AHC Media

Friday, July 17th, 2015

Joint Guidance for Hospital and Health Care Board Compliance

Speaker

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Objectives

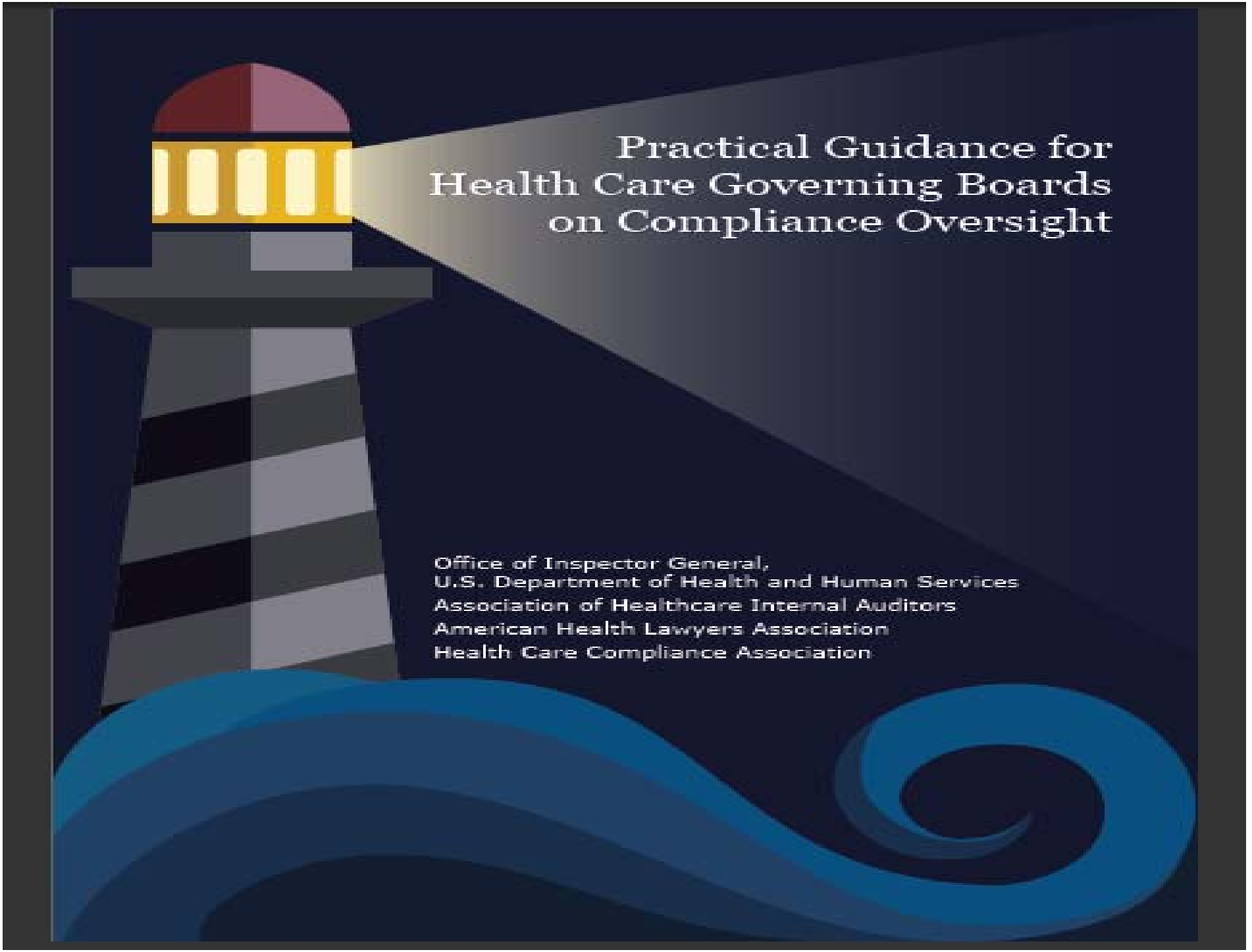
1. Describe how hospital and healthcare boards can foster a culture of compliance to protect the integrity of their compliance program.

2. Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.

3. Evaluate compliance requirements and penalties.

Practical Guidance for Boards

- Full name is the Practical Guidance for Health Care Governing Boards on Compliance Oversight
- Sponsored by:
  - Office of Inspector General (OIG)
  - U.S. Department of Health and Human Services (HHS)
  - Association of Healthcare Internal Auditors (AHIA)
  - American Health Lawyers Association (AHLA)
  - Health Care Compliance Association (HCCA)


Practical Guidance for
Health Care Governing Boards
on Compliance Oversight
Office of Inspector General,
U.S. Department of Health and Human Services
Association of Healthcare Internal Auditors
American Health Lawyers Association
Health Care Compliance Association

Practical Guidance for Boards

- 19 page document
- First published April 20, 2015
- First collaboration of its kind between these groups; HHS OIG, AHLA, AHIA, and HCCA
- This is a joint educational resource to assist boards of hospitals and other health care organizations to carry out their compliance oversight obligations
  - Document available at no charge at http://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf

Practical Guidance for Boards

- Document also found at:
  - www.healthlawyers.org
  - www.hcca-info.org
  - www.ahia.org
- Provides practical advise that boards can adopt in their hospitals
- Guidance helps to identify risk, tool for improvement to the compliance program's objectives, and effective reporting tools for board meetings

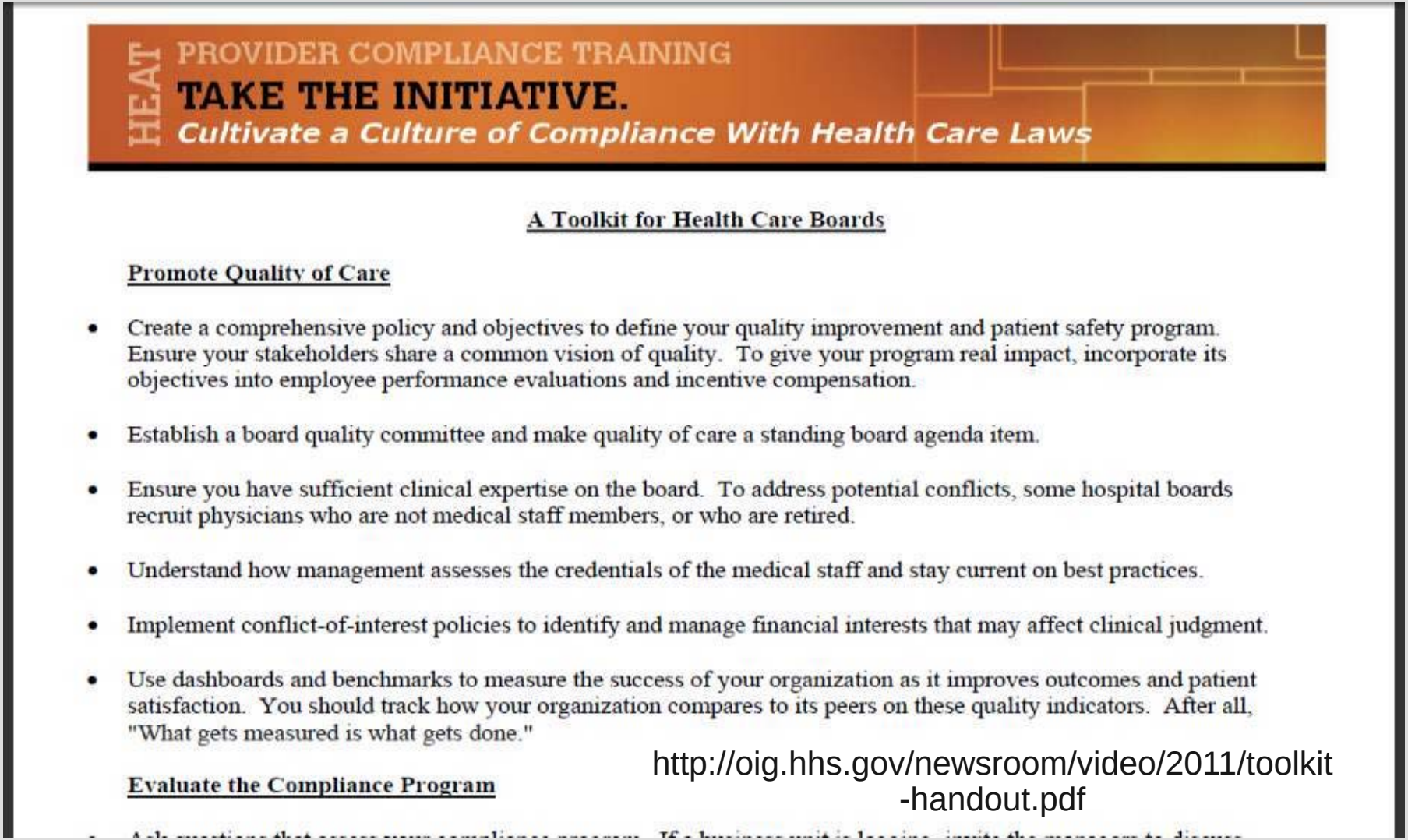
Practical Guidance for Boards

- This document will also help the hospital compliance officer, internal auditors, and attorneys who report to the board
- This document shows the relationship between the internal audit, compliance, and legal functions of the hospital or healthcare compliance program
- The board is ultimately responsible for everything that happens in the hospital or healthcare organization including compliance activities

