Responding to Government Enforcement Efforts: Surviving and Thriving Under Pressure

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Roadmap

- Overview: Government Enforcement Efforts and Potential Consequences
- Program Integrity Audits: A Practical Approach to an Effective Response
- OIG Audits and Investigations: Taking Audits Public
- TPE / ADRs: “Routine” Oversight has Renewed Significance
- Medicaid Audits and Investigations: A Different Set of Rules
- Department of Justice Activity: The False Claims Act, Whistleblower, and Qui Tam

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Take Home Tools (Handouts)

1. 10 Questions Every Hospice Employee Should Be Able To Answer
2. Sample Patient Document Request List
3. Sample Business Records Request List
4. Checklist for Hospice Audit Interviews and Conferences
5. Prepare for Actual On-site Auditor Questions and Requests
6. Documentation Order List and Tips for Organizing Patient-Specific Records
7. Summary of Federal Administrative Appeal Process for Disputing Claim Denials and Overpayment Demands
8. Medicare Hospice Regulatory Conditions of Payment
9. Sample Investigation Plan
10. Overview of the Federal False Claims Act

Government Enforcement Efforts and Potential Consequences

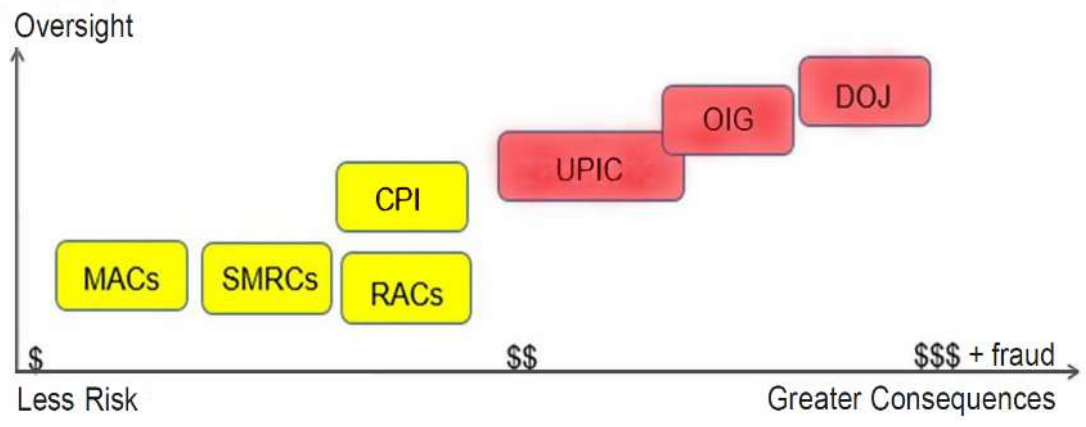
Government Enforcers: Who Are They?

Government Enforcers

- **Department of Justice (DOJ)**: Civil and criminal divisions, which includes the United States Attorneys Office (USAO) and Federal Bureau of Investigation (FBI), both of which investigate and enforce applicable laws.
- **Department of Health & Human Services (HHS)**: Includes the Office of the Inspector General (OIG) and Centers for Medicare & Medicaid Services (CMS).
  - OIG: Conducts investigations and audits to combat fraud, waste, and abuse under HHS programs (*e.g.*, Medicare and Medicaid). Can result in criminal, civil, or administrative enforcement actions.
  - CMS: Relies heavily on audits and can conduct enforcement through provider enrollment.
- **Congress**: Certain committees may impact investigations and enforcement, such as the Senate Finance Committee's 2010 investigation of the home health industry.
- **Government Contractors**: There are many types of contractors with varying responsibilities, requirements, and incentives.

