

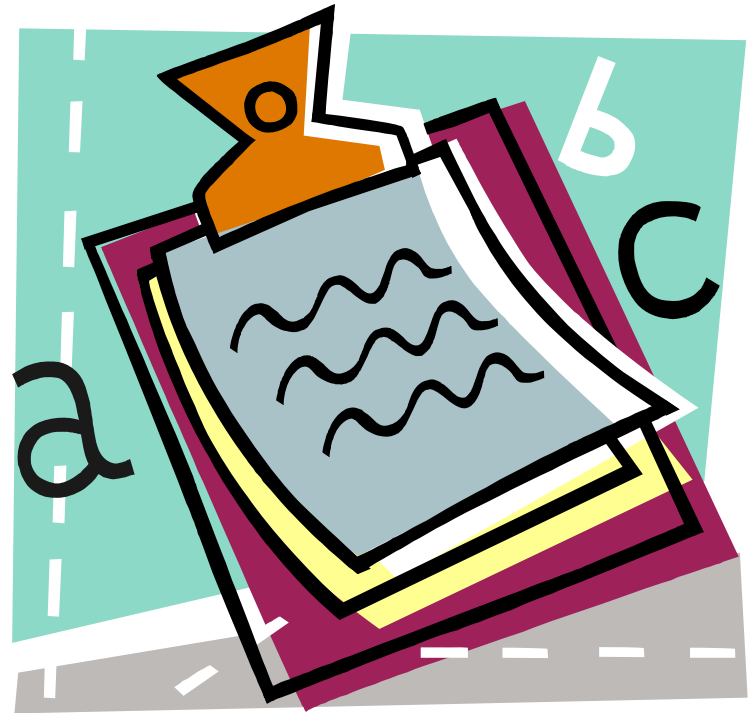
Oregon Medical Association  
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# **Compliance in Business Transactions**

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# Transactions Overview

- Due diligence
- Legal diligence
- Business diligence



# Due Diligence

- A process to research and analyze the legal and business risks associated with a particular business transaction
- Documentation in your files that you intended to do the right thing



# Legal Diligence

Legal diligence is about:  
learning what the law really  
says,  
and coming up with solutions  
to make your transaction  
compliant with the law.



