Sean M. Weiss. Partner and VP of Compliance, DoctorsManagement, LLC

The Compliance Guy

Sean has dedicated his career to serving and advocating on behalf of health care providers, hospital networks, and integrated health systems to ensure a level playing field and due process. Over the past 27-years Sean has focused on helping organizations achieve measurable financial results to ensure stability in their market all while significantly reducing the risk of non-compliance. Sean's knowledge of the inner workings of government agencies at both the state and federal level make him an invaluable asset to clients.

Sean leads the strategic litigation defense and audit team for DoctorsManagement, LLC. Sean is engaged by the largest and most revered law firms in the nation on matters tied to the False Claims Act and Health Care Fraud Statute cases to ensure the best possible defense for clients targeted by government agencies, their contractors, and commercial payer special investigative units.

Sean serves as a third-party Compliance Officer for numerous nationally recognized organizations across the country creating and ensuring a "Culture of Compliance" to mitigate risk and culpability.

Sean is a published author and the host of The Compliance Guy Podcast, the intersection where Compliance and the Business of Medicine meet... bringing to life regulatory compliance and health law related issues, reaching tens of thousands of health care professionals weekly. A sought-after healthcare speaker, Sean has an engaging, no-nonsense style and has delivered keynote addresses for countless professional societies and healthcare organizations. In his educational sessions, Sean presents workable solutions to the latest issues surrounding healthcare compliance, medical auditing, and practice and revenue cycle management. In May of 2021 Sean created The Compliance Guy Podcast©, bringing industry experts in the areas of operations, clinical, and legal together to ensure the highest-level of learning and guidance to healthcare professionals.

Sean serves on boards of directors for both for-profit and non-profit organizations. He is a published author and a contributing author, and his written voice has reached tens of thousands of readers. His contributions to print and online publications (JAMA, Medical Economics, Part B News, BC Advantage, The Coding Edge, and MGMA Connections) cover a wide range of healthcare topics.