Other OIG Important Documents

- The OIG has a number of other important documents for board members and compliance officers
- Handout: A Toolkit for Health Care Boards
- The Healthcare Director's Compliance Duties; A Continued Focus of Attention and Enforcement
- Driving for Quality in Acute Care: A Board of Directors Dashboard
- Corporate Responsibility and Healthcare Quality- A Resource for Health Care Boards of Directors

A Toolkit for Healthcare Boards



HEAT
PROVIDER COMPLIANCE TRAINING
TAKE THE INITIATIVE.
Cultivate a Culture of Compliance With Health Care Laws

A Toolkit for Health Care Boards

Promote Quality of Care

- Create a comprehensive policy and objectives to define your quality improvement and patient safety program. Ensure your stakeholders share a common vision of quality. To give your program real impact, incorporate its objectives into employee performance evaluations and incentive compensation.
- Establish a board quality committee and make quality of care a standing board agenda item.
- Ensure you have sufficient clinical expertise on the board. To address potential conflicts, some hospital boards recruit physicians who are not medical staff members, or who are retired.
- Understand how management assesses the credentials of the medical staff and stay current on best practices.
- Implement conflict-of-interest policies to identify and manage financial interests that may affect clinical judgment.
- Use dashboards and benchmarks to measure the success of your organization as it improves outcomes and patient satisfaction. You should track how your organization compares to its peers on these quality indicators. After all, "What gets measured is what gets done."

Evaluate the Compliance Program

http://oig.hhs.gov/newsroom/video/2011/toolkit-handout.pdf

Evaluate the Compliance Program

- Ask questions that assess your compliance program. If a business unit is lagging, invite the managers to discuss their strategy for improvement. Our website offers resources that can help at http://www.oig.hhs.gov/compliance/compliance-guidance/compliance-resource-material.asp.

- Protect the compliance officer's independence by separating this role from your legal counsel and senior management. All decisions affecting the compliance officer's employment or limiting the scope of the compliance program should require prior board approval. If your compliance officer leaves, the audit committee should conduct an exit interview.

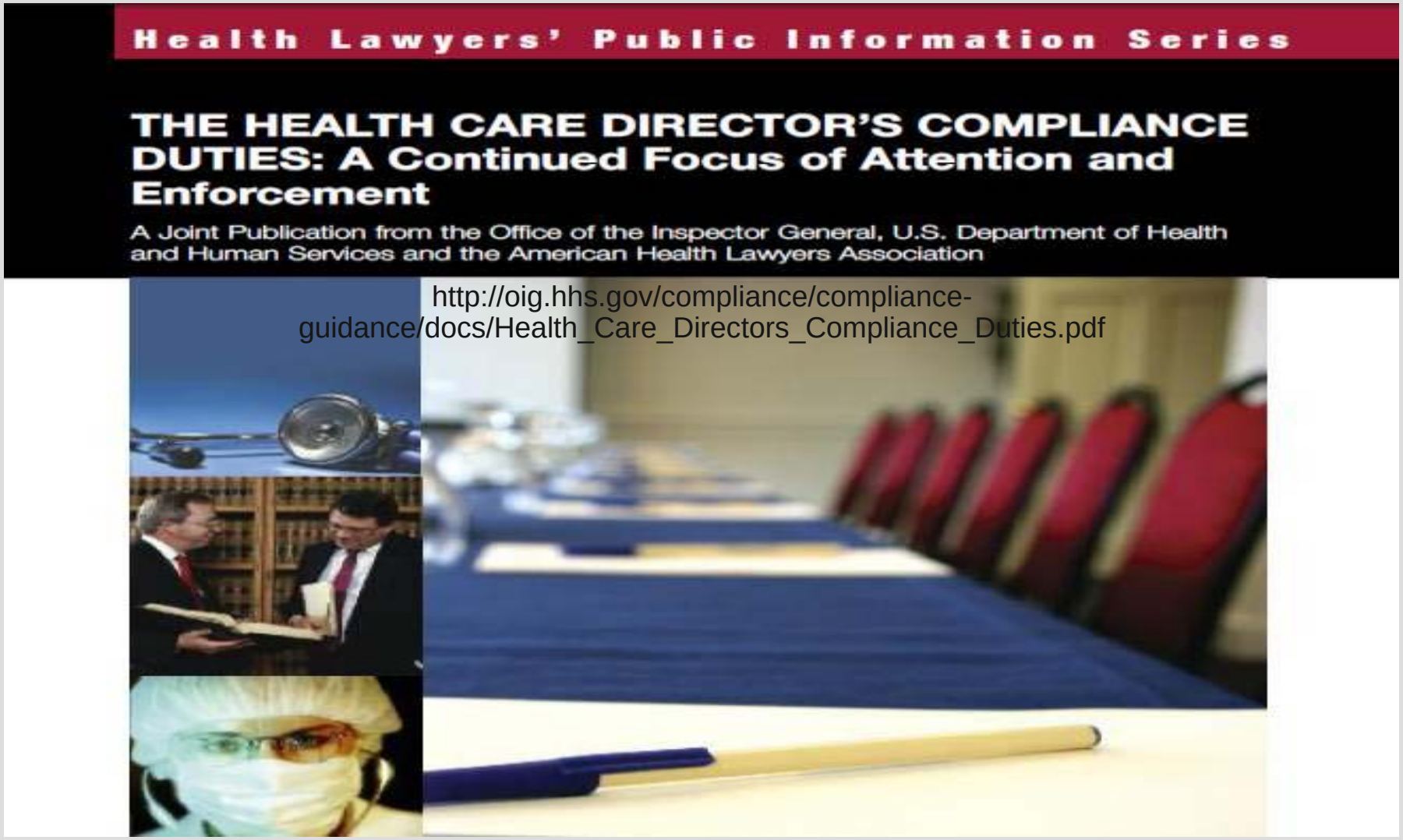
- Learn how quality, patient safety and compliance information flows to the board. Educate the board on the structure of the compliance program, and the organization's fraud and abuse risk areas. Publicize training so employees know the board considers compliance a priority.

- Ensure that your organization can validate the accuracy of its quality data. Federal program reimbursement is tied to quality of care. Accurate data is critical. Concealing unfavorable information or failing to investigate significant inconsistencies not only undercuts your quality improvement program; it can lead to criminal and civil liability.

- Talk to employees to learn how they see the organization's values and culture of compliance. Personal appearances by board members at staff meetings demonstrate a top-down commitment to quality and compliance.

- Perform regular self-assessments of your board and its committees. Evaluate the composition of your compliance, quality committees. Review the board's responses to systemic failures and lapses in patient care.

Director's Compliance Duties



http://oig.hhs.gov/compliance/compliance-guidance/docs/Health_Care_Directors_Compliance_Duties.pdf

Board's Dashboard

"Driving for Quality in Acute Care: A Board of Directors Dashboard"
Government-Industry Roundtable

A Report on the Office of Inspector General and Health Care Compliance Association Roundtable on Hospital Board of Directors' Oversight of Quality of Care

Introduction

On November 10, 2008, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services and the Health Care Compliance Association (HCCA) co-sponsored a government-industry roundtable called Driving for Quality in Acute Care: A Board of Directors Dashboard. The meeting was the most recent in a series of government-industry discussions designed to foster dialogue between the various stakeholders that are committed to improving compliance to Federal health care program rules and requirements and promoting the care of beneficiaries.