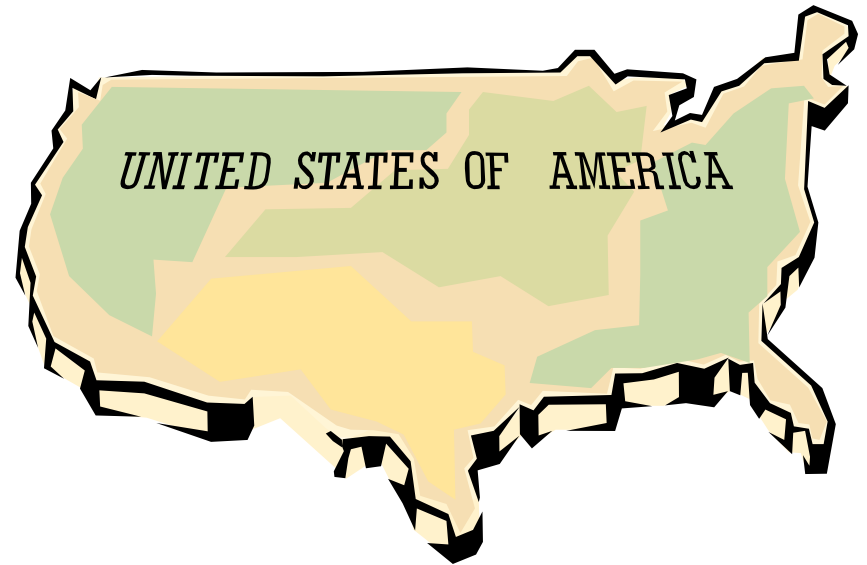
# Legal Diligence

- Federal laws
- State laws
- Non-law guidance



# Federal Laws

- Anti-Kickback Statute
- Stark Law
- Medicare Rules
- CMS/FTC Rules



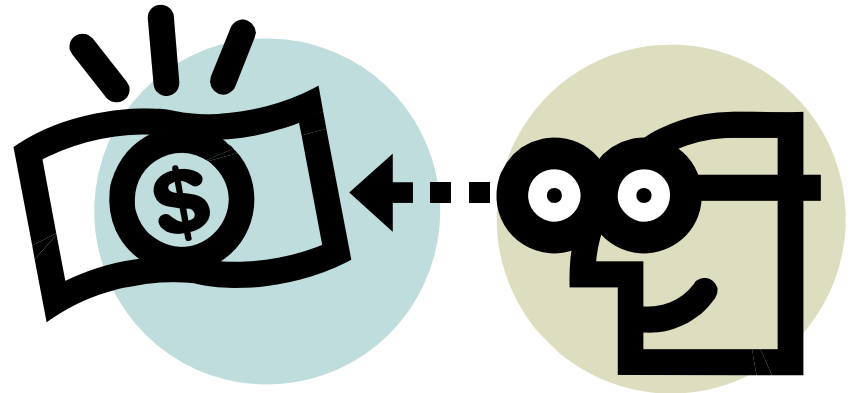
# Anti-Kickback Statute

- Cannot bribe physicians for their federal program referrals (e.g., Medicare)
- Almost every transaction involving the receipt of money or anything else of value could be viewed as a kickback
- Study safe harbors and advisory opinions



# Stark Law

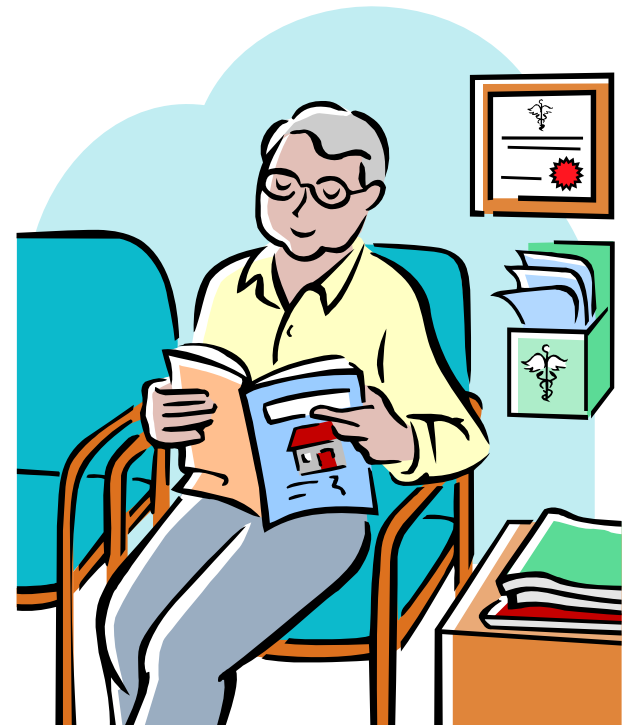
- Cannot improperly profit off of your own referrals of Medicare patients
- Becoming known as a strict liability statute (i.e., either you meet an exception to the rule such as the “in-office ancillary services exception” or you do not)
- Moving target regulations so keep up to date





# Medicare Rules

- Do not overlook substantive Medicare rules (i.e., re-assignment, conditions of coverage)
- Look to Medicare Manuals for agency interpretation of rules and look to Local Coverage Determinations (LCDs) for carrier interpretation of rules
- Constantly changing so get updates from billing company or coding staff



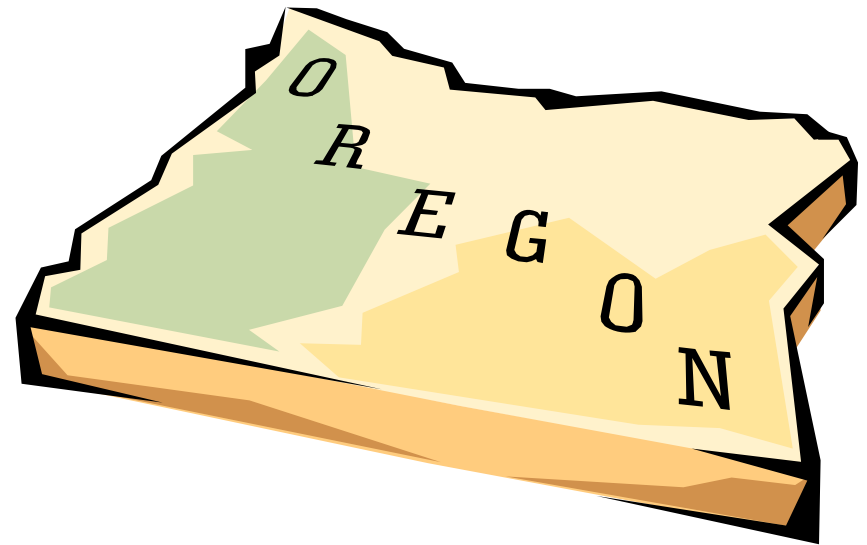
# CMS/FTC Rules

- Whole new body of regulatory compliance related to HIPAA
- May be new compliance obligations related to identity theft
- Use agency FAQ pages as starting point



