

VALUE BASED PAYMENTS AND COMPLIANCE:

RESPONDING TO THE GOVERNMENT'S FOCUS ON QUALITY OF CARE AND MEDICAL NECESSITY

HCCA Compliance Institute
April 17, 2016 at 9:00 a.m.
Aria Hotel
Las Vegas, Nevada

Presented by:

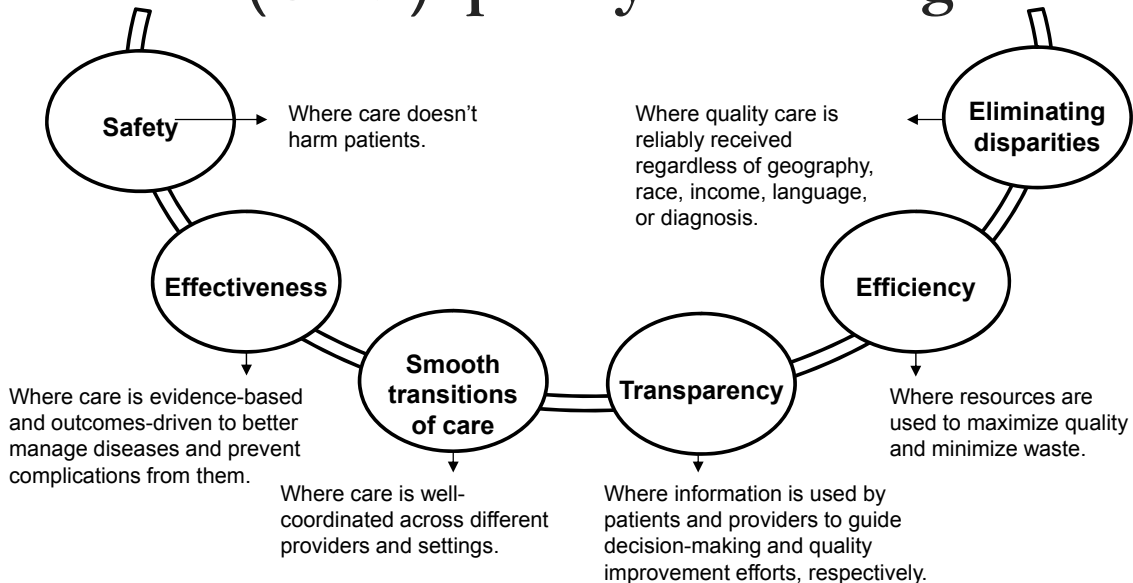
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Center for Medicare and Medicaid Services (CMS) quality measure goals



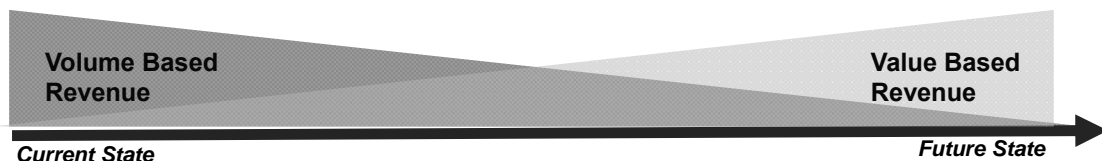
Focus On Quality: Health Care Reform Implements Payment Reform

“The law is also a serious platform for improving the quality of healthcare and changing the delivery system so we stop doing things that don’t work for patients and start doing things that will work. It’s about better care: care that is safe, timely effective, efficient, equitable and patient centered.”

Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
IHI Annual Meeting
December 7, 2010

2

The Shift from Volume to Value



3

Focus on Quality: HHS Announces Shifting Medicare Reimbursements from Volume to Value

- 1/26/2015

- Goal:

- Tie 30% of traditional or fee for service Medicare payments to quality or value through models such as ACO's or bundled payment arrangements by 2016; 50% by 2018.
- Tie 85% of all traditional Medicare payments to quality or value by 2016; 90% by 2018 through Hospital Value Based Purchasing and Hospital Readmissions Reduction Programs.

4

Focus on Quality: HHS Announces Effort To Scale Beyond Medicare Payments

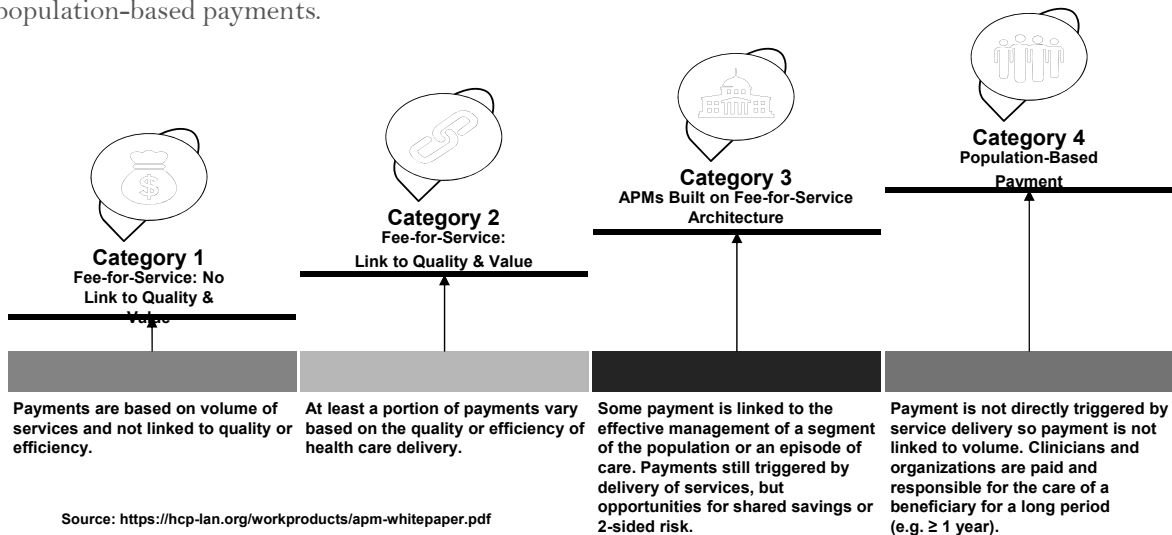
Creation of Health Care Payment Learning and Action Network.

- HHS to work with private payors, employers, consumers and states to expand alternative payment models into their programs.

5

APM Framework

The Health Care Payment Learning & Action Network’s final white paper on an APM Framework highlighted four categories of payment models, ranging from traditional fee-for-service to population-based payments.