Orthopedic Audit Targets

Sean M. Weiss

Partner & Chief Compliance Officer

DoctorsManagement, LLC

Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

LOCAL COVERAGE DETERMINATIONS CREATE INCONSISTENCY IN MEDICARE COVERAGE

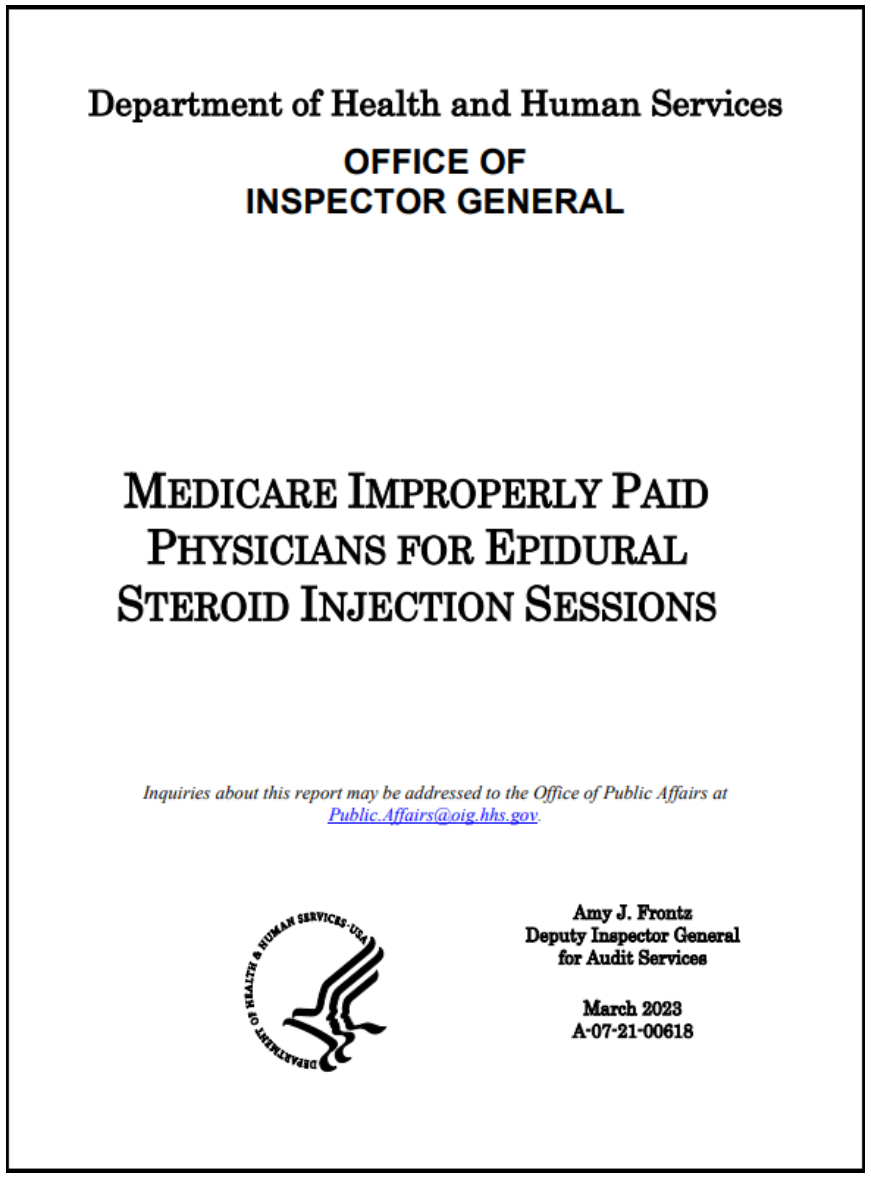
Daniel R. Levinson
Inspector General

January 2014
OEI-01-11-00500

CMS and their issues!!!

The Crux of The Study…

- Over half of Part B procedure codes were subject to an LCD in one or more States.
- The presence of these LCDs was unrelated to the cost and utilization of items and services.
- LCDs limited coverage for these items and services differently across States.
- LCDs also defined similar clinical topics inconsistently.
- Finally, CMS has taken steps to increase consistency among LCDs, but it lacks a plan to evaluate new LCDs for national coverage as called for by the MMA.



Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

MEDICARE IMPROPERLY PAID PHYSICIANS FOR EPIDURAL STEROID INJECTION SESSIONS

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Amy J. Frontz
Deputy Inspector General
for Audit Services

March 2023
A-07-21-00618

A Prime Example!

What the study found. . .

- Medicare did not always pay physicians for epidural steroid injection sessions in accordance with Medicare requirements.
- Medicare improperly paid physicians $3.6 million on behalf of beneficiaries who received more epidural steroid injection sessions than were permitted by the coverage limitations in the applicable LCDs.
- These improper payments occurred because neither the Centers for Medicare & Medicaid Service's (CMS's) oversight nor the MACs' oversight was adequate to prevent or detect improper payments for epidural steroid injection sessions.
- After our audit period, all 12 MAC jurisdictions updated their LCDs with revised coverage limitations that were specific to epidural steroid injections.

Medicare Voluntary Refund – Potential Language Change

- CMS issued a proposed change that would essentially eliminate the language at 42 C.F.R. § 401.305(a)(2) which states, "A person has identified an overpayment when the person has or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that a person has received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person received an overpayment..."
- If the proposed language changes, 42 C.F.R. § 401.305(a)(2) "A person has identified an overpayment when the person has or should have determined it through reasonable diligence. The term "knowingly" has the meaning set forth in 31 U.S.C. 3729(b)(1)(A)."
- That means, you have to understand what 31 U.S.C. 3729(b)(1)(A) means "that a person, with respect to information, acts in deliberate ignorance of the truth or falsity of the information..."
- The problem I have with the proposed change is that CMS does not address the issues that the proposed definition creates. Key to this centers around the 60 Day Rule (for refunds)... If conducting a bona fide investigation, you may not know the amount of an overpayment until the investigation is complete, and that can take months (currently allowed up to 8 months and then the 60 day calendar starts). However, the way it is written in the proposed language, just the mere existence of the overpayment requires a refund within 60-days of it being known. How can we issue a refund if we do not quantify the amount through a proper lookback?

