Preparing for the On-Site Regulatory Inspection

Lela Goldwyn, MS, CHC, CPC, CPMA

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…
Four Obvious Reasons to Conduct a Regulatory Inspection

1. Safeguarding your reputation
2. Developing a new compliance plan
3. Mitigating risks in satellite offices
4. Due diligence for new office acquisitions

A chain saw under the sink?
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...
Receptionist has business cards for a physical therapy clinic on her desk, attached to a long list of patient names with dates.

Preparing the Staff
What areas are observed?

- Front Door
- Lobby
- Check-In
- Nurse’s Station
- Exam Rooms
- Breakroom

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
• 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

Mitigating Negativity

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

Determine Criteria Scope

- Where is the office located?
- What services are provided?
- Who is providing the services?
- Accrediting agencies used?
Other Considerations

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

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

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

Note: Questionable findings should be escalated to a Fair Market Valuator
**Government payers and Non-Profit FMV Concerns**

- Violations could be based on many or possibly all
- Physician salary in excess of FMV
- Sharing Receptionist between to practices
- Ex: US Tech working per-diem

**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?
Why Include Specific Services?

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

- Improves venous return and augments diastolic blood pressure in patients with 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

First step, what is ECP?

- Improves venous return and augments diastolic blood pressure in patients with 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
Cardiologist never met with all the patients, some procedures were performed without a physician's presence.

Staff were instructed to indicate that “every patient had disabling angina”.

Double-billing occurred using bundled codes.

Questionable tests and substandard clinical care were identified.

Compare patient schedules to physician schedules.

Interview staff on coding knowledge and policies.

Review charges and denials.

Add peer-review for medical necessity.

Putting the Criteria together
**Bolding = Common Failures**

**Standards - Signage**

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<tr>
<th>Validation Source</th>
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<th>NA</th>
<th>Corrective Action Needed</th>
<th>Due Date</th>
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<tbody>
<tr>
<td><em>(Suggest Hyper-Links)</em></td>
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</table>

**Examples** are not all inclusive and may or may not apply depending on ownership model, site, services, etc.

Outside signage contains legal/DBA name & HOURS that match Medicare enrollment


Occupational/Business licenses current & posted in view of consumers/patients

Federal (and state) Employee Posters current and in view


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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**Admin/Signage Requirements per Arizona State Licensing (Example)**

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<tr>
<th>Validation Source</th>
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<tr>
<td><em>(Suggest Hyper-Links)</em></td>
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The following must be conspicuously posted for Outpatient Treatment Centers in the state of Arizona

License for center issued by AZ state

[https://apps.azsos.gov/public_service/Title_09/9-10pdf](https://apps.azsos.gov/public_service/Title_09/9-10pdf)

Name, address and telephone number of state licensing department

As above

State Notice that patient may file a complaint with licensing department

As above

Schedule rate or a notice that rates are available for review upon request

As above

List of patient rights

As above

Map of evacuating the facility

As above

License inspection reports identified and are viewable upon request by consumer/patient

As above
<table>
<thead>
<tr>
<th>Standards – Administrative</th>
<th>Validation Source</th>
<th>Met Not Met NA</th>
<th>Corrective Action Needed</th>
<th>Due Date</th>
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</thead>
<tbody>
<tr>
<td>Note that in many cases the inspection is verifying a written process is in place versus the inspector completing the process</td>
<td>(Suggest Hyper-Links)</td>
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<tr>
<td>Space, staff or services shared with others have written agreements that meet fair market values</td>
<td>Stark Law, AKS, FCA &amp; IRS Code</td>
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<tr>
<td>If financial patient assistance is provided, assure patient documentation supports Federal Poverty Guidelines</td>
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<tr>
<td>PHI is protected throughout location</td>
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<tr>
<td>Business Associate Agreements for Vendors</td>
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<tr>
<td>FAX Machine process supports best practice</td>
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<tr>
<td>Review process for checking/review Exclusion lists, Open Payments, Conflict of Interest, etc.</td>
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<tr>
<td>Patient referrals for designated health services meet req. for conflict of interest, etc.</td>
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</tbody>
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<thead>
<tr>
<th>Publications Required by California for Physician-Patient Communication (Example)</th>
<th>Validation</th>
<th>Met Not Met NA</th>
<th>Corrective Action Needed</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are the following Publications available on-site and are staff aware of the requirements?</td>
<td>(Suggest Hyper-Links)</td>
<td></td>
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</tr>
<tr>
<td>Woman’s Guide to Breast Cancer Diagnosis &amp; Treatments</td>
<td>As above</td>
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<td></td>
<td></td>
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<tr>
<td>Professional Therapy Never Includes Sex-(Psychiatry)</td>
<td>As above</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Things to Consider Before Your Silicone Implant Surgery</td>
<td>As above</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>What You Need to Know About Prostate Cancer</td>
<td>As above</td>
<td></td>
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</tr>
</tbody>
</table>

