Speaker Firms and Organization:

Cozen O'Connor
John R. Washlick
Member Co-chair, Health Law Practice Group

Community Care Physicians, P.C.
Kathleen K. Hogan, Esq.
Director of Corporate Compliance

Katten Muchin Rosenman LLP
Michael R. Callahan
Partner, Health Care Practice Group

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Brief Speaker Bios:

John R. Washlick

John R. Washlick is a member of the firm, co-chair of the Health Law Practice Group, and practices in the Philadelphia and Cherry Hill, N.J., offices. His practice includes advising hospitals, physicians, entrepreneurs, and health care organizations on a variety of corporate, tax, and health care regulatory matters and he directs the firm's health care transactional and corporate compliance practices. Prior to joining Cozen O'Connor, he was a partner at Morgan, Lewis & Bockius LLP, where he directed the firm's commercial health care practice.

He regularly counsels clients, as both general counsel on routine matters for health care industry clients and outside counsel on specialized issues and projects for clients with in-house legal departments, concerning employment and medical staff relationships; clinical trials; professional service agreements; management and provider contracts; physician recruitment incentives; state and federal fraud and abuse and antireferral prohibitions; patient health care information privacy and security matters under state law and HIPAA; and income producing activities of tax-exempt hospitals.

Kathleen K. Hogan, Esq.

Ms. Hogan is the Director of Corporate Compliance for Community Care Physicians, P.C., a physician-owned, physician-run multi-specialty medical group with more than 1,000 employees and over 180 doctors and other clinicians practicing out of 35 offices throughout the New York Capital District. In her current position, Ms. Hogan directs programs, policies and practices to ensure that business units are in compliance with financial policy and reporting regulations.

Prior to joining Community Care Physicians in January of 2012, Ms. Hogan was Acting Chief of Staff and Special Assistant to the Medicaid Inspector General at the New York State Office of the Medicaid Inspector General (OMIG) from June 2008 to January 2012. She served under two governors and two Medicaid Inspector Generals. Under the direction of the Medicaid Inspector General, Ms. Hogan was responsible for oversight and coordination of various agency projects at the Executive level, including evaluating program processes and procedures to promote efficiency and transparency in OMIG's efforts to preserve the integrity of the NYS Medicaid program. As Acting Chief of Staff, she was also responsible for general oversight of all state-wide operations.

Brief Speaker Bios:

Michael R. Callahan

Michael R. Callahan has been a practicing health care attorney for 30 years, assisting hospital, health system and medical staff clients on a variety of health care legal issues including accountable care organizations, patient safety organizations, health care antitrust, HIPAA and regulatory compliance, accreditation matters, general corporate, medical staff credentialing and hospital/medical staff relations.

Mr. Callahan is recognized for his experience and knowledge of the health care industry. He is a frequent speaker all around the country on topics including medical staff matters, integrated delivery systems, physician recruitment and retention, Joint Commission and HFAP accreditation, Medicare fraud and abuse, and accountable care organizations.

► *For more information about the speakers, you can visit: http://www.knowledgecongress.org/event_2010_Vendor.html*

Summary

The Affordable Care Act aims to improve the quality and accessibility of healthcare in the country. However in doing so, it will affect nearly every organization in the industry from manufacturers to providers. With this new regulatory activity, a number of challenges await manufacturers and other healthcare professionals and providers in terms of proper compliance. What are the best practices to mitigate risks and errors?

The Knowledge Group is assembling a panel of key thought leaders and regulators to discuss the fundamentals and updates regarding this topic.

Featured Speakers:

SEGMENT 1:

John R. Washlick
Member Co-chair, Health Law Practice Group
Cozen O'Connor

SEGMENT 2:

Kathleen K. Hogan, Esq.
Director of Corporate Compliance
Community Care Physicians, P.C.

SEGMENT 3:

Michael R. Callahan
Partner, Health Care Practice Group
Katten Muchin Rosenman LLP

SEGMENT 1:

John R. Washlick
Member Co-chair, Health Law Practice Group
Cozen O'Connor

Introduction

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He regularly counsels clients, as both general counsel on routine matters for health care industry clients and outside counsel on specialized issues and projects for clients with in-house legal departments, concerning employment and medical staff relationships; clinical trials; professional service agreements; management and provider contracts; physician recruitment incentives; state and federal fraud and abuse and antireferral prohibitions; patient health care information privacy and security matters under state law and HIPAA; and income producing activities of tax-exempt hospitals.

SEGMENT 1:

John R. Washlick
Member Co-chair, Health Law Practice Group
Cozen O'Connor

The Affordable Care Act:
Understanding the Changes -- New Rules, New Challenges

January 19, 2012

Presented by:

John R. Washlick
jwashlick@cozen.com

SEGMENT 1:

John R. Washlick
Member Co-chair, Health Law Practice Group
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Funding of Health Care Fraud Initiatives Increased

- Additional $10 million per year for FY 2011-2020 (PPACA Sec. 6402)
- Additional $250 million over FY 2011-2016 (Sec. 1303 of Reconciliation Act)
- Expect significant increases in False Claims Act enforcement and Stark-related FCA cases!

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New and Enhanced Civil Monetary Penalties

- Sec. 6408 of PPACA adds new and enhanced CMP penalties for false statements and delayed inspections:
  - Knowingly making, using or causing to be made, a false record or statement material to a claim for payment for items or services furnished under a Federal health care program
  - Failing to grant timely access, on reasonable request to the OIG (as to be defined in regulations) for carrying out audits, investigations, evaluations or other statutory functions
  - $50,000 for each false record or statement, and $15,000 for each day of delay

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New Civil Monetary Penalties

- Sec. 6402(d)(2) of PPACA establishes CMPs for:
  - Ordering or prescribing services while excluded
  - Knowingly making or causing false statements in application, bid or contract to participate as a provider (including Medicare Advantage plan, Part D drug plan sponsor, or Medicaid MCO)
  - Knowingly failing to repay an overpayment

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Suspension of Payments

- Under Sec. 6402(h) of PPACA, Secretary may suspend payments to a Medicare provider or supplier "pending investigation" of a "credible allegation of fraud," absent good cause not to do so
- Regulations required
- Parallel provisions for Medicaid

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Suspension of Payments

- Proposed regulation published at 75 Fed. Reg. 58204, 58222 (Sept. 23, 2010)
- Adds a new regulation, 42 C.F.R. 405.371(b), which defines "credible allegation" of fraud as based on allegations derived from:
  - "hotline" sources
  - claims data mining
  - patterns identified through audits
  - civil FCA claims and law enforcement investigation

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Program Exclusions Enhanced

- Permissive exclusion for obstructing investigation or audit (not limited to criminal investigation) (PPACA Sec. 6402)
- Permissive exclusion for false statements or omissions in any "application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a Federal health care program" (PPACA Sec. 6402)