The False Claims Act

- Under the FCA, a person is deemed to have acted "knowingly" when the person "acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information."
  - 31 U.S.C. § 3729(b).
- As the Ninth Circuit has pointed out, the FCA knowledge standard does not extend to honest mistakes, but only to "lies." "Claims are not 'false' under the FCA unless they are furnished in violation of some controlling rule, regulation or standard".
  - *See, e.g., United States ex rel. Local 342 v. Caputo Co.,* 321 F.3d 926, 933 (9th Cir.2003); *United States v. Southland Mgmt. Corp.,* 326 F.3d 669, 674-75 (5th Cir.2003) ("[W]hether a claim is valid depends on the contract, regulation, or statute that supposedly warrants it.
- It is only those claims for money or property to which a Defendant is not entitled that are 'false' for purposes of the False Claims Act") (citation omitted) (en banc);
  - *United States ex rel. Hochman v. Nackman,* 145 F.3d 1069, 1073-74 (9th Cir.1998) (no falsity when Defendants' acts conformed with Veteran Administration payment guidelines);
  - *United States ex rel. Lindenthal v. Gen. Dynamics Corp.,* 61 F.3d 1402, 1412 (9th Cir.1995) (whistleblower's FCA claims for payment based on work that satisfied contractual obligations "could not have been 'false or fraudulent' within the meaning of the [False Claims Act]");
  - *United States ex rel. Glass v. Medtronic, Inc.,* 957 F.2d 605, 608 (8th Cir.1992) (a statement cannot be "false" or "fraudulent" under FCA when the statement is consistent with regulations governing program).
  - *Additionally, a Defendant does not knowingly submit false claims when he follows Government instructions regarding the claims. See United States ex rel. Butler v. Hughes Helicopters, Inc., 71 F.3d 321 (9th Cir.1995); Wang v. FMC Corp., 975 F.2d 1412, 1421 (9th Cir.1992).*

Evaluation and Management Services Prior to 2021 & 2023

- If history has taught us anything is that we cannot ignore prior services just because guidelines have changed (e.g., 1995 and 1997 EM Guidelines)
  - As part of the organization's compliance efforts, include audits of prior years' services to ensure compliance and that, in the event you are the subject of a government audit/investigation, your documentation will support what was billed and paid.
  - Ensure that if your provider's billed based on time that counseling and/or coordination of care dominates greater than 50% of the encounter.
  - Regardless of the level(s) of service your providers are billing, you should be using a bell curve tool / coding analyzer (i.e., Compliance Risk Analyzer) to understand coding behavior. It is critical to do your own data mining to identify outliers or aberrant coding patterns.

Split / Shared Services

For CY 2023, CMS finalized a year-long delay of the split (or shared) visits policy based on the established rulemaking for 2022.

This policy determines which professional should bill for a shared visit by defining the "substantive portion" of the service as more than half of the total time.

Therefore, for CY 2023, as in CY 2022, the substantive portion of a visit is comprised of any of the following elements:

- History
- Performing a physical exam
- Medical Decision Making
- Spending time (more than half of the total time spent by the practitioner who bills the visit)

As finalized, clinicians who furnish split (or shared) visits will continue to have a choice of history, or physical exam, or medical decision making, or more than half of the total practitioner time spent to define the "substantive portion" instead of using total time to determine the substantive portion, until CY 2024.

2023 Areas of Focus

OIG, CMS and Commercial Payer Areas of Focus;

- Evaluation and Management Services
- Telehealth and Telefraud
- Medically Unbelievable Day
- Amniotic Fluid for MSK
- Medical Necessity
- Strict Liability Situations
- Cloning and Clinical Plagiarism
- Infusion Services
  - Evaluation and Management Services and Application of 25 modifier
- Incident-to & Split Shared Services

Evaluation and Management Services

- Medical Necessity as it relates to coding – 30.6.1 – Evaluation and Management Services – Medical Necessity is the overarching criteria in addition to the individual elements of the CPT Codes
- History
  - Medical Necessity and how we use it to determine the level of intensity for an encounter
  - Chief Complaint
  - History – Focus on the History of Present Illness / the history should be clinically relevant
  - Exam – It needs to be clinically relevant
  - Medical-Decision Making – This was changed in 2021. Expect further guidance from the MACs and CMS in the coming months.

