REVIEWING YOUR COMPLIANCE PROGRAM

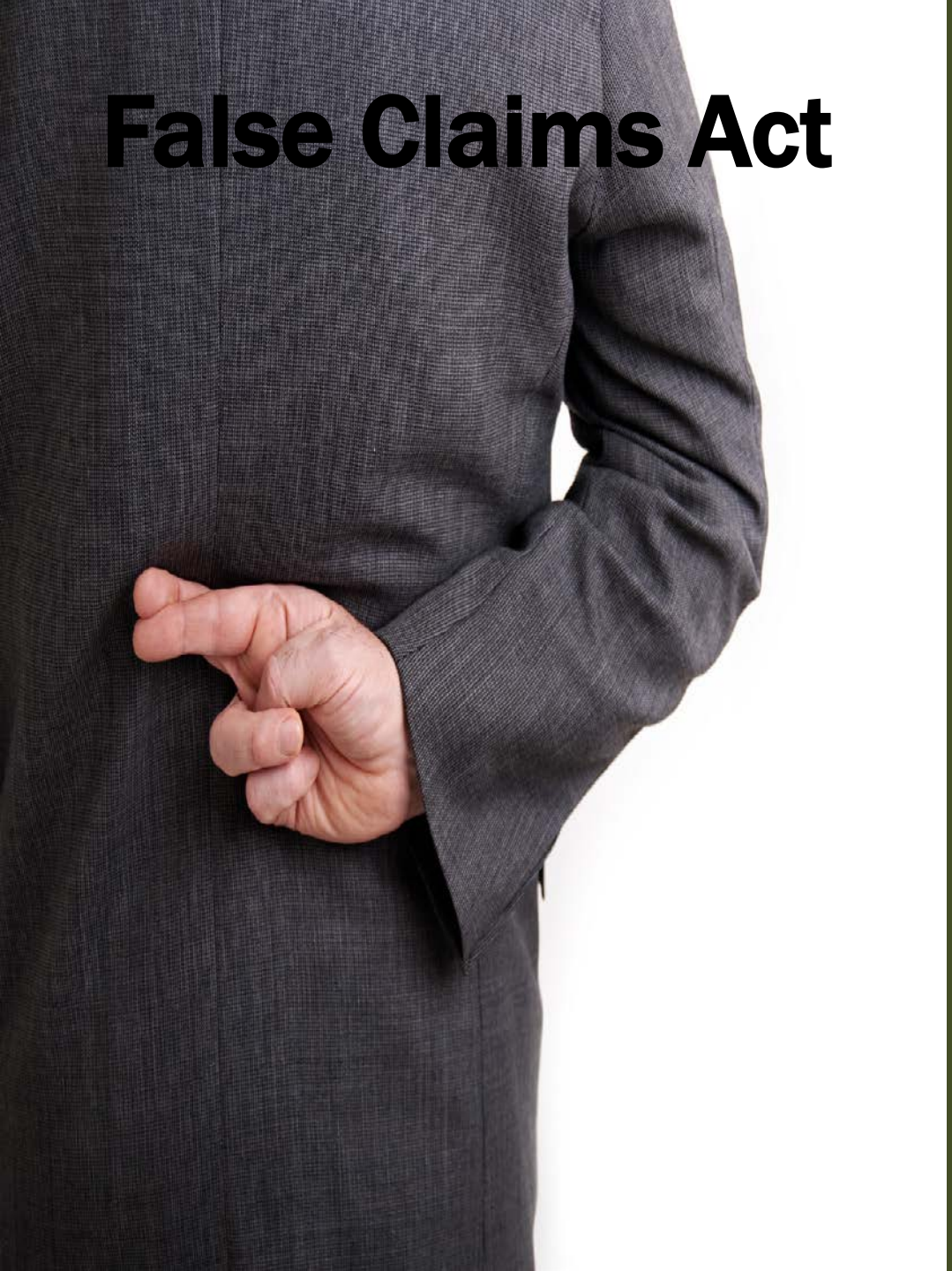
Affordable Care Act

"…under section 6401(a) of the ACA, which established a new section 1866(j)(8) of the Act, a provider of medical or other items or services or a supplier shall, as a condition of enrollment in Medicare, Medicaid or CHIP, **establish a compliance program** that contains certain "**core elements**." The statute requires the Secretary, in consultation with the HHS OIG, to establish the core elements for providers or suppliers within a particular industry or category.."