6

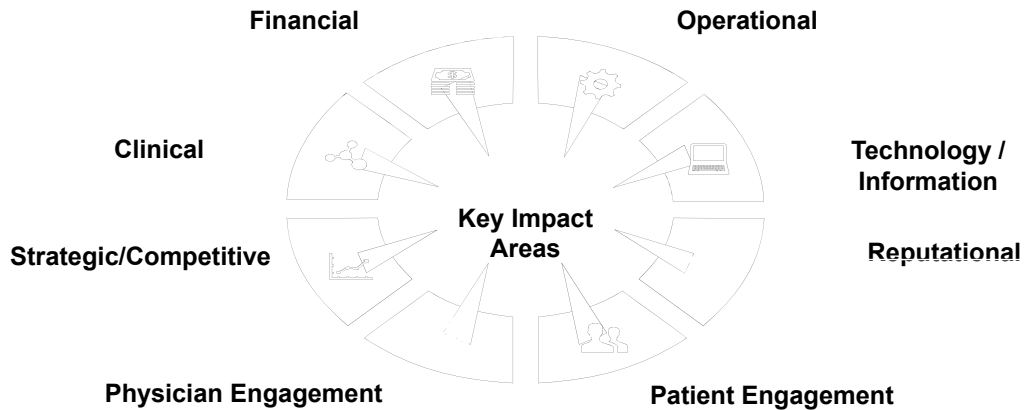
CMS quality measure initiatives

Hospital Quality	Physician Quality	Post Acute Care & Other Setting Quality	Payment Model	“Population” Quality
<ul style="list-style-type: none"> EHR Incentive Program (MU) PPS Exempt Cancer Hospitals QR Inpatient Psychiatric Facilities Outpatient Quality Reporting Hospital Acquired Conditions (HAC) Program Readmission Reduction Program Inpatient Quality Reporting Ambulatory Surgical Centers QR 	<ul style="list-style-type: none"> Physician Quality Reporting System (PQRS) Electronic Health Record Incentive Program (Meaningful Use/MU) Physician Feedback/Value Based Modifier CAHPS 	<ul style="list-style-type: none"> Inpatient Rehabilitation Facility Nursing Home Compare Measures Long Term Health Care (LTHC) Quality Reporting Hospice Quality Reporting Home Health Quality Reporting 	<ul style="list-style-type: none"> Medicare Shared Savings Program (MSSP) Hospital Value Based Purchasing (VBP) End Stage Renal Disease Quality Incentives 	<ul style="list-style-type: none"> Comprehensive Primary Care Initiative (CPCI) Million Hearts Medicaid Adult Quality Reporting CHIPRA Quality Reporting (Medicaid – Child) Health Insurance Exchange Quality Reporting Medicare Part C Medicare Part D DSRIP Programs

Revenue Increasingly Linked to Clinical Quality

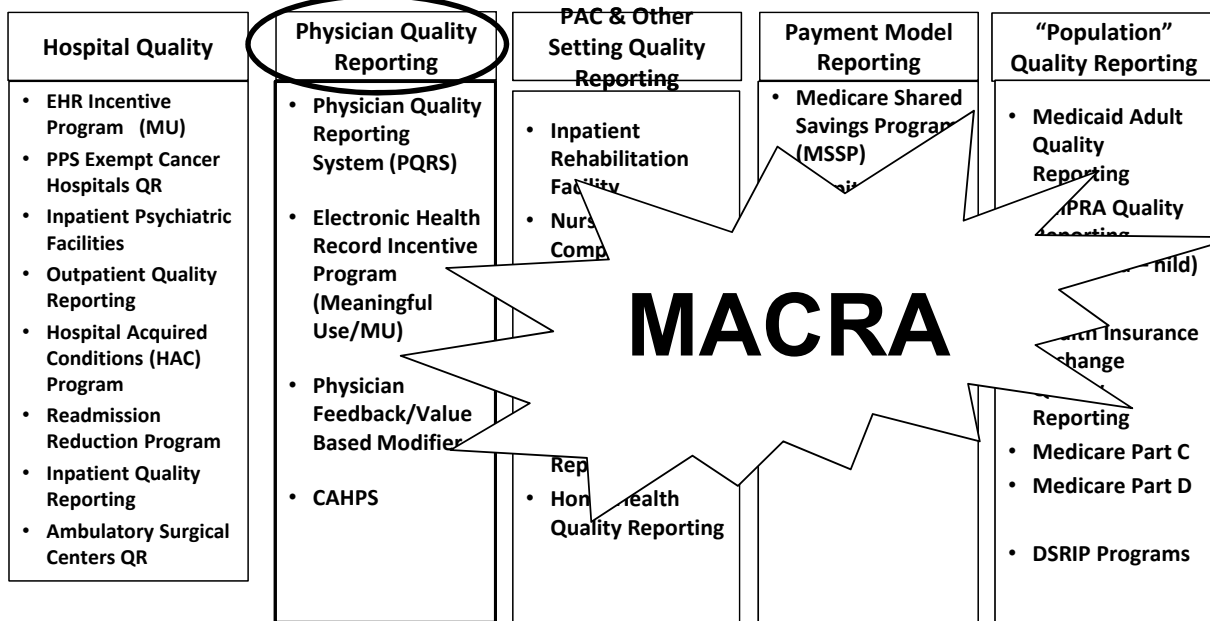
7

Clinical Quality Measurement and Reporting: Implications to your Organization



8

CMS quality measure initiatives



9

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MACRA: Disruptive by Design

MACRA is a new Medicare payment law that will drive the future of health care payment and delivery system reform across the payer mix



Repeals the Sustainable Growth Rate formula for physician payments



Establishes a path toward a new payment system more closely aligned to quality and outcomes



Offers significant financial incentives for health care professionals to participate in risk-bearing, coordinated care models

10

Payment Basics Under MACRA

MACRA creates separate paths for payments under the Medicare physician fee schedule



Alternative Payment Models (APMs)

- **2019-2024:** Lump sum payments equal to **5%** of all reimbursement for services rendered under the Medicare Physician Fee Schedule
- **2026+:** Annual payment updates of **0.75%** to the Medicare Physician Fee Schedule



Merit-based Incentive Payment System (MIPS)

- **2019-2026+:** **Positive or negative** payment adjustments based on performance relative to peers
- **2026+:** Annual payment updates of **0.25%** to the Medicare Physician Fee Schedule

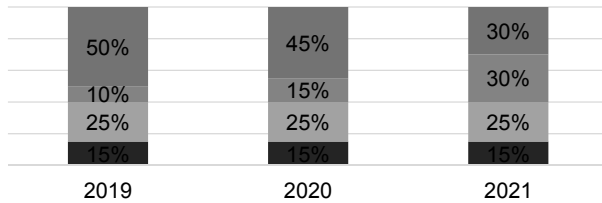
11

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Overview of Merit-based Incentive Payment Systems (MIPS)

Existing incentive programs will sunset in 2018 and an updated composite score will determine the new MIPS payment adjustment for 2019 and beyond

Components of MIPS Composite Score (2019-2021)



