

# Preparing for the On-Site Regulatory Inspection

{ Lela Goldwyn, MS, CHC, CPC, CPMA

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## Agenda

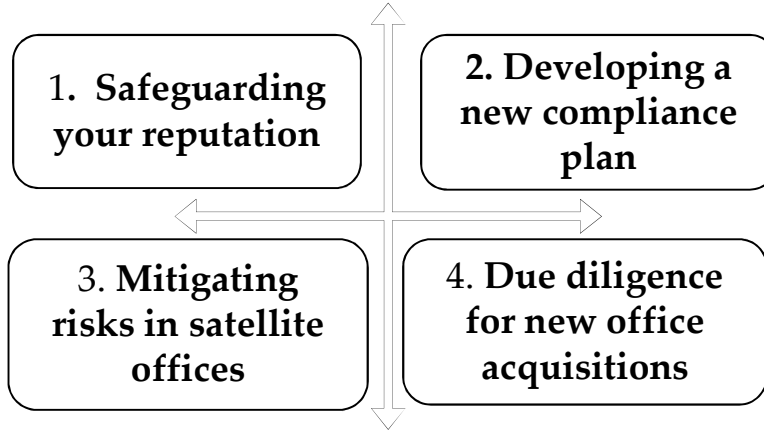
### How to conduct an internal inspection

- Reasons why-lessons learned along the way
- Preparing and including your staff
- Developing inspection criteria
- Assuring corrective action
- And Bernie Madoff too...

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## Four Obvious Reasons to Conduct a Regulatory Inspection



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## A chain saw under the sink?



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## Shocked

*by Eye Wash Stations!*

1. Installed backward-water spraying toward wall
2. Connected to hot water only

*Tip: Don't just look, test!*

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## Common Failure?

### Over-filled Sharps Box

But wait! Site does not provide services that require Sharps of any kind...

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What might this suggest?

Receptionist has business cards for a physical therapy clinic on her desk, attached to a long list of patient names with dates.

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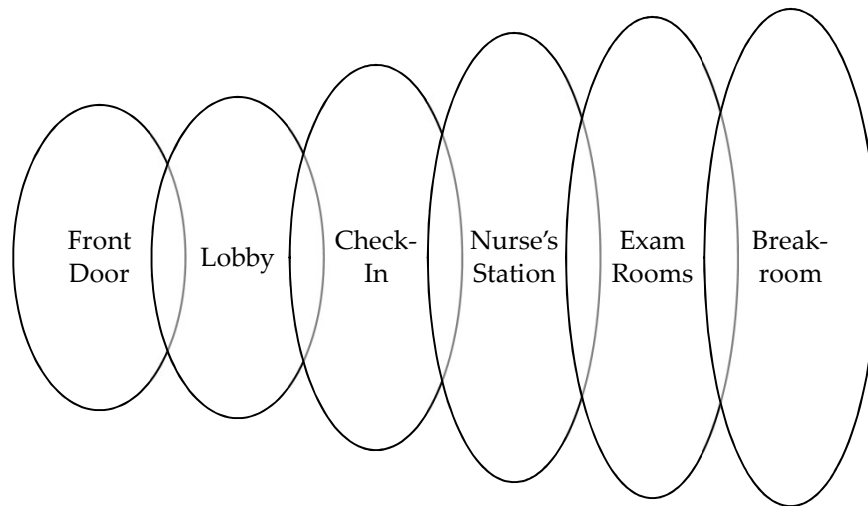
## Preparing the Staff



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## What areas are observed?



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## Involve the Team

- ✓ **Give Notice-** *Internal inspections are not a test-give staff a chance to correct before the inspection*
- ✓ **Designee-** *A point person who will communicate with staff, escort you during the inspection and who will be held accountable for corrective action*

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- **Designee should feel they are learning new skills, not being interrogated**
- **Teach them how to relate to external inspectors by working through this process with you**

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### Mitigating Negativity

INVASIVE	Less INTRUSIVE
Asking for petty cash to be counted and compared to receipts-in your presence	Send an outline of all the inspection criteria and ask that it be shared with staff
Asking for locked doors and cabinets to be opened	Ask Designee to unlock cabinets and doors for you
Surveying staff desks for visible PHI, passwords, external business cards, etc.	You are looking for the obvious, so there is no need to intrude on staff privacy
Asking to meet the on-site "Supervising" or "Covering", physicians- <i>why a problem?</i>	Be polite and professional while explaining your process as necessary with validations.

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## Developing Inspection Criteria based on Authoritative Sources



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## Determine Criteria Scope

Where is the office located?

What services are provided?

Who is providing the services?

Accrediting agencies used?

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## Other Considerations

- ‡ Ownership model?
- ‡ Scope of practice?
- ‡ Equipment used for procedures?
  - ‡ Payer mix?
- ‡ Do procedures match policies?