Fraud and Abuse Laws

- False Claims Act
- Anti-Kickback Statute
- Physician Self-Referral Statute
- Exclusion Statute
- Civil Monetary Penalties Law

False Claims Act



Prohibits the submission of false or fraudulent claims to the Government

Deliberate ignorance

2000 Seven Components

1. Conducting internal monitoring and auditing;
2. Implementing written compliance and practice standards;
3. Designating a compliance officer or contact;
4. Conducting appropriate training and education;
5. Responding appropriately to detected offenses and developing corrective action;
6. Developing open lines of communication; and
7. Enforcing disciplinary standards

Seven Fundamental Elements

1. Implementing written policies, procedures and standards of conduct;
2. Designating a compliance officer and compliance committee
3. Conducting effective training and education
4. Developing effective lines of communication
5. Conducting internal monitoring and auditing
6. Enforcing standards through well publicized disciplinary guidelines
7. Responding promptly to detected offenses and undertaking corrective action

Comparison

	2000	2012
1.	Internal monitoring & auditing	Implement written P&P & standards of conduct
2.	Implement compliance standards	Designate Officer and Committee
3.	Designate officer or contact	Effective training & education
4.	Appropriate training or education	Effective lines of communication
5.	Respond appropriately to offenses	Internal monitoring & auditing
6.	Develop Open communication	Enforce disciplinary standards
7.	Enforce Disciplinary Standards	Respond promptly to detected offenses and undertake corrective action

5 Practical Tips

1. Make compliance plans a priority now.
2. Know your fraud and abuse risk areas.
3. Manage your financial relationships.
4. Just because your competitor is doing something doesn't mean you can or should. Call 1-800-HHS-TIPS to report suspect practices.
5. When in doubt, ask for help.

https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf

HHS/DOJ Health Care Fraud Prevention and Enforcement Action Team's ("HEAT")

OIG's provider compliance training initiative is an outgrowth of the HHS/DOJ Health Care Fraud Prevention and Enforcement Action Team's ("HEAT") efforts. In Spring 2011, OIG and its government partners provided in-person trainings in Houston, Tampa, Kansas City, Baton Rouge, Denver, and Washington, D.C. The trainings focused on the realities of Medicare and Medicaid fraud and the importance of implementing an effective compliance program. View the webcast and hear our three-pronged message about provider compliance.

Get the Facts. Understand the law and the consequences of violating it.

Make a Plan. Cultivate a culture of compliance within your health care organization.

Know Where To Go. Learn what to do when a compliance issue arises.

Operating an Effective Compliance Program

Policies and Procedures

- Regularly review and update with department managers and Compliance Committee.
- Assess whether they are tailored to the intended audience and their job functions.
- Ensure they are written clearly.
- Include “real-life” examples.

Measuring Effectiveness

- Develop compliance program with benchmarks and measurable goals.
- Set up a system to measure how well you are meeting those goals.
- Involve the Board in creating the program and regularly update the Board regarding compliance risks, audits, and investigations.
- If one or more goals are not met, investigate why and how to improve in the future.
- Assess whether the compliance program has sufficient funding and support.

TRAINING

- Regularly review and update training programs. Try different approaches. Use “real-life” examples.
- Make training completion a job requirement.
- Test employees’ understanding of training topics.
- Maintain documentation to show which employees received training.
- Train the Board.
- Train yourself and your compliance staff. Attend conferences and webinars, subscribe to publications and OIG’s email list, monitor OIG’s website, and network with peers to stay up-to-date and get ideas.

Some Questions Compliance Professionals Should Ask as They Prepare for Health Care Reform

Excerpt from a keynote address delivered by Daniel R. Levinson, Inspector General for the

Department of Health & Human Services, at the Health Care Compliance Association's

Annual Compliance Institute on April 19, 2010

Transparency: Are you prepared to operate in a more transparent health care system?

