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Meet the Presenters…

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I. Introduction

- **Compliance v. Ethics**
  - **Compliance** has to do with the adherence to laws, regulations, standards and mandates. Strictly speaking, remaining “compliant” does not require a medical professional to engage in the moral calculation of what is “right” or what is “wrong.”
  
  - **Ethics** involves rules of conduct. Ethics are moral codes which guide us in determining what is “right” and what is “wrong.”
  
  - Compliance violations of government regulatory or statutory requirements can result in administrative, civil and / or criminal sanctions.
I. Introduction

• Compliance v. Ethics

- In many industries, violations of an individual's ethical obligations will not typically result in administrative sanctions. Health care is different.

- Licensed medical professionals are regularly sanctioned by State Medical Boards, Professional Societies and other industry groups. Depending on the facts, these sanctions can result in the suspension or revocation of one's medical license, membership in an organization and certification status.

- As medical professionals, you are required to comply with applicable regulatory and statutory requirements AND meet the ethical obligations imposed on the industry as a whole and your profession in particular.

HHS-OIG has develop various types of compliance program guidance based on the agency’s belief that:

“... a health care provider can use internal controls to more efficiently monitor adherence to applicable statutes, regulations and program requirements.”

With respect to the ethical duties of a medical practice's employees, HHS-OIG has written that:

“A compliance program also sends an important message to a physician practice’s employees that while the practice recognizes that mistakes will occur, employees have an affirmative, ethical duty to come forward and report erroneous or fraudulent conduct, so that it may be corrected.”
I. Introduction

• Among the various duties to be assigned to a practice’s Compliance Officer, one of the key responsibilities is for the Compliance Officer to:

“Investigate any report or allegation concerning possible unethical or improper business practices, and monitoring subsequent corrective action and/or compliance.”


• Notably, health care enforcement efforts are not limited to only Strike Force territories. Each of the 94 U.S. Attorneys Offices around the country have dedicated civil and criminal prosecutors investigating health care fraud and abuse matters.

- During FY 2015, the federal government won or negotiated over $3.5 billion in judgments and settlements under the False Claims Act. Of this total, $1.9 billion came from individuals and entities in the health care industry.

- Since January 2009, the federal government has recovered $16.5 billion from health care fraud cases brought under the civil False Claims Act.
I. Introduction

- During FY 2015, DOJ opened 963 new criminal fraud cases and filed criminal charges in 463 cases.
- Last fiscal year, DOJ opened 808 new civil health care fraud cases.
- Administratively, during FY 2015, HHS-OIG excluded 4,112 individuals and entities from participating in the Medicare, Medicaid and other federal health care programs.

Impact of the “Yates Memo”

On September 9, 2015, Deputy Attorney General Sally Yates issued a Memorandum entitled:

“Individual Accountability for Corporate Wrongdoing”

This important document instructs DOJ prosecutors to stop resolving corporate cases that release individuals from personal liability, absent extraordinary circumstances.
I. Introduction
Impact of the “Yates Memo”

• While individual defendants have occasionally been prosecuted, over the past decade, most DOJ prosecutors have focused on seeking large financial fines and penalties from corporations.

• On September 9, 2015, Deputy Attorney General Sally Yates issued a Memorandum entitled “Individual Accountability for Corporate Wrongdoing.” This historic document instructs DOJ prosecutors to stop resolving corporate cases that release individuals from personal liability, absent extraordinary circumstances.

I. Introduction
Impact of the “Yates Memo”

• As the Yates Memo requires:
  ❖ Corporations will be eligible for cooperation credit only if they provide DOJ with “all relevant facts” relating to all individuals responsible for misconduct, regardless of the level of seniority.

  ❖ Both criminal and civil DOJ investigations should focus on investigating individuals “from the inception of the investigation.”

  ❖ Criminal and civil DOJ attorneys should be in "routine communication" with each other, including by criminal attorneys notifying civil counterparts "as early as permissible" when conduct giving rise to potential individual civil liability is discovered (and vice versa).
I. Introduction
Impact of the “Yates Memo”

• As the Yates Memo requires (continued):
  ❖ “Absent extraordinary circumstances,” DOJ should not agree to a corporate resolution that provides immunity to potentially culpable individuals.
  ❖ DOJ should have a “clear plan” to resolve open investigations of individuals when the case against the corporation is resolved.
  ❖ Finally, civil attorneys should focus on individuals as well, taking into account issues such as accountability and deterrence in addition to the ability to pay.