Contractor Type	Responsibilities / Duties
Medicare Administrative Contractors (MACs)	• Process submitted claims, remit payment, and issue demand letters. • Conduct pre- and post-payment claim review (*i.e.*, targeted probe and educate edits). • Process redetermination requests and issue redetermination decisions. • Develop local coverage determinations (LCDs). • Key players in provider enrollment. • *Examples*: National Government Services, Inc., CGS Administrators, LLC, and Palmetto GBA.
Recovery Audit Contractors (RACs)	• Conduct automated and complex reviews. • Possible financial incentive to deny claims. • Recent uptick in hospice RAC audits. • *Example*: Performant Recovery, Inc.
Unified Program Integrity Contractors (UPICs)	• Replaced ZPICs and MICs. • Focused on fraud, waste, and abuse detection. • High risk, as they may extrapolate overpayments and refer cases to the FBI, OIG, and DOJ. • *Examples*: Qlarant Integrity Solutions LLC, SafeGuard Services, LLC, and CoventBridge, Inc.
Supplemental Medical Review Contractor (SMRC)	• Only 1 SMRC – Noridian Healthcare Solutions, LLC. • Conduct subject- or project-focused reviews. • Opportunity for a "discussion and education" session prior to a final determination.
Center for Program Integrity (CPI)	• CPI audits are also conducted by the SMRC (Noridian), but there is no discussion / education. • Typically focused on long length of stay patients.

Risk Continuum of Auditors



Government Enforcement Tools

Limiting Enrollment

- CMS can enhance Medicare provider screening and enrollment requirements.
  - There are no active Medicare Provider Enrollment Moratoria in place.
  - Must disclose “affiliations” and “disclosable events” (payment suspension, exclusion, etc.).
- States can also limit enrollment: “Hospice licensure: moratorium on new licenses” prohibits the CA Dept. of Health from issuing new hospice licenses between 1/1/22 – 1/1/27.

Mandatory / Permissive Exclusions

- OIG can exclude individuals and entities from participation in federally funded health care programs for program violations.
- OIG maintains the List of Excluded Individuals and Entities (LEIE).
- Providers may not hire those on the LEIE or bill for services, and doing so can lead to a civil monetary penalty and/or exclusion.
- *See* Social Security Act Section 1128.

Suspend Payments from Medicare / Medicaid

- "Reliable information" that an overpayment exists or that the payments to be made may not be correct.
- "Credible allegation of fraud" exists against provider (low standard).
- Survey non-compliance can result in payment suspension pending correction.

Audits, Investigations, and Fraud Cases

- Assess overpayments (*e.g.*, reopen claims and collect the face value or extrapolated value of claims).
- Issue investigative tools, such as letter requests, subpoenas, civil investigative demands, and search warrants.
- Intervene in or initiate its own false claims act (FCA) cases.
- *See* 42 C.F.R. part 405 (Audits, Appeals, and Regulatory Enforcement Rules).

What Enforcers Pay Attention To: Trends and Developments

Data Analysis is Driving Policy

Federal OIG Hospice Reports and Audits

- July 2018: "Vulnerabilities in the Medicare Hospice Program…"
- July 2019: "Hospice Deficiencies Pose Risks to Medicare Beneficiaries"
- July 2019: "Safeguards Must Be Strengthened To Protect Medicare Hospice Beneficiaries From Harm"
- August 2019: "Medicare Part D is Still Paying Millions for Drugs Already Paid for Under Part A Hospice Benefit"
- 2020 – Present: Specific Audits of Several Hospices Focusing on Eligibility; Tens of Millions in "Overpayments"
- 2022 – 2023: OIG Work Plan Focus on Hospice Eligibility Nationwide

The federal government is supporting its enforcement efforts with data.

- PEPPER Reports
- MedPAC Reports
- Post-Acute Care and Hospice Provider Utilization and Payment Public Use File (PUF)
- Abt Associates Reports collecting more data on claims for future analysis

Recent Audit Focus

- **Program Integrity (UPIC & CPI) Audits**: Focused on long lengths of stay, dementia diagnoses, and documentation issues (*e.g.*, election statements, certifications, face-to-face encounters, and physician visits).
- **TPE Audits**: Focused on certain subjects, such as new providers, general inpatient (GIP) care episodes ≥ 7 days, 313-515 day lengths of stay, and bene sharing.
- **OIG Audits**: Has identified "problem areas," including care quality deficiencies, ineligible patients, unnecessary services / higher level of care episodes (*i.e.*, GIP), and increased fraud schemes.

Other Recent Trends

- **Subpoenas, Civil Investigative Demands, and Search Warrants**
  - An indicator of a possible Whistleblower lawsuit.
  - Targeted enforcement priorities (FCA violations, anti-kickback, eligibility, incentive compensation, etc.).
- **Compliance and Enforcement Through Litigation**: Cases being tested at trial and on appeal (*e.g., Care Alternatives*, *AseraCare, Paulus*).
- The Government remains committed to fighting alleged health care fraud.