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## Consider the Five Most Relevant Laws Per the OIG

1. The False Claims Act
2. The Anti-Kickback Statute
3. The Physician Self-Referral Statute
4. The Exclusion Authorities
5. The Civil Monetary Penalties Law

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***A few other risk areas to consider including in the criteria...***

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**Fair Market Value**

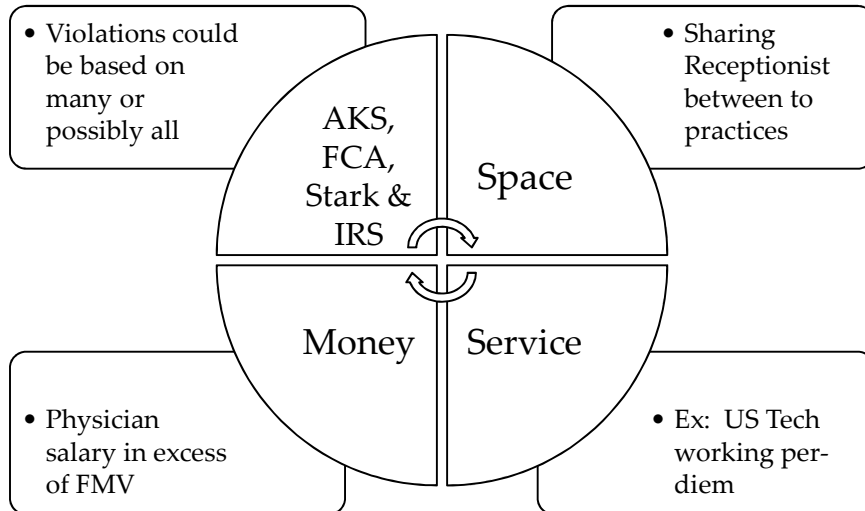
- Employment Contracts
- Office Space Sharing Arrangements
  - Coverage Agreements
- Ancillary Service Agreements

*Note: Questionable findings should be escalated to a Fair Market Valuator*

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## Government payers and Non-Profit FMV Concerns



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## Services Provided

- Is equipment inspected, calibrated and cleaned?
- Is staff trained/certified to provide the service?
- Is Level of Supervision being met?
- Are coding requirements adhered to?

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## Why Include Specific Services?

Cardiologist convicted of  
fraudulent billing in  
\$13 million dollar billing scheme for  
External Counter Pulsation Therapy (ECP)

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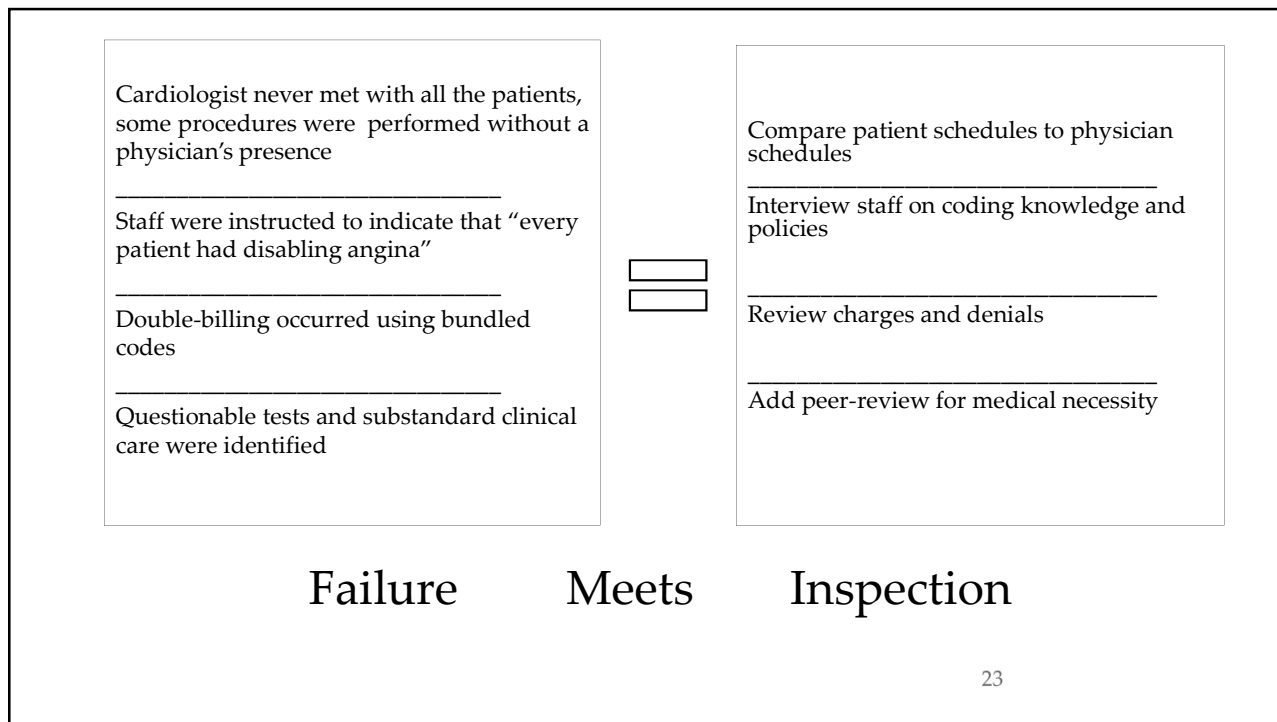
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### First step, what is ECP?