# State Laws

- Licensing Laws
- Medicaid Rules
- Private Insurers (i.e., contract law)



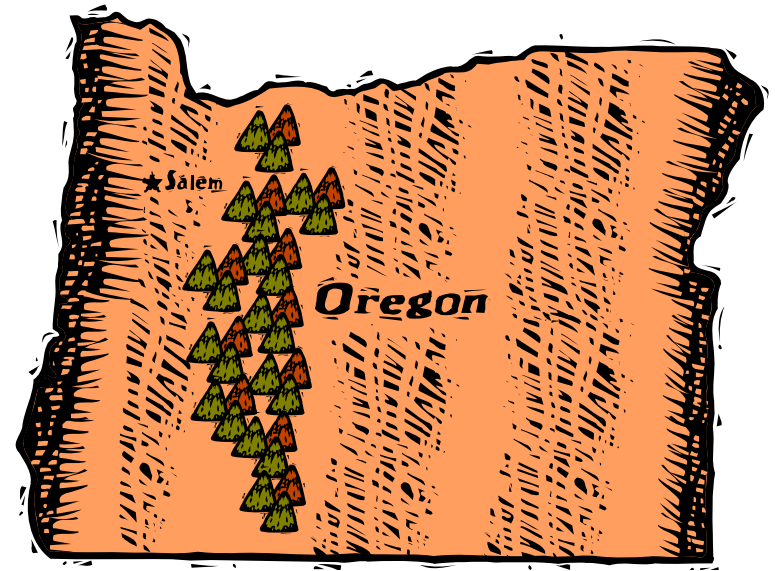
# Licensing Laws

- Check licensing and enabling statutes for the scope of practice related to your office (i.e., ORS)
- Review every two years (after Oregon Legislative sessions)
- Review agency administrative rules as well (i.e., OAR)
- Use your trade associations for updates



# Medicaid Rules

- If your office participates, understand that this is different from Medicare and compliance generally is a state issue (i.e., DMAP)
- Mandatory fraud and abuse obligations if receive more than \$5 million annually



# Private Insurers

- Private insurer issues generally are a matter of contract law
- Insurers increasingly conducting their own audits
- Insurer auditors do meet with government agencies periodically to discuss fraud and abuse trends



# Non-Law Guidance

- Agency guidance (e.g., letters, advisory opinions, etc.)
- Trade association guidance (e.g., newsletters, handbooks, etc.)
- Law and accounting firm guidance
- Remember, guidance is “not law” so if there is any doubt about how to comply with a law, get legal advice



# Business Diligence

Business diligence is about active management of a transaction: before it is entered into, during its operation, and after it is completed.





# Getting Into the Transaction

- Understand the transaction
- Clarify vague issues
- Review all documents before signing off on them



# Living With the Transaction

- Actively manage the transaction
- Use of amendments
- Resolving disputes



# Getting Out of the Transaction

- Follow the terms for termination and notice
- Avoid the temptation to breach
- Watch out for clauses that survive termination