Results of Government Efforts

- In FY 2022, the Federal government won or negotiated over $2.2B in FCA judgments and settlements.
  - Down substantially from FY 2021's $5.7B recovery.
  - 90% of the $2.2B originated from whistleblower actions; whistleblowers filed 652 qui tam actions.
  - $1.7B related to health care industry.
  - More new FCA matters initiated in FY 2022 than in any prior year.
- The Federal government receives high return on investment for its health care fraud enforcement efforts (average ROI = $4.30 for every $1.00 expended).

Results of Government Efforts

Metric	FY 2022	FY 2023
Number of FCA Settlements and Judgments Recorded	351	543
Value of FCA Settlements and Judgments Collected	$2.2 Billion	$2.68 Billion
New FCA Matters Initiated by the DOJ	305	500
Qui Tam Suits Filed by Whistleblowers	652	712

- The Federal government receives a high return on investment for its healthcare fraud enforcement efforts.
  - Average ROI = $4.30 for every $1.00 expended.
  - The healthcare industry is the leading source of DOJ recoveries.

Program Integrity Audits

A Practical Approach to an Effective Response

Start Preparing for the Inevitable Now!

- Ask yourself:
  - If a record request for an audit arrived tomorrow, how quickly could we respond?
  - If auditors arrived on-site tomorrow, would our staff members know how to talk to them?
- While audits are not entirely "preventable" events, this *does not* mean that you are powerless or that there is nothing to be done.
- An "audit readiness" action plan can make all the difference in how well you fare in the process.

Developing Your Audit Response Infrastructure

- Create an active Audit Response Team comprised of key leadership, trusted members in other departments, and legal counsel.
- Educate your employees; knowledge creates credibility and confidence.
  - Interviews or entrance conferences are on the rise in UPIC audits.
  - Train employees in interview procedures and techniques.
  - *See* handouts 1. 10 Questions Every Hospice Employee Should Be Able To Answer, 4. Checklist for Hospice Audit Interviews and Conferences, and 5. Prepare for Actual On-site Auditor Questions and Requests.
- Develop audit response protocols.
  - Build confidence in your team by knowing *what* documents you have, *where* they are located, and *how* they are stored.
  - Identification of audit notification, procedure for onsite interview, location of records, etc.
  - Conduct mock testing and follow-up education and training.

Key Considerations for Document Production

- Understand the request, including the types of documents requested and the deadline for submission.
- Work with legal counsel to consider whether it is helpful to submit a letter with the responsive documents to:
  - Memorialize understanding of the request (*i.e.*, identify any assumptions you are making);
  - Reserve the right to provide additional information; and/or
  - Address other legal issues.
- Keep the end goal in mind: producing *responsive* and *organized* documents.
- *See* handouts 2. Sample Patient Document Request List and 3. Sample Business Records Request List.

Produce Responsive and Organized Records

- Organize the records in a way that "tells the story."
  - Fully chronological, or chronological by discipline.
  - *See* handout 6. Documentation Order List and Tips for Organizing Patient-Specific Records.
- Good housekeeping:
  - Consecutively paginate documents for future reference.
  - Verify no original documents are given.
  - Retain a copy of what you have produced.

In General, When Responding to a Request…

- Fully cooperate with the request.
- Demonstrate credibility through knowledge, responsiveness, and professionalism—from a facility tour, to interviews, to record production.
- Keep the investigation focused and efficient.
- Gather information about the investigation.
- Engender a positive and favorable perception of your organization.