Defining "Medical Necessity"

"Medically Necessary" or "Medical Necessity" shall mean health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are: a) *in accordance with generally accepted standards of medical practice;* b) clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and c) not primarily for the convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

"Generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community or otherwise consistent with the standards set forth in policy issues involving clinical judgment.

Incident-to

- I-2 Services and the specifics:
  - Direct Supervision
  - Immediately Available
  - Treatment Plan must be established by a Physician
  - Changes to a treatment plan made by the NPP results in the visit being billed under their number

Medicaid and Medicare 72 Hour Rule

- **Kentucky's** Medicaid rule regarding authentication of medical records and timing requirements. 907 Kentucky Administrative Regulations (KAR) 1:102 §2(4)(b)2 states: "The individual who provided the service shall date and sign the health record within seventy-two (72) hours from the date that the individual provided the service." Kentucky implemented this rule effective on **July 6, 2015**.
- **Alaska** 72 Hour Contemporaneous Documentation FAQs
  - Q1. Please clarify the 72 hour requirement for documentation of services; is this a straight 72 hours or is its 72 business hours. The 72 hour requirement applies to the initial documentation of services. The regulation states 72 hours from the end date of service. This is a straight 72 hours from the end of date of service.
    - An example is the date of service is June 15, 2018, the 72 hour clock starts at 12:00 am June 16, 2018 and is to be documented by 11:59 pm June 18, 2018.
  - Q2. What about weekends and holidays? The 72 hour requirement does not allow an extension for weekends and holidays.
  - **Noridian** - Q3. After a service has been rendered, what amount of time is acceptable to Medicare for the doctor to sign the notes?
    - A3. In most cases, Noridian expects that the notes are signed at the time services are rendered. Further delays may require an explanation. See CMS Internet Only Manual (IOM), Publication 100-08, Medicare Program Integrity Manual, Section 3.3.2.5

Signature Requirements

CMS's vague guidance is found in Chapter 12 of the Manual in the following statement, "The service should be documented during, or as soon as practicable after it is provided in order to maintain an accurate medical record"

Check with your MAC. Some give reasonable direction:

- WPS which states, "A reasonable expectation would be no more than a couple of days away from the service itself."
- Noridian states that they expect, "In most cases the notes would be signed at the time services are rendered."
- Palmetto is a little more direct stating "Providers should not add a late signature to the medical record, (beyond the short delay that occurs during the transcription process)." It is understood that there are circumstances, like waiting for transcription to be complete that might preclude signing the record at the time of service. In general, it is best to sign the record at the time of service, if not within a day or two at the latest.
- You may not add late signatures to orders or medical records (beyond the short delay that occurs during the transcription process). MLN Fact Sheet – Complying with Medicare Signatures - ICN 905364 May 2018

Signature Requirements

- FCSO memo (see pages 3-6), followed by practical compliance tips that apply to each issue raised.
- **Medicare Comment No. 1**
  - *"Medicare expects the documentation to be generated at the time of service or shortly thereafter. Delayed entries within a reasonable time frame (24 to 48 hours) are acceptable for purposes of clarification, error correction, the addition of information not initially available, and if certain unusual circumstances prevented the generation of the note at the time of service."*
- **Medicare Comment No. 2**
  - *"The medical record cannot be altered. Errors must be legibly corrected so that the reviewer can draw an inference as to their origin. These corrections or additions must be dated, preferably timed, and legibly signed or initialed."*
- **Medicare Comment No. 3**
  - "*Every note must stand alone, i.e., the performed services must be documented at the outset. Delayed written explanations will be considered. They serve for clarification only and cannot be used to add and authenticate services billed and not documented at the time of service or to retrospectively substantiate medical necessity. For that, the medical record must stand on its own with the original entry corroborating that the service was rendered and was medically necessary."*
- **Medicare Comment No. 5**
  - *"Documentation is considered cloned when each entry in the medical record for a patient is worded exactly alike or similar to the previous entries. Cloning also occurs when medical documentation is exactly the same from patient to patient. It would not be expected that every patient had the exact same problem, symptoms, and required the exact same treatment."*
  - *"Cloned documentation does not meet medical necessity requirements for coverage of services rendered due to the lack of specific, individual information. All documentation in the medical record must be specific to the patient and her/his situation at the time of the encounter. Cloning of documentation is considered a misrepresentation of the medical necessity requirement for coverage of services. Identification of this type of documentation will lead to denial of services for lack of medical necessity and recoupment of all overpayments made."*