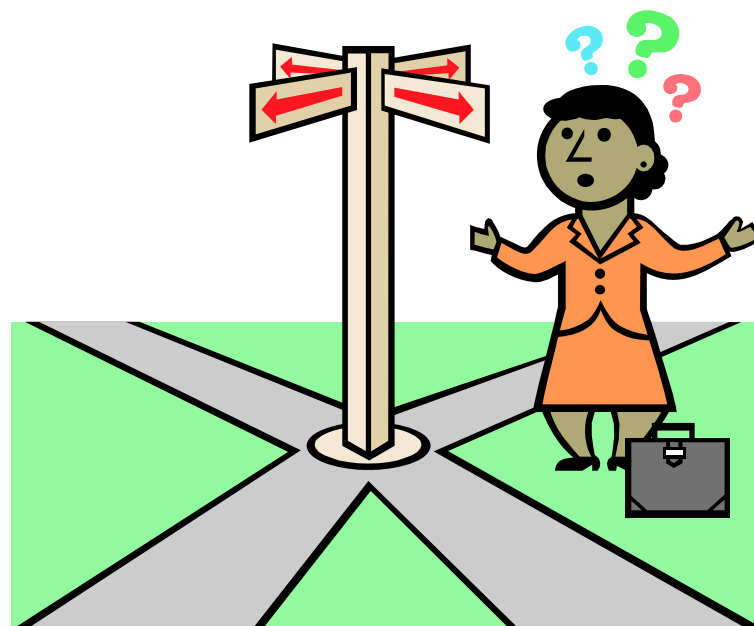
# Example One

*“ Hey, let’s get some of these drug company and medical device consulting agreements because everyone else is getting their free money so why shouldn’t we? ”*



# Example One

- Due diligence asks:
- What is the nature of the transaction?
- Is there a legal problem?
- Is there a business problem?



# Example One

- Nature of transaction
- How much money is involved?
- What work is required?
- What product or service is involved?
- Is there any way a physician referral could be involved even if indirectly?
- Is it too good to be true?



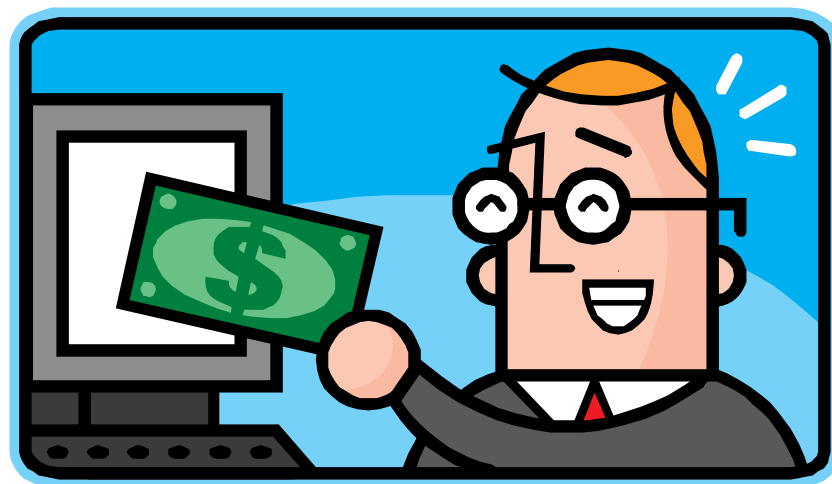
# Example One

- Legal diligence
- Does a federal law apply?
- Does a state law apply?
- Is there industry guidance?



# Example One

- Legal diligence
- Possible federal kickback to promote a drug or device?
- Is there safe harbor?
- Maybe ... for personal services agreements.





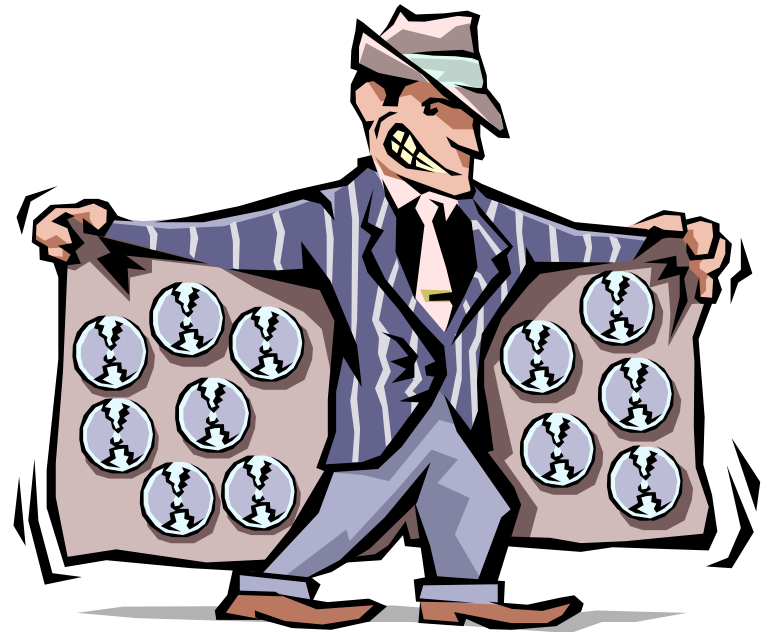
# Example One

- Business diligence
- Has agreement been reviewed prior to signing?
- Is process in place to comply with safe harbor?
- Do you know how to get out of the agreement?