DOJ now places a significant weight on the role of Compliance Officers: On November 2, 2015 (shortly after the Deputy Attorney General issued what is now known as the “Yates Memo”), Leslie Caldwell, Assistant Attorney General for the Criminal Division, addressed a group of compliance, financial and legal professionals at a conference in New York. As she noted at that time:

“You are often the first line of defense against money laundering and other financial crimes. Prosecutors cannot be everywhere, and by the time the Criminal Division gets involved, it’s usually too late to stop criminal activity. Well before a grand jury subpoena is served or a witness is interviewed, compliance officers like you can and do step in and stop issues from becoming problems down the road.”
I. Introduction
Issuance of the “Yates Memo”

• As much as full-throated compliance programs are essential to preventing fraud and corruption, the quality and effectiveness of a compliance program is also an important factor that prosecutors consider in determining whether to bring charges against a business entity that has engaged in some form of criminal conduct. In this after the fact review, the department looks closely at whether compliance programs are simply “paper programs,” or whether the institution and its culture actually support compliance.”

II. How Would You Handle the Following?

Scenario: Your practice physician examines a patient and determines that care is medically necessary. However, the physician is concerned that if her correctly codes a procedure, it won’t qualify for coverage and payment by the responsible payor. The physician is therefore faced with “upcoding” a service or treatment, exaggerating the severity of the patient’s condition OR likely submitting a claim that won’t be paid by the payor.
II. How Would You Handle the Following?

- If a physician exaggerates the severity of a patient’s condition or the symptoms presented in order to get a claim covered, what would you do?
- Is the physician’s conduct a compliance violation?
- Is the physician’s conduct an ethical violation?
- If a physician exaggerates the severity of a patient’s condition or the symptoms presented in order to get a claim covered, do you have a legal obligation to report this compliance violation?
- Do you have an ethical obligation to report this compliance violation?

Survey Results for Survey

Survey Data Courtesy of Medscape
II. How Would You Handle the Following?

Scenario: Your practice physician examines a patient and determines that a specific invasive procedure is not clearly medically required. Nevertheless, in rare cases, this invasive modality could prove helpful in addressing a patient’s medical condition. Your physician is concerned that unless every treatment option is pursued, the patient’s family will sue him for malpractice, despite the fact that this invasive procedure is not medically necessary.

II. How Would You Handle the Following?

- If a physician performs an unnecessary operation, is this conduct a violation of the physician’s and / or practice’s compliance obligations?
- Is the physician’s conduct an ethical violation?
- Are you potentially liable if you “knowingly” process practice claims for services that are medically unnecessary?
II. How Would You Handle the Following?

Procedures and Malpractice Fear
By Profession

- Neurology 27%
- Emergency Medicine 26%
- Radiology 25%
- Pathology 24%
- Gastroenterology 24%
- Anesthesiology 23%
- Cardiology 23%
- Dermatology 22%
- Urology 22%
- Allergy & Immunology 21%
- Plastic Surgery 21%
- Orthopedics 20%
- Family Medicine 20%
- Internal Medicine 19%
- OB/GYN & Women's Health 19%
- Nephrology 19%
- General Surgery 18%
- HIV/AIDS 18%
- Pulmonary Medicine 19%
- Oncology 18%
- Ophthalmology 18%
- Rheumatology 18%
- Hematology 18%
- Critical Care 17%
- Psychiatry & Mental Health 16%
- Diabetes & Endocrinology 16%
- Pediatrics 15%
II. How Would You Handle the Following?

**Scenario:** Understandably, your physician is frustrated by the fact that reimbursement rates are steadily declining each year – despite the fact that unfunded mandates imposed on the practice (such as HIPAA compliance) are rising.