Cloning

- The word 'cloning' refers to documentation that is worded exactly like previous entries. This may also be referred to as 'cut and paste', copy and paste, or 'carried forward.' Cloned documentation may be handwritten, but generally occurs when using a preprinted template or a Promoting Interoperability (PI) Programs electronic record.
- Promoting Interoperability (PI) Programs electronic records replace traditional paper medical records with computerized record keeping to document and store patient health information. EHRs may include patient demographics, progress notes, medications, medical history, and clinical test results from any health care encounter.
- While these methods of documenting are acceptable, it would not be expected the same patient had the same exact problem, symptoms, and required the exact same treatment or the same patient had the same problem/situation on every encounter. Authorship and documentation in an EHR must be authentic.
- Cloned documentation does not meet medical necessity requirements for coverage of services. Identification of this type of documentation will lead to denial of services for lack of medical necessity and recoupment of all overpayments made.
- Over-documentation is the practice of inserting false or irrelevant documentation to create the appearance of support for billing higher level services. Some PI Programs technologies auto-populate fields when using templates built into the system. Other systems generate extensive documentation on the basis of a single click of a checkbox, which if not appropriately edited by the provider may be inaccurate.

Compliance Programs for Physicians

Establishing and following a compliance program will help physicians avoid fraudulent activities and ensure that they are submitting true and accurate claims.

Core Elements of a Compliance Program

- Conduct internal monitoring and auditing.
- Implement compliance and practice standards.
- Designate a compliance officer or contact.
- Conduct appropriate training and education.
- Respond appropriately to detected offenses and develop corrective action.
- Develop open lines of communication with employees.
- Enforce disciplinary standards through well-publicized guidelines.
    - ***With the passage of the Patient Protection and Affordable Care Act of 2010, physicians who treat Medicare and Medicaid beneficiaries will be required to establish a compliance program.***

Don't Believe Me!

U.S. Department of Health and Human Services
Office of Inspector General

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- Where To Go for Help
- What To Do If You Think You Have a Problem
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Compliance Programs for Physicians

Establishing and following a compliance program will help physicians avoid fraudulent activities and ensure that they are submitting true and accurate claims. The following seven components provide a solid basis upon which a physician practice can create a voluntary compliance program:

For more information on compliance programs for physicians, see OIG's Compliance Program Guidance for Individual and Small Group Physician Practices

- Conduct internal monitoring and auditing.
- Implement compliance and practice standards.
- Designate a compliance officer or contact.
- Conduct appropriate training and education.
- Respond appropriately to detected offenses and develop corrective action.
- Develop open lines of communication with employees.
- Enforce disciplinary standards through well-publicized guidelines.

With the passage of the Patient Protection and Affordable Care Act of 2010, physicians who treat Medicare and Medicaid beneficiaries will be required to establish a compliance program.

The Federal Register

by physician practices. The guidance should not be viewed as mandatory or as an all-inclusive discussion of the advisable components of a compliance program. Rather, the document is intended to present guidance to assist physician practices that voluntarily choose to develop a compliance program.

Office of Inspector General's Compliance Program Guidance for Individual and Small Group Physician Practices

I. Introduction

This compliance program guidance is intended to assist individual and small group physician practices (''physician practices'') [1] in developing a voluntary compliance program that promotes adherence to statutes and regulations applicable to the Federal health care programs (''Federal health care program requirements''). The goal of voluntary compliance programs is to provide a tool to strengthen the efforts of health care providers to prevent and reduce improper conduct. These programs can also benefit physician practices[2] by helping to streamline business operations.