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Medicaid Program Exclusions

- States required to terminate any provider or supplier who has been terminated by Medicare or another states' Medicaid Program (PPACA Sec. 6501)
- States required to exclude individuals or entities that "own, control, or manage" or are "affiliated with" an entity that is suspended, excluded, or terminated (PPACA Sec. 6502)
- Requires Medicaid exclusions for failures of "affiliates" to repay overpayments deemed "delinquent" (PPACA Sec. 6502)

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AKS as FCA Predicate

- Before PPACA:

  some courts held that the fact that program claims resulted from AKS violations did not render claims for payment false or fraudulent under AKS. See, e.g., U.S. ex rel. Westmoreland v. Amgen, Inc., 2010 U.S. Dist. LEXIS 40001 (D. Mass. April 23, 2010) (rejecting false implied certification theory)

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AKS as FCA Predicate

- PPACA Change (Sec. 6402(f)(1)): any claims for items or services "resulting from" a violation of the AKS constitute "false or fraudulent claims" under the FCA
- Codifies U.S. ex. rel. Pogue v. Diabetes Treatment Ctrs., 238 F. Supp. 2d 258 (D.D.C. 2002); U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899 (5th Cir. 1977); U.S. ex rel. Schmidt v. Zimmer, 386 F.3d 235 (3d Cir. 2004) (false implied cost report certification of compliance with Stark or AKS laws is actionable under FCA)

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Amendments to Anti-Kickback Statute (AKS)

Expansion of "Knowingly and Willfully" (Mens Rea) Standard of § 1128B

- **Before PPACA**, construed to require:
  - knowledge that AKS prohibits remuneration for referrals; and
  - engage in alleged conduct with specific intent to violate the law

- **After PPACA** "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]." (Sec. 6402(f)(2), amending 42 U.S.C. § 1320a-7b)

  - Reverses "heightened mens rea" requirements of U.S. v. Jain, 93 F.3d 436 (8th Cir. 1996), cert. denied, and Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995)

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False Claims Act (FCA): Expanded Protections For Qui Tam Relator's Actions

- Fraud Enforcement and Recovery Act of 2009 (FERA) expanded protection of employee whistle blowers to include contractors and agents
- PPACA limits public disclosure defenses

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Reverse False Claims

- Before FERA, "false record" or statement was required under the FCA as predicate for "reverse false claim"
- FERA amended the "reverse false claim" provisions of the FCA (U.S.C. § 3729(a)(1)(G)) to impose liability for:

  "Any person who … knowingly makes, uses or causes 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 conceals or knowingly and improperly avoids or decreases* an *obligation to pay* or transmit money or property to the Government (emphasis added)"

- FERA reduced intent requirements (material element versus intent to cause payment) and applies FCA to claims against government contractors (i.e., Medicaid MCOs and MA Plans)

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Reverse False Claims cont'd

- An "obligation" under 31 U.S.C. § 3729(b)(3), as amended by FERA, is:

> "an established duty, whether or not fixed, *arising from* an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, *from statute or regulation, or from the retention of any overpayment* (emphasis added)."

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Reverse False Claims cont'd

Before PPACA, sources of repayment obligations included . . .

- Social Security Act ("SSA") § 1877(g)(2), 42 U.S.C. § 1395nn(g)(2):
  Timely refunds "to individuals" for amounts billed in violation of Stark self-referral restrictions

- SSA § 1128B(a)(3), 42 U.S.C. § 1320a-7b(a)(3):
  [whoever] having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized

After PPACA . . .

- Innocent overpayments can become false claims upon failure to satisfy PPACA refund "obligation"

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Reverse False Claims cont'd

Effective March 23, 2010, PPACA § 6402(a) adds SSA § 1128J(d), providing:

"(d) REPORTING AND RETURNING OVERPAYMENTS –

(1) IN GENERAL – If a person has received an overpayment, the person shall –

- (A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address, and
- (B) notify the Secretary, the State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayments

(2) DEADLINE FOR REPORTING AND RETURNING OVERPAYMENTS – An overpayment must be reported and returned under paragraph (1) by the later of -

- (A) The date which is **60 days** after the date on which the overpayment was **identified**; or
- (B) The date any corresponding cost report is due, if applicable.

(3) ENFORCEMENT – "Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31 of the United States Code) for purposes of section 3729 of such title. . ." (emphasis added)

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Reverse False Claims cont'd

- "Person" includes providers, Medicare Advantage plans, and Medicaid MCOs
- What does "identified " connote?
- "Overpayment" is defined as retention after "applicable reconciliation." Requires "finally determined funds." (House Rep. No. 111-443 on H.R. 4872 at 500)
  - At what point and to what degree is an overpayment identified by self-audits?
  - What is the applicable reconciliation?
  - What about netting of underpayments? What about credit balances?
- Medical exclusion provision of PPACA (§ 6502) presumes that "unpaid overpayments" will be defined by the Secretary

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60-Day Repayment and Reporting Considerations

- Review your compliance program
- Review monitoring of overpayments and credit balances
- What is your process for repayment?
  - Who is responsible?
  - Are issues run through counsel (privilege)?
  - Is it time sensitive?
  - Are your CFO and board on board?

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Hospital Overpayment "Tick List"

Derived from "risk areas" identified in OIG model compliance plans. These include:

- Billing for services not provided/covered
- Duplicate claims
- MSP refunds
- Improper observation service billing
- Same day discharges/readmits
- Billing transfers as discharges
- Providing medically unnecessary services
- Improper claims for "clinical trials"
- Claims for "never events"
- Upcoding
  - Incorrect coding
  - Multiple procedure codes
  - E&M coding

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Hospital Overpayment "Tick List" cont'd

- Unbundling of codes (routine costs; three-day window)
- APC miscoding
- Prohibited/problematic cost report claims
  - Not "under protest"
  - Misallocations
  - Unallowable costs
  - Related party identification
  - Bad debts
- Accurate/timely credit balance reporting
- Record Retention
- Improper "provider-based payments"
  - Outpatient site for physician office
  - Physicians billing o'pt as office-based

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Hospital Overpayment "Tick List" cont'd

- Teaching physician services lacking requisite supervision/documentation
- Discounts/waivers not based on financial need
- Payments resulting from AKS violations
- Contracts/financial relations with physicians that violate Stark (see below)
- Waivers of co-pays, free transportation, and other "patient inducements"
- Payments to reduce or limit services to patients under physicians direct care (CMP)

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Stark Law Compliance as a Condition of Payment

- "No payment may be made under this subchapter for a designated health service which is provided in violation of subsection (2)(1) of this section [i.e., "pursuant to a prohibited referral]". 42 U.S.C. § 1395nn(g)(1)
- Potential overpayment liability, including for purely "technical" violations, is enormous
- Implied certification (FCA) theory applies to each claim arising out of unprotected referrals

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Stark: Self Reporting Disclosure Protocol