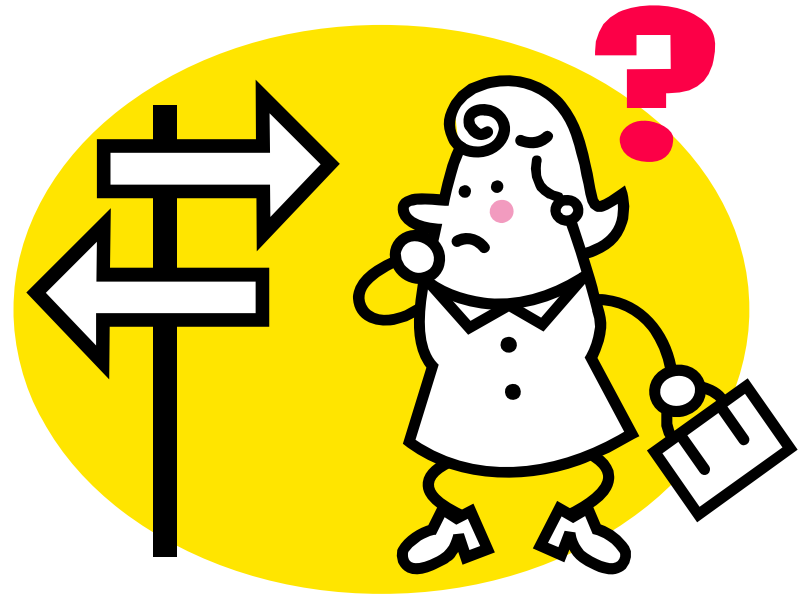
# Example Two

*“ Hey, this new billing company says in its proposed contract it will do all my coding for me and guarantee me the highest rate of return on my billings all for only a rate of three percent. ”*



# Example Two

- Due diligence asks:
- What is the nature of the transaction?
- Is there a legal problem?
- Is there a business problem?



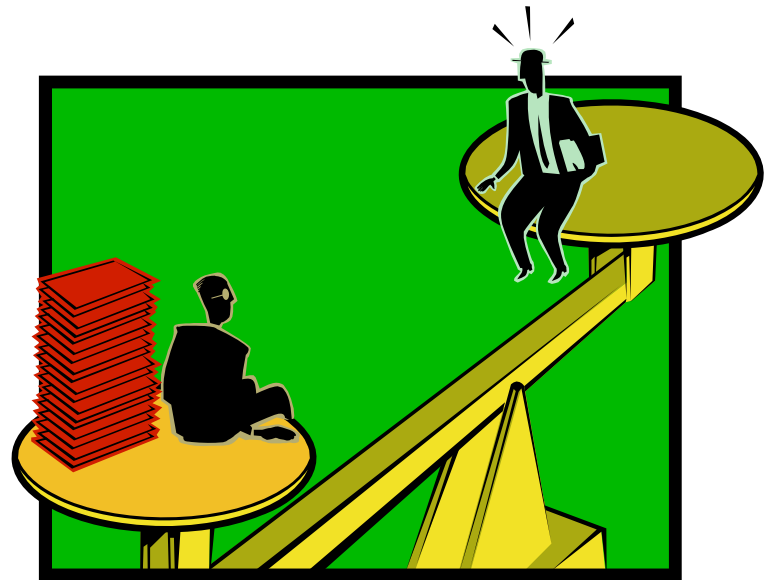
# Example Two

- Nature of transaction
- Is the agreement sufficiently detailed?
- Is the fee structure appropriate and are there hidden costs?
- Are the services appropriate and what really are the services?
- Are there solid references?



# Example Two

- Legal diligence
- Does a federal law apply?
- Does a state law apply?
- Is there industry guidance?



# Example Two

- Legal diligence
- Is contract appropriate and feasible?
- Is there industry guidance?
- Sure ... for third party billing companies.



# Example Two

- Business diligence
- If passes legal diligence, is agreement clear?
- Is process in place to monitor and audit performance under agreement?
- Do you know how to get out of the agreement?



