
- For 2009, hospitals are also required to report 11 outpatient measures on emergency department care for adults with AMI and on surgical care improvement
- Hospitals that do not participate will receive a 2.0 percent reduction in their Medicare Annual Payment Update for 2009

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Driving Quality of Care Through Public Reporting (cont'd)

- Uses website known as Hospital Compare to publicly report the data (www.hospitalcompare.hhs.gov)
- March 6, 2008 GAO report on accuracy and reliability of hospital data reporting to CMS
- Found: CMS has processes for ensuring accuracy, but none for reliability (*i.e.*, completeness of quality data)

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Data Mining

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- ***"We are reviewing assorted sources of quality information on your facility to see what it says and if it is consistent. You should be doing the same."***

  James G. Sheehan

  Medicaid Inspector General, New York

  February 6, 2007

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Data Mining (cont'd)

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Defined:

- Data mining is a ***technology*** that facilitates the ability to ***sort*** through masses of information through database exploration, extract specific information in accordance with defined criteria, and then ***identify patterns of interest*** to its user

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Data Mining (cont'd)

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Goals

- Correct inappropriate behavior
- Identify overpayments
- Deny payment

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Prong 3: Enforcing Quality of Care Through the False Claims Act

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- The FCA is emerging as the government's most powerful tool to enforce quality of care
- Physicians, executives, and board members face *real risks* for poor quality of care

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Enforcing Quality of Care Through the False Claims Act (cont'd)

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- ***"You will see more and more physicians going to jail."***
  - Kirk Ogrosky, Deputy Chief for Health Care Fraud, Department of Justice, Criminal Division (Dec. 4, 2007)
- ***"We're holding those individuals accountable." "You may not go to jail ... but we will take your money."***
  - Lewis Morris, Chief Counsel to the Office of Inspector General, U.S. Department of Health and Human Services (Dec. 4, 2007)

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Enforcing Quality of Care Through the False Claims Act (cont'd)

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- Six themes present in cases:
  - Unnecessary treatment/procedures
  - Kickbacks
  - Big admitters receiving special treatment
  - Fraudulent documentation
  - Poorly structured, or failure to follow, internal process
  - Underlying regulatory violations

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Enforcing Quality of Care Through the False Claims Act (cont'd)

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Traditional Theories

- Claims for services not rendered
- Unbundling
- Claims for services not covered
- Duplicate payments

Quality of Care Theories

- Express False Certification
- Implied False Certification
- Worthless Services
- Criminal Statutes

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Enforcing Quality of Care Through the False Claims Act (cont'd)

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- In 2007, California regulators imposed a $3 million fine on a hospital system for failure to provide adequate oversight of quality assurance programs, including peer review and patient complaint management. The problems were discovered by analyzing randomly-selected charts following patient complaints.
- In 2004, rural hospital was accused of allowing physicians to perform unnecessary cardiac catheterizations, angioplasty, and open heart surgeries. The hospital's parent organization entered into a $54 million settlement with DOJ and agreed to divest the hospital by selling it to an unrelated third party.

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Enforcing Quality of Care Through the False Claims Act (cont'd)

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- New legal/compliance risks to consider:
  - Knowledge arising from data reporting
  - Work force encouragement to "whistleblow"
  - Processes and structures are not effective in identifying quality failures
- May lead to:
  - False Claims Act liability
  - Corporate liability
  - Liability of board members, owners and high-ranking officers

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Enforcing Quality of Care – OIG Work Plan 2009

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- OIG will examine quality of care issues to detect and prevent fraud and abuse perpetrated against beneficiaries and the Medicare and Medicaid programs
- Medically unnecessary services
- Services either not rendered, not rendered as prescribed, or for substandard care that is so deficient that it constitutes a "failure of care."
- Serious medical errors – never events
- Reliability of hospital – reported quality measure data
- Medicaid statistical information system data reporting

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Pay for Quality – A New Approach to Aligning Physicians and Hospitals