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27

28
# Internal Policy Adherence

**OIG Resource**

“Measuring Compliance Program Effectiveness”

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

<table>
<thead>
<tr>
<th>Standards/Policies</th>
<th>Validation</th>
<th>Met</th>
<th>Not Met</th>
<th>Corrective Action Needed</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Policies and Procedures</strong>&lt;br&gt;You may choose to validate some criteria with “Best Practice”</td>
<td><strong>Internal Policy Requirements and Requirements</strong></td>
<td></td>
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<tr>
<td>Can staff demonstrate their access current to current policies?</td>
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<tr>
<td>Are policies reviewed and updated at least every 3 years? (Check for Review period)</td>
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<tr>
<td>Do interviewed staff describe their processes to match written policy procedures?</td>
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</tr>
<tr>
<td>Does policy include details about state Fraud, Waste, Abuse laws? (Sites adhering to Deficit Reduction Act in states with their own FWA law might require)</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Standards/Medications-Chemicals</th>
<th>Validation</th>
<th>Met Not Met NA</th>
<th>Corrective Action Needed</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>List dispensed medications verifying schedule/confirm record keeping requirements</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Logs kept for all sample medications-including Representative name...</td>
<td>State and Federal Pharmacy rules 21 U.S.C. 822 (f)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>On-site medications/supplies found past expiration dates-Corrective action, is there a written process for review and proper disposal</td>
<td></td>
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</tr>
<tr>
<td>Chemotherapy drug adherence to administering procedures, documentation, storage and housekeeping</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>If contrast is used for diagnostic patient testing, is it being stored at appropriate temperature?</td>
<td></td>
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<tr>
<td>Hazardous chemicals-SDS (formerly MSDS) kept in manual w/location known to staff</td>
<td></td>
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<tr>
<td>Radioactive isotopes are stored appropriately? (Pet Scans/Brachytherapy)</td>
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</tbody>
</table>
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?

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
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!

<table>
<thead>
<tr>
<th>Standards/OSHA</th>
<th>Validation</th>
<th>Met Not Met</th>
<th>Corrective Action Needed</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA listed standards for medical and dental offices-Specific criteria may be pulled form each category</td>
<td><a href="https://www.osha.gov/publications/OSHA3187/osha3187.html">https://www.osha.gov/publications/OSHA3187/osha3187.html</a></td>
<td>Met</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td><strong>Electrical</strong> (Subpart S-Electrical 29 CFR 1010.301 to 29 CFR1910.399)</td>
<td></td>
<td>Met</td>
<td>Corrective Action Needed</td>
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</tr>
<tr>
<td>OSHA Poster (OSHA Publication 3165)</td>
<td></td>
<td>Met</td>
<td>Corrective Action Needed</td>
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</tr>
<tr>
<td>Reporting Occupational Injuries and Illnesses (29 CFR 1904)</td>
<td></td>
<td>Met</td>
<td>Corrective Action Needed</td>
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</tr>
</tbody>
</table>
## Local Fire Department Inspections

<table>
<thead>
<tr>
<th>Labeling</th>
<th>Storage</th>
<th>Exits</th>
<th>Electrical</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parking/Fire lanes marked</td>
<td>Sprinkler Clearance widths</td>
<td>Signs illuminated</td>
<td>Electrical equip. not modified</td>
<td>Staff trained in fire prevention</td>
</tr>
<tr>
<td>Address size on building</td>
<td>Combustible material not stored in</td>
<td>Exit passageways have appropriate</td>
<td>Emergency lighting</td>
<td>Fire extinguishers inspected and maintained</td>
</tr>
<tr>
<td>Safety rooms labeled</td>
<td>mechanical rooms</td>
<td>clearance</td>
<td></td>
<td>annually</td>
</tr>
<tr>
<td>Exit doors not locked during</td>
<td>Fire Extinguisher distance from floor</td>
<td>Exit doors accessible through private</td>
<td>Non-use of extension cords</td>
<td>Staff CPR up to date-Fire Dept may help</td>
</tr>
<tr>
<td></td>
<td></td>
<td>entrances</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Signage on Fire Dept connections</td>
<td>Outside combustibles stored away from</td>
<td>Exit doors accessible through private</td>
<td>Electrical outlets have faceplates</td>
<td>Fire Safety Program if required</td>
</tr>
<tr>
<td>(FDC)</td>
<td>bldg</td>
<td>entrances</td>
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<table>
<thead>
<tr>
<th>Standards/Safety</th>
<th>Validation</th>
<th>Met Not Met NA</th>
<th>Corrective Action Needed</th>
<th>Due Date</th>
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<tbody>
<tr>
<td>Are separate refrigerators used</td>
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<td>for staff lunches vs. specimens?</td>
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<tr>
<td>Oxygen tanks are upright &amp;</td>
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<tr>
<td>immobilized</td>
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<tr>
<td>Sharp containers are in work area</td>
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<tr>
<td>&amp; maintained</td>
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<tr>
<td>Eye Wash Station operational?</td>
<td></td>
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<tr>
<td>Exit signs posted and illuminated</td>
<td>29 CFR Subpart E 1910.35, 1910.36,</td>
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<td>1910.37, and 1910.38 and 1910.39</td>
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<tr>
<td>Hallways are clear for allowed</td>
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<tr>
<td>width without obstruction</td>
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<tr>
<td>Radiology Technicians are</td>
<td></td>
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<tr>
<td>wearing updated badges for</td>
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<tr>
<td>exposure amounts</td>
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<tr>
<td>Personal Protective Equipment-Gloves/Masks</td>
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<tr>
<td>X-ray machines using film are</td>
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<tr>
<td>maintained (filter changed &amp;</td>
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<tr>
<td>installed correctly) (EPA/HIPAA)</td>
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For State rules: [https://ecology.wa.gov/de/Amalgam](https://ecology.wa.gov/de/Amalgam)
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.