Audit ≠ Survey

	Survey	ADR	Audit
Reason for Review	Complaint or regular survey.	Generally eligibility-related.	Ultimately do not know—and may never find out—the particular reason for review.
Timeframes (general)	May not have advanced notice. Results are immediate. Resolution within weeks.	One month to respond to request. Results within a month or two. Resolution within years.	Often no advanced notice. May require an immediate response. Results may take 12+ months. Resolution within years.
Scope of Review	Current events. Confined to nature of complaint standard survey.	Typically pre-payment review of clinical documents of current claims.	Typically post-payment review (looking back 4-5 years). Broad record requests and wide scope of employee interviews.
Process and Outcomes	Possible citations and revisit survey.	Non-payment of claim.	Varied and serious, *e.g.*, education, large overpayments, payment suspension, referral to law enforcement, civil monetary penalties, criminal sanctions, exclusion, corporate integrity agreement, etc.
Approach in Responding	Level of transparency; surveyors express concerns and accept clarifying information.	Use standard approach. Provide records and summary of eligibility.	All appeal documents should be tailored depending on the particular audit.

Be Wary of the Traps!

1. **“But why am I getting audited?”**
   - Distracting yourself with “why” is unproductive when staring down a deadline.
   - Do not delay action by trying to figure out “who” complained or “what” the data analysis is; the answers do not change your response.
   - Keep your team focused on the audit goals.

2. **“I need to self-audit these records.”**
   - **DO NOT**: second guess clinical decision-making, alter or “correct” records, or review records for “compliance.”
   - The *government* is auditing the records and has not asked you to perform a “self-audit.”

Be Wary of the Traps! (cont.)

3. **“I know what will be helpful.”**
   - Produce the information requested, not what you think may be "helpful" because you don't know the "why."
   - Doing so may: (a) expand the audit, (b) increase denials, and/or (c) needlessly create more work.

4. **“We were fast.”**
   - It takes time to organize voluminous records.
   - You get no points for responding in record time… Prioritize “thoughtful” over “fast.”
   - “Triple check” that records are responsive, double-sided, and include full care plans.
   - May need to gather records from other providers to support eligibility.

Audit Findings: The results are in… Now what?

What to Expect: The Findings

- Findings are provided in a letter and spreadsheet and typically include:
  - Overpayment determination.
  - Individual patient decisions / denial bases.
  - Statistical decision and methodology, if the overpayment is extrapolated.
- Review the findings and check in with your attorney to confirm you have received all the documents from the auditor.

Sample Findings for One Claim

References: Social Security Act (SSA) Title XVIII, Section 1861(dd)(3)(A); SSA Title XVIII, Section 1862(a)(1)(C); SSA Title XVIII, Section 1833(e); SSA Title XVIII, Section 1812(a)(4) and (d)(1); SSA Title XVIII, Section 1814(a)(7). Code of Federal Regulations (CFR) Title 42, Part 418; CFR Title 42, Part 424. Medicare General Information, Eligibility and Entitlement Manual, Pub. 100-01, Chapter 4, Section 60. Medicare Benefit Policy Manual (MBPM), Pub. 100-02, Chapter 9; Medicare Claims Processing Manual (MCPM), Pub. 100-04, Chapter 11. MCPM, Pub. 100-04, Chapter 30, Section 20.1.3. State Operations Manual, Pub. 100-07, Chapter 2. Medicare Program Integrity Manual (MPIM), Pub. 100-08, Chapter 3. Local Coverage Determinations (LCD) L34548, Local Coverage Article A53054 and 53056. Code on review: 0651. Deny 30 units of 0651 from September 1, 2017 through September 30, 2017. Face-to-Face Encounter requirements not met. Refer to Internet-Only Manuals 100-02, Medicare Benefit Policy Manual Chapter 9, 20. The face to face encounter attestation was dated July 7, 2017 for benefit period July 9, 2017 through September 6, 2017; one day after the certification of terminal illness was signed. Medicare requires the encounter must occur prior to the recertification for the third benefit period and each subsequent benefit period. The encounter must occur no more than 30 calendar days before the benefit period recertification and each subsequent recertification. The physician narrative statement was not present or was not valid. Refer to Internet-Only Manuals 100-02, Medicare Benefit Policy Manual Chapter 9, 20. The certification of terminal illness was dated July 6, 2017 for benefit period July 9, 2017 through September 6, 2017; however, the face to face encounter was not documented to be completed until July 7, 2017. Medicare requires the narrative associated with the third benefit period recertification and every subsequent recertification must include and explanation of why the clinical findings of the face to face encounter support a life expectancy of six months or less. The documentation submitted does not support medical necessity as listed in coverage requirements. Refer to Social Security Act 1862(a)(1)(A), Internet-Only Manuals-Pub 100-08, Chapter 3, Section 3.6.2.1, 3.6.2.2, Medicare Program Integrity Manual Chapter 3, Section 3.4.1.3. The patient was admitted to hospice on March 16, 2016 with a terminal diagnosis of end stage chronic systolic congestive heart failure (CHF) and comorbidities of aortic aneurism, hypertension, atrial fibrillation, aortic insufficiency and coronary artery disease. He lived in an assisted living facility. The submitted admission documentation identified the patient scratched his shins, which caused them to bleed, blister and open up to a wound. The documentation also identified the nursing wound care interventions were effective with healing these wounds, despite the documented vascular insufficiency. The nursing documentation recorded oxygen saturations of 96-98% with supplemental oxygen, 89% on room air and heart rate of 64-72 beats per minute. His blood pressure remained stable for the period under review with a range of 112-146/68-80. There was no recorded cough, wheezing or mucus production. His Dilaudid was increased for shortness of breath but later decreased and still effective. The patient was alert and oriented with occasional confusion. There were no recorded delirium, pneumonia, nor pressure ulcers. His appetite was fair-good, eating three meals a day and his weight was maintained at 183.6 pounds, a loss of six pounds. He was able to ambulate in his apartment with his walker independently. The patient did not have documented emergency room visits during the period under review. The submitted documentation for the dates of service under review did not contain enough information to determine medical necessity. The submitted documentation, for the dates of service under review, identified a patient who required interventions for long-term disease management and did not support a terminal prognosis of six months or less.