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OIG Advisory Opinion 08-16

- Goals of New Structure
  - Integrate physician and hospital clinical practice to meet safety/quality goals
  - Establish structure to provide quality across the continuum
  - Standardize clinical practice
  - Eliminate waste and reduce cost (may include gainsharing)
  - Financially align physician/hospital incentives, but keep physicians/hospitals focused on their respective core business
  - Improve publicly reported data can be strategically advantageous

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OIG Advisory Opinion 08-16 (cont'd)

- Rationale for New Structure
  - National mandates for safety/quality and price transparency are difficult to meet without physician/hospital collaboration
  - "Carrot vs. Stick" approach may reduce need for costly and time consuming peer review
  - Pay for Performance ties reimbursement to achievement of quality outcomes and there is significant savings that can be achieved that payors may be willing to share. CMS will implement VBS soon.
  - Manage legal risk arising from quality of care (liability for failing to comply with evidence based guidelines, corporate liability; false claims liability for poor quality or unnecessary care, negligent credentialing)
  - Participating physicians are incentivized to assist non-participating physicians to comply

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OIG Advisory Opinion 08-16 (cont'd)

- Elements of New Structure
  - Hospitals pay Physicians to meet quality targets. Includes a broad array of services necessary to achieve compliance
  - Pay for Performance dollars may provide funding source
  - Payments made based on achievement of targets (CMS quality indicators) set annually
  - Preamble to new proposed Stark exception recognizes benefits to be achieved through quality incentive program

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OIG Advisory Opinion 08-16 (cont'd)

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- How is "Pay for Quality" Structured
  - A new legal entity is created to which all physicians who have been on the active medical staff in relevant departments for at least one year can join
  - Each physician who joins pays an equal capital contribution to provide for the entity's working capital
  - The physicians joining the entity commit to practice in compliance with certain quality targets established by CMS that form the basis for pay for performance awards under contracts with private insurers (and CMS in the future when Value Based Purchasing is implemented)

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OIG Advisory Opinion 08-16 (cont'd)

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- The entity contracts with the hospital to provide a variety of tasks and services to improve quality
- Payment to the entity is based on a percentage of pay for performance dollars earned by the hospital (up to 50%) and then distributed to the physicians on a per capita basis

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OIG Advisory Opinion 08-16 (cont'd)

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- Certain protections in the structure that must be met to address the anti-kickback and Civil Money Penalty law implications of the structure
  - Only physicians who have been members of the hospital's active medical staff for at least one year are eligible to become owners
  - The physician owners of the physician entity receive distributions on a per capita basis; there are no payments made to induce patient referrals to the hospital
  - The payments by the hospital to the physician entity are capped based upon historical activity levels of the payor(s) at the hospital
  - The hospital will provide written disclosure of its arrangement with the entity to its patients

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OIG Advisory Opinion 08-16 (cont'd)

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- The hospital will monitor both the quality of care provided and the volume and case mix of its patients to ensure that the financial rewards of the program do not reduce quality or inappropriately change referral patterns of the physician participants
- Without further OIG approval, the quality targets that can be incentivized under the program are limited to those listed by the Centers for Medicare & Medicaid Services and Joint Commission in the Specifications Manual for National Hospital Quality Measures
- Year to year changes must consider initiatives where activity is necessary – not just paying to maintain improvements already obtained

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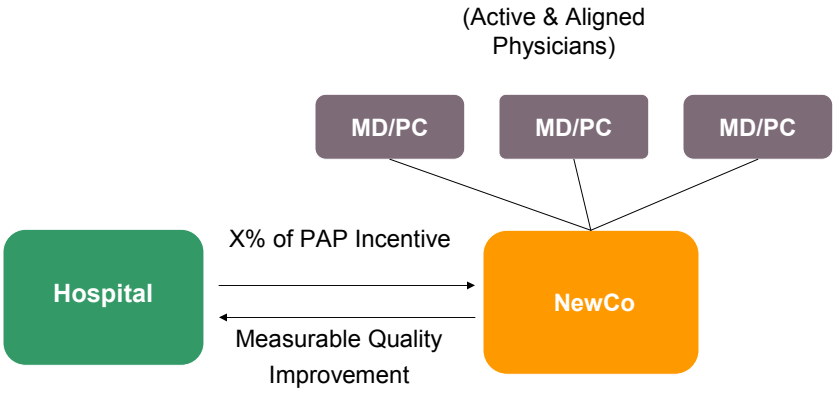
OIG Advisory Opinion 08-16 (cont'd)