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).
<table>
<thead>
<tr>
<th>Standards/Lab</th>
<th>Validation</th>
<th>Met Not Met NA</th>
<th>Corrective Action Needed</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>If labs drawn in office and sent out-review for written agreements and coding</td>
<td>CLIA, HIPAA, PPACA, state &amp; Federal</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>For point of care testing in office are all tests performed in office classified as Waived?</td>
<td><a href="https://www.cms.gov/Regulations-and-Surveillance/Legislation/CLIA/Downloads/waivetbl.pdf">https://www.cms.gov/Regulations-and-Surveillance/Legislation/CLIA/Downloads/waivetbl.pdf</a></td>
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<tr>
<td>If saline bags are used-where are they being disposed? (Check labels on bags)</td>
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<tr>
<td>CLIA/COLA lab adherence to requirements for quality checks, etc? (May have multiple criteria)</td>
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<tr>
<td>Is Centrifuge inspection up to date?</td>
<td></td>
<td></td>
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<tr>
<td>Medical waste is separated/labeled/disposed per local &amp; federal requirements?</td>
<td><a href="https://legacy.azdeq.gov/environment/waste/solid/downloads/bio_medical_waste.pdf">https://legacy.azdeq.gov/environment/waste/solid/downloads/bio_medical_waste.pdf</a></td>
<td></td>
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<tr>
<td>Lab kept in appropriate and clean area  <em>(Where samples collected and stored?)</em></td>
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<tr>
<td>Standards/Revenue Cycle</td>
<td>Validation</td>
<td>Met Not Met</td>
<td>Corrective Action Needed</td>
<td>Due Date</td>
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<td>----------------------------------------------------------------------------------------</td>
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<tr>
<td>Coders use current year coding manuals</td>
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<tr>
<td>Refunds made within 60 days</td>
<td>PPACA</td>
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<tr>
<td>Patient credits processed appropriately/timely</td>
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<tr>
<td>Encounters/Fee sheets reflect accurate codes</td>
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<tr>
<td>Locum Tenens employed, review payer agreement, provider schedule for DOS, billing and modifiers</td>
<td><a href="https://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~JM%20Part%20B~Browse%20by%20Topic~Frequently%20Asked%20Questions~Locum%20Tenens~AK3FKB8?open">Link</a></td>
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<tr>
<td>Compare provider schedule to patient schedules for inconsistencies in supervision, etc.</td>
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<tr>
<td>High volume services audited for erroneous billed units-consider comparing to inventory</td>
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<tr>
<td>Annual and/or Risk audits reflect follow-up audits, corrective action plans/training, etc.</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Systematic Bill Review Required by Florida Agency for Health Care Administration(AHCA) Example</th>
<th>Validation</th>
<th>Met Not Met</th>
<th>Corrective Action Needed</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there a written description available for the means by which the health care clinic conducts systematic reviews of billings?</td>
<td><a href="https://ahca.myflorida.com/MCHQ/Field_Ops/Regulations/Current_Reg_Files/Health_Care_Clincal_ST_U.pdf">Link</a></td>
<td>As above</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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?</td>
<td>As above</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is a log of the reviews kept &amp; maintained in a discrete file for review by request of the agency?</td>
<td>As above</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are there policies, procedures, guidelines, etc. Demonstrating compliance with MR retention?</td>
<td>As above</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

Use Inspection Process to assure Corrective Action

- Authoritative criteria shared prior to inspection
- Failed criteria resolution explained
- Inspection report signed by Designee
- Follow-Up inspection
- Escalate
Lessons from Bernie Madoff

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
Lesson #2

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

Remain Objective:
Inspect vs. Interpret

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
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

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.
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/040203CorpRespRs
cGuide.pdf

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
OIG Resources – Pg. 3


- 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


- Subscription to OIG’s E-mail List with Notifications of New Online Materials: http://oig.hhs.gov/mailinglist.asp

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 Regional Office Overview: http://www.cms.gov/RegionalOffices/

OIG Resources – Pg. 5

- CMS Physician Self-Referral Law Advisory Opinions Library:
  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/

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/
Additional References