- OIG "open letter" of Mar. 24, 2009 discontinued self-reporting of "pure" Stark (i.e., no colorable AKS) violations. Sets floor of $50,000 for self-reporting

- Sec. 6409 of PPACA requires Secretary, in cooperation with OIG, to establish a SRDP for disclosure of actual or potential Stark violations

- CMS published SRDP on September 23, 2010

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Stark: Self Reporting Disclosure Protocol

- Who: Available to all health care providers and suppliers ("disclosing parties")
  - A government inquiry of disclosing party will not automatically preclude disclosure (but disclosing parties must identify pending investigations and audits)
- What: Self-disclosure protocol for actual or potential Stark violations only
  - Not an "Advisory Opinion" process but intended to facilitate resolution of actual or potential Stark violations and overpayment liability; issue is amount due, not liability
  - OIG's Self-Disclosure Protocol available for addressing potential liabilities under other laws

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Stark: Self Reporting Disclosure Protocol

- When: Section 6402 of the PPACA requires the reporting and returning of overpayments by the later of (1) 60 days after which the overpayment was identified or (2) the due date of the "corresponding" cost report
  - Disclosure under the SRDP suspends section 6402 reporting and refund obligation
- Why:
  - PPACA requires reporting and refunding of overpayments; potential FCA liability and CMPs for failure to do so
  - Potential reduction of overpayment liability
    - Section 6409 of the PPACA grants the Secretary the authority to reduce the amount owed for Stark violations (the disclosing party's cooperation and timeliness in disclosing are factors for consideration in establishing and potentially reducing the overpayment)

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Stark: Self Reporting Disclosure Protocol

- How:
  - Disclosure must be submitted electronically and via mail
  - Submission must include:
    - Provider info (name, address, NPI, TIN, corporate structure, etc.)
    - Description of potential or actual violation, including time period and DHS claims at issue
    - Legal analysis of Stark and exceptions as applied to the conduct and potential causes of the violation
    - Circumstances under which the violation was discovered and measures taken to address the issue and prevent future violations
    - Financial analysis, including projected amount of the potential overpayment and methodology used to compute the overpayment
    - Related pending audits and investigations
  - Use SROP with copies of self disclosures related “solely” to Stark violations, to “monitors” for CIAs and CCAs

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Stark: Self Reporting Disclosure Protocol

- Resolution:
  - Upon receipt, CMS will begin verifying disclosure information and may request additional information
  - CMS will not accept payments of presumed overpayments prior to completion of inquiry
  - As a condition of disclosure, disclosing party agrees to waive appeal rights for claims related to disclosed conduct
  - CMS cautions disclosing parties to make disclosure decisions carefully, as CMS reserves its right to refer matter to OIG and DOJ for further investigation/prosecution
  - Matters uncovered during the verification process, which are outside the scope of the disclosed matter, may be treated as new matters for which liability may attach
  - Payment under the SRDP will not relieve disclosing party of criminal, civil, or CMP liability

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Stark: Self-Reporting Disclosure Protocol

- CMS did not issue any agency guidance for reducing "draconian" Stark liability under PPACA § 6409(b), rejecting recommendations of American Hospital Association

- Instead, will apply on a case-by-case basis statutory criteria including:
  - ❑ Nature and extent of unlawful practice
  - ❑ Timeliness of self-disclosure
  - ❑ Cooperation of disclosing party
  - ❑ Litigation risks
  - ❑ Financial position of disclosing party

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John R. Washlick
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Stark Compliance Check List

- Identify “referrals”
- Does an “exception” apply?
- Is a Designated Health Service provided?
- Maintain lists of financial arrangements (compensation; leases; contracts; direct/indirect investments) of referring physicians (and immediate family members) with “a financial relationship.”
- Review contracts with referring physicians for “technical” compliance
  - Signed and dated
  - Expiration date / “evergreen”
  - Describes all services – Review “evergreen” contracts for modified services

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Stark Compliance Check List cont'd

- Ensure contractual payments are FMV and without regard to value or volume of referrals
  - Document independent appraisals of salaries/fees
  - Independent appraisals or market research for leases
  - Service agreements with physicians include documented work product
- Equipment leases
  - Per click issues
- Recruitment fees
- Limits on professional courtesies

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Mandatory Compliance Programs

Sec. 6401(a)(8) of PPACA modifies the conditions of participation under Medicare, Medicaid and Title XXI

- Requires each provider or supplier to adopt a compliance program containing "core elements" established by Secretary in consultation with OIG for particular industry or category
- Secretary shall determine implementation date
- OIG Model Compliance Program for Hospitals
  - 63 Fed. Reg. 8987 (Feb. 23, 1998)
  - 70 Fed. Reg. 4858 (Jan. 31, 2005) (supplemental guidance)

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Core Elements of Comprehensive Compliance Programs

Seven Core Elements:

- Written policies and procedures (code of conduct)
- Compliance Officer
- "Hot lines" and other appropriate "open lines of communications" and reporting
- Appropriate training and education
- Enforcement and disciplinary actions
- Internal monitoring and auditing
- Response to overpayments/deficiencies (reporting/refunding/CAPs)

SEGMENT 2:

Kathleen K. Hogan, Esq.
Director of Corporate Compliance
Community Care Physicians, P.C.

Introduction

Ms. Hogan is the Director of Corporate Compliance for Community Care Physicians, P.C., a physician-owned, physician-run multi-specialty medical group with more than 1,000 employees and over 180 doctors and other clinicians practicing out of 35 offices throughout the New York Capital District. In her current position, Ms. Hogan directs programs, policies and practices to ensure that business units are in compliance with financial policy and reporting regulations.

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SEGMENT 2:

Kathleen K. Hogan, Esq.
Director of Corporate Compliance
Community Care Physicians, P.C.

The Affordable Care Act in 2012: State Implementation of ACA Program Integrity Provisions

January 19, 2012

Presented by:
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SEGMENT 2:

Kathleen K. Hogan, Esq.
Director of Corporate Compliance
Community Care Physicians, P.C.

Patient Protection and Affordable Care Act ("PPACA," "ACA")1

- Effective Date: March 23, 2010

- Title VI: Transparency and Medicaid Program Integrity Provisions
  - Compliance Program Requirements (6102, 6401)
  - Reporting and Returning Overpayments (6402)
  - Termination of Provider Participation (6501)
  - Payment Suspension Provision (6402)
  - RAC Expansion (6411)

- State Medicaid PI Impact: Significant impact on state oversight responsibilities

- Provider Impact: Significant impact on provider community

[1] *H.R. 3590, 111th Cong. (2010).*
http://frwebgate.access.gpo.gov/cgibin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590eas.txt.pdf

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Abuse vs. Fraud

▪Abuse- Provider practices inconsistent with sound fiscal, business or medical practices, and result in unnecessary cost to Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. (42 CFR 455.2- similar to state provision, 18 NYCRR 515.1(b)).