This roundtable focused on how a hospital's board of directors can use performance scorecards, or dashboards as a tool to promote quality of care in its institution. Dashboard reports use graphics to concisely present critical data in summary form. The goal of the meeting was to encourage a dialogue among hospitals that have successfully implemented dashboards, as well as hospitals that are just beginning the effort. The meeting also provided a forum for government representatives (including staff members of OIG and the Centers for Medicare & Medicaid Services (CMS)) to share their perspectives on the issues and challenges surrounding quality of care. This article

http://oig.hhs.gov/fraud/docs/complianceguidance/RoundtableAcuteCare.pdf

Practical Guidance for Boards

- Document has 7 chapters:
  - Introduction
  - Expectations for Board Oversight of Compliance Program Functions
  - Roles and Relationships
  - Reporting to the Board
  - Identifying and Auditing Potential Risk Areas
  - Encouraging Accountability and Compliance
  - Conclusion

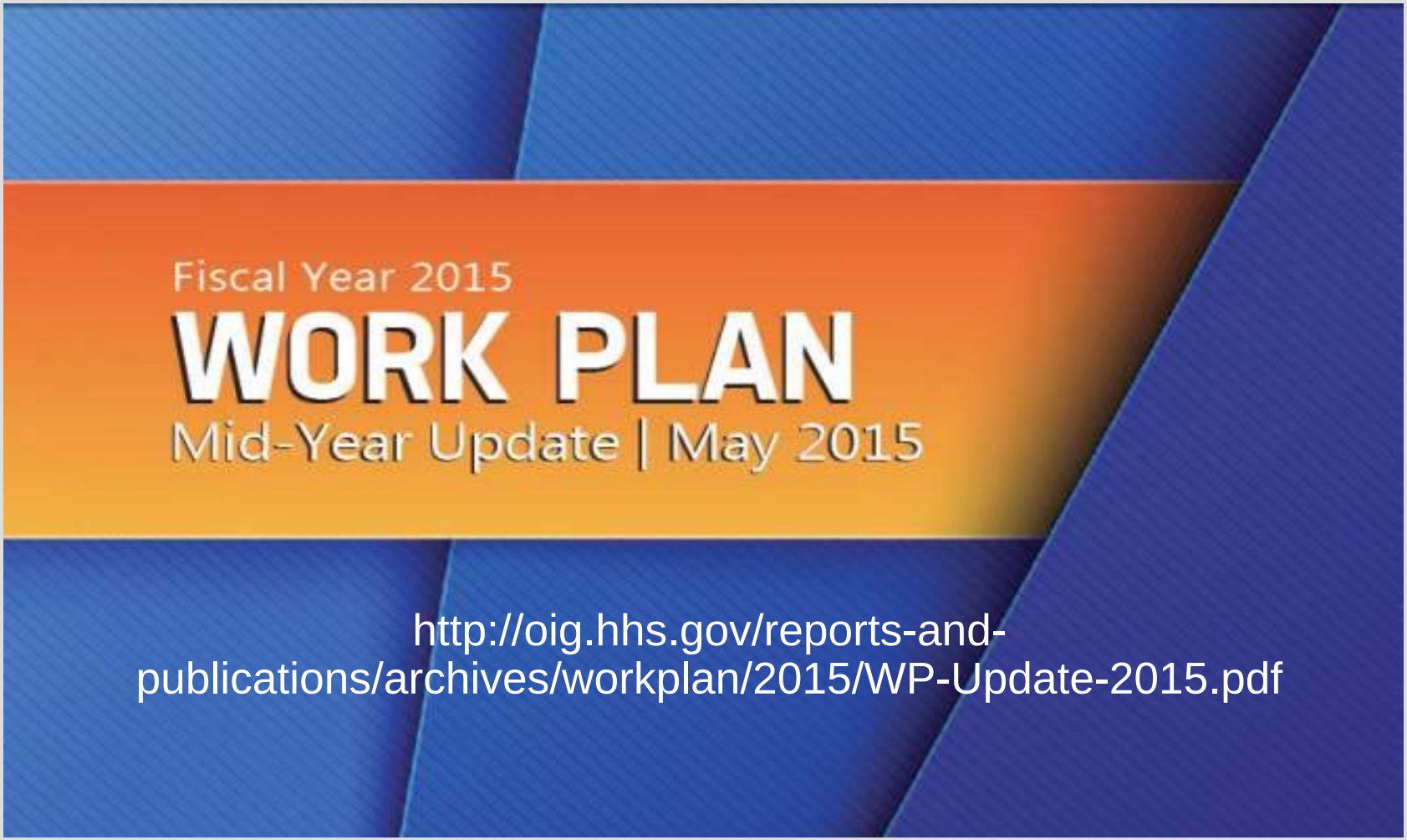
Introduction

- Boards need to be engaged in compliance oversight
- Boards need to ask the right questions of management to ensure the compliance program is effective
- Compliance needs to be a responsibility of all levels of management
- This document discusses the role of the board's oversight of the compliance program
  - Also covers approaches to identifying regulatory risk and methods to encourage accountability

Introduction

- Boards need to be aware of compliance activities because it is a hot area
- Much activity in the area of preventing fraud and abuse
- Want to make sure your hospital has a good compliance plan and compliance officer
- Would want to make sure have appropriate compliance policies and procedures
- The Compliance Committee should monitor also the OIG work plan and 2015 is the first year a mid year update was issued

OIG Work Plan First Ever Mid-Year Update



http://oig.hhs.gov/reports-and-publications/archives/workplan/2015/WP-Update-2015.pdf

Expectation for Board Oversight

- Chapter 2 talks about the expectations for board oversight of compliance program functions
- Board must act in good faith in exercising its oversight responsibilities
- Must ensure there is a **adequate reporting system** to ensure compliance with all laws
  - This is a key compliance program requirement and want to make sure board understands all laws
- Specifically mentions the **Federal Sentencing Guidelines** and **OIG's Voluntary Compliance Program Guidance**

So What's in Your Code of Conduct?

CONTENTS

What's In Your Hospital Compliance Plan

TABLE OF CONTENTS

7 Essential Elements of a Compliance Program

- Establish standards and procedures to prevent and detect violations of law
- Provide appropriate oversight and promote responsibility at all levels
- Exhibit due diligence in hiring and assigning personnel to positions with substantial authority
- Communicate compliance standards and procedures to all employees and provide training at all levels

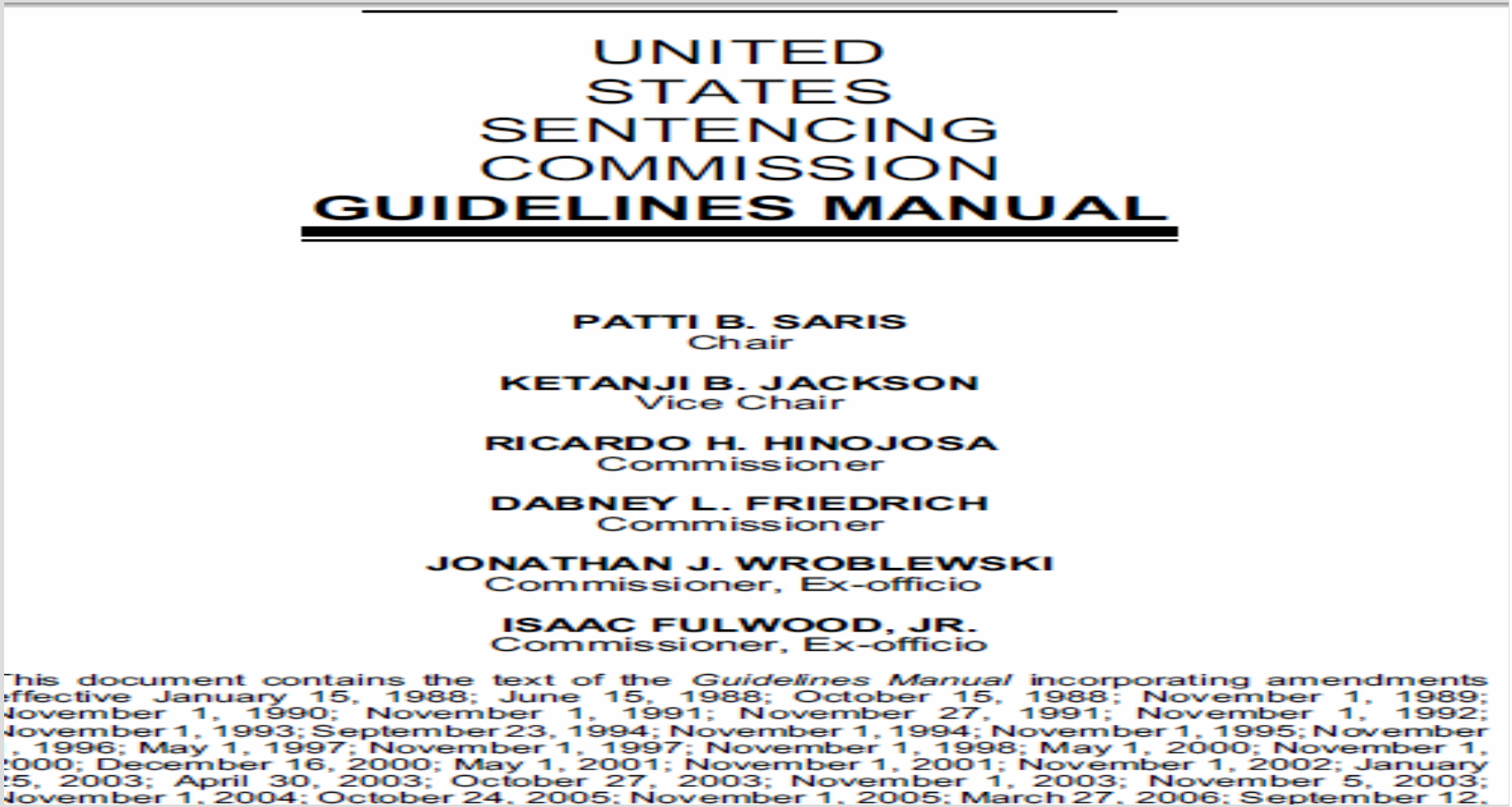
7 Essential Elements of a Compliance Program