- ⊗ Improves venous return and augments diastolic blood pressure in patients w/CAD & angina.
- ⊗ Cuffs are wrapped around the lower extremities.
- ⊗ Billed w/93922 Limited/93923 Complete (3 areas)
- ⊗ National Coverage Determination (NCD) by Medicare exists explaining requirements such as diagnosis and supervision requirements

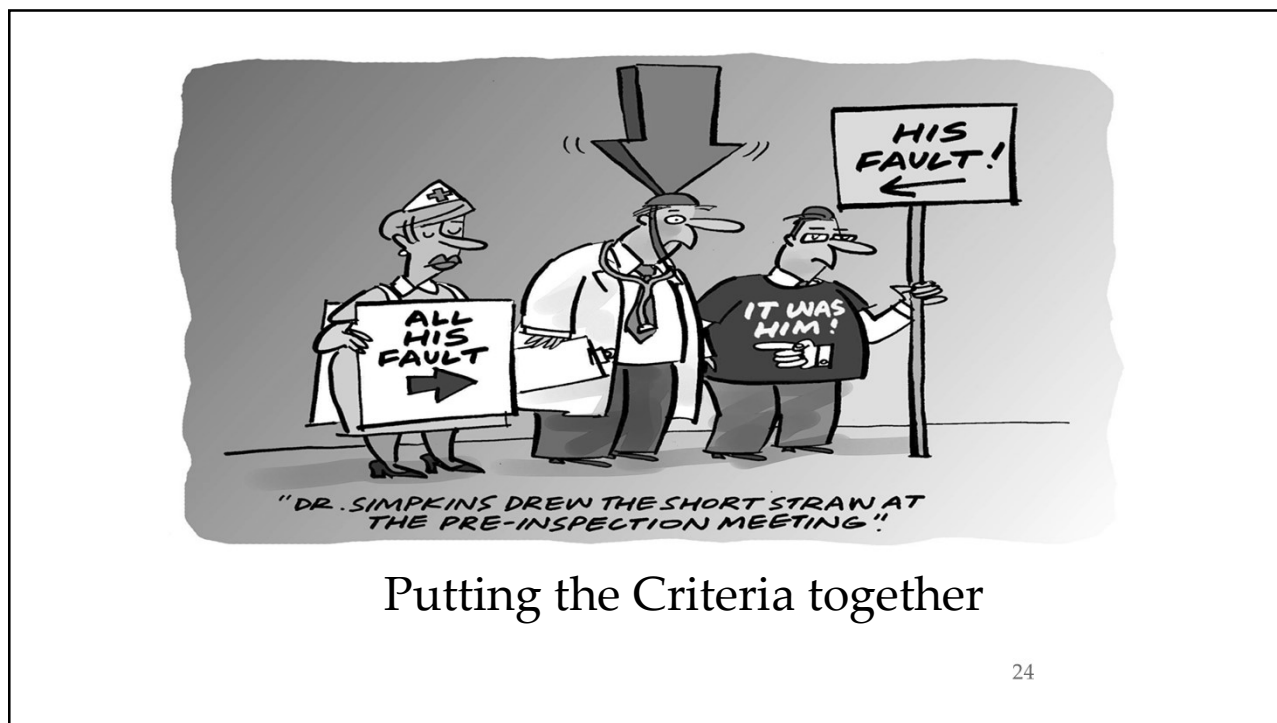
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Putting the Criteria together