# Example Three

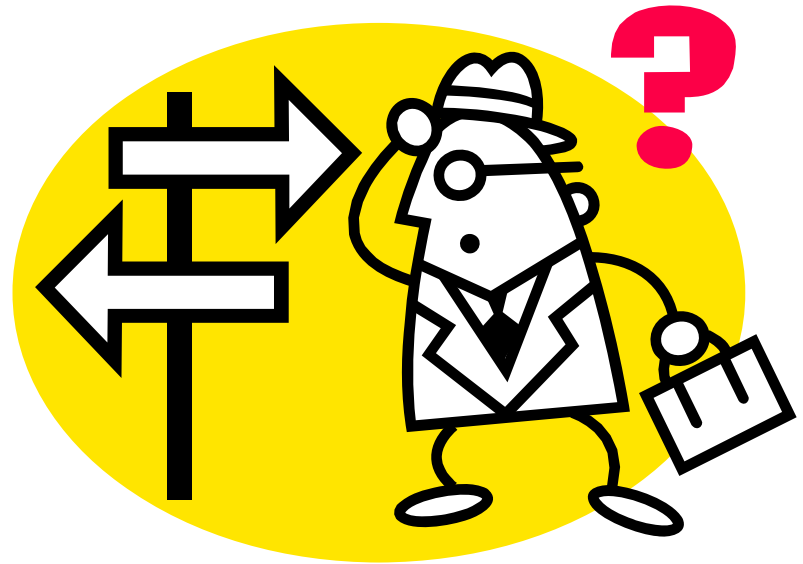
*“ Hey, this revenue recovery firm says it will help us find lost money and send everything to its exclusive collection agency for a small fee. They do not use contracts so just send them our old business associate agreement to get this going today. ”*





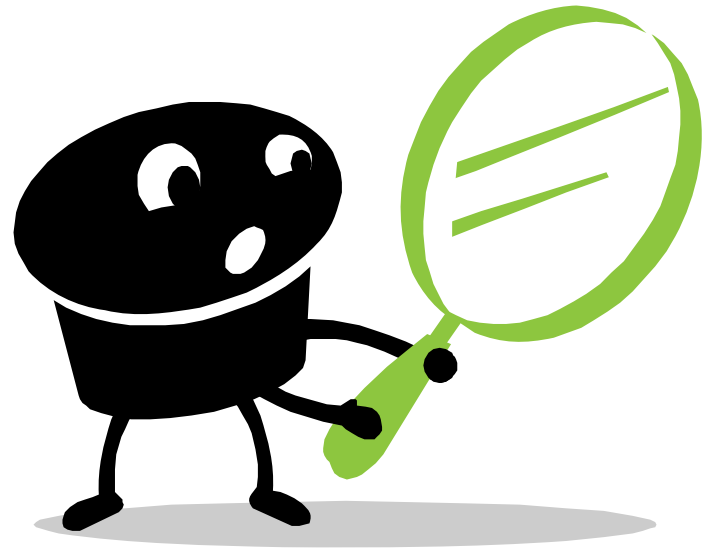
# Example Three

- Due diligence asks:
- What is the nature of the transaction?
- Is there a legal problem?
- Is there a business problem?



# Example Three

- Nature of transaction
- References?
- Who is the real party and what are they actually providing for services?
- Why is there no agreement?
- Is HIPAA in play? Other laws?



# Example Three

- Legal diligence
- Does a federal law apply?
- Does a state law apply?
- Is there industry guidance?



# Example Three

- Legal diligence
- Possible HIPAA issue?
- Possible consumer protection issue?
- More detail please?



# Example Three

- Business diligence
- Have references been checked?
- Have legal issues been resolved?
- Do you know how to get out of the transaction if nothing is in writing?



# Do's and Don'ts

## Do

- Be like Jerry Maguire and “Show me the law!”
- Document compliance
- Be frugal but not cheap



# Do's and Don'ts

## Don't

- Be an ostrich
- Believe everything you hear
- Make matters worse



# Resources

- OIG

[oig.hhs.gov/fraud.asp](http://oig.hhs.gov/fraud.asp)

- CMS

[cms.hhs.gov/center/physician.asp](http://cms.hhs.gov/center/physician.asp)

- AHLA

[healthlawyers.org](http://healthlawyers.org)