As the nonpartisan Congressional Budget Office (CBO) has written:

“*Considerable evidence suggests that a reduction in payment rates leads physicians to increase the volume and intensity of services they perform.*”


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II. How Would You Handle the Following?

- This has led to shorter visits and less direct-patient care time. In some instances, it has inadvertently resulted in overscheduling and overstating the E/M level of service administered. Does your physician sometimes “upcode” a claim for reasons other than getting the payor to pay for the services rendered (i.e. to increase reimbursement)?

- Is the physician’s conduct a compliance violation?

- Is the physician’s conduct an ethical violation?

- Are you potentially liable if you “knowingly” process practice claims for services that have been improper coded?
II. How Would You Handle the Following?

Scenario: Your practice is a participating provider in a number of government and private payor plans, several of which are managed care plans. Each year, your practice is “rated” by the managed care plan based on the physician’s utilization practices.
II. How Would You Handle the Following?

❖ Would your physician purposely avoid prescribing some treatment modalities because he or she fears being penalized by the managed care plan?
❖ Is the physician’s conduct a compliance violation?
❖ Is the physician’s conduct an ethical violation?
❖ Are you potentially liable if you “knowingly” process practice claims for deficient or medically inadequate services?

II. How Would You Handle the Following?

Avoiding Treatment If Facing A Penalty?

- Yes 19%
- No 8%
- It Depends 73%

Survey Data Courtesy of Medscape
II. How Would You Handle the Following?

- You show up for work and suspect that a caregiver is “impaired.” What are your legal obligations? What are your ethical obligations?
- A family member is pressuring the physician to “withhold” medically necessary from an elderly patient without a DNR order on file?
- A patient discloses that she intends to go to another physician’s office to obtain a second prescription for pain medications, even though your practice physician has already issued such a prescription?
- A physician instructs you to waive the collection of a patient’s deductible due to the fact that the patient's husband is a referral source.
- You witness a co-worker stealing cash from the petty cash box maintained by the practice. What are your obligations?

III. Ultimately, Mere “Compliance” With the Law Isn’t Enough

- Merely complying with the law isn't enough. Ethics are a key component to the success of your practice.
- Don’t make the mistake of confusing “Form” over “Substance.” A beautifully written, comprehensive Compliance Plan, incorporating both a practice’s legal and ethical obligations is worthless if it sits in a drawer and isn’t an integral part of your day-to-day operations and your overall compliance efforts.
- Every practice is unique. A Compliance Plan that has been specifically developed to address your practice’s unique needs (and recognizes the specific legal and ethical risks your organization may face) is essential. Copying a sample off of the internet isn’t sufficient to meet your obligations – in fact, it may even heighten your potential liability.
III. Ultimately, Mere “Compliance” With the Law Isn’t Enough

- **Merely complying with the law isn’t enough. Ethics are a key component to the success of your practice (continued).**
  
  - An effective Compliance Plan is a work in progress. An effective Compliance Plan is a living, breathing document. It is applied as you run your practice on a daily basis. As statutory, regulatory or operational changes occur, you are reviewing, revised and updating your plan to better ensure that any changes have been incorporated into your plan. Similarly, what are the ethical and / or “professionalism” mandates required by State Medical Boards and Professional Societies”

- **Detailed policies and procedures can provide essential guidance to your staff.** Through the active reference and application of your practices policies and procedures, statutory and regulatory compliance can be achieved and maintained. Well thought-out policies and procedures can assist in streamlining your organization’s business operations, reduce the likelihood of statutory violations, help avoid ethical breaches, and serve as evidence that your organization is doing its best to fully comply with applicable rules and regulations.
III. Ultimately, Mere “Compliance” With the Law Isn’t Enough

- Merely complying with the law isn’t enough. Ethics are a key component to the success of your practice (continued).

- An effective Compliance Plan can lead to patient care improvements. When compliance begins to be a part of the daily culture of your organization, you can better serve your patients and stay within both the four corners of the law and the ethical obligations of your profession.