- **Quality: PQRS**
- **Resource Use: Value-based Payment Modifier measures**
- **Meaningful Use of EHRs: EHR Incentive Payment measure**
- **Clinical Improvement Activities:** Expanded access (e.g. potential Medicaid), population management, care coordination, beneficiary engagement, patient safety, and alternative payment models

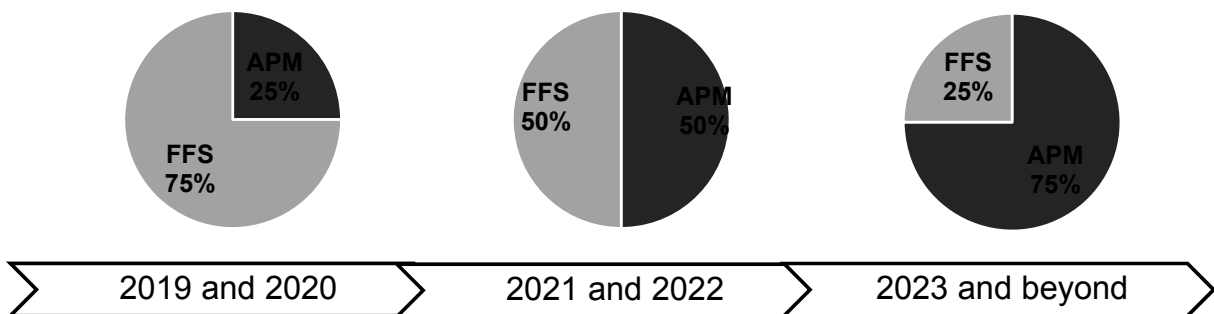
Source: Public Law 114-10 (April 16, 2015)
12

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APM Qualifying Thresholds

Thresholds for risk based percentages under APM increase over time

Percentage of Medicare charges through eligible APM entities versus Fee-for-Service

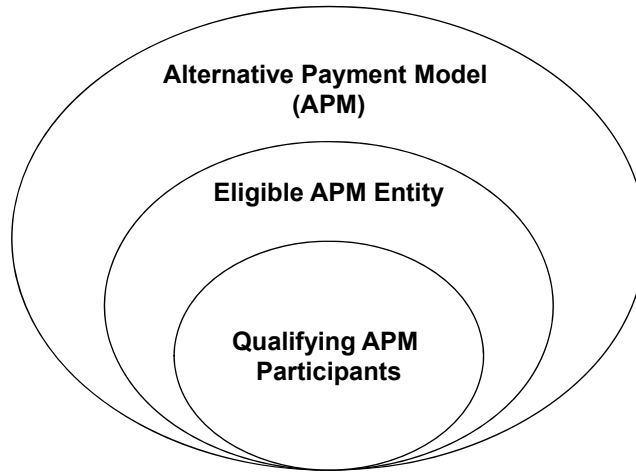


Source: Public Law 114-10 (April 16, 2015)
13

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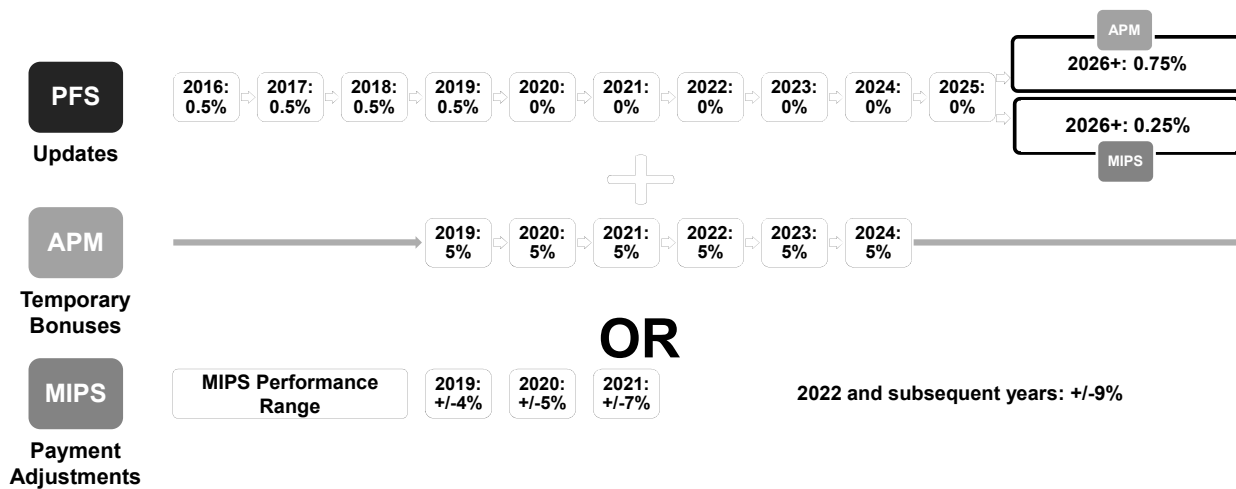
Key Definitions for APMs

Organizations currently participating in ACOs or other coordinated care delivery models must determine if their current arrangements meet MACRA's criteria for downside risk and payments linked to quality



Payment Updates, Bonuses & Adjustments Under MACRA

Reimbursement levels for physician fee schedule, APM and MIPS evolve over time as well



MACRA: Implications to Compliance

What role should the Compliance Department have with regard to MACRA?

While in previous discussions about the organization's value-based care strategies and arrangements, the Compliance Officer may have been more of a passive observer, MACRA catalyzes their participation as a key stakeholder in planning, preparation and implementation efforts. The stakes are high and the requirements are too complex to ignore their perspective and involvement. So what are a few examples of how Compliance Officers can assist their organizations prepare for and operationalize strategies related to MACRA initiatives?

1. Assist management in establishing a program management structure to lead the MACRA preparation, implementation, and monitoring activities that considers all angles of the law, and reinforces a "compliance first" mentality.
2. Interview Meaningful Use (MU), Physician Quality Reporting System (PQRS) and Value-Based Modifier (VBM) process owners to understand and evaluate existing processes supporting the following MIPS related activities:
 - Provider tracking / identification
 - Eligibility determination
 - Quality score calculation and monitoring
 - Score reporting
 - Measure selection
3. Understand the implications of MACRA on the education and auditing and monitoring elements for the following areas:
 - Coding and Billing
 - Clinical Documentation
 - Use of EHR
 - Physician Contracts

16

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Short Term: Requirements remain as you prepare for change

By the time Stage 3 begins in 2018 (or 2017 for early adopters), there will be no Medicare incentive payments available. The latest an EP or EH can receive a Medicare incentive payment is 2016