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<b>Bolding = Common Failures Standards - Signage</b>	<b>Validation Source</b>	<b>Met Not Met NA</b>	<b>Corrective Action Needed</b>	<b>Due Date</b>
<i>Examples are not all inclusive and may or may not apply depending on ownership model, site, services, etc.</i>	<b>(Suggest Hyper-Links)</b>			
<b>Outside signage contains legal/DBA name &amp; HOURS that match Medicare enrollment</b>	<a href="https://www.govinfo.gov/content/pkg/CFR-2016-title42-vol3/pdf/CFR-2016-title42-vol3-sec424-516.pdf">https://www.govinfo.gov/content/pkg/CFR-2016-title42-vol3/pdf/CFR-2016-title42-vol3-sec424-516.pdf</a>			
Occupational/Business licenses current & posted in view of consumers/patients				
<b>Federal (and state)Employee Posters current and in view</b>	<a href="https://webapps.dol.gov/elaws/firststep/poster_direct.htm?p_flsa=1">https://webapps.dol.gov/elaws/firststep/poster_direct.htm?p_flsa=1</a>			
HIPAA Privacy Notice in patient view?				
Professional licenses posted-check state requirements				
Are staff wearing name badges identifying their credentials-check state requirements				
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<b>Admin/Signage Requirements per Arizona State Licensing (Example)</b>	<b>Validation</b>	<b>Met Not Met NA</b>	<b>Corrective Action Needed</b>	<b>Due Date</b>
The following must be conspicuously posted for <i>Outpatient Treatment Centers</i> in the state of Arizona	<b>(Suggest Hyper-Links)</b>			
License for center issued by AZ state	<a href="https://apps.azsos.gov/public_service/Title_09/9-10pdf">https://apps.azsos.gov/public_service/Title_09/9-10pdf</a>			
Name, address and telephone number of state licensing department	<i>As above</i>			
<b>State Notice that patient may file a complaint with licensing department</b>	<i>As above</i>			
Schedule rate or a notice that rates are available for review upon request	<i>As above</i>			
List of patient rights	<i>As above</i>			
Map of evacuating the facility	<i>As above</i>			
<b>License inspection reports identified and are viewable upon request by consumer/patient</b>	<i>As above</i>			
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<b>Standards – Administrative</b>	<b>Validation Source</b>	<b>Met Not Met NA</b>	<b>Corrective Action Needed</b>	<b>Due Date</b>
<i>Note that in many cases the inspection is verifying a written process is in place versus the inspector completing the process</i>	<i>(Suggest Hyper-Links)</i>			
<b>Space, staff or services shared with others have written agreements that meet fair market values</b>	Stark Law, AKS, FCA & IRS Code			
If financial patient assistance is provided, assure patient documentation supports Federal Poverty Guidelines				
PHI is protected throughout location				
Business Associate Agreements for Vendors				
FAX Machine process supports best practice				
Review process for checking/review Exclusion lists, Open Payments, Conflict of Interest, etc.				
Patient referrals for designated health services meet req. for conflict of interest, etc.				
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<b>Publications Required by California for Physician-Patient Communication (Example)</b>	<b>Validation</b>	<b>Met Not Met NA</b>	<b>Corrective Action Needed</b>	<b>Due Date</b>
<i>Are the following Publications available on-site and are staff aware of the requirements?</i>	<i>(Suggest Hyper-Links)</i>			
Patient's Guide to Blood Transfusions	<a href="http://www.mbc.ca.gov/Download/Documents/laws-guide-pdf">www.mbc.ca.gov/Download/Documents/laws-guide-pdf</a>			
Woman's Guide to Breast Cancer Diagnosis & Treatments	As above			
Professional Therapy Never Includes Sex-(Psychiatry)	As above			
Things to Consider Before Your Silicone Implant Surgery	As above			
What You Need to Know About Prostate Cancer	As above			
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# Internal Policy Adherence

OIG Resource  
 “Measuring Compliance Program  
 Effectiveness”

© Survey - Can your staff readily access or  
 reference policies and  
 procedures?

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Standards/Policies	Validation	Met Not Met NA	Corrective Action Needed	Due Date
<p align="center"><b><i>Policies and Procedures</i></b>  <i>You may choose to validate some criteria with                      “Best Practice”</i></p>	<p align="center"><b><i>Internal Policy                      Requirements and                      Requirements</i></b></p>			
<p>Can staff demonstrate their access current to current policies?</p>				
<p>Are policies reviewed and updated at least every 3 years?  <i>(Check for Review period)</i></p>				
<p><b>Do interviewed staff describe their processes to match written policy procedures?</b></p>	<p><a href="https://oig.hhs.gov/compliance/compliance-resource-portal/files/HCCA-OIG-Resource-Guide.pdf">https://oig.hhs.gov/compliance/compliance-resource-portal/files/HCCA-OIG-Resource-Guide.pdf</a></p>			
<p>Does policy include details about state Fraud, Waste, Abuse laws? <i>(Sites adhering to Deficit Reduction Act in states with their own FWA law might require )</i></p>	<p>See state laws</p>			
<p align="right">30</p>				

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# MEDICATIONS

- Controlled Substance Act
- Drug Addiction Treatment Act- Waived Physicians
- Pharmacy Regulations- Practices dispensing medications including samples, must adhere to **state and federal** pharmacy regulations

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Standards/Medications-Chemicals	Validation	Met Not Met NA	Corrective Action Needed	Due Date
List dispensed medications verifying schedule/confirm record keeping requirements				
<b>Logs kept for all sample medications-including Representative name...</b>	State and Federal Pharmacy rules <a href="#">21 U.S.C. 822 (f)</a>			
On-site medications/supplies found past expiration dates- Corrective action, is there a written process for review and proper disposal				
<b>Chemotherapy drug adherence to administering procedures, documentation, storage and housekeeping</b>	<a href="https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf?id=10.26616/NIOSHPUB2016161">https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf?id=10.26616/NIOSHPUB2016161</a>			
If contrast is used for diagnostic patient testing, is it being stored at appropriate temperature?				
<b>Hazardous chemicals-SDS (formerly MSDS) kept in manual w/location known to staff</b>	<a href="https://www.osha.gov/html/faq-hazcom.html">https://www.osha.gov/html/faq-hazcom.html</a>			
Radioactive isotopes are stored appropriately? (Pet Scans/Brachytherapy)				
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# OSHA

22 states have their own OSHA-approved workplace safety and health programs and may be more stringent with differing requirements.