- Establish procedures for monitoring and auditing, including periodic evaluation of program effectiveness as well as non-retaliatory internal guidance and reporting systems
- Employ consistent disciplinary mechanisms to promote and enforce compliance and ethical conduct
- Investigate and remediate upon detecting a violation

Federal Sentencing Guidelines

- What are the federal sentencing guidelines?
- There are rules on uniform sentencing policy for individuals and organizations convicted of felonies and serious misdemeanors in the federal court system
- Created in 1984 by the Sentencing Reform Act
- Goal was to alleviate the sentencing disparities
- So what do the federal sentencing guidelines have to do with hospitals and the healthcare system?

Federal Sentencing Guidelines 590 Pages



UNITED
STATES
SENTENCING
COMMISSION
GUIDELINES MANUAL

PATTI B. SARIS
Chair

KETANJI B. JACKSON
Vice Chair

RICARDO H. HINOJOSA
Commissioner

DABNEY L. FRIEDRICH
Commissioner

JONATHAN J. WROBLEWSKI
Commissioner, Ex-officio

ISAAC FULWOOD, JR.
Commissioner, Ex-officio

This document contains the text of the *Guidelines Manual* incorporating amendments effective January 15, 1988; June 15, 1988; October 15, 1988; November 1, 1989; November 1, 1990; November 1, 1991; November 27, 1991; November 1, 1992; November 1, 1993; September 23, 1994; November 1, 1994; November 1, 1995; November 1, 1996; May 1, 1997; November 1, 1997; November 1, 1998; May 1, 2000; November 1, 2000; December 16, 2000; May 1, 2001; November 1, 2001; November 1, 2002; January 25, 2003; April 30, 2003; October 27, 2003; November 1, 2003; November 5, 2003; November 1, 2004; October 24, 2005; November 1, 2005; March 27, 2006; September 12,

www.ussc.gov/sites/default/files/pdf/guidelines-manual/2013/manual-pdf/2013_Guidelines_Manual_Full.pdf

Federal Sentencing Guidelines

- The Sentencing Guidelines are important because they mandate lesser criminal sanctions for hospitals that have an effective compliance plan
- The US Department of Justice also treats defendants more leniently if they have an effective compliance plan so what is in your compliance plan and program?
  - Discusses code of conduct, basic elements, compliance hotline, compliance officer responsibilities, compliance policies and procedures, training and education, list of excluded individuals, self disclosure, signage requirements, HITECH Security Breaches, fraud and abuse considerations, state and federal laws on physician self referral, RACs, MACs, false claims act, record retention, fair market value, audits, overpayments, etc.

Federal Sentencing Guidelines

- The Sentencing Guidelines provide a framework for conferences, articles, and best practices on how to build a compliance program that really works
- The OIG took note of these in drafting its Compliance Guidance for Hospitals
- The OIG expanded on the seven steps of the sentencing guidelines
- So important in the starting point in developing a sound and credible health care compliance program
  - Also to provide oversight such as the Corporate Integrity Agreements or CIAs

Federal Sentencing Guidelines

UNITED STATES SENTENCING COMMISSION

Sentencing Guidelines for United States Courts

AGENCY: United States Sentencing Commission.

ACTION: Notice of submission to Congress of amendments to the sentencing guidelines effective November 1, 2010.

SUMMARY: Pursuant to its authority under 28 U.S.C. 994(p), the Commission has promulgated amendments to the sentencing guidelines, policy statements, commentary, and statutory index. This notice sets forth the amendments and the reason for each amendment.

DATES: The Commission has specified an effective date of November 1, 2010, for the amendments set forth in this notice.

FOR FURTHER INFORMATION CONTACT: Michael Courlander, Public Affairs Officer, 202–502–4597. The amendments set forth in this notice also may be accessed through the Commission's Web site at *http://www.ussc.gov*.

Authority: 28 U.S.C. 994(a), (o), and (p); USSC Rule of Practice and Procedure 4.1.

William K. Sessions III,
Chair.

1. *Amendment:* Chapter Five, Part A, is amended in the Sentencing Table by redesignating Zones A, B, C, and D (as designated by Amendment 462, *see* USSG Appendix C, Amendment 462 (effective November 1, 1992)) as follows: Zone A (containing all guideline ranges having a minimum of zero months); Zone B (containing all guideline ranges having a minimum of at least one but not more than nine months); Zone C (containing all guideline ranges having a minimum of at least ten but not more than twelve months); and Zone D (containing all guideline ranges having a minimum of fifteen months or more).

The Commentary to § 5B1.1 captioned "Application Notes" is amended in Note 1(b) by striking "six" and inserting "nine"; and in Note 2 by striking "eight" and inserting "ten".

The Commentary to § 5C1.1 captioned "Application Notes" is amended in Note 3 in the first paragraph by striking "six" and inserting "nine"; in Note 4 by striking "eight, nine, or ten months" and inserting "ten or twelve months"; by striking "8–14" and inserting "10–16" both places it appears; by striking "sentence of four" and inserting "sentence of five" both places it appears;

Examples: The following examples both assume the applicable guideline range is 12–18 months and the court departs in accordance with this application note. Under Zone C rules, the defendant must be sentenced to at least six months imprisonment. (1) The defendant is a nonviolent drug offender in Criminal History Category I and probation is not prohibited by statute. The court departs downward to impose a sentence of probation, with twelve months of intermittent confinement, community confinement, or home detention and participation in a substance abuse treatment program as conditions of probation. (2) The defendant is convicted of a Class A or B felony, so probation is prohibited by statute (*see* § 5B1.1(b)). The court departs downward to impose a sentence of one month imprisonment, with eleven months in community confinement or home detention and participation in a substance abuse treatment program as conditions of supervised release."

In Note 7 by striking the last sentence; in Note 8 by striking "twelve" and inserting "15"; and by redesignating Note 8 as Note 9 and inserting after Note 7 the following:

"8. In a case in which community confinement in a residential treatment program is imposed to accomplish a specific treatment purpose, the court should consider the effectiveness of the residential treatment program."

Reason for Amendment: This amendment is a two-part amendment

OIG's Voluntary Compliance Program

- The OIG issues Compliance Guidance Program for Hospitals in 1998
- January 31, 2005, the OIG issued a Supplemental Compliance Guidance for Hospitals that was published in the Federal Register
  - Supplements but does not replace the 1998 document
  - Provides recommendations to hospitals
  - To help prevent fraud and abuse and to prevent erroneous claims
  - Set of guidelines to consider in hospital compliance programs

OIG Hospital Compliance Program

741–8138 (301–443–0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 12, 1998, the committee will discuss a proposed draft of a guidance document for the development of drugs for the treatment of diabetes mellitis. On March 13, 1998, the committee will discuss New Drug Application 20–766, Xenical™, (orlistat tetrahydrolipstatin, Hoffman-LaRoche) for long term treatment of obesity.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 6, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m. on March 12 and 13, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 6, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 18, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–4529 Filed 2–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0260]

Agency Information Collection Activities; Announcement of OMB

Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1471.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 2, 1997 (62 FR 63721), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0360. The approval expires on January 31, 1999.