Post-Results: Repayment or Recoupment

- **Demand Letter(s)**
  - Issued by the MAC and identify the amount due.
  - Dictate appeal deadlines:
    - Standard = 120 days from date of demand letter
    - Expedited (halting recoupment) = 30 days from date of demand letter
  - For PIP (Periodic Interim Payment) providers:
    - Demand letters are not issued.
    - Appeal deadlines are calculated from the decision date or claims adjustment date.
- **Repayment vs. Recoupment**
  - Prompt repayment avoids the interest accrual.
  - Allowing recoupment creates an opportunity to win back interest.
  - Halting recoupment is temporary and comes at a cost (*e.g.*, 12%+ interest).

Current 60-Day Repayment Rule

- General Requirement. Providers must investigate "credible information" of a potential overpayment, and report and return any overpayments that are identified as a result of that investigation.
  - Audit findings constitute "credible information" of an overpayment that trigger the obligation to investigate.
  - Investigation (*i.e.*, "reasonable diligence" review) should take, at most, 6 months from the receipt of "credible information."
  - Appealing stays the obligation to investigate until the appeal has concluded.
- 6-Year Lookback Period. "An overpayment must be reported and returned [under the Rule] if a person identifies the overpayment . . . within 6 years of the date the overpayment was received."

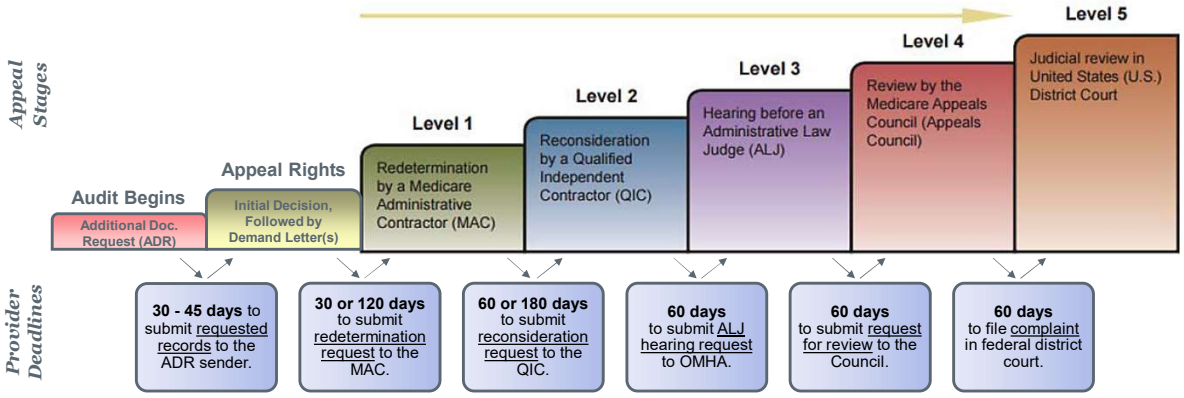
Proposed Changes to the 60-Day Repayment Rule

- CMS issued a proposed rule (12/27/2022) amending the 60-day repayment rule.
- Providers would *still* be required to report and return overpayments to the government.

