

Health Care Compliance Association  
Healthcare Enforcement Compliance Conference  
Strategies and Best Practices for Responding to Enforcement Activities  
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- Strategies for responding to criminal, civil or administrative enforcement actions
- Best practices for interaction with government attorneys, agents and auditors
- Preparing current and former employees for government contacts
- Responding to reports of non-compliant activity; Internal Investigations and self-disclosure
- Tips for handling False Claims Act cases

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## YOU HAVE MAIL

- Request for records:
  - MAC
  - PSC, ZPIC, BISC
  - RAC
  - Medicaid
  - Private insurance
  - CERT
  - Subpoena
- Revalidation.
- On-site surveyors (especially DME).

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## WHAT CAN YOU DO TO PREVENT AN AUDIT?

- A trick question.
- Get an "Anomalies Happen" bumper sticker.
- Goal: Know that you can defend yourself if you are audited.
- Means: Investigate like an auditor.

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## WHAT DO YOU LOOK FOR BEFORE AN AUDIT?

- Documentation.
- Code distribution patterns.
  - Variation from the norm.
  - Changes.
- Total Production.
- Bundling.
- Nervous employees: get quarterly certifications!
- Credit Balances.
- RAC issues list.
- OIG Workplan.

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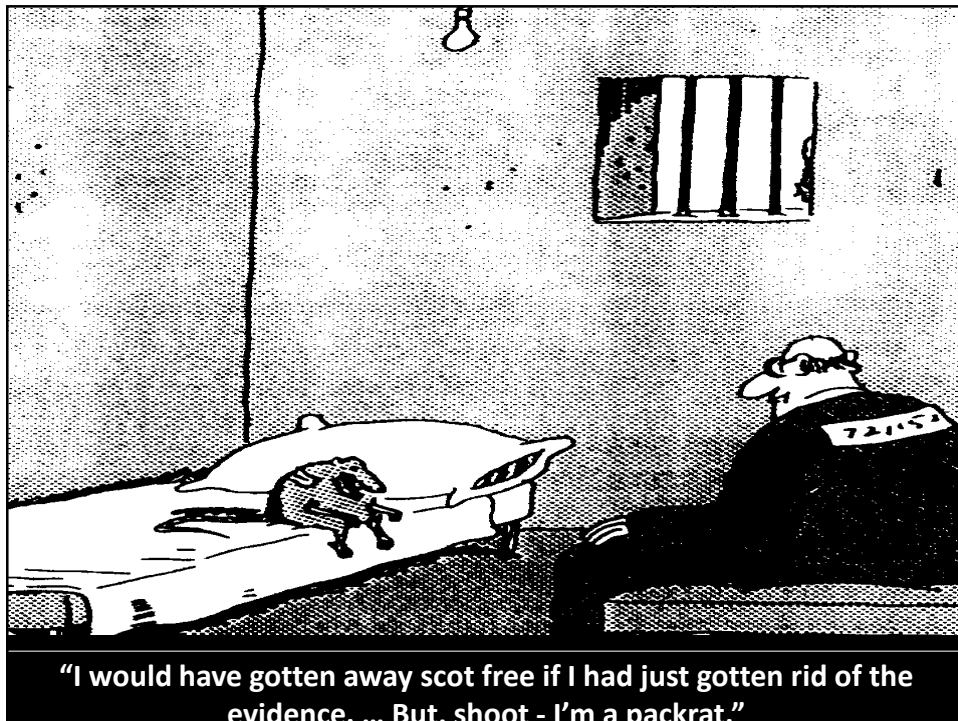
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## EVEN BEFORE THE LETTER ARRIVES . . .

- Educate your staff about directing letters from the government to the correct person in your organization. **Covid-19 makes this more difficult and absolutely vital**
- Have a process for opening practitioners' mail.
- Staff should understand that appeals are time sensitive.
- Date stamping.
- Calendar deadlines.
- Envelopes. (Be a packrat!!)