Dated: February 13, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–4374 Filed 2–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of the OIG Compliance Program Guidance for Hospitals

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the recently issued compliance program guidance for hospitals developed by the Office of Inspector General (OIG) in cooperation with, and with input from, several provider groups and industry representatives. Many providers and provider organizations have expressed an interest in better protecting their operations from fraud and abuse through the adoption of voluntary compliance programs. The first compliance guidance, addressing

combating fraud and abuse. In developing these compliance guidances, the OIG has agreed to work closely with the Health Care Financing Administration, the Department of Justice and various sectors of the health care industry. The first of these compliance guidances focused on clinical laboratories, and was intended to provide clear guidance to those segments of the health care industry that were interested in reducing fraud and abuse within their organizations. The compliance guidance was reprinted in an OIG **Federal Register** notice published on March 3, 1997 (62 FR 9435). This second compliance program guidance developed by the OIG continues to build upon the basic elements contained in our initial compliance guidance, and encompasses principles that are applicable to hospitals as well as a wider variety of organizations that provide health care services to beneficiaries of Medicare, Medicaid and all other Federal health care programs.

Like the previously-issued compliance program guidance for clinical laboratories and future compliance program guidances, adoption of the hospital compliance program guidance set forth below will be voluntary. Future compliance program guidances to be developed will be similarly structured and based on substantive policy recommendations, the elements of the Federal Sentencing Guidelines, and applicable statutes, regulations and Federal health care program requirements.

A reprint of the OIG compliance program guidance follows.

Compliance Program Guidance for Hospitals

I. Introduction

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) continues in its efforts to promote voluntarily developed and

http://oig.hhs.gov/authorities/docs/cpghosp.pdf

OIG's Supplement Compliance Program

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Supplemental Compliance Program Guidance for Hospitals

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the Supplemental Compliance Program Guidance (CPG) for Hospitals developed by the Office of Inspector General (OIG). Through this notice, the OIG is supplementing its prior compliance program guidance for hospitals issued in 1998. The supplemental CPG contains new compliance recommendations and an expanded discussion of risk areas, taking into account recent changes to hospital payment systems and regulations, evolving industry practices, current enforcement priorities, and lessons learned in the area of corporate compliance. The supplemental CPG provides voluntary guidelines to assist hospitals and hospital systems in identifying significant risk areas and in evaluating and, as necessary, refining

relevant risk areas. Copies of these CPGs can be found on the OIG Web page at *http://oig.hhs.gov.*

Supplementing the Compliance Program Guidance for Hospitals

The OIG originally published a CPG for the hospital industry on February 23, 1998. (*See* 63 FR 8987 (February 23, 1998), available on our Web page at *http://oig.hhs.gov/authorities/docs/cpghosp.pdf.*) Since that time, there have been significant changes in the way hospitals deliver, and are reimbursed for, health care services. In response to these developments, on June 18, 2002, the OIG published a notice in the **Federal Register**, soliciting public suggestions for revising the hospital CPG. (*See* 67 FR 41433 (June 18, 2002), available on our Web page at *http://oig.hhs.gov/authorities/docs/cpghospitalsolicitationnotice.pdf.*) After consideration of the public comments and the issues raised, the OIG published a draft supplemental compliance program guidance for hospitals in the **Federal Register** on June 8, 2004, to ensure that all parties had a reasonable and meaningful opportunity to provide input into the final product. (*See* 69 FR 32012 (June 8, 2004), available on our

Services (the Department) publishes this Supplemental Compliance Program Guidance (CPG) for Hospitals.[1] This document supplements, rather than replaces, the OIG's 1998 CPG for the hospital industry (63 FR 8987; February 23, 1998), which addressed the fundamentals of establishing an effective compliance program.[2] Neither this supplemental CPG, nor the original 1998 CPG, is a model compliance program. Rather, collectively the two documents offer a set of guidelines that hospitals should consider when developing and implementing a new compliance program or evaluating an existing one.

We are mindful that many hospitals have already devoted substantial time and resources to compliance efforts. We believe that those efforts demonstrate the industry's good faith commitment to ensuring and promoting integrity. For those hospitals with existing compliance programs, this document may serve as a benchmark or comparison against which to measure ongoing efforts and as a roadmap for updating or refining their compliance plans.

In crafting this supplemental CPG, we considered, among other things, the

http://garnerhealth.com/wp-content/uploads/2012/02/70-fr-4858.pdf

OIG's Supplement Compliance Program

- Discusses issues such as:
  - Benefits of a compliance program
  - Honest corporate conduct, encourage employees to report, prevent and identify unethical behavior etc.
  - EMTALA
  - Physician self-referral
  - Federal anti-kick back law
  - Joint ventures, billing, admissions, discharges, readmissions
  - Practitioner recruitment, improper claims, discounts
  - Furnishing sub standard care

Corporate Integrity Agreements CIAs

- OIG negotiates CIAs with hospitals and other healthcare providers as part of the settlement of federal investigations under a variety of false claims laws
- Providers, hospitals, or other entities agree to the follow the obligations and things set forth in the agreement
  - Many common elements such as a compliance officer, compliance committee, employee training program, independent audits and annual reviews, restrict employment of ineligible persons, report overpayments, reportable events, provide annual report to OIG, etc.

Read Some Corporate Integrity Agreements

http://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp

INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MOHAMMAD A. CHOUDHARY, M.D. AND ROLLA NEUROLOGY PAIN AND SLEEP CENTER

I. PREAMBLE

Mohammad A. Choudhary, M.D. (Dr. Choudhary) and Rolla Neurology Pain and Sleep Center (Rolla Neurology) (hereinafter collectively, Choudhary-Rolla Neurology) hereby enter into this Integrity Agreement (IA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, program requirements, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this IA, Choudhary-Rolla Neurology is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE IA

A. This IA shall have a term of three years from the Effective Date. The Effective Date shall be the date on which the final signatory signs this IA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days from OIG's receipt of: (1) Choudhary-Rolla Neurology's final Annual Report; or (2) any additional materials submitted by Choudhary-Rolla Neurology pursuant to OIG's request, whichever is later.

C. The term "Covered Persons" includes:

1. Choudhary-Rolla Neurology and all owners and employees of Choudhary-Rolla Neurology; and

Corporate Integrity Agreements CIAs

- Basic CIA elements mirror those in the sentencing guidelines
- These are good resources to review as they show what things the OIG is looking for such as one where hospital failed to use interpreters
- If CIA usually require each board member to sign
- States board members should inquire about the scope and adequacy of the compliance program
  - Design of compliance program will depend on how big the hospital is and the resources
  - Must demonstrate commitment to ethical conduct

Expectation for Board Oversight

- Boards should develop a formal plan to stay abreast of the ever changing landscape and environment
- This would include periodic updates from staff
- It could include a review of regulatory resources
- Boards with an understanding of the regulatory environment can ask more pertinent questions of management (Page 4)
- Will also make better decisions related to funding and resource allocation (Page 5)

Expectation for Board Oversight

- Board members may want management to create a formal education calendar for them on the hospital's greatest risks (Page 5)
- Board members can increase their expertise by consulting with an experienced compliance officer
  - Experts can provide insight into best practices or can provide consultation
- Board members are generally entitled to rely on the advice of experts in fulfilling their duties

Roles and Relationships

- The third chapter is on roles and relationships
- The hospital should define the relationship of compliance, audit, and legal functions
- This should include the reporting relationship which would be on the hospital's organization chart
- This should include interaction of functions such as quality, patient safety, risk management and HR
- The **compliance function** promotes prevention, detection, and resolution of actions that do not conform to legal or business standards

Roles and Relationships

- The **compliance function:**
  - Develop policies and procedures to guide employee actions
  - Create incentives to promote employee compliance
  - Develop plans to improve or sustain compliance
  - Implement corrective actions
  - Develop reports and dashboards for the board to evaluate the effectiveness of the compliance program