Eligible Professional Payment Timeline

Funding Year	Adoption Year				
	2011	2012	2013	2014	2015 +
2011	\$ 18,000				
2012	\$ 12,000	\$ 18,000			
2013	\$ 8,000	\$ 12,000	\$ 15,000		
2014	\$ 4,000	\$ 8,000	\$ 12,000	\$ 12,000	
2015	\$ 2,000	\$ 4,000	\$ 8,000	\$ 8,000	
2016		\$ 2,000	\$ 4,000	\$ 4,000	
Total	\$ 44,000	\$ 44,000	\$ 39,000	\$ 24,000	

Eligible Hospital Payment Timeline

Fund year	Adoption year					
	2011	2012	2013	2014	2015	2016
2011	1	0	0	0	0	0
2012	0.75	1	0	0	0	0
2013	0.5	0.75	1	0	0	0
2014	0.25	0.5	0.75	0.75	0	0
2015	0	0.25	0.5	0.5	0.5	0
2016	0	0	0.25	0.25	0.25	0

EPs and EHs who participate in the Medicaid program can continue to receive incentives through 2020. EPs and EHs can receive six and four total incentive payments respectively through the Medicaid program, so early adopters may likely be out of incentives by the time Stage 3 begins.

For EHs, payment adjustments will continue to be applied under the existing rules. However, CMS is sunsetting EHR Incentive Program penalties for EPs in 2018 since they will be subject to new payment adjustments under the Merit-Based Incentive Payment System/Medicare Access and CHIP Reauthorization Act of 2015 (MIPS/MACRA). Until these new regulations are finalized, payment adjustments will continue to be applied on a two-year lag, per the chart below.

For an EH and EP who has demonstrated MU in 2011 - 2013						
Payment Adjustment Year	2015	2016	2017	2018	2019	2020
Based on EHR Reporting Period in Year	2013	2014	2015	2016	2017	2019
Penalty Amount – EP (Medicare Part B)	1%	2%	3%	3%	MACRA / MIPS	
Penalty Factor – EH (IPPS Payment Rate)	0.25%	0.50%	0.75%	0.75%	0.75%	0.75%

17

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Short Term: Requirements remain as you prepare for change

What about our Reporting Requirements for 2016? 2017?

MEANINGFUL USE

2016

- MU Stage Criteria = Modified Stage 2
- Reporting Period = Full Calendar Year*
- CEHRT Requirement: 2014 and/or 2015 Edition

2017

- MU Stage Criteria = Modified Stage 2 (Stage 3 Optional)
- Reporting Period = Full Calendar Year*^
- CEHRT Requirement: 2014 and/or 2015 Edition

* First Year Participants are able to use a 90 day reporting period between 1/1 – 9/30 and can avoid penalties in the subsequent year if they attest by 10/1

^Those who elect to attest using the optional stage 3 criteria may use a 90 day reporting period

18 Sources: CMS, Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 FR 62761, <https://federalregister.gov/a/2015-25595>

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What Changes in 2018 ?

MEANINGFUL USE

2018

- MU Stage Criteria = Stage 3
- Reporting Period = Full Calendar Year for All Providers
- CEHRT Requirement: 2015 Edition
- Electronic Reporting vs. Attestation

19 Sources: CMS, Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 FR 62761, <https://federalregister.gov/a/2015-25595>

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EHR use at your Organization: Why should the Compliance Department care?

Electronic Health Record (EHR) adoption has increased rapidly in the United States through the EHR Incentive Program and Affordable Care Act,

With the increased use of EHRs, increased attention from regulators has followed.

The 2014 OIG work plan stated that EHR fraud would remain a high priority through 2018

The OIG's 2015 work plan justification stated the need to "adopt oversight approaches that are suited to an increasingly sophisticated healthcare system and that are tailored to protect programs and patients from existing and new vulnerabilities."

20

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Benefits Associated with Proper Use of EHR Technology

Proper use of electronic documentation can potentially provide a number of benefits as compared to paper-based documentation, including:

- **Improved legibility,**
- **Real time accessibility,**
- **Reduction of medical errors, and;**
- **Decreased cost**

Benefits of properly utilized documentation assist features include improved efficiency of:

- **Data capture,**
- **Timeliness,**
- **Consistency, and;**
- **Completeness**

21

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Risks Associated with Improper Use of EHR Technology

Misuse of EHR technology functionality has the potential to result in or contribute to several challenges, with significant Regulatory, Financial and Legal implications .

However, it is important to note that the risks of improper EHR use extend well beyond *Regulatory, Financial and Legal* risks, including but not limited to:

- **Quality of Patient Care**
- **Patient Safety**
- **Reputation**
- **Patient Trust and Satisfaction,**
- **Clinical Collaboration**

22

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Risks Associated with Improper Use of EHR Technology

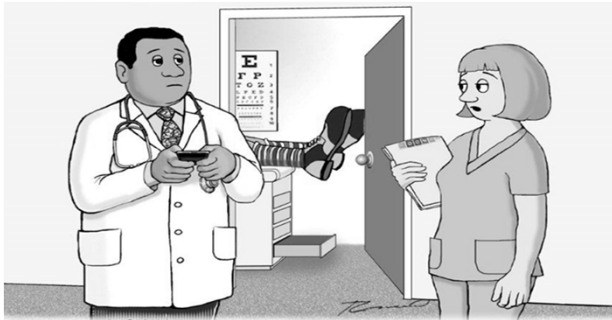
Many hospitals have recommended audit and compliance functions but are not fully utilizing them to assess or mitigate risk related to the improper use of EHR technology.

Risk Considerations related to the proper use of EHR technology and some of the common documentation assist features include but are not limited to:

- **Copy and Paste**
- **Access / Authorship / Authentication**
- **Documentation Templates**
- **Amendments**
- **Availability / Use of Audit Log Functionality**
- **Patient Identification**
- **Patient Portals**

23

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"Doctor, I don't think it's appropriate that you wrote in the patient's EMR that he's a big clown."



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"Janet, would you please delete all of my personal snide remarks and print a copy of Ms. Cole's electronic medical record?"

24

Common Causes of EHR Documentation Errors

Basic Data Entry Errors - Wrong data / wrong field, typos, general sloppiness, etc.