▪Centers for Medicare and Medicaid Services (CMS) defines abuse as “payment for items or services that are billed by mistake by providers, but should not be paid for by Medicare.”

▪Note: No evidence of intent of specific individual required, nor fault.

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The Changing Landscape of "Improper Payments"

- Executive/Presidential Goal: Reduce government-wide improper payments by $50 billion, and to recapture under existing criteria and authorities at least $2 billion in actual improper payments by FY 2012

- Executive Order 13520 on Reducing Improper Payments (November 2009)

- Improper payments focus of FY 2011 Presidential budget

- Improper Payment- Any payment that should not have been made or that was made in an incorrect amount under statutory, contractual, administrative, or other legally applicable requirements.

- Balance between decreasing improper payments and ensuring/promoting access

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Compliance Program Requirements
ACA § 6102, 6401

General Compliance Program Requirements (6401)

- Certain providers and suppliers will be required as condition of enrollment to establish a compliance program.

Nursing Home/Skilled Nursing Facility Accountability Requirements (6102)

- Effective Compliance & Ethics Programs

- On/after 36 months of enactment (3/23/2013), facilities must implement a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care . . .

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Core Elements of an Effective Compliance and Ethics Program

1. Development and distribution of written policies, procedures and standards of conduct to prevent and detect inappropriate behavior.
2. Designation of chief compliance officer and others charged with responsibility of operating and monitoring compliance program and who report directly to high-level personnel and governing body.
3. Use of reasonable efforts not to include any individual in the substantial authority personnel whom the organization knew, or should have known, has engaged in illegal activities or other conduct inconsistent with an effective compliance program.
4. Development and implementation of regular, effective education and training programs for governing body and all employees.

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Core Elements of an Effective Compliance and Ethics Program

5. Maintenance of a process (such as a hotline) to receive complaints and adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation.

6. Development of a system to respond to allegations of improper conduct and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies.

7. The use of audits and/or other evaluation techniques to monitor compliance and assist in reduction of identified problem areas.

8. Investigation and remediation of identified systematic problems including making any necessary modifications to the organization's compliance and ethics programs.

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Compliance Program Requirements ACA § 6102, 6401

Required Components of Ethics & Compliance Program (6102)

- Established compliance standards and procedures reasonably capable of reducing prospect of criminal, civil and administrative violations
- Specific individuals with high-level personnel responsibility assigned to oversee compliance
- Must take steps to communicate effectively its standards and procedures to all employees and other agents
- Standards consistently enforced through appropriate disciplinary mechanisms (including as appropriate disciplining individuals responsible for failure to detect an offense)
- After offense detected, must have taken all reasonable steps to respond appropriately and prevent further similar offenses (necessary modifications to program)

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NYS Mandatory Compliance Program

- NY Medicaid law and regulation- Every provider receiving more than $500,000 per year must have, and certify to, an effective compliance program with eight mandatory elements.
- Mandatory compliance elements consistent with U.S. Federal Sentencing Guidelines elements.
- NYS OMIG Compliance Division
  - Effectiveness Reviews
    - Yearly certifications, audit program, disclosure to state of overpayments when identified, risk assessment and data analysis, response to hotline complaints and employee issues
    - Best practices, enhancement opportunities, identified insufficiencies
  - Compliance Alerts
  - Self-Assessment Tools

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Compliance Program Best Practices

- Publication of code of conduct and/or compliance plan document on provider's intranet and/or public website.
- Communication lines between President/Director, senior management and employees should be open and transparent.
- Use electronic training and education system that tracks mandatory compliance education of employees (specialized to lines of business)
- Results of online compliance training tracked to identify areas of weakness and further training opportunities.
- Employee performance evaluations incorporates compliance as an indicator of performance and adherence to applicable laws, regs and policies.
- Use of comprehensive self assessment tool for the compliance program is used in planning and development of an annual compliance work plan.

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Reporting and Returning Overpayments ACA § 6402

▪Report, Explain and Repay Provision

• Overpayments must be reported and returned within 60 days of identification or the date a corresponding cost report is due, whichever is later.

•Explain reason for overpayment upon submission of overpayment monies.

•Any overpayment retained after the deadline is considered an obligation for purposes of the False Claims Act.

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Report, Explain and Repay Provision

"Overpayments"

- Any funds that a person receives or retains under Medicaid (or Medicare) to which the person is not entitled.

- Overpayments under ACA include any reason for the overpayment- fraud, abuse, waste, mistake, system error.

- "Person" – includes managed care plan, individual program enrollee, corporation or partnership, as well as program provider or supplier.

- "Receives" – Payment need not come directly from Medicaid, if a person retains an overpayment that is due the program, a violation has occurred.

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Report, Explain and Repay Provision

"Identification"

- Fact that there is an overpayment, not that the amount of overpayment has been identified.
- Critical date: When overpayment is identified, not when it is received.

"Returned"

- NY - For voids and small overpayments, providers may use void process through CSC.

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Report, Explain and Repay Provision

Provider Impact:

- Federal mandate to self-police and audit
- No need for bad intent
- Obligations of Managed Care Organizations and MCO Network Providers (report, repay and explain) and other multi-layered systems

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Report, Repay and Explain Provision

State Impact: NY Enforcement Tools

- Current established formats for disclosure are Self Disclosure Protocol- (www.omig.ny.gov)
- Amounts in excess of $5,000 use self disclosure process.
- Targeting, Compliance Reviews, Investigations (Warning & Education Letters)
- Assessing other state models- Self-disclosure process for MCOs and network providers in MCOs is evolving in NYS and nationally.

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NY Self Disclosure Trend Demonstrates Significant Increase in Provider Self-Reporting Activity

- **Number of Self Disclosures Initiated**
  - 2009 (CY) - 136
  - 2010 (CY) - 227
  - 2011 (Q 1-3) – 344
- **Increase in self disclosure overpayment amounts over last 3 years:**
  - Findings - $42.5 million
  - Recoveries - $37.9 million