- Does your organization have the right systems and technologies to meet new demands to collect, organize, track, retain, and report information and data accurately and completely?
- Do you have security and privacy protections in place for creating, transmitting, and storing data?
- Do you have systems in place to meet enhanced reporting and disclosure requirements applicable to your industry segment?

Quality: Are you focused on quality as a compliance issue?

- Do your clinicians understand that quality is a compliance concern and that quality of care is increasingly integral to payment?
- Do you have systems that will ensure that charting, collection and reporting of quality data and clinical documentation are accurate, complete, and sufficient to justify payment?
- Are you present during conversations and involved in decisions about quality in your organization?
- Does your compliance department have the expertise to address quality-related compliance issues?
- Are your board of directors and management informed about the heightened role of quality of care under health care reform?

Conducting internal monitoring and auditing

- Whether individuals are properly carrying out their responsibilities and claims are submitted
- There are two types of reviews that can be performed as part of this evaluation: (1) A standards and procedures review; appropriately.
- Standards and Procedures
- Claims Submission Audit
- five to ten medical records per physician.

OIG has developed a list of four potential risk areas

- (a) Coding and billing;
- (b) reasonable and necessary services;
- (c) documentation; and
- (d) improper inducements, kickbacks and self-referrals.

Knowing misuse of provider identification numbers, which results in improper billing;

An example of this is when the practice bills for a service performed by Dr. B, who has not yet been issued a Medicare provider number, using Dr. A's Medicare provider number. Physician practices need to bill using the correct Medicare provider number, even if that means delaying billing until the physician receives his/her provider number.

Billing for non-covered services as if covered;

For example, Dr. Y bills Medicare using a covered office visit code when the actual service was a non-covered annual physical. Physician practices should remember that ‘‘necessary’’ does not always constitute ‘‘covered’’ and that this example is a misrepresentation of services to the Federal health care programs.

Good documentation
helps ensure
quality patient care.
Accurate medical
records are critical.

Implementing compliance and practice standards

- Physician practices should establish clear standards and procedures governing gift-giving because such exchanges may be viewed as inducements to influence business decisions.
- There are various Federal regulations governing the privacy of patient records and the retention of certain types of patient records. Many states also have record retention statutes. Practices should check with their state medical society and/or affiliated professional association for assistance in ascertaining these requirements for their particular specialty and location. cements to influence business decisions.

Designating a compliance officer or contact

- It is acceptable for a physician practice to designate more than one employee with compliance monitoring responsibility. In lieu of having a designated compliance officer, the physician practice could instead describe in its standards and procedures the compliance functions for which designated employees, known as ‘‘compliance contacts,’’ would be responsible.

Conducting appropriate training and education

There are 3 basic steps for educational objectives:

1. Determining who needs training (both in coding and billing and in compliance);
2. Determining the type of training that best suits the practice's needs (*e.g., seminars, in-service training, self-study or other programs); and*
3. Determining when and how often education is needed and how much each person should receive.

Responding appropriately to detected offenses and developing corrective action

As appropriate, such steps may involve a corrective action plan, the return of any overpayments, a report to the Government, and/or a referral to law enforcement authorities

Developing open lines of communication

In the small physician practice setting, the communication element may be met by implementing a clear ‘‘open door’’ policy between the physicians and compliance personnel and practice employees.

This policy can be implemented in conjunction with less formal communication techniques, such as conspicuous notices posted in common areas and/or the development and placement of a compliance bulletin board where everyone in the practice can receive up-to-date compliance information.

Enforcing disciplinary standards

Disciplinary actions could include: Warnings (oral); reprimands (written); probation; demotion; temporary suspension; termination; restitution of damages; and referral for criminal prosecution.

Inclusion of disciplinary guidelines in in-house training and procedure manuals is sufficient to meet the ‘‘well publicized’’ standard of this element.

Notice of Privacy Practices (NPP)

September 23, 2013

..must review and may need to revise their existing notice of privacy practices (NPP) to reflect several changes required by the final rule, including the addition of statements addressing:

That uses and/or disclosures of psychotherapy notes, PHI for marketing purposes and the sale of PHI will now require authorization from the individual.