Roles and Relationships

- **The legal function:**
  - Provides advice and counsel to management and the board on risks of business strategies
  - Advises about laws and regulations
    - Many laws such as HITECH, HIPAA, EMTALA, GINA, SMDA, CDC, OSHA, CMS CoPs, Patient Self Determination Act, Drug and Alcohol, Organ Procurement, Volunteer Protection Act, NIOSH, Family and Medical Leave Act, National Practitioner Data Bank, OIG Exclusion Program, Stark law, Right to Know Law, Born Alive law, Civil Rights Act, Americans with Disability, Fair Credit Reporting Act, Affordable Care Act etc.
  - Defends the hospital in legal proceedings

Roles and Relationships

- The **internal audit function**:
  - Provide an objective evaluation of existing risk
  - Assess internal control systems and how well they are working or not working
  - Audits ensure monitoring is effective
  - Auditing may identify where additional board oversight is needed
  - Internal audits can fulfill the auditing requirements of the sentencing guidelines

Roles and Relationships

- The **human resource function:**
  - Manages the recruitment, screening, and hiring of employees
  - Coordinates employee benefits
  - Provides employee training
  - Provides development opportunities

Roles and Relationships

- The **quality improvement function**:
  - Promotes consistent, safe, and high quality practices
  - Improves efficiency and health outcomes by measuring and reporting on quality outcomes
  - Recommends changes to clinical processes to the board and management
  - It important to minimize the risk of harm to patients
  - CMS has QAPI standards and worksheet

Roles and Relationships

- Hospitals measure all kinds of QAPI to ensure safe and efficient patient care
- Such as fall rate, medication rate, incidence of pressure ulcers, patient flow to prevent overcrowding and boarding, hand hygiene rate, number of surgical site infections, catheter associated UTIs, central line infections, injuries from restraint and seclusion, timely antibiotics in pneumonia patients, PCI within 90 minutes, antibiotic stewardship, retained surgical items, burns, patient experience or satisfaction, stroke measures, prevention of PE and DVT, etc.

Roles and Relationships

- Boards should evaluate the performance of different functions on a periodic basis
- OIG believes compliance officer should not be legal counsel for the hospital
- OIG believes person should not be a subordinate to the legal department or hospital counsel
- However, these two should collaborate to further the interests of the hospital
  - See OIG and AHLA, An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors, 3 (2004) (citing Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8,987, 8,997 (Feb. 23, 1998)).

Roles and Relationships

- Compliance, legal, and internal audit should have adequate resources
- Board needs a process to ensure access to information such as the audit reports
- Boards should evaluate how management works to address risks (Page 8)
- This includes identifying compliance risks, investigating them, implementing appropriate corrective actions and communicating them
- How are conflicts or disagreements handled

Conflicts of Interest Policies

DISCLOSURE OF CERTAIN INTERESTS AND CONFLICTS

WHEREAS, The proper governance of the nation's health care institutions depends on governing board members and others who give of their time for the benefit of their health communities; and,

WHEREAS, The giving of this service, because of the varied interests and backgrounds of the governing board members and others, may result in situations involving a dual interest that might be interpreted as conflict of interest; and,

WHEREAS, This service nevertheless carries with it a requirement of loyalty and fidelity to the institution served, it being the responsibility of the members of the governing board members and others acting in the institution's affairs honestly and economically, exercising their best care, skill and judgment for the benefit of the institution; and,

WHEREAS, The matter of any duality of interest or possible conflict of interest can best be handled through full disclosure of any such interest, together with non-involvement in any vote wherein the interest is involved;

NOW THEREFORE, BE IT RESOLVED: That the following policy of duality and conflict of interest is hereby adopted:

1. Any duality of interest or possible conflict of interest on the part of any governing board member, administrative staff member, management staff member, and medical staff members with administrative responsibilities, or a member of his or her immediate family, should be disclosed to the board and made a matter of record, through an annual procedure and when the

Reporting to the Board

- The fourth chapter addresses reporting to the board:
- Board should enforce and set expectations for receiving compliance related information
- Should receive regular reports of risk mitigation and compliance efforts
- From many key players such as audit, compliance, legal, risk, quality, HR and information technology
- Board should hold staff accountable for informing the board and implementing corrective action plans

Reporting to the Board

- This might include score cards, hot line activity, allegations of material fraud, sentinel events, internal or external investigations, or code of conduct violations
- Some boards use dashboards to get information in an appropriate format that can be understood
  - Might include financial, operational, or compliance indicators
- Can have risk based reporting system so board gets report when criteria is made
  - RCA for unexpected death of patient, infant abduction, etc.

Identifying and Auditing Risk Areas

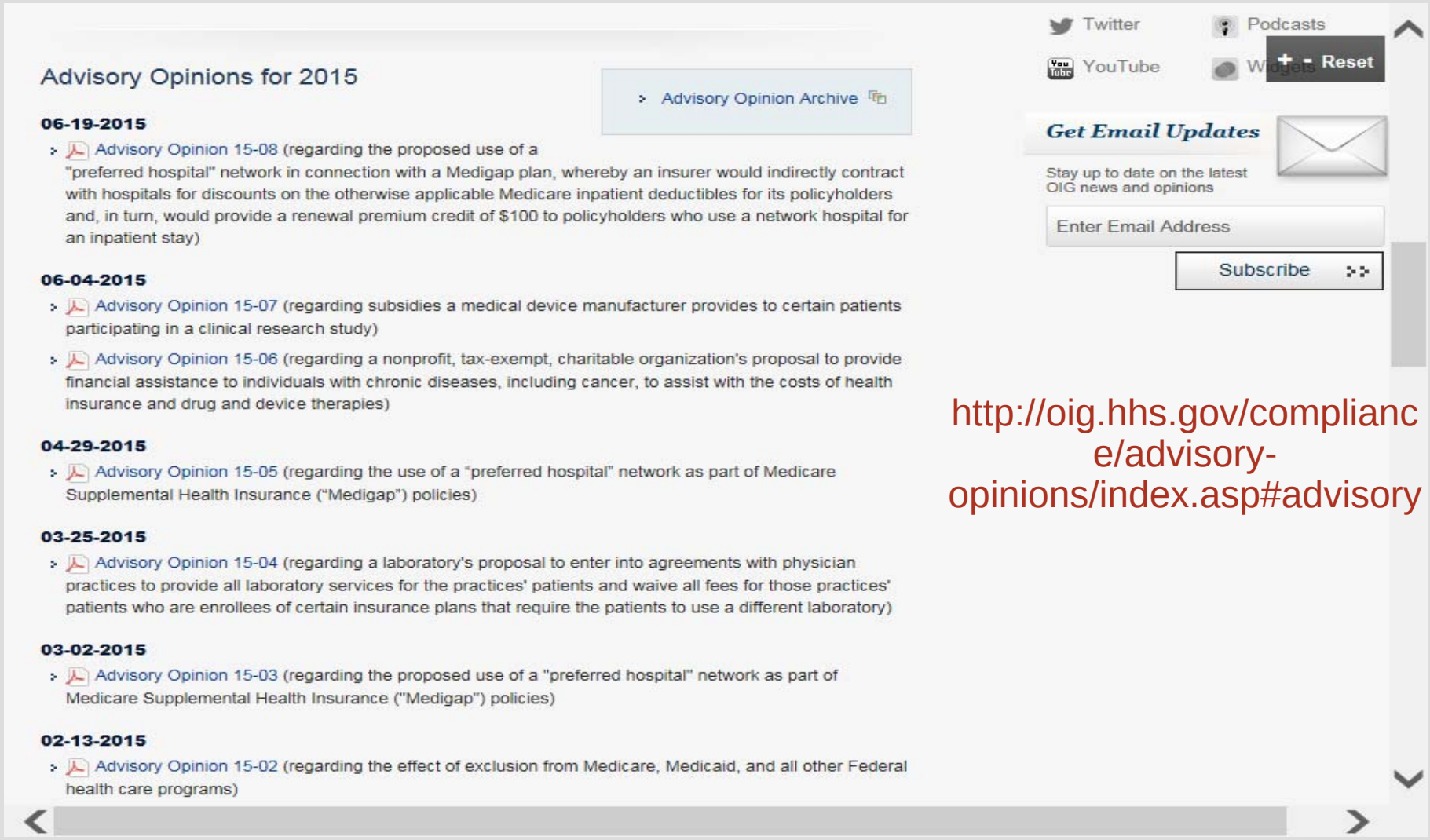
- Chapter five addresses identifying and auditing potential risk areas
- Some risks are common to all healthcare providers
- Need to monitor activities that are highly vulnerable to fraud and other violations including referral relationships, privacy breaches, billing problems
  - Upcoding, submitting claims for services not rendered, or medically unnecessary services
- Board needs to have a process for identifying risk areas