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NYS OMIG Provider Portal

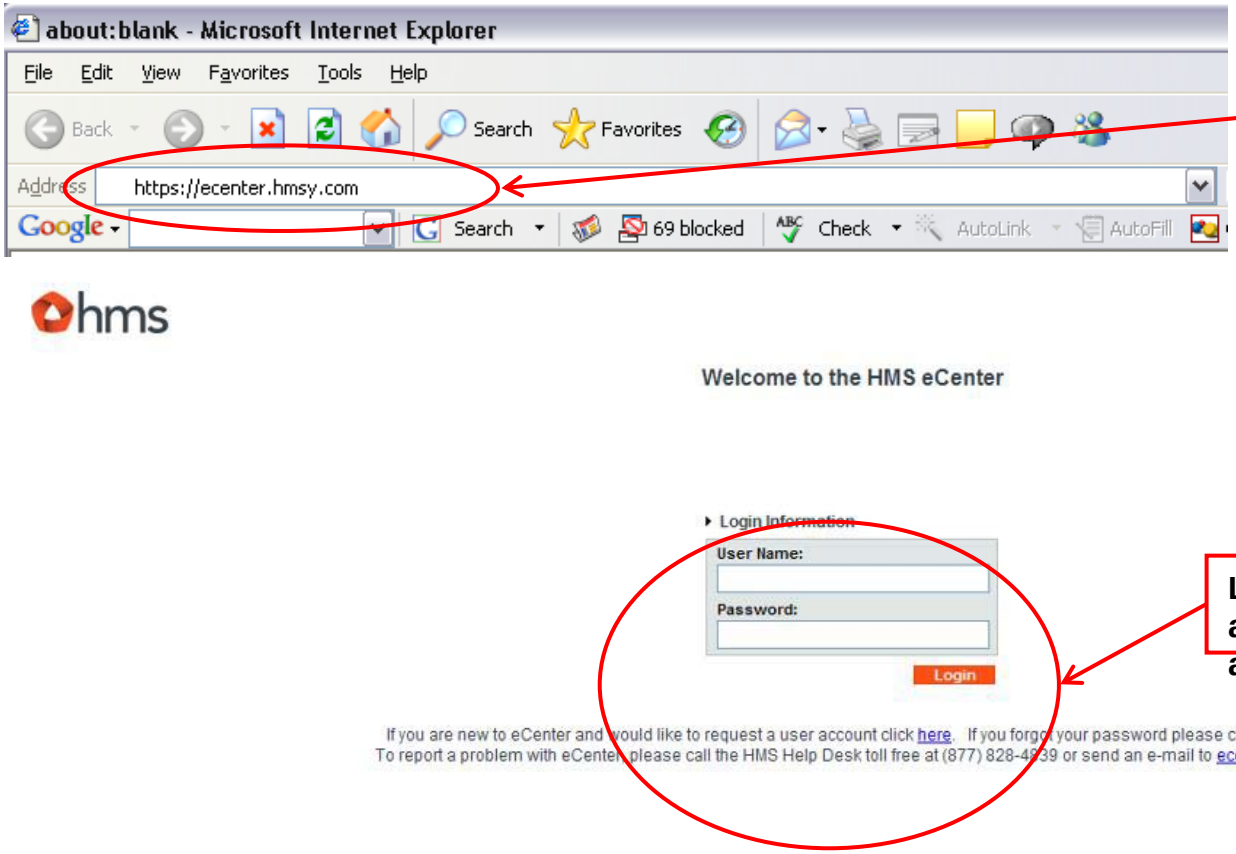
Addressing the "HOW?" Issue

- Provider portal is a web-based application that allows providers a single point of entry for multiple OMIG reviews

- Provider portal designed to accommodate multiple functionalities

  - Provider Self-Disclosure
  - Third Party Reviews
  - Payment Integrity Reviews
  - Medicaid Credit Balance Reporting