Speed Clicking - Unintended consequences of moving too quickly through fields, screens, warnings and reminders

Garbage In / Garbage Out - Incomplete or inaccurate documentation when originally converted

Lack of Signatures / Time Stamps - Failure to verify or sign clinical notes evidencing "who" and "when"

Log in and Password Sharing - Potential inability to determine who prescribed treatments, medications and tests as well as who made updates and edits to the health records

25

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Mitigating Risks Associated with Improper Use of EHR Technology

Many hospitals have recommended audit and compliance functions but are not fully utilizing them to assess or mitigate risk related to the improper use of EHR technology

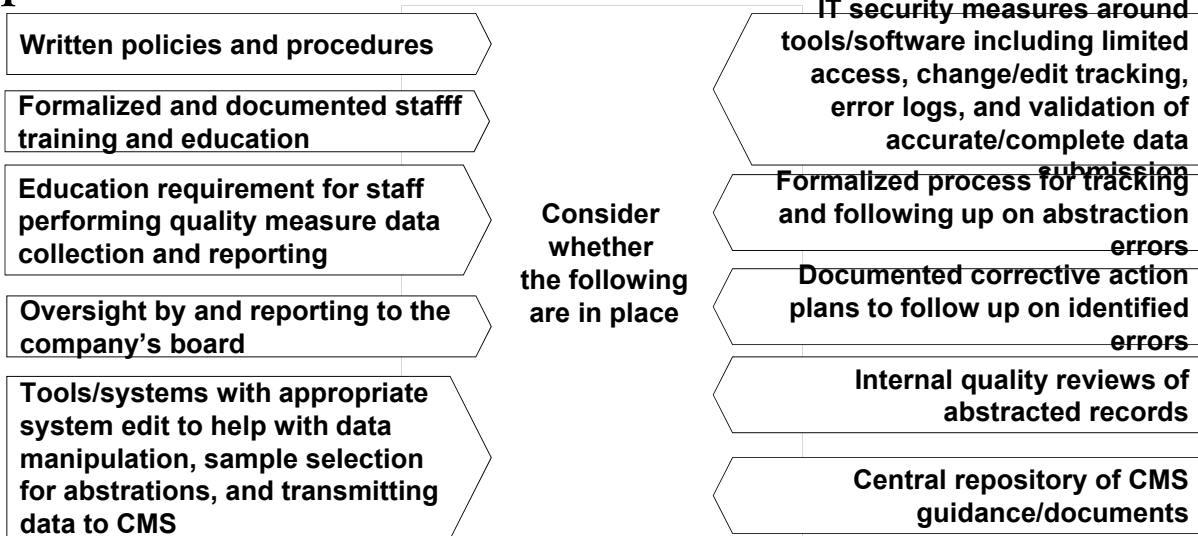
Risk mitigating considerations include but are not limited to:

- Policies and Procedures
- Education and Training
- Performing Independent and Departmental Auditing and Monitoring Activities
- Enabling the EHR Audit Log and Monitoring Capabilities
- Regulatory Environment Awareness
- Tone at the Top – Messaging and Consistency
- Key Stakeholder Collaboration (not just IT and Clinical Leadership)
- Peer Pressure to Collectively Own the Patient's Care
- Consistent, Open, Inclusive Dialogue and Healthy Debate

Intersection of Quality / Payment / EHR Functionality

- Increase in patient convenience = better clinical outcomes
 - E-prescriptions = more compliance with medication regimens
 - Electronic referrals = better access to follow-up care
 - Patient portals = better patient to provider access for inquires / timely access to health information
 - Less repetitive forms and questions = reduction in inconsistent answers; reduced wait times
 - Patient reminders = more knowledge about care / more consistent treatment

Example of assessing quality measure reporting process



28

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What questions should I ask when I go back to work on Monday?

Who?	Who participates?	Who manages / governs?	Who monitors results?	Who audits results?
What?	What is at stake? (\$)	What is the risk of non-compliance?	What are the challenges?	What is the plan?
Where?	Where does the data reside?	Where will the data be stored / archived?	Where will the results be publicized?	Where do Clinicians go for help / questions?
When?	When are the reporting deadlines?	When will we get paid?	When will we be penalized?	When will we be audited?
How?	<p><u>How do we team together to make this work?</u></p> <p><u>How do we ensure that we are compliant?</u></p>			

29

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INTERMISSION

30

Medically Necessary Care

In 1998, the *American Medical Association* published this patient-and-physician oriented definition of “medical necessity”:

Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily ... for the convenience of the patient, treating physician, or other health care provider.

AMA Policy, H-320.953: Definitions of “Medical Necessity.”

31

Medically Necessary Care

- The criterion of “medical necessity” is a fundamental element for both the provision and payment of health care.
- Within Medicare there are coverage categories.
 - Medicare coverage is limited to items and services that are “reasonable and necessary for the diagnosis or treatment of illness or injury.” 42 USC 1395y(a)(1)(A)
 - Medicare requires health care practitioners and providers to assure that health services ordered for government patients are “provided economically and only when, and to the extent, medically necessary.” 42 USC 1320c-5(a)(1)

32

Medically Necessary Care

- Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) Compliance Program for Individual and Small Group Physician Practices. *OIG Compliance Program for Individual and Small Group Physician Practices*, 65 Fed. Reg. 59,434,59,438-39 (Oct. 5, 2000):
 - “A physician practice should be aware that Medicare will only pay for services that meet the Medicare definition of reasonable and necessary.” *Id.* at 59,439.
 - Physicians may “only bill those services that meet the Medicare standard of being reasonable and necessary for the diagnosis and treatment of a patient.” *Id.*

33

Quality Care

- Medicare requires submission of claims that are “of a quality which meet professionally recognized standards of health care.” In addition each claim must be supported by evidence that it is medically necessary and of the appropriate quality. 42 U.S.C. 1320c-5(a)(2)
- Medicaid requires services that “are within accepted professional standards of practice.”*
- TRICARE regulations require that “professional services be provided in accordance with good medical practice and established standards of quality.” 32 C.F.R. §§ 199.4(c)(1)

* Georgia Medicaid Program Part I; section 106(k) (Varies by State).

34

HEALTH CARE BY THE NUMBERS

Number of People who Purchased Healthcare Insurance through the Exchanges:

- Nearly 11.3 million people selected or were automatically reenrolled with the Health Insurance Marketplace from January 1, 2015 to December 26, 2015.
- More than 2.7 million individuals selected plans or reenrolled in 2016 plans through State-Based Marketplaces (SBMs), and 8.5 million selected plans or reenrolled through the Federally-facilitated Marketplace (FFM).

SOURCE: Dept. of Health & Human Services Assistant Secretary for Planning and Evaluation (ASPE) Issue Brief - "HEALTH INSURANCE MARKETPLACES 2016 OPEN ENROLLMENT PERIOD: JANUARY ENROLLMENT REPORT," issued January 2016

35

HEALTH CARE BY THE NUMBERS

Number of New Medicaid Beneficiaries:

- Medicaid and CHIP enrollment increased by over 13.5 million people since open enrollment began for the new Health Insurance Marketplaces in October 2013.
- The enrollment increase does not reflect the 950,000 individuals enrolled under early expansions in 7 states (CA, CO, CT, DC, MN, NJ, and WA), since most individuals enrolled in these expansions were already enrolled in Medicaid by the July-September 2013 comparison period before the ACA.

SOURCE: Kaiser Family Foundation May 2014 issue brief - "How is the ACA Impacting Medicaid Enrollment?"