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## USING COUNSEL

- Start early. Strategy matters.
- Use someone who knows the ropes.
- Using counsel doesn't mean you can't do much of the leg work.
- Create an assembly line. Use a team.
- Understand how privilege works.
- Choose counsel wisely
  - Do you want an "attack dog?"
  - Do you want the person who worked on "the biggest settlement in history?"
  - Don't forget about insurance!

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## WHAT IS PRIVILEGED?

- Attorney-client privilege:
  - Oral and written communications.
  - Communications from the client as well as advice from the attorney and retained agents.
  - Key issue: whether the communication was in furtherance of obtaining legal advice?
- Work product privilege:
  - Materials prepared or assembled at the direction of counsel.
  - Must be in anticipation of potential litigation.
  - Beware of overlabelling: it may trigger a document retention obligation.

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## HIRING CONSULTANTS

- Consider using work product privilege.
- Discuss the consultant's role; is s/he an advocate or a cop?
- A consultant can win or lose your case.
- Get references. There are some horror stories.

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## WHO IS RESPONSIBLE FOR THE APPEAL?

- Identify your appeals team.
- Involve a physician early.
  - Treating physician versus reviewing physician?
  - Think ahead to who will testify at the ALJ hearing. Capture the argument early.

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## GATHERING THE RECORD

- Inside versus outside records. (Information blocking?!)
- Defining the relevant time frame.
- The importance of pagination.
- Make (and keep!!) an exact copy.
- Thorough review by the physician.

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## PRESENTATION OF YOUR ARGUMENTS

- What is the best format to present your case?
  - Always include a cover letter.
  - Consider the use of tables or spreadsheets for claim-by-claim arguments.
  - Exhibit books.
  - Bottom line: make it easy for the reviewer to see your arguments and evidence.

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## WRITING THE APPEAL LETTER

- The goal: write one good appeal letter to use at all levels:
  - Redetermination.
  - Reconsideration.
  - Administrative law judge.

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## WRITING THE APPEAL LETTER

- Make it terse.
- Frame the argument using authority (regulation, manual). Don't let the auditor control this!
- Use plain language.
- Include only facts relevant for the standard.

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## REQUIRED CONTENTS OF APPEAL

- The request MUST include:
  - Beneficiary name;
  - Beneficiary Medicare health insurance claim number;
  - Item(s)/service(s) underlying appeal;
  - Date(s) of service; and
  - Name and signature of party or representative.
- Appointment of Representative form.

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## SENDING THE LETTER

- Use the address provided in the initial determination.
- Copy the right parties. (Beneficiary!!?)
- Use tracking.

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## WHAT ABOUT PRIVATE PAYORS?

- Contract (and manual??) control.
- Refund requirement is gov. only, but “health fraud” is a federal crime.
- State statute of limitations apply.
- State insurance law.
- Is Medicare Advantage a private payor?

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## THE REFUND LETTER

- Do you ever send a “placeholder” letter?
- Who is it from?
- Who is it to?
- How much detail do you provide?
- What about small issues where cost of investigation exceeds overpayment?
- What don't you say?

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## DR. C'S LETTER

We **recently** discovered that one of our physicians **was committing billing fraud**. She was **not documenting services properly**. We **inadvertently** billed for these services. We did a **statistically valid sample**. We **have corrected the problem**.

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## THE REFUND LETTER

- "As part of our ongoing compliance process."
- "More appropriate" is a great phrase.
- "Possible issues."
- Reserve the right to recant.
- "Level we are confident defending..."
- Beware of "our attorney has told us . . ."
- "Refund" vs. "overpayment."
- "Steps to improve...."

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## PREPARING FOR TROUBLE

- CMS
- OIG
- FBI
- MFCU
- Postal Inspector
- IG Railroad Retirement Board
- DCIS
- Licensing boards
- NRC
- FDA
- DEA
- Patients



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## BEWARE OF:

- Personalized correspondence.
- Medicare bulletins.
- Overpayment letters.
- Frequent denials.
- "Routine audit"/survey.