- Does your practice currently have a Compliance Program in place? Is one required? Does your practice take Medicaid? If so, it is imperative that you review your state’s Medicaid participation agreement. In recent years, most states have revised their Medicaid participation agreements to require that participating providers certify that they have implemented a Compliance Program.
III. Ultimately, Mere “Compliance” With the Law Isn’t Enough

• Using Texas an example:

   Pursuant to the Texas Medicaid Provider Enrollment Application, prospective Texas Medicaid providers must attest to its Compliance Program Requirement. Under this condition, a provider must verify that in accordance with requirement TAC 352.5(b)(11), the provider has a Compliance Program containing the seven core elements as established by the Secretary of Health and Human Services referenced in §1866(j)(8) of the Social Security Act (42 U.S.C. §1395cc(j)(8)), as applicable.

• Using Texas an example (continued):

   Texas Medicaid providers are not required to affirmatively attest that the provider (or supplier) has a Compliance Program in place prior to submitting an application for enrollment.

   Did you simply check the box “YES,” without even realizing that a Compliance Program is required under this section? A resulting audit of your practice could result in serious penalties for failure to comply and for falsification of an application.
III. Ultimately, Mere “Compliance” With the Law Isn’t Enough

• What does the Affordable Care Act provide for in terms of Compliance Programs / Plans?
  
  ❖ Under the Affordable Care Act, the Secretary, HHS can mandate that ALL participating providers (including Medicaid providers) and suppliers implement an effective Compliance Program.
  
  ❖ While a firm date to meet this requirement has not been announced for health care providers, recent enforcement cases have made it clear that providers without an effective plan in place are already being held accountable for their failure to take steps to avoid regulatory violations.

III. Ultimately, Mere “Compliance” With the Law Isn’t Enough

• What does this mean for your practice?
  
  ❖ Given the fact that having a Compliance Plan is inevitable, small and mid-sized private duty agencies should take the steps to implement a plan now, before it is forced upon them within a short timeframe.
  
• What should expect from private payor plans in the future?
  
  ❖ Health care providers should care read the private payor agreements they have signed. Over the past year, we have identified a number of private payor participation agreements that now require that a participating provider have a Compliance Plan in place.
III. Ultimately, Mere “Compliance” With the Law Isn’t Enough

• How did you obtain your current Compliance Plan?

   We don’t have a Compliance Plan.
   Our current plan is based on a “sample” we found on the internet.
   We obtained a copy of another practice and drafted a similar one for our organization.
   We contacted DK. He reviewed our practice and developed the Compliance Plan we now use in our office.
   We hired Liles Parker to audit our practice and assist us in putting a Compliance Plan into place.

Don’t fall victim to consultants who discourage the implementation of an effective Compliance Plan or Compliance Program. Consultants promoting this idea promote the argument that since you did not “know” that a practice was improper, it will be more difficult to hold you liable for a violation. Frankly, this argument is just plain wrong, especially for home care providers who participate in Medicaid.
III. Ultimately, Mere “Compliance” With the Law Isn’t Enough

- Under the civil False Claims Act, “knowingly” is defined as (a) actual knowledge, (b) deliberate ignorance or (c) reckless disregard. Therefore, ignoring the issue is tantamount to sticking your head in the proverbial sand, like an ostrich. This is the same as acting in “deliberate ignorance.” This approach would clearly qualify as having knowledge under the False Claims Act.

- Get back to basics. Work through each of the seven elements, conduct a “GAP” analysis and pay back any monies that you owe.

IV. Building an Effective Compliance Plan / Compliance Program

- HHS-OIG has identified seven fundamental elements to an effective Compliance Program. These elements would be applicable for your private duty agency even if you do not take Medicaid.
- These elements include:
  - **Element 1:** Implementing written policies, procedures and standards of conduct.
  - **Element 2:** Designating a compliance officer and compliance committee.
  - **Element 3:** Conducting effective training and education.
  - **Element 4:** Developing effective lines of communication.
  - **Element 5:** Enforcing standards through well-publicized disciplinary guidelines.
  - **Element 6:** Conducting internal monitoring and auditing.
  - **Element 7:** Responding promptly to detected offenses and developing corrective action.
QUESTIONS

• This outline is provided for educational purposes and general information only. It does not constitute legal advice nor does it create an attorney-client relationship. This information should not be used as a substitute for seeking qualified health care legal counsel.

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