SOURCE: Dept. of Health & Human Services Center for Medicaid and CHIP Services (CMS) Report - "MEDICAID & CHIP: OCTOBER 2015 MONTHLY APPLICATIONS, ELIGIBILITY DETERMINATIONS AND ENROLLMENT REPORT," issued December 30, 2015

SOURCE: Dept. of Health & Human Services Assistant Secretary for Planning and Evaluation (ASPE) Issue Brief - "HEALTH INSURANCE MARKETPLACE 2015 OPEN ENROLLMENT PERIOD: MARCH ENROLLMENT REPORT," issued March 2015

36

Enforcing Quality Care Through The False Claims Act

Some Say The False Claims Act Was Inspired By Poor Quality:

"For sugar, it often got sand; for coffee, rye; for leather, something no better than brown paper; for sound horses and mules, spavined beasts and dying donkeys; and for serviceable muskets and pistols, the experimental failures of sanguine inventors or the ruse of shops and foreign armories."

United States ex rel. Newsham v. Lockheed Missiles and Space Co., Inc., 722 F. Supp. 607, 609 (N.D. Cal. 1989) (quoting 1 F. Shannon, *The Organization and Administration of the Union Army*, 1861-1865, at 5456 (1965) (quoting Tomes, *Fortunes of War*, 29 *Harpers Monthly Mag.* 228 (1864))).

37

Enforcing Quality Care Through The False Claims Act

- “Fighting health care fraud has been a top priority for the President, the Attorney General and for me here in the Division.”
- For the ... numbers we are announcing today, you’ll see a variety of cases ... (c)ases that go to the heart of providing quality care to our most vulnerable citizens....”

Tony West
Assistant Attorney General for the Civil Division
Pen and Pad Briefing on Civil Fraud Recoveries
November 22, 2010

38

The False Claims Act

- Basic Elements:
 - Submitting or causing to be submitted a false or fraudulent claim for payment;
 - Making a false record or statement material to a false or fraudulent claim in order to secure payment of a claim, or to avoid, decrease or conceal an obligation to transmit money to the Government;
 - Scier: “knew or should have known”, “deliberate ignorance” of truth or falsity or “reckless disregard” of the truth or falsity of the claim;
 - Liability to both those who submit claims, as well as those who cause claims to be submitted, and for conspiring to violate the Act.
- **No specific intent needed.**
- Damages:
 - Treble Damages
 - Civil Penalties \$5,500-11,000 per claim*.
- Additional Risks:
 - Exclusion from participation in Federal healthcare programs.
 - Corporate Integrity Agreement

39

Qui Tam Relators

The federal False Claims Act is a *qui tam* statute, meaning that private citizens (“relators”) may file complaints alleging violations of the FCA under seal on behalf of the U.S. Government and receive at least 15%, but not more than 25%, of any amount recovered.

Once a whistleblower files a suit, the Department of Justice must decide whether to “intervene” (i.e., take over and prosecute the suit).

If the government does not intervene, the case is unsealed and the whistleblower may proceed on his/her own.

31 U.S.C. §3730(b)

40

Whistleblowers Setting The Agenda

(Current) Assistant Attorney General for the Civil Division, Joyce R. Branda, May 15, 2014:

“Amendments to the False Claims Act in 2009 and 2010 have radically shifted the civil-fraud landscape; since then, the number of *qui tam* complaints has increased to the point where they dominate the focus of the DOJ’s civil commercial branch.”

“It’s a clear and unmistakable result of the statute,” Branda said. “There’s no question it has brought cases of complex corporate wrongdoing we otherwise wouldn’t know about.”*

FY 2015

- 638 FCA cases filed by whistleblowers
 - \$2.8 billion recovered from whistleblower cases.
 - \$597 million paid in whistleblower awards.
 - \$1.1 billion recovered from whistleblower cases declined by the Government.

* (<http://www.law360.com/articles/538432/health-fraud-whistleblowers-drive-doj-agenda-official-says>)

41

False Claims Act Enforcement – By The Numbers

- FY 2015 Recoveries
 - More than \$3.5 billion in FCA recoveries (settlements and judgments)
 - \$1.9 billion from healthcare cases
 - 638 whistleblower suits filed in FY 2016
 - \$2.8 billion recovered
 - \$597 million whistleblower awards
 - \$1.15 billion from declined cases

42

Recent Legislation Makes Enforcement Easier Through The False Claims Act

- FERA and ACA enacted significant changes to the FCA.
- Lowered the bar for prosecutors and *qui tam* whistleblowers in FCA cases:
 - Lowered public disclosure standard.
 - Amended the “original source” provisions.
 - Expanded conspiracy liability.
- Expanded the scope of “reverse false claims”.
 - “Improper” retention of overpayments.
 - Overpayments must be reported and returned to the government within 60 days of “identification” or becomes actionable under the FCA. CMS has yet to issue a final rule on reportable overpayments.

43

ACA Presents Increased Risk Of False Claims Act Exposure – Fraud In The Exchanges

- ACA specifically provides that payments made by, through, or in connection with an Exchange are subject to the False Claims Act “if those payments include any Federal funds”. [Section 1313(a)(6) of the ACA]
 - “Funds” include tax credits and cost sharing reductions.
 - Increases damages to no less than three (3) and no more than six (6) times the amount of damages the Government sustains.

44

“Reverse” False Claims - Health Reform and Overpayments

The Patient Protection and Affordable Care Act (“ACA”) requires any person who has received “an overpayment” to return it, and report the reason for the overpayment, to the payor within 60 days after the overpayment was “identified,” or the date the any corresponding cost report is due, whichever is later.

Overpayment is defined as “any funds that a person receives or retains . . . to which the person, after applicable reconciliation, is not entitled.”

Penalties can be imposed on anyone who “knows of an overpayment” and fails to report and return it.

Under this law, the retention of an overpayment beyond 60 days constitutes an “obligation” within the meaning of the FCA.

Became effective upon enactment of ACA on March 23, 2010.

45

Overpayments:

Final Rule Published February 12, 2016

- In Parts A & B:

1. Report and Return Overpayments with 60 days of “Identification”

- The 60 day clock does not start to run until after reasonable diligence and quantification of the alleged overpayment.

- Presumptive Period - 6 Months.

2. 6 year look back period for retrospective overpayment reviews.

46

Enforcement Trends Reflect A Focus On Quality And Medical Necessity

- More Cases Filed
- More Inquiries
- More Referrals
- More Investigations
 - Use of multi-agency data to identify outliers
- More Prosecutors and Agents
- Bigger Budgets
- More Cases Pursued By Whistleblowers

47

Enforcing Quality Of Care Through The False Claims Act

Theories:

- False Certification – Express and Implied
- Quality of Care and Medical Necessity
 - Worthless Services
 - Inadequate Services

48

False Certification

- Express False Certification
 - Allegation that party falsely certified compliance with a statute, rule or regulation in connection with a submission for payment.
- Implied False Certification
 - In submitting a claim, a party is impliedly certifying compliance with statutes/rules/regulations that are a precondition to payment.