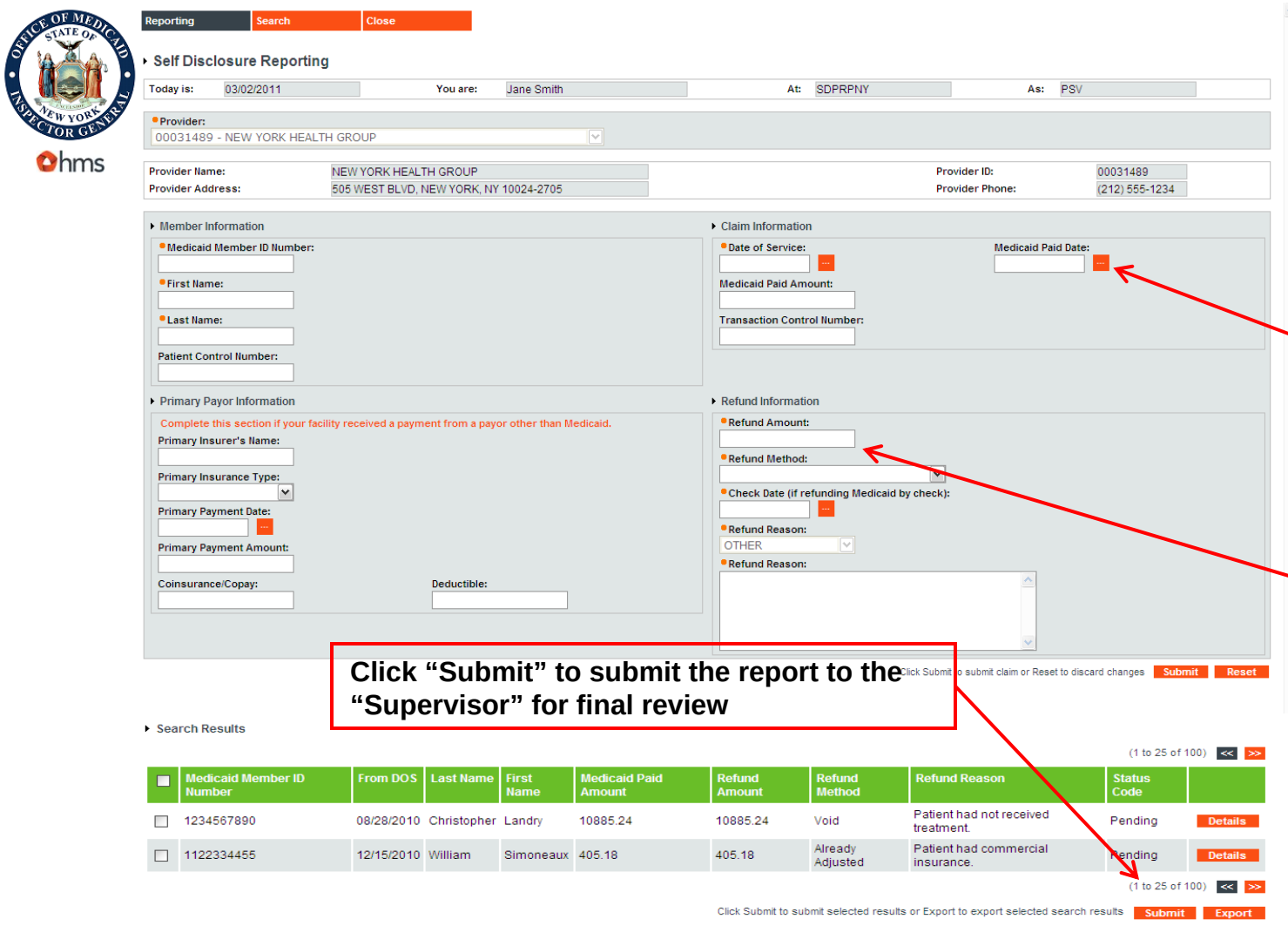
Accessing the Provider Portal



Web-based with 128-bit security encryption

Login for existing users and requesting a user account

Self-Disclosures - Input



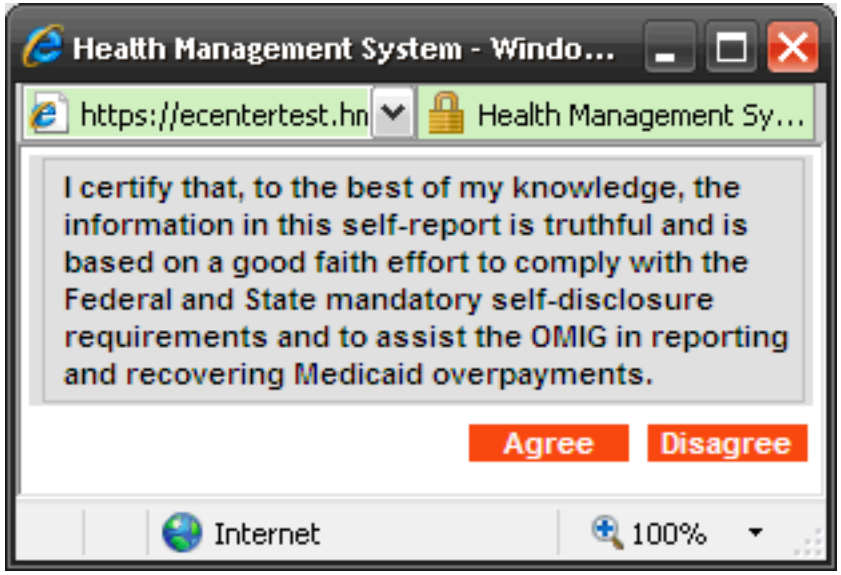
Enter basic claim information needed to identify the claim

Enter refund amount and reason(s) for overpayment

Click "Submit" to submit the report to the "Supervisor" for final review

Self-Disclosures - Attestation

Only the users with "Supervisor" access will be able to formally submit self-disclosures to OMIG-HMS. When submitting the final report, the "Supervisor" will be asked to attest to the information being submitted.



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Termination of Provider Participation ACA § 6501

- States are required to terminate providers, individuals or entities from Medicaid programs if individuals/entities were terminated from Medicare or other State's Medicaid or CHIP program.

- A Medicaid exclusion from one state will effectively exclude a provider from Medicaid in all states.

- CMS is working towards the development of a system that will enable information on terminated providers and suppliers to be shared across programs in an automated manner. In the interim, CMS is will disseminating information to States on a recurring basis via portal.

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2012 HHS OIG Reviews of Federally Excluded Providers and Suppliers

- Federal HHS OIG Focused Reviews in 2012 –Medicare & Medicaid

- OIG will review M/A payments to providers to determine extent to which payments were for services provided during periods of exclusion from M/A. Excluded providers and suppliers are not permitted to receive payments for services provider during periods of exclusion.

- OIG will review Medicare payments for services ordered or referred by excluded providers. No payments shall be made for any items or services furnished, ordered, or prescribed by excluded individuals or entities.

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Suspension of Payments Pending Investigation ACA § 6402(h)

- Medicaid payments may be suspended pending investigation of a credible allegation of fraud, unless HHS determines good cause not to suspend payment.

- "Credible allegation of fraud"

  - Allegation verified by state that has "indicia of reliability"

  - States must review evidence carefully considering the totality of facts and circumstances

- Purpose: Make states guarantor of accurate billing by their providers.

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Suspension of Payments Pending Investigation ACA § 6402(h)

Significant Potential Fiscal Impact on Providers and State

- CMS may recover payments from State
- Proposed rule 45 CFR 447.90 would deny FFP in the event that a state fails to appropriately suspend.

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Suspension of Payments Pending Investigation ACA § 6402(h)

State Impact – NY Enforcement Tools

- Pending investigations of credible allegations of fraud → Suspend payments

- Fraud allegations referred to MFCU → State required to suspend payments, FFP stops

- ** Immediate impact** - All current and future referrals to MFCU will be placed on suspension (w/ good cause exceptions)

If MFCU rejects referral, state can refer to local law enforcement. If MFCU and local law enforcement reject, payment suspension is released immediately.

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Suspension of Payments Pending Investigation ACA § 6402(h)

What constitutes "good cause" for non-suspension?

- Requests by law enforcement
- Suspension might alert perpetrator or jeopardize undercover investigation/investigator
- May expose whistleblowers/confidential sources
- State determines that other available remedies implemented by the State could more effectively or quickly protect Medicaid funds than would implementing (or continuing) a payment suspension
- Suspension not in best interests of M/A program
- Access to necessary items or services may be jeopardized
- Law enforcement chooses not to accept referral

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Expansion of Recovery Audit Contractor Program (RAC) ACA § 6411

Extending RAC to Medicaid (& Medicare Parts C&D)

- Expansion to all states by December 31, 2010.

- States must implement RACs for MA and must use contingency-based fee payment system.

- Purpose of identifying underpayments and overpayments and recouping overpayments under State plan.

- Coordination requirement: The State and any such contractors under contract with State shall coordinate such recovery audit efforts with other contractors or entities performing audits of entities – including efforts with Federal and State law enforcement , DOJ, FBI, HHS OIG, State Medicaid Fraud Control Unit.

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Introduction

Michael R. Callahan has been a practicing health care attorney for 30 years, assisting hospital, health system and medical staff clients on a variety of health care legal issues including accountable care organizations, patient safety organizations, health care antitrust, HIPAA and regulatory compliance, accreditation matters, general corporate, medical staff credentialing and hospital/medical staff relations.

Mr. Callahan is recognized for his experience and knowledge of the health care industry. He is a frequent speaker all around the country on topics including medical staff matters, integrated delivery systems, physician recruitment and retention, Joint Commission and HFAP accreditation, Medicare fraud and abuse, and accountable care organizations.