Identifying and Auditing Risk Areas

- Board can identify risks from internal sources such as employee who reports to hotline or results of an internal audit
- Board may identify risks from external sources such as professional publications, OIG issued guidance's, or news articles
  - Anyone can sign up to get OIG advisory opinions which all hospitals should monitor
  - OIG has free education material including compliance education material for healthcare boards
  - Anyone can sign up at OIG website to receive emails on compliance issues

OIG Advisory Opinions

Sign Up for Email Updates



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Advisory Opinions for 2015

Advisory Opinion Archive

06-19-2015

- Advisory Opinion 15-08 (regarding the proposed use of a "preferred hospital" network in connection with a Medigap plan, whereby an insurer would indirectly contract with hospitals for discounts on the otherwise applicable Medicare inpatient deductibles for its policyholders and, in turn, would provide a renewal premium credit of $100 to policyholders who use a network hospital for an inpatient stay)

06-04-2015

- Advisory Opinion 15-07 (regarding subsidies a medical device manufacturer provides to certain patients participating in a clinical research study)
- Advisory Opinion 15-06 (regarding a nonprofit, tax-exempt, charitable organization's proposal to provide financial assistance to individuals with chronic diseases, including cancer, to assist with the costs of health insurance and drug and device therapies)

04-29-2015

- Advisory Opinion 15-05 (regarding the use of a "preferred hospital" network as part of Medicare Supplemental Health Insurance ("Medigap") policies)

03-25-2015

- Advisory Opinion 15-04 (regarding a laboratory's proposal to enter into agreements with physician practices to provide all laboratory services for the practices' patients and waive all fees for those practices' patients who are enrollees of certain insurance plans that require the patients to use a different laboratory)

03-02-2015

- Advisory Opinion 15-03 (regarding the proposed use of a "preferred hospital" network as part of Medicare Supplemental Health Insurance ("Medigap") policies)

02-13-2015

- Advisory Opinion 15-02 (regarding the effect of exclusion from Medicare, Medicaid, and all other Federal health care programs)

http://oig.hhs.gov/compliance/advisory-opinions/index.asp#advisory

OIG Has Free Compliance Education Material

Compliance Education Materials

Tweet

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Welcome to OIG's Compliance 101 Web page. OIG developed the free educational resources listed on this Web page to help health care providers, practitioners, and suppliers understand the health care fraud and abuse laws and the consequences of violating them. These compliance education materials can also provide ideas for ways to cultivate a culture of compliance within your own health care organization.

General Compliance Education Materials

Compliance Program Guidance

OIG has developed a series of voluntary compliance program guidance documents directed at various segments of the health care industry, such as hospitals, nursing homes, third-party billers, and durable medical equipment suppliers, to encourage the development and use of internal controls to monitor adherence to statutes, regulations, and program requirements. The documents provide principles to follow when developing a compliance program that best suits your organization's needs. The documents also identify fraud and abuse risks to watch out for when creating a program.

- Compliance Guidance

http://oig.hhs.gov/compliance/101/index.asp

Provider Compliance Training

Below are links to free training for health care providers, compliance professionals, and attorneys. OIG's Provider Compliance Training was an outreach initiative developed as part of HHS's and the U.S. Department of Justice's Health Care Fraud Prevention and Enforcement Action Team.

- Videos and Audio Podcasts
- Webcast

Compliance Education for Boards

Compliance Education Materials for Health Care Boards

Because of their oversight responsibilities, boards of directors have a unique opportunity to influence their health care organizations to promote quality of care and embrace compliance with the law. These resources can help directors, who may not be lawyers or health care providers, create a corporate culture that promotes high-quality care and embraces compliance with the law.

+ - Reset

- Compliance Resources for Health Care Boards
- Video and Presentation Materials: Guidance for Health Care Boards
- Video: Compliance Oversight for Health Care Leaders

Identifying and Auditing Risk Areas

- There are many free publications
- The Health Care Compliance Association (HCCA) has an excellent newsletter and has weekly articles on compliance issues
- When articles published, board should ask hospital if they have a process in place to monitor and make sure it is not a problem in their hospital
  - Many compliance officers monitor this and add new issues to the agenda for the compliance committee meeting
- Board should make sure management reviews audit areas and implements correction action plans as needed

HCCA Weekly Compliance Newsletter

This Week in Corporate Compliance

Add TWCC to your Address Book to Ensure Delivery. Click here

Health Care Compliance Association | News For the Health Care Compliance Professional

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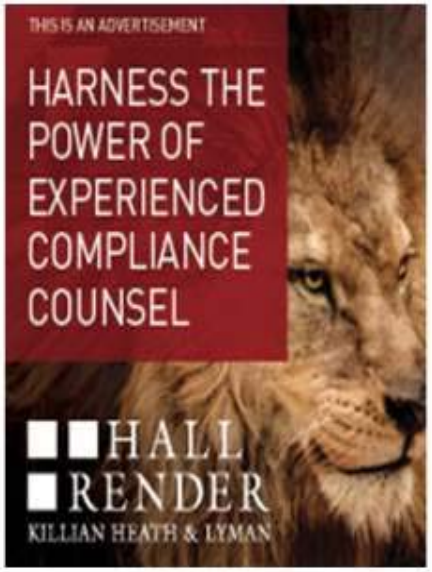

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This Week's Headlines – June 19, 2015

National Medicare fraud takedown results in charges against 243 individuals for approximately $712 million in false billing

MDH board of directors hears of medical data breach

Registered nurse co-owner of Ultimate Care Home Health Services, Inc. pleads guilty to role in health care fraud conspiracy

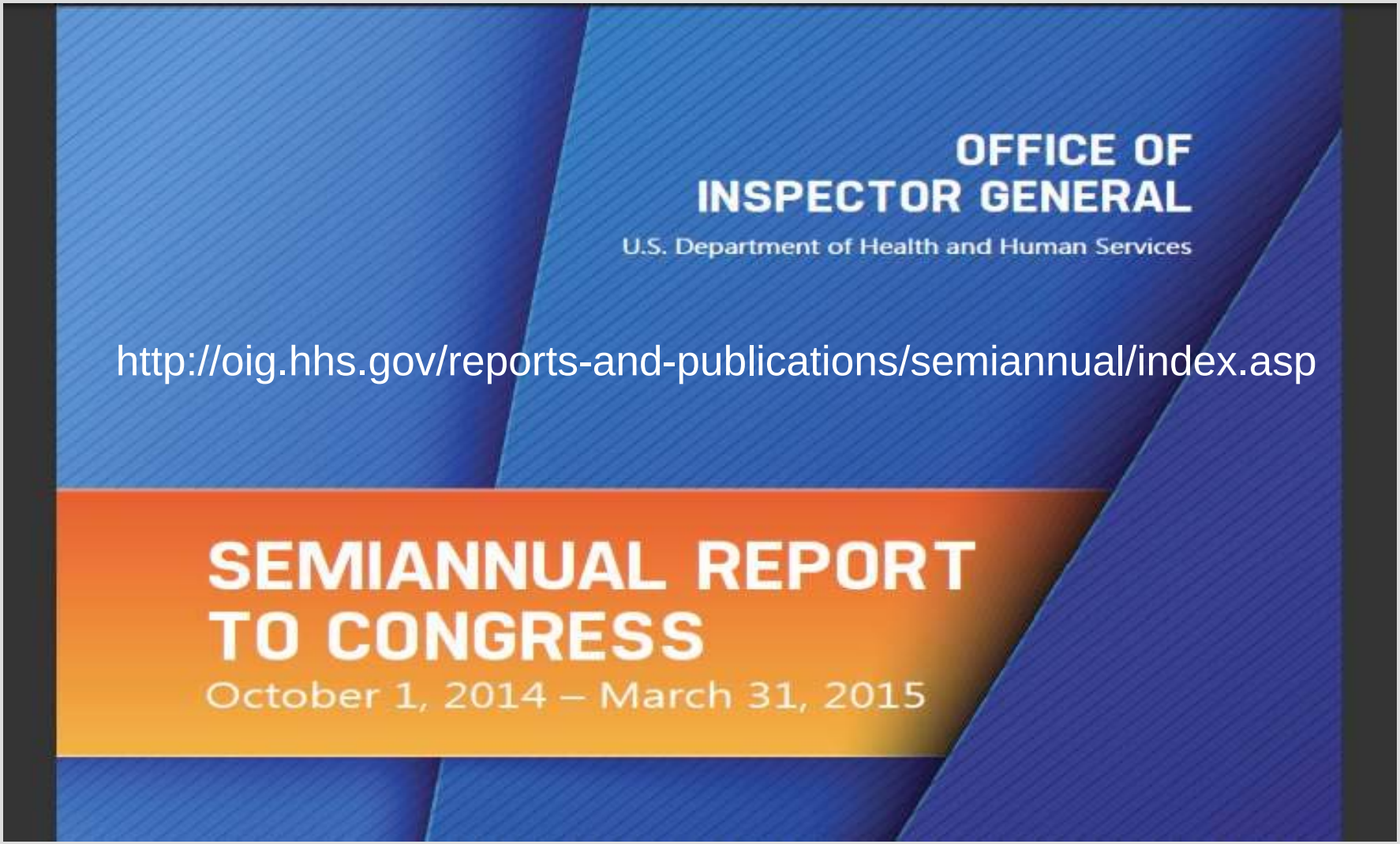
Conspirators charged with defrauding Medicare of millions using California clinic