Many physicians have expressed an interest in better protecting their practices from the potential for erroneous or fraudulent conduct through the implementation of voluntary compliance programs. The Office of Inspector General (OIG) believes that the great majority of physicians are honest and share our goal of protecting the integrity of Medicare and other Federal health care programs. While this document presents basic procedural and structural guidance for designing a voluntary compliance program, it is not in and of itself a compliance program. Indeed, as recognized by the OIG and the health care industry, there is no ''one size fits all'' compliance program, especially for physician practices. Rather, it is a set of guidelines that physician practices can consider if they choose to develop and implement a compliance program.

As with the OIG's previous guidance, [3] these guidelines are not mandatory. Nor do they represent an all-inclusive document containing all components of a compliance program. Other OIG outreach efforts, as well as other Federal agency efforts to promote compliance,[4] can also be used in developing a compliance program. However, as explained later, if a physician practice adopts a voluntary and active compliance program, it may well lead to benefits for the physician practice.

A. Scope of the Voluntary Compliance Program Guidance

This guidance focuses on voluntary compliance measures related to claims submitted to the Federal health care programs. Issues related to private payor claims may also be covered by a compliance plan if the physician practice so desires.

The guidance is also limited in scope by focusing on the development of voluntary compliance programs for individual and small group physician practices. The difference between a small practice and a large practice cannot be determined by stating a was to provide guidance to those physician practices whose financial or staffing resources would not allow them to implement a full scale, institutionally structured compliance program as set forth in the Third Party Medical Billing Guidance or other previously released OIG guidance. A compliance program can be an important tool for physician practices of all sizes and does not have to be costly, resource-intensive or time-intensive.

B. Benefits of a Voluntary Compliance Program

The OIG acknowledges that patient care is, and should be, the first priority of a physician practice. However, a practice's focus on patient care can be enhanced by the adoption of a voluntary compliance program. For example, the increased accuracy of documentation that may result from a compliance program will actually assist in enhancing patient care. The OIG believes that physician practices can realize numerous other benefits by implementing a compliance program. A well-designed compliance program can:

- Speed and optimize proper payment of claims;
- Minimize billing mistakes;
- Reduce the chances that an audit will be conducted by HCFA or the OIG; and
- Avoid conflicts with the self-referral and anti-kickback statutes.

The incorporation of compliance measures into a physician practice should not be at the expense of patient

The Patient Protection and Affordable Care Act of 2010 (the "Healthcare Reform Act," or the "Act") was signed into law on March 23, 2010

The Act:

- requires closer scrutiny of providers and suppliers seeking to participate in Medicare and other federally funded healthcare programs
- allows for the collection and centralization of billing and claims data and makes that information available to law enforcement and oversight agencies for the purpose of investigating suspected fraud
- increases the penalties for those who abuse the system
- amends the False Claims Act and the Anti-kickback Act to make it easier for the government to bring actions under those statutes
- provides substantial amounts in additional resources to government agencies, investigators, and prosecutors to pursue wrongdoers