Proposed Structure to Reward Physicians for Quality



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Assessments to Enhance Quality and Compliance

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Why are Assessments Critical for Hospitals Today?

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- Quality is now the top compliance issue for hospitals today
- Many Hospitals are unaware of their compliance vulnerabilities related to quality because they have not subjected their quality of care processes to the same scrutiny they devote to other compliance concerns (i.e. billing/claims submission; physician financial relationships)
- OIG 2009 Work Plan emphasizes quality as an enforcement priority
- Data Mining, RAC and other government initiatives increase the risk of enforcement based on quality failures
- Do you know where you may have risks?

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The Foley/Huron Team

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- Recognizing that Assessments to Enhance Quality of Care require both legal/compliance and clinical/operational expertise, Foley and Huron have teamed together to develop a streamlined approach
- Assessments must be done under Attorney/Client Privilege
- The team is comprised of experts in healthcare regulatory and clinical/operational issues with a specific focus on the compliance risks raised by quality issues
- The team can help organizations adjust structures and processes to address quality of care and compliance issues proactively to avoid costly and public enforcement actions

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What Does the Assessment Accomplish?

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- Streamlined approach to assess quality controls and legal risks -- can be accomplished in 2-3 days
- Looks at Medicare COP requirements, fraud and abuse risks, quality data reporting processes, HAC and Never Events compliance, Medical Necessity requirements and processes, OIG work plan, data mining, state Medicaid enforcement, etc.
- Bring together billing and quality issues and filter through compliance lens to provide global risk assessment and compliance endeavor

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What is the Post-Assessment Process?

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- The Assessment will identify specific areas of process gaps, quality control weaknesses and fraud and abuse risks (if any)
- The client will be in a position to develop a structured plan to address the issues
- Results of the Assessment are immediately available
- Foley and Huron are available to help with corrective action planning or implementation as requested

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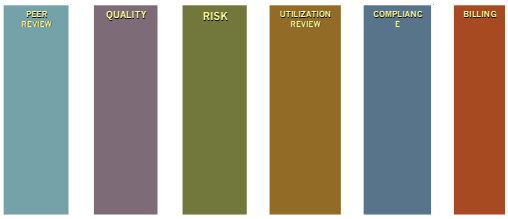
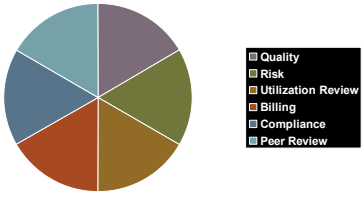
Integrating Quality and Compliance

- Policies and education to address compliance risks associated with quality
- Need to investigate compliance implications of quality failures. Reporting procedures need to be established. Be careful to maintain the privilege

SILO Approach



Integration



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Questions & Answers

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Contact Us

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Jan Anderson
Partner
Foley & Lardner LLP
321 N. Clark St., Suite 2800
Chicago, IL 60654
Tel: 312.832.4530
janderson@foley.com

Cheryl Wagonhurst
Partner
Foley & Lardner LLP
555 S. Flower St., Suite 3500
Los Angeles, CA
Tel: 213.972.4681
cwagonhurst@foley.com

Cory Flickinger
Healthcare Consultant, Quality/Patient Safety & Compliance
Huron Consulting Group
1120 Avenue of the Americas, 8th Flr.
New York, NY 10036
Tel: 312.714.6425
cflickinger@huronconsultinggroup.com

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