	Current Rule	Proposed Rule
"Identification"	An overpayment is "identified" when its scope is determined and its amount is quantified.	Eliminates "quantification" element.
"Reasonable Diligence"	Commentary anticipates a 6-month investigation to "identify" an overpayment	Unclear what amount of time is allowed to "identify" an overpayment
Audit Appeals	Audit appeal suspends need to investigation potential overpayment.	Unclear whether audit appeals will affect obligation to investigation, report, and return.

Audit Appeals: Timelines & Strategies for Success

Appeal Stages



See handout 7. Summary of Federal Administrative Appeal Process.

General Appeal Considerations

- Role of hospice vs. legal counsel.
- Understand the implications of technical vs. clinical denials.
- Validity of the statistical report and underlying methodology, if extrapolated.
- Limiting "scope creep":
  - Review is limited to the reason(s) the specific claim or line item was initially denied.
  - *See* MLN Matters Special Edition Article, SE1521 (August 13, 2015).

Key Legal Arguments Supporting Appeal

- Conditions of payment vs. conditions of participation.
  - *See* handout 8. Medicare Hospice Regulatory Conditions of Payment.
- Role (and limitations) of LCD guidelines (*see, e.g., Vista Hospice Care*, stating that meeting LCD guidelines is only "one path to eligibility").
- Central role of physicians in determining eligibility (*see, e.g.*, *AseraCare*, stating that the mere difference of opinion between physicians cannot prove "falsity").
- Failure to offset amounts otherwise payable by Medicare.
- Social Security Act waiver and limitation of liability provisions.

Trends in Clinical Denials

- Unfounded expectation of decline, uncontrolled symptoms, or a poor response to treatments / interventions.
- Misapplication of LCD guidelines.
- Erroneous belief that “custodial care” precludes eligibility, or that “chronic” and “terminal” are mutually exclusive.
- Heavy focus on quantitative (“measurable” or “objective”) data and specific clinical data points (weights, MAC, PPS, FAST, vital signs, etc.).
- Facts found do not support the decision made.
- Misunderstanding of the standards for higher levels of care.

Trends in Technical Denials

- Missing (or overlooked) documentation.
- Insufficient or untimely face-to-face documentation.
- “Scope creep” issues.
- Insufficient physician certification narratives.
- Separately billed physician visits (“administrative” or “supervisory”).
- Validity of the election statement or its addendum.

Other Appeal Trends

- The backlog at the Office of Medicare Hearings and Appeals (OMHA) is cleared.
- More contractor participation in administrative hearings.
- Less favorable administrative law judge (ALJ) decisions.
  - Higher remaining overpayments.
  - Weaker / more egregious denial rationales.
  - Highly variable and subjective approaches across ALJs.
- More hospices proceeding to the Medicare Appeals Council and federal district court.

Prevention Tips

- Establish and maintain a robust compliance plan.
  - Proactive: Pre-billing audits of potential risk areas.
  - Reactive: Handling complaints and notices of possible compliance issues.
  - *See* handout 9. Sample Investigation Plan.
- Use data (*e.g.*, PEPPER, Abt Reports, PUF) to manage your dashboard.
- Analyze and improve document filing and organization.

OIG Audits and Investigations

Taking Audits Public

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OIG Audit Process

1. OIG requests records (~100-claim sample) and conducts an on-site visit.
    - Focus: Clinical eligibility, GIP level of care, service intensity add-on, and documentation.
2. Review results are **extrapolated** across the entire universe of claims within the two-to-three-year audit period.
3. OIG provides preliminary findings and gives the hospice an opportunity to submit additional information / evidence.
4. OIG presents clinical findings at an **exit conference** and issues a Draft Report.

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OIG Audit Process (cont.)