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The Affordable Care Act in 2012: Understanding the Changes

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The Changing Healthcare Landscape

- Consolidation of market
  - Hospital mergers
  - Practice acquisitions
- Provider margins are under attack
  - Reductions in Medicare/Medicaid reimbursement
  - Higher costs
  - Private payer reductions
- New models of provider integration are emerging
  - Co-management arrangements
  - Patient centered medical home
  - ACOs

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The Changing Healthcare Landscape (cont'd)

- Shift from "Volume to Value" as a basis of reimbursement
  - –Pay for performance
  - –ACO quality metrics
  - –Value Based Purchasing
  - –Reduced or denied reimbursement for:
    - ➢Hospital acquired conditions
    - ➢Never events – (Billing Medicare for a never event is considered a false claim)

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The Changing Healthcare Landscape (cont'd)

- Increased enforcement
  - 2012 OIG Work Plan
    - ➢Reliability of hospital-reported quality measures data
    - ➢Hospital admissions with conditions coded as "present-on-admission" and accuracy of "present on admissions" indicators
    - ➢Review of Medicaid payments for HACs and never events
    - ➢Acute-care inpatient transfers to inpatient hospice care
    - ➢Safety and quality of surgeries and procedures in surgicenters and hospital outpatient departments

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The Changing Healthcare Landscape (cont'd)

- Quality of care and safety of residents and quality of post-acute care for nursing homes
- Hospital reporting of adverse events
- Hospital same-day readmissions
- Hospitalizations and re-hospitalization of nursing home residents
- Review effectiveness of PSO programs

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The Changing Healthcare Landscape (cont'd)

– January, 2012 OIG Report: "Hospital Incident Reporting Systems Do Not Capture Most Patient Harm"

- All hospitals have incident reporting systems to capture events and are heavily relied on to identify problems
- These systems provide incomplete information about how events occur
- Of the events experienced by Medicare beneficiaries, hospital incident reporting systems only captured an estimated 14% due to events that staff did not perceive as reportable or were simply not reported
- Accrediting bodies only review incident reports and outcomes but not the methods used to track errors and adverse events

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Examples of Quality Standards

- Never Events
  - –Surgery on wrong body part
  - –Surgery on wrong patient
  - –Wrong surgery on a patient
  - –Death/disability associated with use of contaminated drugs
  - –Patient suicide or attempted suicide resulting in disability
  - –Death/disability associated with medication error

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Examples of Quality Standards (cont'd)

- Hospital Acquired Conditions
  - –Foreign object left in patient after surgery
  - –Death/disability associated with intravascular air embolism
  - –Death/disability associated with incompatible blood
  - –Stage 3 or 4 pressure ulcers after admission

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Examples of Quality Standards (cont'd)

- ACO Standards and Quality Metrics
  - Have a management structure that includes clinical and administrative systems
  - Have defined processes to:
    - Report the necessary data to evaluate quality and cost measures; this could incorporate requirements of other programs, such as the Physician Quality Reporting Initiative (PQRI), Electronic Prescribing (eRx), and Electronic Health Records (EHR)
    - Coordinate care

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Examples of Quality Standards (cont'd)

- Demonstrate it meets patient-centeredness criteria, as determined by the Secretary
- Quality assurance program must establish internal performance standards for quality, costs and outcomes improvements and hold ACO providers accountable, including termination

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Examples of Quality Standards (cont'd)

- Consistent with the overall purpose of the Affordable Care Act, the intent of the Shared Savings Program is to achieve high-quality health care for patients in a cost-effective manner. As part of CMS's goal to provide better care for individuals, defined as "safe, effective, patient-centered, timely, efficient, and equitable," the regulations propose:
  - Measures to assess the quality of care furnished by an ACO;
  - Requirements for data submission by ACOs;
  - Quality performance standards

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Examples of Quality Standards (cont'd)

  - Incorporation of reporting requirements under the Physician Quality Reporting System; and
  - Requirements for public reporting by ACOs.

- ACOs that do not meet quality performance thresholds for all measures would not be eligible for shared savings, regardless of how much per capita costs were reduced.

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Examples of Quality Standards (cont'd)

- ACO Quality measures are in four domains**:**
  - Patient/caregiver experience (7)
  - Care coordination/patient safety (6)
  - Preventive health (8) and,
  - At-risk populations (12): includes 6 measures for diabetes (5 scored as a single composite), 1 for hypertension, 2 for IVD, 1 for heart failure, and 2 for CAD
  - *EHR adoption by PCPs will be included as a quality measure in the Care Coordination/Patient Safety domain and will be given double weight in scoring*
- Changes over time:
  - CMS can specify higher standards and/or new measures to improve quality of care

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Examples of Quality Standards (cont'd)

- Patient experience survey**:**
  - CMS will pay to administer patient experience surveys (CAHPS) in 2012 and 2013
  - Beginning in 2014, ACOs must select an approved survey vendor to administer the survey and report results to CMS

- Alignment with PQRS reporting
  - Use of GPRO tool to report ACO measures qualifies you for the physician quality reporting bonus payments – *good example of alignment and reinforcing incentive for ACO*

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Examples of Quality Standards (cont'd)

- Value Based Purchasing Program Measures
  - Starting in October, 2012, will reward hospitals based on the quality of inpatient acute care services provided and not just on the quality delivered.
  - Under the VBP Program, CMS will pay acute care inpatient prospective payment system (IPPS) hospitals value-based incentive payments for meeting minimum performance standards for certain quality measures with respect to a performance period designated for each fiscal year.

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Examples of Quality Standards (cont'd)

- Clinical Process of Care Measures
  - Acute myocardial infarction
    - Primary PCI received within 90 minutes of hospital arrival
  - Heart Failure
    - Discharge Instructions
  - Pneumonia
    - Blood cultures performed in ED prior to initial antibiotic received in hospital

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Examples of Quality Standards (cont'd)

- Survey Measures
  - Communication with Nurses
  - Communication with Doctors
  - Responsiveness of Hospital Staff
  - Pain Management
  - Communication About Medicines
  - Cleanliness and Quietness of Hospital Environment
  - Discharge Information
  - Overall Rating of Hospital

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Examples of Quality Standards (cont'd)

- Other Criteria for FY 2014
  - Eight Hospital Acquired Condition Measures
    - Foreign object retained after surgery
  - AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs), and Composite Measures
  - Mortality measures

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Corporate Responsibility in Health Care Quality

- In 2007 the OIG and AHLA collaborated on a publication titled “Resource for Health Care Boards of Directors on Corporate Responsibility and Health Care Quality”
- Was published “for the specific purpose of identifying the role and responsibility of corporate boards and management with respect to its fiduciary obligations to meet its charitable mission and legal responsibilities to provide health care quality services”
- Cites ten key questions reflective of standards against which hospital boards will be measured

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Corporate Responsibility in Health Care Quality (cont'd)

- What are the goals of the organization's quality improvement program?
  - What metrics and benchmarks are used to measure progress towards each of the performance goals? How is each goals specifically linked to management accountability?
  - How does the organization measure and improve the quality of patient/resident care? Who are the key management and clinical leaders responsible for these quality and safety programs?
  - How are the organization's quality assessment and improvement processes integrated into overall corporate policies and operations? Are clinical quality standards supported by operational policies? How does management implement and enforce these policies? What internal controls exist to monitor and report on quality metrics?

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Corporate Responsibility in Health Care Quality (cont'd)

- Does the board have a formal orientation and continuing education process that helps members appreciate external quality of patient safety requirements? Does the board include members with expertise in patient safety and quality improvement issues?