*What does an OSHA inspection look like?*

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## OSHA Inspection Protocol

- ✓ OSHA Compliance Officer (CO) researches inspection history of a worksite, reviews operations and processes in use and standards to apply
- ✓ OSHA CO presents credentials, (photograph and serial number) and explains the scope of the inspection during the opening conference
- ✓ Employer may select representatives to accompany the OSHA CO
- ✓ OSHA CO may consult privately with a reasonable number of employees
- ✓ The walk through is inspecting for hazards and will also review worksite injury and illness records and posting of the official OSHA poster
- ✓ Reports of inspection details may be available to public

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## Authoritative Sources for Hazardous and Medical Waste

Resource Conservation and Recovery Act (RCRA)

Medical Waste Tracking Act of 1988 (Mwta)

The Environmental Protection Agency (EPA)

### OSHA (CDC Monitors)

Department of Transportation (DOT)

**Individual States:** Biohazardous bags are not always red! Look to your state regulations!

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Standards/OSHA	Validation	Met Not Met NA	Corrective Action Needed	Due Date
<i>OSHA listed standards for medical and dental offices-Specific criteria may be pulled form each category</i>	<a href="https://www.osha.gov/Publications/OSHA3187/osh3187.html">https://www.osha.gov/Publications/OSHA3187/osh3187.html</a>			
Hazard Communication, (29 CFR 1910.1200)	As above			
Ionizing Radiation (29 CFR 1910.1096)	As above			
Electrical (Subpart S-Electrical 29 CFR 1010.301 to 29 CFR1910.399)	As above			
OSHA Poster (OSHA Publication 3165)	As above			
Exit Routes (29 CFR Subpart E 1910.35, 1910.36, 1910.37, and 1910.38 and 1910.39)	As above			
Reporting Occupational Injuries and Illnesses (29 CFR 1904)	As above			
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## Local Fire Department Inspections

Labeling	Storage	Exits	Electrical	Records
Parking/Fire lanes marked	Sprinkler Clearance widths	Signs illuminated	Electrical equip. not modified	Staff trained in fire prevention
Address size on building	<b>Combustible material not stored in mechanical rooms</b>	<b>Exit passageways have appropriate clearance</b>	Emergency lighting	Fire extinguishers inspected and maintained annually
<b>Safety rooms labeled</b>	Fire Extinguisher distance from floor	<b>Exit doors not locked during business hours</b>	Non-use of extension cords	Staff CPR up to date-Fire Dept may help
Signage on Fire Dept connections (FDC)	Outside combustibles stored away from bldg	<b>Exit doors accessible through private entrances</b>	Electrical outlets have faceplates	Fire Safety Program if required

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Standards/Safety	Validation	Met Not Met NA	Corrective Action Needed	Due Date
Are separate refrigerators used for staff lunches vs. specimens?				
Oxygen tanks are upright & immobilized				
Sharp containers are in work area & maintained				
Eye Wash Station operational?				
<b>Exit signs posted and illuminated</b>	(29 CFR Subpart E 1910.35, 1910.36, 1910.37, and 1910.38 and 1910.39)			
Hallways are clear for allowed width without obstruction				
Radiology Technicians are wearing updated badges for exposure amounts				
Personal Protective Equipment-Gloves/Masks				
<b>X-ray machines using film are maintained (filter changed &amp; installed correctly) (EPA/HIPAA)</b>	Per State rules: <a href="https://ecology.wa.gov/dentists#Amalgam">https://ecology.wa.gov/dentists#Amalgam</a>			

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## In-Office Labs

Laboratory ownership, billing, and referral practices are subject to criminal and civil law:

- Federal False Claims Act (42 U.S.C. § 1320a-7b)
- Anti-Kickback Statute (42 U.S.C. § 1320a-7b)
- Physician Self-Referral (Stark) Law (42 U.S.C § 1359)
- 42 CFR Part 411 Subpart J)]
- State laws
- Medicare and other payer coverage policies
- Certifying agencies such as CLIA, COLA, etc.

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## Lab Risks

The Clinical Laboratory Improvement Amendments (CLIA) classifies lab tests as *waived*, moderate, or high complexity.