Florida skilled nursing facility agrees to pay $17 million to resolve False Claims Act allegations

Identifying and Auditing Risk Areas

- For example, the OCR is conducting HIPAA audits
- The semiannual report to Congress from Oct 2015 to March 2015 shows they collected over **18 billion** dollars from providers and healthcare facilities
  - This report summarizes the activities of the OIG which is also an important resource for the compliance officer and compliance committee to monitor
  - Mentions the largest settlement of its kind (38 million) against a LTC facility where poor quality of care was considered fraud including billing for unnecessary rehab
  - Oncologist pleads guilty to providing aggressive chemotherapy that was not indicated

OIG Semiannual Report Recovers 18 Billion



Identifying and Auditing Risk Areas

- In 6 months the OIG reported 486 criminal activities against individuals or entities
- It included 326 civil actions which included false claims and issues related to provider self-disclosure
- 1,735 individuals and entities were excluded from participating in Federal health care programs
- This illustrates the importance of the board in ensuring there is an effective compliance program
  - Partly due to the strike force created in 2009 called HEAT or the Health Care Fraud Prevention and Enforcement Action Team

Identifying and Auditing Risk Areas

- Hospital should take reasonable steps to monitor and audit to detect criminal conduct (Page 11)
- Make sure it includes monitoring of new areas of risk that emphasis quality and changes in reimbursement such as VBP and bundling of services for a single payment
- Payment policies must align with quality of care
  - There are new payment models
  - Want to make sure hospitals are reviewing these for compliance with Stark (physician self-referral) and anti-kick back laws

Identifying and Auditing Risk Areas

- Increase in transparency can provide opportunities but also new risks
  - For example, CMS is now publishing data on health outcomes and quality data
  - Reporting billing data on hospitals and physicians and in fact and a number of physicians with the highest billings are being investigated
  - Third annual report for hospitals and second for physicians and all data is from CY 2013
  - Shows information on 100 most common hospital stays
  - See report at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier2013.html

Medicare Provider Utilization and Payment Data

- Medicare Provider Utilization and Payment Data: Physician and Other Supplier
- Medicare Provider Utilization and Payment Data: Inpatient
- Medicare Provider Utilization and Payment Data: Outpatient
- Medicare Provider Utilization and Payment Data: Part D Prescriber
- Public Comment on the Release of Medicare Physician Data

Physician and Other Supplier Data CY 2013

As part of the Obama Administration's efforts to make our healthcare system more transparent, affordable, and accountable, the Centers for Medicare & Medicaid Services (CMS) has prepared a public data set, the Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File (Physician and Other Supplier PUF), with information on services and procedures provided to Medicare beneficiaries by physicians and other healthcare professionals. The Physician and Other Supplier PUF contains information on utilization, payment (allowed amount and Medicare payment), and submitted charges organized by National Provider Identifier (NPI), Healthcare Common Procedure Coding System (HCPCS) code, and place of service. This PUF is based on information from CMS's National Claims History Standard Analytic Files. The data in the Physician and Other Supplier PUF covers calendar year 2013 and contains 100% final-action physician/supplier Part B non-institutional line items for the Medicare fee-for-service population.

While the Physician and Other Supplier PUF has a wealth of information on payment and utilization for Medicare Part B services, the dataset has a number of limitations. Of particular importance is the fact that the data may not be representative of a physician's entire practice as it only includes information on Medicare fee-for-service beneficiaries. In addition, the data are not intended to indicate the quality of care provided and are not risk-adjusted to account for differences in underlying severity of disease of patient populations. For additional limitations, please review the methodology document available below.

Data are available in two formats:

- Tab delimited file format (requires importing into database or statistical software; SAS® read-in language is included in the download ZIP package)
- Microsoft Excel format (.xlsx), split by provider last name (note: organizational providers with name starting with a

Identifying and Auditing Risk Areas

- Boards should consider all this newly available information such as the payment data information
- Boards may want to compare data against organizational peers and incorporate benchmarks
- Boards that employee physicians should be cognizant of the relationship and the impact on clinical and research decision making
  - For example; the OIG put out a fraud alert June 9, 2015 related to physician compensation arrangements
  - Recent settlement with 12 physicians who received money for a medical directorship because they did not provide the services under the agreement-violated anti-kick back law

Sample Fraud Alert

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability

June 9, 2015

Physicians who enter into compensation arrangements such as medical directorships must ensure that those arrangements reflect fair market value for bona fide services the physicians actually provide. Although many compensation arrangements are legitimate, a compensation arrangement may violate the anti-kickback statute if even one purpose of the arrangement is to compensate a physician for his or her past or future referrals of Federal health care program business. OIG encourages physicians to carefully consider the terms and conditions of medical directorships and other compensation arrangements before entering into them.

OIG recently reached settlements with 12 individual physicians who entered into questionable medical directorship and office staff arrangements. OIG alleged that the compensation paid to these physicians under the medical directorship arrangements constituted improper remuneration under the anti-kickback statute for a number of reasons, including that the payments took into account the physicians' volume or value of referrals and did not reflect fair market value for the services to be performed, and because the physicians did not actually provide the services called for under the agreements. OIG also alleged that some of the 12 physicians had entered into arrangements under which an affiliated health care entity paid the salaries of the physicians' front office staff. Because these arrangements relieved the physicians of a financial burden they otherwise would have incurred, OIG alleged that the salaries paid under these arrangements constituted improper remuneration to the physicians. OIG determined that the physicians were an integral part of the scheme and subject to liability under the Civil Monetary Penalties Law.

http://oig.hhs.gov/compliance/alerts/guidance/Fraud_Alert_Physician_Compensation_06092015.pdf

Encouraging Accountability & Compliance

- Chapter 6 addresses encouraging accountability and compliance
- Compliance is an enterprise-wide responsibility
- Need a compliance program for the entire hospital
- Compliance is “a way of life”
- Board may assess employees performance in promoting and adhering to compliance if compliance metrics are met
- Assessments can be used to withhold incentives or provide bonuses including quality outcomes

Encouraging Accountability & Compliance

- Boards need to encourage self-identification and voluntary disclosure to the government
  - Under the Affordable Care Act, a hospital must report and return an over payments within 60 days
  - Failure to report can result in civil monetary penalties
  - Boards should ask hospitals what their policies are for identifying and returning overpayments
  - OIG has self-disclosure protocols which will result in faster resolution of the case, lower payments which is usually 1.5 times the damages instead of double or treble damages and often no CIA

OIG Provider Self-Disclosure Protocol

Encouraging Accountability & Compliance

- The board should ask management how it handles identification of potential violations including voluntary self-disclosure
- Boards should ensure there is effective communication through out the hospital
- They should inquire if employees feel confident raising concerns, questions, or complaints without retaliation or retribution
- Board should make sure to evaluate if hospital's responses to identified violations are appropriate

Conclusions

- The last section is on conclusions
- Board should increase its knowledge of relevant and emerging risks (Page 15)
  - Some of this information may be found in the compliance committee minutes
- Board should be knowledgeable about the hospital's compliance program
- Board should encourage compliance accountability
- Board responsible to make sure hospital follows all federal and state laws

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The End! Questions??

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