The individual's right to opt out of receiving communications from the covered entity related to fundraising.

The requirement that the covered entity must agree to an individual's requested restriction on disclosure of PHI if the disclosure pertains solely to a health care item or service for which the individual has paid the covered entity in full (i.e., paid out of pocket).

That the covered entity is required to notify affected individuals following a breach of unsecured PHI

Redistribution of NPP

Existing HIPAA rules require that an NPP must be redistributed to participants within 60 days after a material change to the notice. In the preamble to the regulations HHS states that these changes are to be considered material changes to the NPP.

Business Associate Agreements

The final rule expands the definition of business associates (BA) to include subcontractors of existing business associates, and makes significant changes extending the direct liability for HIPAA compliance to business associates and their sub-contractors. It also affirms that covered entities are liable for penalties for the failure of a business associate "agent" to perform a function on the covered entity's behalf. As a result, plan sponsors will need to review, and possibly revise, existing business associate agreements.

Employers should make sure that their BA agreements include the following requirements for their business associates:

- Comply with requirements of the HIPAA Privacy Rule applicable to business associates
- Comply with the HIPAA Security Rule with regard to electronic PHI
- Report breaches of unsecured PHI to the covered entity
- Ensure that all subcontractors of the business associate agree to the same restrictions that apply to the business associate

If changes in existing BA agreements are required to be made, and the covered entity and business associate had an agreement in place on January 25, 2013, the parties can rely on the existing agreement until the earlier of either the date such agreement is renewed or modified, or September 22, 2014. If the parties did not have an agreement in place prior to January 25, 2013, an agreement complying with the requirements of the Final Rule must be in place by September 23, 2013

Breach Notification

Under the previous Interim Regulations, a breach of unsecured PHI must only be reported if it poses "… a significant risk of financial, reputational, or other harm to the individual." The final rule eliminates this "significant risk of harm" standard. In its place, an impermissible use or disclosure of unsecured PHI is presumed to be a breach requiring notification unless the covered entity can demonstrate through a documented risk assessment that there is a "low probability that the PHI has been compromised."

Fraud includes obtaining a benefit through intentional misrepresentation or concealment of material facts

Waste includes incurring unnecessary costs as a result of deficient management, practices, or controls

Abuse includes excessively or improperly using government resources

Medicare Program Integrity Manual

Chapter 1 - *Medicare Improper Payments: Measuring, Correcting, and Preventing Overpayments and Underpayments*

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(Rev. 313, 11-20-09)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Compliance Program for Individual and Small Group Physician Practices

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

ACTION: Notice.

SUMMARY: This **Federal Register** no
sets forth the recently issued
Compliance Program Guidance for
Individual and Small Group Phys
Practices developed by the Office
Inspector General (OIG). The OIG
previously developed and publis
voluntary compliance program g
focused on several other areas a
aspects of the health care indus
believe that the development a
ssuance of this voluntary com
rogram guidance for individu
mall group physician practic
erve as a positive step towar
roviders in preventing the s
erroneous claims or engag
lawful conduct involving
alth care programs.