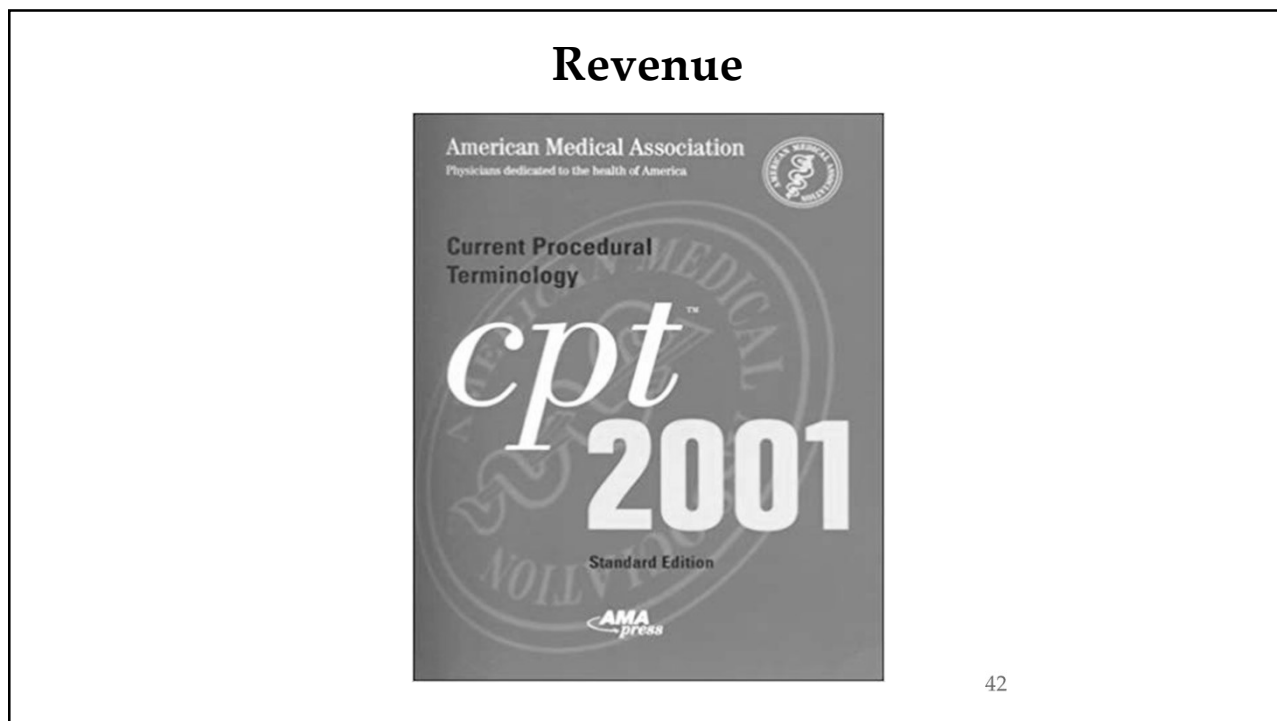
Only Waived tests may be performed in point of care testing sites (physician offices).

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Standards/Lab	Validation	Met Not Met NA	Corrective Action Needed	Due Date
If labs drawn in office and sent out-review for written agreements and coding	CLIA, HIPAA, PPACA, state & Federal			
<b>For point of care testing in office are all tests performed in office classified as Waived?</b>	<a href="https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/waivetbl.pdf">https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/waivetbl.pdf</a>			
<b>If saline bags are used-where are they being disposed? (Check labels on bags)</b>	<a href="https://www.hhs.gov/hipa/index.html">https://www.hhs.gov/hipa/index.html</a>			
CLIA/COLA lab adherence to requirements for quality checks, etc? <i>(May have multiple criteria)</i>				
Is Centrifuge inspection up to date?				
<b>Medical waste is separated/labeled/disposed per local &amp; federal requirements?</b>	<a href="https://legacy.azdeq.gov/environ/waste/solid/download/bio_medical_waste.pdf">https://legacy.azdeq.gov/environ/waste/solid/download/bio_medical_waste.pdf</a>			
<b>Lab kept in appropriate and clean area</b> <i>(Where samples collected and stored?)</i>				
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<b>Standards/Revenue Cycle</b>	<b>Validation</b>	<b>Met Not Met NA</b>	<b>Corrective Action Needed</b>	<b>Due Date</b>
<b>Coders use current year coding manuals</b>				
<b>Refunds made within 60 days</b>	PPACA			
Patient credits processed appropriately/timely				
Encounters/Fee sheets reflect accurate codes				
<b>Locum Tenens employed, review payer agreement, provider schedule for DOS, billing and modifiers</b>	<a href="https://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~JM%20Part%20B~Browse%20by%20Topic~Frequently%20Asked%20Questions~Locum%20Tenens~AK3FKB8442?open">https://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~JM%20Part%20B~Browse%20by%20Topic~Frequently%20Asked%20Questions~Locum%20Tenens~AK3FKB8442?open</a>			
Compare provider schedule to patient schedules for inconsistencies in supervision, etc.				
High volume services audited for erroneous billed units-consider comparing to inventory				
Annual and/or Risk audits reflect follow-up audits, corrective action plans/training, etc.				
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<b>Systematic Bill Review Required by Florida Agency for Health Care Administration(AHCA) Example</b>	<b>Validation</b>	<b>Met Not Met NA</b>	<b>Corrective Action Needed</b>	<b>Due Date</b>
Is there a written description available for the means by which the health care clinic conducts systematic reviews of billings?	<a href="https://ahca.myflorida.com/MCHQ/Field_Oops/Regulations/Current-Reg_Files/Health_Care_Clinic_ST_U.pdf">https://ahca.myflorida.com/MCHQ/Field_Oops/Regulations/Current-Reg_Files/Health_Care_Clinic_ST_U.pdf</a>			
Are records maintained (for at least 3 years) identifying the medical records reviewed and when/what corrective action were taken for fraudulent or unlawful billings?	As above			
Is a log of the reviews kept & maintained in a discrete file for review by request of the agency?	As above			
Are there policies, procedures, guidelines, etc. Demonstrating compliance with MR retention?	As above			
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## Corrective Action Plan (CAP)