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Office of Audit Services  
Region I  
John F. Kennedy Federal Building  
Boston, MA 02203  
(617) 565-2684

Dear Dr.

The Office of Inspector General of the Department of Health and Human Services is currently conducting an audit of payments for clinical laboratory services under the Medicare program. In this regard, we need your assistance to confirm that you (1) requested the services provided and billed to the Medicare program by a laboratory and (2) received and considered the test results in the treatment of your patient. Your response will be vital in assisting our efforts to ensure that Medicare dollars are appropriately spent on deserving beneficiaries.

As part of this audit, we are reviewing Medicare payments to laboratories for additional automated hemogram indices that were billed with hematology profiles (CBCs or other hematology profiles). Examples of additional automated hemogram indices include red cell distribution width (RDW), mean platelet volume (MPV), red blood cell histogram, platelet histogram and white blood cell histogram. These indices are in addition to the "standard" indices which are part of a CBC: the mean corpuscular volume (MPV), the mean corpuscular hemoglobin (MCH), and the mean corpuscular hemoglobin concentration (MCHC).

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1. Did you order a complete blood count (sometimes referred to as a "CBC") or other hematology profiles for this patient on this date?

\_\_\_\_\_ Yes \_\_\_\_\_ No

2. Did you specifically request any of the additional automated hemogram indices referenced above for this patient on this date?

\_\_\_\_\_ Yes \_\_\_\_\_ No

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**4. If you answered “No” to question 2, please answer questions 4a through 4e below.**

**4a. Did you receive the additional automated hemogram indices as part of the test result provided from the laboratory?**

Yes     No

**4b. Were the additional automated hemogram indices routinely provided as part of your request for the hematology profiles?**

Yes     No     Not Applicable

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**4c. Did the laboratory notify you that these additional automated hemogram indices were automatically included as part of hematology profiles?**

Yes     No     Not Applicable

**4d. Were you aware that these additional automated hemogram indices or other indices were billed separately under the Medicare program?**

Yes     No     Not Applicable

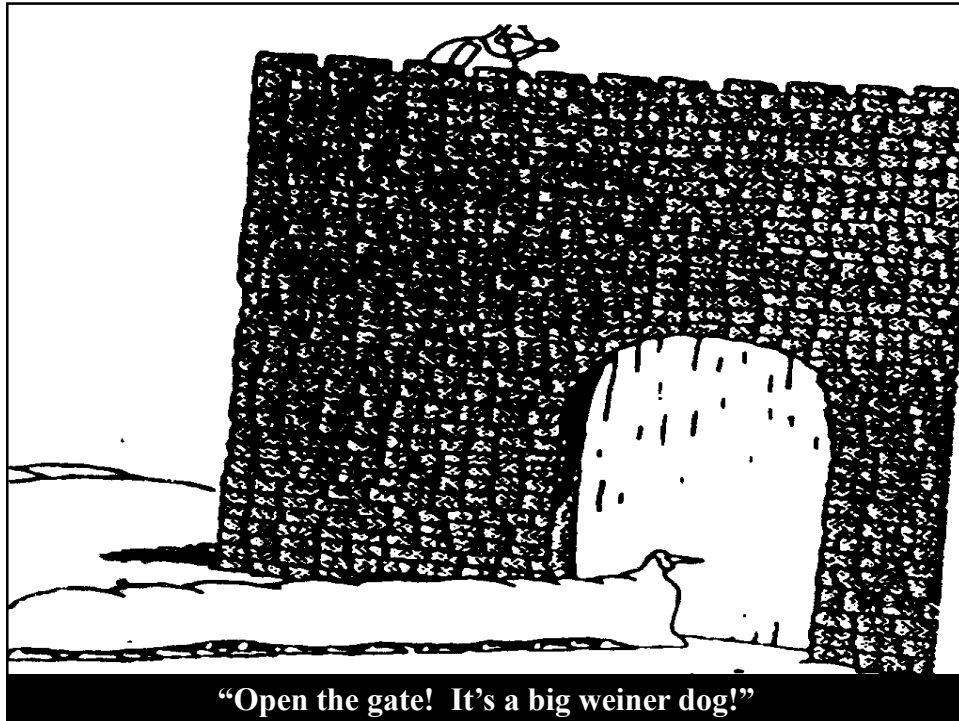
**4e. If you received the additional automated hemogram indices as part of the laboratory results, were the indices useful to you in the treatment of the Medicare patient?**