49

False Certification

Is it a: Condition of Participation or Condition of Payment

Condition of Payment:

- Submitting claim only certifies compliance with quality requirements that are a condition of payment.
- Rule/Regulation must expressly state that compliance therewith is a condition of payment.

50

Express False Certification

US ex. rel Riley v. St. Luke's Episcopal Hospital, 355 F.3d 370 (5th Cir. 2004)

- Hospital submitted Medicare claim forms stating that the “services on this form were medically necessary for the health of the partners.”
- Relator alleged the claim that these certifications were false – services were not medically necessary.
- Fifth Circuit – hospital executed claim forms that were knowingly false.

51

Implied False Certification

US ex. rel. Mikes v. Straus, 274 F.3d 687 (2nd Cir. 2001)

False Certification Theory

- 42 USC § 1320c-5(a)
 - Relator alleged that services were not “of a quality which meets professionally recognized standards of care”.
 - Alleged that compliance with this obligation was a prerequisite for reimbursement under Medicare.
 - ❑ Court rejected Relator’s theory.
 - ❑ Found it would improperly broaden the reach of the False Claims Act
 - “[I]mplied false certification is appropriately applied only when the underlying statute or regulation expressly states that the provider must comply in order to be paid.
 - 42 § 1320c-5(a) establishes conditions of participation, not prerequisites to payment.

52

Implied False Certification

Ebeid ex. rel. United States v. Lungwitz, 616 F. 3d 993 (9th Cir. 2010)

- Court adopted implied false certification theory.
- Compliance with Stark was both material and a condition precedent to the government’s decision to pay.
- Compliance with 42 CFR § 424.22(d) (physician certification requirement) was material and a condition precedent to payment.
- But, Relator’s allegations were deficient under 9b.

53

Implied False Certification: 2015 Cases

United States ex rel. Badr v. Triple Canopy, Inc., No. 13-2190, 775 F.3d 628 (4th Cir. Jan. 8, 2015).

- Fourth Circuit recognized for the first time the implied certification theory of FCA liability.
- “The Government pleads a false claim when it alleges that the contractor, with the requisite scienter, made a request for payment under a contract and withheld information about its noncompliance with material contractual requirements.”
- “The pertinent inquiry is whether, through the act of submitting a claim, a payee knowingly and falsely implied that it was entitled to payment.”
- “[c]ourts [may] infer implied certifications from silence where certification was a prerequisite to the government action sought.”
- Noted “that this theory is prone to abuse by parties seeking to turn the violation of minor contractual provisions into an FCA action.”

54

Implied False Certification: 2015 Cases

United States v. Sanford-Brown, Limited, No. 14-2506, 788 F.3d 696 (7th Cir. June 8, 2015).

- Seventh Circuit declined to adopt the implied false certification theory to establish liability under the False Claims Act.
- Agreed with the district court’s finding that compliance was a condition of *participation* in the program, but not *payment*.
- Noted that any violations – as alleged here – were better dealt with through an administrative proceeding.

55

Implied False Certification: 2015 Cases

U.S. ex re. Ligal, et. al v. Esco Technologies, Inc., et. al No. 14-23067 (5th Cir. Aug. 4, 2015)(unpublished decision).

- Fifth Circuit affirmed without oral argument the dismissal of an FCA implied certification claim for failure to comply with Rule 9(b).
- A false certification theory can succeed only “only when certification is a *prerequisite* to obtaining payment from the government.”
- Relators’ complaint failed to identify any specific statute, regulation, or contract provision providing that compliance with the applicable standards, “let alone certification of compliance,” was a prerequisite to the government’s payment.

56

Implied False Certification: 2015 Cases

Universal Health Services, Inc. v. Escobar, 780 F.3d 504 (1st Cir. 2015)

- *Escobar* alleged daughter treated by unlicensed/unsupervised staff and that bills for care were resultantly fraudulent
- District Court dismissed complaint, holding that elements of falsity had not been sufficiently pled – compliance with regulations not a condition of payment
- 1st Circuit reversed – held that pleading sufficient based on implied certification test and compliance with regulations was a condition of payment.
- Petition for *Certiorari* Granted – Questions Presented:
 - Is the implied certification test valid?
 - If yes, does the relevant statute need to explicitly state the conditions of payment with which defendant must comply?

57

False Certification Cases and Quality

- Anticipate that relators and the government will push FCA cases into substandard care allegations involving services provided by
 - acute care hospitals,
 - outpatient specialty clinics, and
 - providers that bill on an itemized fee-for-service basis.

58

False Certification Cases – Key Defense Arguments

- Submitting claims for payment only certifies compliance with requirements that are a condition of payment.
- Can only imply certification if the quality provision relied upon expressly states that compliance therewith is a condition precedent to payment.

59

Worthless Services

- Knowing submission of a claim for reimbursement for a procedure with no medical value violates the FCA , regardless of any certification.
- “Worthless Services” are services so deficient in quality as to constitute no service at all.

60

Worthless Services Cases

US ex. rel. Mikes v. Straus, 274 F.3d 687 (2nd Cir. 2001)

- Second Circuit held that worthless services is a distinct claim under the FCA.
- It is effectively derivative of an allegation that a claim is factually false because it seeks reimbursement for a service not provided.
 - The services are “so deficient that for all practical purposes it is the equivalent of no performance at all”.
- Defendants submitted Medicare claims for spirometry; Relator alleged that the services were substandard because the spirometer was not properly calibrated.
- Defendants submitted evidence that they relied upon the spirometer instruction manual which provided that it was properly calibrated at the time of shipment and a product information book indicating that it was calibrated according to Federal regulations. Additionally, the spirometer was sent out once for recalibration and no issues found.
- Court found ample evidence that there was medical value to the tests.

61

Worthless Services - Recent Cases

- *U.S. ex rel. Absher v. Momence Meadows Nursing Center*, Nos. 13-1886 §13-1936 (7th Cir. 2014).
 - Relators alleged failure to provide care and inadequate records
 - Jury verdict \$28mm, reduced by Court to \$9mm.
 - 7th Circuit vacated.
 - ❑ Not enough to offer evidence that services provided were “worth less” than services billed and paid for.
 - ❑ Diminished value not a basis for a worthless services claim.

See also - U.S. ex rel. Wall v. Circle C Construction, No. 14-6150 (6th Cir., Feb 4, 2016).