*Identification – Authoritative Criteria*

*Evaluation – Walk Through Inspection*

*Root Cause Analysis – Discussions with Designee*

*Action Plan – Resolutions Explained at Exit Interview*

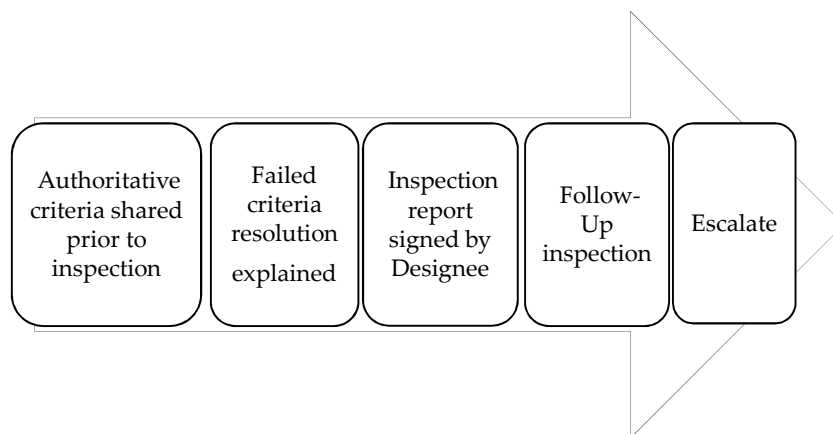
*Implementation -Time between Exit and Follow-Up*

*Follow-Up –Inspection of Failed Criteria & Escalation*

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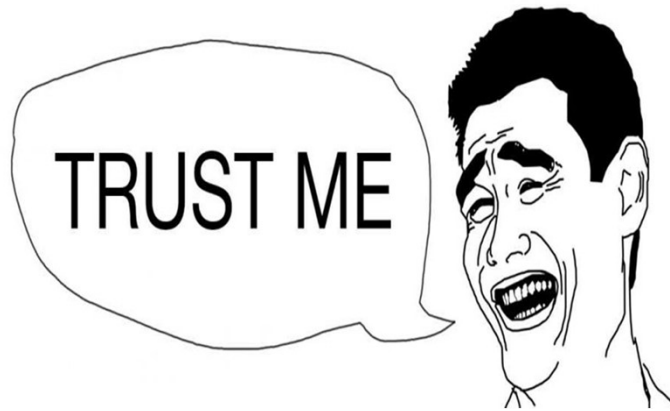
## Use Inspection Process to assure Corrective Action



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## Lessons from Bernie Madoff



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### Lesson #1

(SEC) Enforcement staff almost immediately caught Madoff in lies and misrepresentations, **but failed to follow up on inconsistencies.**

*Validate answers with  
documented evidence*

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Lesson #2

Madoff made efforts during the examination to impress and even intimidate the junior examiners from the SEC.

*Remain Objective:  
Inspect vs. Interpret*

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Lesson #3

One of the examiners characterized Madoff as “a wonderful storyteller” and “very captivating speaker” and noted that he had “an incredible background of knowledge in the industry.”

*Be Professional:  
Skip Happy Hour and Dinner*

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## Lesson #4

Throughout the examination, the examiners "had a real difficult time dealing with Madoff" as he was described as growing "increasingly agitated" during the examination, and attempting to dictate to the examiners what to focus on in the examination and what documents they could review.

*Use well researched inspection criteria backed up by authoritative sources*

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## Questions?

Thank you for your participation in this presentation!