Yes     No     Not Applicable

**NOTE: If available, please provide an example copy of the laboratory requisition form.**

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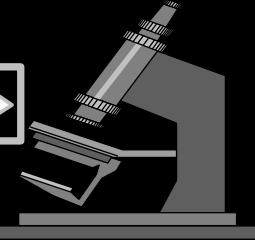


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## YOU'RE UNDER THE MICROSCOPE IF:

- Medicare requests multiple medical records. (Don't worry about individual prepayment reviews.)
- You receive an overpayment letter.
- The carrier or Office of Inspector General contacts you with specific questions or seeks a meeting.
- Armed agents pop up at employees homes (or maybe office).

 You are here



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## PREP WORK IS KEY

- You need to inoculate your employees.
- The half life of the vaccine is very, very short.
- An emergency plan must include how to contact people at odd hours.

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## THE SUBPOENA

You get a grand jury subpoena from Atlanta that says "The United States Attorney requests that you do not disclose the existence of this subpoena. Any such disclosure would impede the investigation being conducted and thereby interfere with the enforcement of the law."

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## INTERACTING WITH AUDITORS

- Be friendly.
- Keep them in a room where you know what they have.
- Make sure they don't get any originals.
- Keep them in a low trafficked area.
- Take advantage of any exit conference. Involve your counsel if possible.

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## TELEPHONE CALLS

- Get the caller's name.
- Find out what they are talking about.
- Call the person back. This will allow you to verify the caller's identity, and gather your thoughts.

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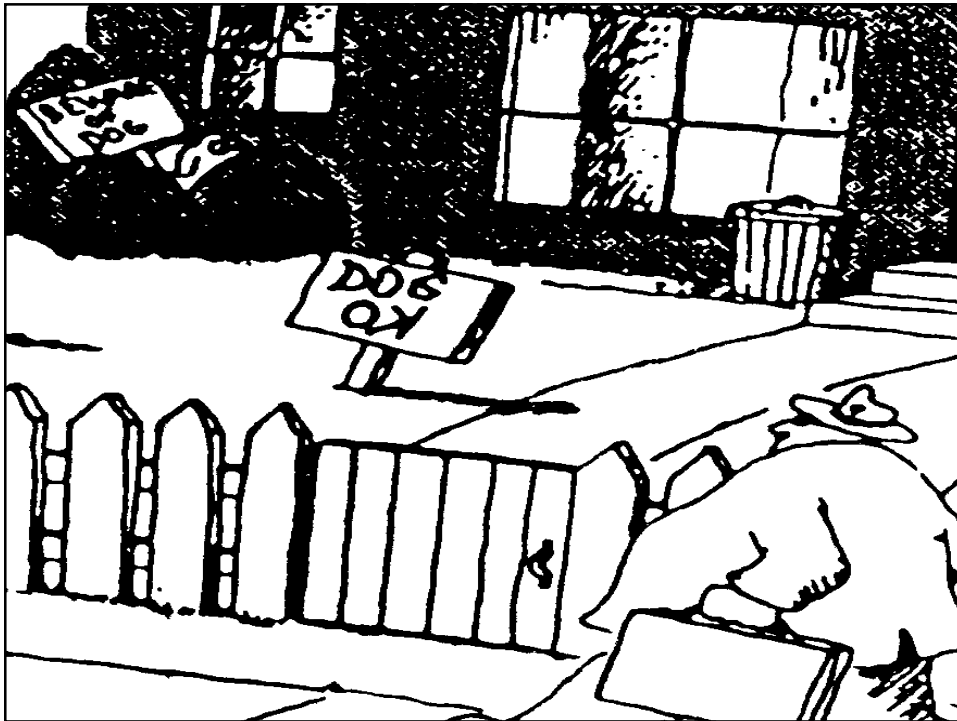
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## ARMED AGENTS AT THE DOOR