5. The hospice must submit a **rebuttal to the Draft Report** within ~30 days.
6. Then the OIG issues a Final Report that is **publicly available** and contains **recommendations** that the hospice:
    a. Repay amounts associated with "disallowed" claims within the 4-year reopening period.
    b. Conduct a "reasonable diligence" review under the 60-day repayment rule.
7. Referred to the MAC for recoupment and issuance of demand letters.
8. Hospice may then begin the typical administrative appeals process.

Unique OIG Audit Implications

- **Exorbitant Overpayments**: Extrapolation results in significant payment demands.
- **Unwanted Publicity**: Publication of the Final Report (on the OIG website) may lead to inquiries from the media, referral sources, employees, patients, and families.
- **Potentially Broad Repayment Obligations**: Audit findings constitute "credible information" that can trigger repayment obligations beyond the audited claims.
- **Legal Consequences**: Can result in criminal, civil, or administrative enforcement actions.

TPE / ADRs

"Routine" Oversight has Renewed Significance

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TPE and ADRs

- **Targeted Probe and Educate**
  - Focus on specific areas: GIP ≥ 7 days, 313-515 day lengths of stay, and bene sharing.
  - Up to three rounds of review (and sometimes even a fourth round).
  - 20-40 claims reviewed at each stage.
  - A low payment error rate can eliminate TPE.

NGS	Palmetto	CGS
15%	20%	25%

- **Additional Document / Development Request**
  - Typically requires production of records within 30-45 days.
  - Focus area varies based on current "edits."
  - Track results to prevent duplicative review.

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Medicaid Audits and Investigations

A Different Set of Rules

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Medicaid Audit Overview

- **UPIC-Initiated Medicaid Audits**
  - May be combined with a Medicare audit.
  - Federal auditor conducts the audit and issues a report.
  - Appeals go through a state-run process.
- **State-Initiated Medicaid Audits**
  - State authorities conduct the audit.
  - Meeting with auditors to review results is not uncommon.
  - Appeals go through a state-run process.

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Key Considerations in Medicaid Audits

- **State-Specific Requirements**: Check state Medicaid regulations and handbooks for documentation requirements (*e.g.*, pre-authorization, use of particular forms or billing codes, etc.) in addition to Medicare requirements.
- **Appeal Process**: Rebuttal → Desk Review → ALJ Hearing.
- **Repayment / Recoupment Details**: Will repayment / recoupment occur before or after appeals / hearings?
- **Settlement Opportunities**: Settlement conferences, mediations, and party-to-party negotiations.

Department of Justice Activity

The False Claims Act, Whistleblower, & Qui Tam

Common FCA Theories of Liability

- **Factually False Claim**
  - Example: Submitting a claim for GIP services when patient was on routine home care.
- **Legally False Claim**
  - Express certification: Explicitly stating that provider has complied with all applicable regulations.
  - Implied certification: Merely by submitting a claim, provider is implicitly stating that it has complied with all applicable (and material) statutory, regulatory, and contractual requirements.
- **Reverse False Claim**
  - Violation of the 60-day Repayment Rule
- *See* handout 10. Overview of the Federal False Claims Act.

FCA Primer

The FCA "[p]rohibits **knowingly** presenting . . . a false or fraudulent claim for payment to the U.S." or making or using a false record or statement material to a false or fraudulent claim.

What Constitutes "Knowingly"?

Acting "knowingly" requires "**deliberate ignorance or reckless disregard**."

What *Does Not* Constitute "Knowingly"?

Does "not punish **honest mistakes** or incorrect claims submitted through **mere negligence**."

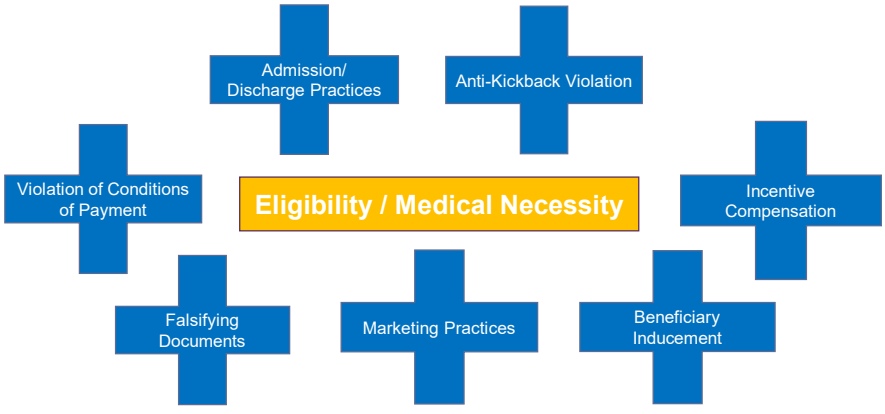
See 31 U.S.C. secs. 3729 et. seq.