- What information is essential to the board's ability to understand and evaluate the organization's quality assessment and performance improvement programs? Once these performance metrics and benchmarks are established, how frequently does the board receive reports about the quality improvement effort?

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Corporate Responsibility in Health Care Quality (cont'd)

- Are human and other resources adequate to support patient safety and clinical quality? How are proposed changes in resource allocation evaluated from the perspective of clinical quality and patient care? Are systems in place to provide adequate resources to account for differences in patient acuity and care needs?

- Do to the organization's competency assessment and training, credentialing and peer review processes adequately recognize the necessary focus on clinical quality and patient safety issues?

- How are these "adverse patient events" and other medical errors identified, analyzed, reported and incorporated into the organization's performance improvement activities? How do management and the board address quality deficiencies without unnecessarily increasing the organization's liability exposure?

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Corporate Responsibility in Health Care Quality (cont'd)

- How are the organization's quality assessment and improvement processes coordinated with its corporate compliance program? How are quality of care and patient safety issues addressed in the organization's risk management and corrective action plans?

- What processes are in place to promote the reporting of quality concerns and medical errors and to protect those who ask questions and report programs? What guidelines exist for reporting quality and patient safety concerns to the board?

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Examples of Quality Enforcement Efforts

- The OIG has identified that its principal enforcement tools include allegations of violations of the False Claims Act, use of corporate integrity agreements, including the use of external quality of care monitors, as well as civil fines and, in extreme circumstances, exclusion from the Medicare program

- The OIG has made the following statements:

  "To hold responsible individuals accountable and to protect additional beneficiaries from harm, the OIG excludes from participation in federal health care programs individuals and entities whose conduct results in poor care. In enforcement actions against corporate entities, . . . OIG places particular emphasis on high level officials, such as owners and chief executive officers. . . ."

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Examples of Quality Enforcement Efforts (cont'd)

- Grand Jury indicted a Michigan hospital based on its failure to properly investigate medically unnecessary pain management procedures performed by a physician on the medical staff.

- A California hospital paid $59.5 million to settle a civil False Claims Act allegation that the hospital inadequately performed credentialing and peer review of cardiologists on its staff who perform medically unnecessary invasive cardiac procedures.

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Examples of Quality Enforcement Efforts (cont'd)

– In a settlement with Tenet Health Care Corporation and pursuant to a Corporate Integrity Agreement, a hospital board was required to:

  - Review and oversee the performance of the compliance staff.
  - Annually review the effectiveness of the compliance program.
  - Engage an independent compliance consultant to assist the board and review an oversight of tenant's compliance activities.
  - Submit a resolution summarizing its compliance efforts with the CIA and federal health care program requirements, particularly those relating to delivery of quality care.

– A Pennsylvania hospital recently entered into a $200,000 civil False Claims Act settlement to resolve substandard care allegations related to the improper use of restraints.

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Examples of Quality Enforcement Efforts (cont'd)

- Rogers v. Azmat (2010)
  - DOJ interviewed in a False Claims Act lawsuit alleging that Satilla Regional Medical Center and Dr. Najam Azmat submitted claims for medical substandard and unnecessary services to Medicare and Medicaid . The complaint alleges, among other things, that the defendants submitted claims for medical procedures performed by Dr. Azmat in Satilla's Heart Center that the physician was neither qualified nr properly credentialed to perform. As a result, at least one patient died and others were seriously injured.

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Examples of Quality Enforcement Efforts (cont'd)

– The complaint states that Satilla placed Dr. Azmat on staff even after learning that the hospital where he previously worked had restricted his privileges as a result of a high complication rate on his surgical procedures. The complaint also states that after Dr. Azmat joined the Satilla staff, the hospital management allowed him to perform endovascular procedures in the hospital's Heart Center even though he lacked experience in performing such procedures and did not have privileges to perform them.

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Examples of Quality Enforcement Efforts (cont'd)

– The complaint further states that the nurses in Satilla's Heart Center recognized that Dr. Azmat was incompetent to perform endovascular procedures and repeatedly raised concerns with hospital management. Despite the nurse's complaints and Dr. Azmat's high complication rate, Satilla's management continued to allow him to perform endovascular procedures and to bill federal health care programs for these services.

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So Now What?

- Compliance plans need to be updated or prepared which reflect the provider's commitment to improving quality as per the areas identified by the OIG
- Even if not seeking ACO certification at this time, hospital should review the ACO final rules as a future standard on which private and public reimbursement and standards of care will be based

SEGMENT 3:
Michael R. Callahan
Partner, Health Care Practice Group
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So Now What? (cont'd)

- A failure to comply with ACO, VBP and other developing standards, including a pattern of HACs and Never Events, may also have a direct or indirect impact on provider responsibilities:
  - Accreditation standards
  - Doctrine of corporate negligence and related civil liability theories
  - DOJ/OIG expectations on board responsibility for delivering quality health care services which could trigger False Claims Act exposure (Azmat case)

SEGMENT 3:
Michael R. Callahan
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So Now What? (cont'd)

- Providers therefore need to incorporate these quality metrics and standards into their policies and procedures
- Standards need to be developed that track performance and ensure that they are communicated to providers and then monitored for compliance
- Providers need to receive periodic reports regarding their individual and comparative performances

SEGMENT 3:
Michael R. Callahan
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So Now What? (cont'd)

- Remedial action plans need to be developed that are designed to assist providers in meeting standards but can include the ability to suspend or terminate participation

- Performance results should be taken into consideration at the time of appointment, reappointment and contract renewal, and some internal administrative process/fair hearing for participants who are excluded should be provided

SEGMENT 3:
Michael R. Callahan
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So Now What? (cont'd)

- It is important that provider evaluate its processes and procedures, reports, analyses, etc., so as to maximize available confidentiality and immunity protections under state and federal law (e.g., participation in a Patient Safety Organization under Patient Safety and Quality Improvement Act of 2005).

SEGMENT 3:
Michael R. Callahan
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So Now What? (cont'd)

- Is an ACO a "health care entity" under the Health Care Quality Improvement Act for purposes of:
  - Data Bank query and reporting obligations
  - Immunity protections
- Can an ACO be sued under the Doctrine of Corporate Negligence?
- Should there be an ACO medical/provider staff in lieu of a hospital medical staff?

SEGMENT 3:
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So Now What? (cont'd)

- Will new bylaws, rules, regulations and policies be required given the fact that the ACO must be al legal entity?

- Should the standard hearing procedures remain the same or be modified?
  - Is non-compliance with utilization standards reportable if terminated or if membership denied?
  - Is non-compliance with quality metrics standards reportable if terminated or if membership denied?
  - Should termination from ACO result in termination from a hospital/provider staff and visa versa?

Q&A:

SEGMENT 1:

John R. Washlick
Member Co-chair, Health Law Practice Group
Cozen O'Connor

SEGMENT 2:

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Director of Corporate Compliance
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SEGMENT 3:

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