- If they have a warrant, let them in.
- Do not talk to them.
- Get I.D. and call a lawyer.

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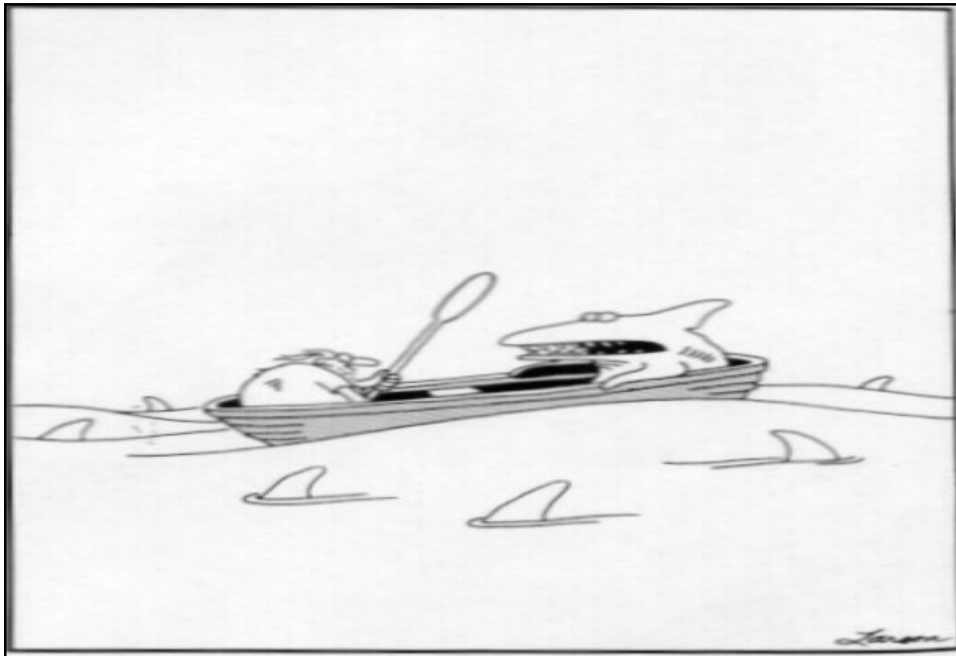
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## DEALING WITH INVESTIGATIONS

- Agents want you to talk. They will use your:
  - Fear.
  - Confidence.
- Your biggest weapon:
  - Silence.
- Be especially wary of saying “my lawyer told me it was ok.” You will have waived the attorney-client privilege.



“OK. I’ll go back and tell my people that you’re staying in the boat, but I warn you they’re *not* going to like

## THE AGENTS ARE NOT YOUR FRIENDS:

- Don't try to convince the agent "It is all a misunderstanding."

*Remember two key points:*

- Medicare rules are complicated. You may have violated one without knowing it.
- To many investigators - there is no such thing as an "innocent mistake."

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## KNOW YOUR RIGHTS

Agent:

- Can't require anyone to attend interview.
- Can't obtain documents without a warrant or subpoena.
- Can't obtain privileged information.
- Can't prevent you from talking about the interaction.

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## KNOW YOUR OBLIGATIONS:

- Cannot prevent employees from talking.
- If you talk, you must tell the truth.
- Never destroy/hide documents.

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