Consequences of FCA Violations

- **Liability – Damages and Penalties**: Failure to report may result in liability under the FCA and the Civil Monetary Penalties Law.
- **Fines and Multipliers**: Any person who knows of an overpayment and does not report and return the overpayment is liable for a fine for each item or service, *plus* an assessment of up to *three times* the amount claimed for each such item or service.
- **Exclusion:** May lead to exclusion from federal health programs.

FCA Risk Areas

Central issue of clinical eligibility / medical necessity central *plus* one or more additional factors.



FCA Cases: *AseraCare*

- Landmark 2019 decision by 11th Circuit Court of Appeals (AL, FL, GA).

Standard	Description
Clinical	Two physicians using clinical judgment regarding a patient's condition could disagree about their prognosis and neither be wrong.
Documentation	Medical records need only support, not *prove*, a physician's clinical judgment.
Competency	Only a trained hospice physician is competent to evaluate the exercise of clinical judgment by the experienced hospice physicians.

- Also held that there are no "clinical benchmarks" or "criteria" that must be satisfied to establish eligibility.

FCA Cases: *Care Alternatives*

- 2020 decision by 3rd Circuit Court of Appeals (DE, NJ, PA).
- Less hospice-friendly approach than *AseraCare:*
  - *AseraCare*: If government witness "disagrees" with treating physician, the government has not met its burden → Case dismissed.
  - *Care Alternatives*: If government witness "disagrees" with treating physician, the jury decides who is right → Case goes to trial.
- Jurisdiction matters… Where you are located may affect your approach to compliance!

FCA Cases: *Escobar* and "Materiality"

- The U.S. Supreme Court held that the regulatory requirement in question must be "material to the Government's payment decision."
- The Court did not define what is material, but provided some guidance:
  - Conditions of payment are "relevant but not dispositive."
  - Minor noncompliance is not material.
  - Government actions may determine materiality.
    - It may be *material* if a provider knows the government consistently refuses to pay certain noncompliant claims.
    - "Very strong evidence" a requirement is *immaterial* if the government pays a claim despite knowing the requirement was not met.
- Upon receiving notice of noncompliance, evaluate whether a "material" requirement is at stake – look beyond the conditions of payment.

Whistleblowers and Qui Tam

- The FCA allows private citizens to file private causes of action on behalf of the government ("qui tam" or "whistleblower" suits).
- Whistleblowers who bring a successful suit share in the award – typically 15-30%.
- Management of potential whistleblower risk is more important than ever.
  - Ignored internal complaints are the primary driver of whistleblower actions and tips to enforcement agencies.
  - Whistleblowers are supported by ineffective internal compliance and investigation process.

Common FCA Whistleblower Allegations

- Admission of ineligible patients.
- Admission of patients with long lengths of stay and ill-defined diagnoses.
- Delays in discharging ineligible patients.
- Backdating physician certifications or recertifications.
- Providing kickbacks to referral sources.
- Paying incentive compensation that results in the retention of ineligible patients.
- Offering to provide free goods or services to Medicare beneficiaries to encourage them to elect services.
- Alteration of clinical documentation to portray the patient as eligible for hospice or home health.

Initial Government Steps in FCA Investigations

- Letter Requests, Civil Investigative Demands, or Subpoenas (records, interviews, etc.).
- Conduct interviews of patients and/or current or former employees.
- Perform expert review of claims data.
- Conduct an “undercover” investigation.

Provider Responses to CIDs and Subpoenas

- Contact and engage counsel immediately – high stakes!
- When possible, contact the issuing or executing authority through counsel.
- Conduct an internal investigation.
- Do not destroy or delete information.
- Narrow or guard the scope.
- Cooperate, but do not provide more than required.

Thank You!

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