62

Worthless Services – 2015 Cases

U.S. ex rel. Bellevue v. Universal Health Services of Hartgrove, Inc., No. 1:2011 cv 05314 (N.D. Ill. October 5, 2015)

- Dismissal of false Medicaid claims FCA case.
- Allegation: Housing patients in dayrooms with rollaway beds, rather than individual rooms.
 - Does not constitute worthless services.

63

FCA And Value Based Purchasing

U.S. ex rel. Duffy v. Lawrence Memorial Hospital, No. 2:14-cv-02256 (D.KS.)

- Allegation: Hospital submitted false IQR and OQR reports.
 - Some measures tracked on IQR and OQR connected to reimbursement under Value Based Purchasing Program.
 - Designed to increase higher incentive payments.
- Government declined; relator pursued and matter currently in discovery stage.

64

INTERMISSION

65

NEW RISKS

The Yates Memorandum

On September 9, 2015, Deputy U.S. Attorney General Sally Quillian Yates issued a memorandum to all DOJ attorneys entitled “Individual Accountability for Corporate Wrongdoing” (the “Yates Memo”).

Addresses “how the Department approaches corporate investigations, and identified areas in which it can amend its policies and practices in order to most effectively pursue the individuals responsible for corporate wrongs.”

66

NEW RISKS

The Yates Memorandum – Key Provisions

Corporations must provide all relevant facts about individuals involved;

Both criminal and civil corporate investigations should focus on individuals from inception;

Criminal and civil attorneys should be in routine communication;

Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for individuals;

Corporate cases should not be resolved without a clear plan to resolve related individual cases; and

Civil attorneys should consistently focus on individuals as well as the company.

67

NEW RISKS

The Yates Memo In Action?

10/29/15 - DOJ announces Warner Chilcott's agreement to pay \$125 million to resolve criminal and civil liability arising from alleged illegal marketing of certain drugs.

Same day, DOJ announces the indictment of a former Warner Chilcott president with conspiring to pay kickbacks to physicians to induce them to prescribe the company's drugs.

DOJ Press Release: "Today's enforcement actions demonstrate that the government will seek not only to hold companies accountable, but will identify and charge corporate officials responsible for the fraud."

68

How Can You Prepare Proactively for Quality of Care and Medical Necessity Investigations and Litigations?

- Listen To and Investigate Complaints
- Education
- **Build Relationships**
- Coordination and Oversight of Peer Review and Compliance Functions
- Set Up Processes For Your Response
- Test Your Processes

69

Listen To and Investigate Complaints and Criticisms

- Must have systems in place to carefully monitor complaints.
 - RM/Grievance process for patients
 - Integrity Hotline
 - Recognize that compliance and risk management functions are different.
- Need for systems and to review results
 - How do you determine what to monitor?

70

Education

- Staff needs to be educated about, and be sensitive to, quality of care and medical necessity issues.
 - Including risks to the organization and individual provider – Yates Memo.
 - Providers need to appreciate the connection between quality and enforcement efforts.
- Need to monitor NCD's, LCD's, Proposed Rules, reported cases, settlements, OIG Work Plan.
- Clear and accurate documentation is critical.
- Process if they detect an issue
- Impact of ICD-10?

71

Coordination and Oversight of Peer Review and Compliance Functions

- The Peer Review Function
 - Protect brand health & maintain standard of care
- Should/how/can this be used to address quality of care issues?
 - PSO vs. Attorney Client Privilege
- Ensure Peer Review has access to needed resources.
- Is it a "Quality of Care" or "Standard of Care" issue?
 - Are the terms synonymous?
 - If there is a "bad result" - does that mean you have a potential overpayment?

72

Set Processes and Test Those Processes

- Set up Processes that implement the best elements of compliance and peer review's functions to to avoid government scrutiny.
- Audit/Track outcomes for early detection of quality issues
- Need to address quality issues promptly and in a documented fashion.
 - But what about confidentiality issues?
- Compliance can educate Peer Review about needed processes, assessment, review and other functions.

73

HOW CAN YOU PROTECT YOURSELF AND YOUR BUSINESS? Mandatory Compliance

Section 6401 of ACA (Medicare/Medicaid/CHIP suppliers/providers)

- Mandates compliance programs for Medicare/Medicaid/CHIP providers and suppliers as condition of enrollment.
- Compliance program must contain “core elements” to be determined by Secretary.
- Implementation date for providers/suppliers required to have compliance program in place to be determined by Secretary.
- Secretary to determine scope of requirement for particular industry sector.

74

Compliance and DOJ – A New Hire

On 11/3/15, DOJ announced the hiring of a full-time compliance expert **Hui Chen** to assist DOJ in:

- determining whether corporations subject to DOJ investigation have maintained a good faith compliance program.
- developing benchmarks for evaluating corporate compliance and remediation measures.
- Setting the standard for what an “effective compliance program” should look like given size and resources of your organization.

75

Compliance and DOJ – Compliance Metrics

- Does the corporation ensure that its officers, board members, directors and managers offer strong support for corporate compliance policies?
- Do compliance department staff have authority within the company?
 - Are the compliance teams adequately funded and able to access needed resources?
 - Do they have a seat at the table?
- Are compliance policies clear, in writing and accessible?
 - Are they easily understood by employees?
- Are the compliance program guidelines effectively communicated to employees?
 - Do employees get repeated training?

76

Compliance and DOJ – Compliance Metrics

- Are the compliance policies subject to periodic review and updated as to evolving risks and circumstances?
 - Policy “review” annually?
- Do mechanisms exist to enforce the compliance policies, is compliance incentivized, and are violators likely disciplined on an even-handed basis?
 - Manager attestation
- Are third parties (e.g., vendors, agents, consultants) informed of (and held accountable for) compliance expectations?
 - Template contract language
 - BAA Agreements

77

Key Takeaways

- Government focus on quality and value has never been higher.
- Government is using the False Claims Act to enforce Quality and Medical Necessity.
 - Administration/ Compliance/In-House Counsel have critical roles to play.
 - Practitioners need to appreciate risk areas (individual enforcement / exclusion) and be involved in compliance from the outset.
 - Need to change the “not my problem” paradigm.
 - ❑ It is not just about money!
 - Need to be proactive with education and compliance efforts - Receipt of a subpoena is too late!

78

Key Takeaways

Who Needs to Be Involved?

Providers

Corporate Executives, including in-house counsel

Chief's of Medicine

Quality Committees

Standards Committees

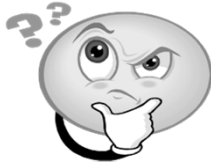
Compliance

79

Key Takeaways

- Proactive tracking and trending.
 - Local, regional and national.
 - If an outlier, medical case documentation and hospital documents should proactively support outlier status.
- Company determination of appropriate standards of care.
- Commonly accepted, defined and used markers for demonstration of medical necessity.
- Development of processes to proactively know circumstances when medically necessary care diverges from payor coverage guidelines.

80



QUESTIONS?

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81