ckground

The creation

OFFICE OF INSPECTOR GENERAL

Special Fraud Alert

RENTAL OF SPACE IN PHYSICIAN OFFICES BY PERSONS OR ENTITIES TO WHICH PHYSICIANS REFER

Proposed Rules

ARTMENT OF HEALTH AND
MAN SERVICES

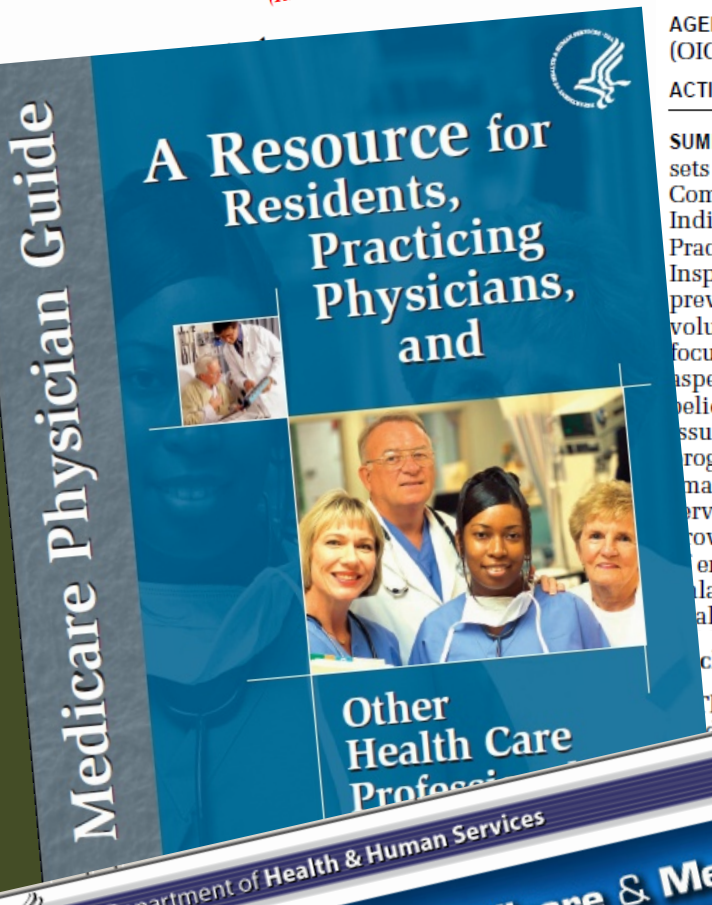
ice of Inspector General

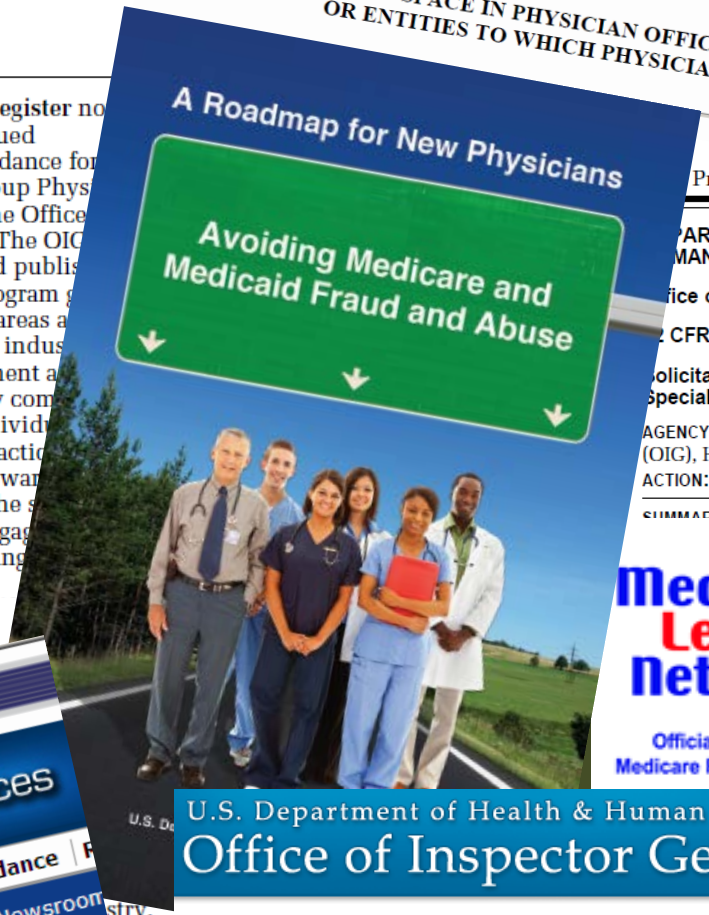
CFR Part 1001

olicitation of New Safe Harbors an
pecial Fraud Alerts

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

ACTION: Intent to develop regulations





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OIG.HHS.GOV/Recovery

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Online Exclusions Database

News Room

Fight Back Against Medical Identity Theft

Self-Disclosure Information

Enforcement Actions

RECOMMENDED COMPLIANCE RESOURCES

59434 Federal Register / Vol. 65, No. 194 / Thursday, October 5, 2000 / Notices

https://oig.hhs.gov/compliance/

http://www.cms.gov/

http://oig.hhs.gov/fraud.asp