Contact: Lela Goldwyn  
lagoldwyn@gmail.com

*This presentation has no affiliation with Seattle Children's Hospital or other organizations.*

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## Office of Inspector General Website References

### I. OIG Resources – Pg. 1

- ◎ OIG homepage: <http://oig.hhs.gov/>
- ◎ OIG Fraud Prevention & Detection webpage:  
<http://oig.hhs.gov/fraud.asp>
- ◎ OIG's Compliance Program Guidance:  
<http://oig.hhs.gov/fraud/complianceguidance.asp>
- ◎ Corporate Responsibility and Corporate Compliance Guide:  
<http://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespsceGuide.pdf>

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### OIG Resources – Pg. 2

- ◎ OIG Advisory Opinions:  
<http://oig.hhs.gov/fraud/advisoryopinions.asp>
- ◎ Frequently Asked Questions about the Advisory Opinion Process:  
<http://oig.hhs.gov/fraud/advisoryopinions/aofaq.asp>
- ◎ OIG's Self-Disclosure Protocol:  
<http://oig.hhs.gov/fraud/selfdisclosure.asp>
- ◎ OIG Exclusions: <http://oig.hhs.gov/fraud/exclusions.asp>
- ◎ Anti-Kickback Safe Harbor Regulations:  
<http://oig.hhs.gov/fraud/safeharborregulations.asp>

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### **OIG Resources – Pg. 3**

- © The current text of all the regulatory safe harbors is available at:  
[http://edocket.access.gpo.gov/cfr\\_2010/octqtr/pdf/42cfr1001.952.pdf](http://edocket.access.gpo.gov/cfr_2010/octqtr/pdf/42cfr1001.952.pdf).
- © Medical Identity Theft & Medicare Fraud: <http://oig.hhs.gov/fraud/IDTheft/>
- © OIG Fraud Hotline: <http://oig.hhs.gov/fraud/hotline/> or 1-800-HHS-TIPS
- © OIG Brochure “A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse”:  
<http://oig.hhs.gov/fraud/PhysicianEducation>
- © Subscription to OIG’s E-mail List with Notifications of New Online Materials: <http://oig.hhs.gov/maillinglist.asp>

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### **OIG Resources – Pg. 4**

#### **II. CMS and Other Resources**

- © CMS homepage: <http://www.cms.gov/>
- © CMS Contacts Information Page: <http://www.cms.gov/ContactCMS/>
- © CMS Contacts Database: <http://www.cms.gov/apps/contacts/>
- © CMS Regional Office Overview:  
<http://www.cms.gov/RegionalOffices/>
- © CMS Physician Self-Referral Law (“Stark Law”) Information:  
<http://www.cms.gov/PhysicianSelfReferral/>

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### **OIG Resources – Pg. 5**

© CMS Physician Self-Referral Law Advisory Opinions Library:  
[http://www.cms.gov/PhysicianSelfReferral/95\\_advisory\\_opinions.asp](http://www.cms.gov/PhysicianSelfReferral/95_advisory_opinions.asp)

© HIPAA Privacy and Security Rules:  
<http://www.hhs.gov/ocr/privacy/index.html>

© National Plan and Provider Enumeration System:  
<https://nppes.cms.hhs.gov/NPPES/Welcome.do>

© Homepage for U.S. Departments of Health & Human Services and Justice Joint Campaign against Health Care Fraud:  
<http://www.stopmedicarefraud.gov/>

© Website managed by the U.S. Department of Health & Human Services regarding Affordable Care Act: <http://www.healthcare.gov/>

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### **OIG Resources – Pg. 6**

© Homepage for U.S. Departments of Health & Human Services and Justice Joint Campaign against Health Care Fraud:  
<http://www.stopmedicarefraud.gov/> © Website managed by the U.S. Department of Health & Human Services regarding Affordable Care Act: <http://www.healthcare.gov/>

© National Plan and Provider Enumeration System:  
<https://nppes.cms.hhs.gov/NPPES/Welcome.do>

© Homepage for U.S. Departments of Health & Human Services and Justice Joint Campaign against Health Care Fraud:  
<http://www.stopmedicarefraud.gov/>

© Website managed by the U.S. Department of Health & Human Services regarding Affordable Care Act: <http://www.healthcare.gov/>

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## Additional References

© CMS. Medicare Coverage Determination Process. 2015 :  
<https://www.cms.gov/Medicare/Coverage/DeterminationProcess/>

© CMS. Pub 100-04 Medicare Claims Processing, Transmittal 3666, T:  
New Waived Tests. 2016 : [https://www.cms.gov/Regulations-  
andGuidance/Guidance/Transmittals/Downloads/R3666CP.pdf](https://www.cms.gov/Regulations-andGuidance/Guidance/Transmittals/Downloads/R3666CP.pdf).

Designated Health Care Services/Physician Self-Referral/Stark Law:  
[https://www.cms.gov/medicare/fraud-and-  
abuse/physicianselfreferral/index.html](https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/index.html)

SEC and OIG summary on Bernie Madoff:  
[https://www.sec.gov/spotlight/secpostmadoffreform/oig-500-exec-  
summary.pdf](https://www.sec.gov/spotlight/secpostmadoffreform/oig-500-exec-summary.pdf)