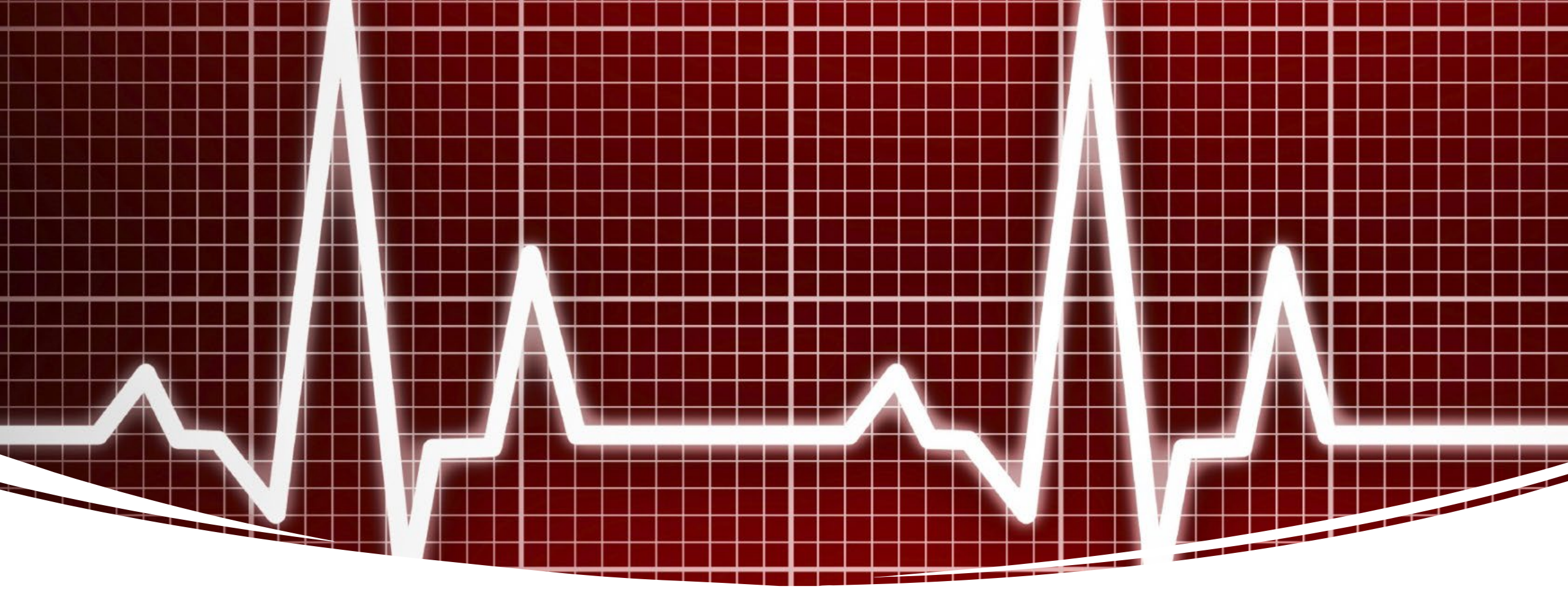
Mandatory Compliance

Section 6401(a)(7) of the Act requires providers and suppliers enrolled in federal healthcare programs to create and maintain compliance programs as a condition of their continued participation.

- This Section directs the Department of Health and Human Services (HHS), in consultation with the HHS Office of Inspector General (HHS-OIG) to establish the "core elements" of such programs through regulation and to determine the timeline for implementing compliance programs.
- Further, ***the Act empowers HHS to disenroll non-compliant providers and suppliers and/or to impose civil monetary penalties or other Immediate sanctions.***
- ***The Act requires screening before providers or suppliers can participate in Medicare.***
- ***HHS has the authority to establish such screening procedures which shall include state licensure checks, criminal background checks, fingerprinting, unscheduled and unannounced site visits, database checks and other such screening as HHS deems appropriate***

Healthcare Fraud Criminal Offense

- The Act amends 18 U.S.C. 1347 (criminal healthcare fraud) to *eliminate any requirement that the defendant have "actual knowledge" of the healthcare fraud statute or specific intent to violate it*.
  - Sources slides 6-10
    - Patient Protection and Affordable Care Act of 2010, H.R. 3590, March 23, 2010.
    - H.R. 3590, Sec. 6401 (a)(7).
    - H.R. 3590, Sec. 6401 (a)(7).
    - H.R. 3590, Sec. 6401 (a)(7).
    - http://oig.hhs.gov/fraud/complianceguidance.asp
    - 2009 United States Sentencing Commission Guidelines Manual, §8B2.1 Effective Compliance and Ethics Program (2009).
    - H.R. 3590, Sec. 6401 (a).
    - H.R. 3590, Sec. 10104(j).
    - H.R. 3590, Sec. 10104(j).
    - H.R. 3590, Sec. 10104(j).
    - H.R. 3590, Sec. 10606.



Thank You!!!

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