The American Association of Nurse Attorneys (TAANA)

TAANA 2018 Annual Meeting & Educational Conference
Denver, CO
August 16-18, 2018

Simione HEALTHCARE CONSULTANTS

What do C-Suite Executives, Governing Boards, and Managers Need to Know About Healthcare Compliance?

Driving Results

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Simione Healthcare Consultants advances quality and cost efficiency, providing reliable experts, technology and tools to grow and improve home- and community-based services.

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Simione-at-a-Glance

- Founded in 1966
- First organization of its kind dedicated to home health, hospice and other community-based services
- Specializing in business performance improvement to advance quality and efficiency, reduce cost and minimize risk
- Serving a wide range of organizations including free-standing agencies, multi-state and national providers, hospitals and health systems
- Corporate headquarters in Hamden, CT, with offices in Sturbridge, MA, and Rohnert Park, CA
- Consultants based in 30 states across the U.S.

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Key Expertise & Services

Consulting
- Operations
- Finance
- Compliance & Risk
- Sales & Marketing
- Information Technology
- Mergers & Acquisitions

Talent Management
- Recruiting
- Executive Search
- Interim Management
- Compensation Analysis
- Employee Engagement

ExactRecruiting

Data Analytics
- Cost Reporting
- Financial Benchmarking
- Market Intelligence
- Clinical Process Transformation

Simione Financial Monitor

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Presentation Objectives

- Define a Corporate Integrity Agreement (CIA) and state its relationship with a Settlement Agreement in a Healthcare matter
- Identify at least three requirements of a CIA
- Identify at least two responsibilities of the C-Suite and one of the Health Care Governing Board
- Discuss/analyze a CIA in terms of best practices

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Definition of Corporate Integrity Agreement

- A corporate integrity agreement (CIA) is a document that outlines the obligations to which an entity agrees as part of a civil settlement. An entity agrees to the CIA obligations in exchange for the Office of Inspector General's (OIG) agreement that it will not seek to exclude the entity from participation in Medicare, Medicaid, or other Federal health care programs. CIAs have common elements, but each one is tailored to address the specific facts of the case and may incorporate elements of a preexisting compliance program.
- An integrity agreement (IA) is a document that outlines the obligations to which an individual practitioner, small group practice, or small provider agree as part of a civil settlement.

Oig.hhs.gov/faqs/corporate-integrity-agreements-faq.asp

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CORPORATE INTEGRITY AGREEMENTS

- Definition of a CIA
- Why is a provider subject to a CIA?
- When is a CIA appropriate?
- Who is subject to a CIA?
- Length of Agreement
- Contents
- Other

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What Providers Types are subject to CIAs?

- All Providers who receive Medicare, Medicaid or other Government healthcare funds
  - Hospitals
  - Physician Groups/Individuals
  - Ambulance Services
  - Home Health
  - Hospice
  - Rehabilitation Centers
  - Pharmacies
  - Skilled Nursing Facilities
  - Other

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Corporate Integrity Agreement Enforcement

- CIA/IA Breach and default provisions allow the OIG to impose certain monetary penalties (referred to as Stipulated Penalties) for the failure to comply with certain obligations set forth in the CIA/IA
- This site lists enforcement actions for breach of CIA:
- https://www.oig.hhs.gov/fraud/enforcement/ciae/index.asp0520.asp
- Types of Breach:
  - 7/2018: eClincal Works, LLC-$132,500 for failure to comply with obligations to timely report Patient Safety Issues as Reportable Events
  - 12/2017: CT Dentist paid $12,000 for failure to screen Covered Persons against the OIG Exclusion List
  - 10/2017: New York Physician and Practice Pay IA Stipulated Penalty of $12,00o for failure to screen Covered Persons against OIG Exclusion List
  - 12/2016: CA Skilled Nursing Facilities pay $70,00 for failure to report adverse survey issues
  - 11/2016: Missouri Hospital Management CO and Owner pay $30,00.failure to conduct legal review of new …and existing Focus Arrangement
  - **09/2016: Kindred pays over $3 Million ..improper billing**

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Examples of Home Health Enforcement by the Numbers: From HHS OIG Attorney for AHLA Annual Mtg. 2018

Home Health Agency-related Stats		
	CY2016	CY2017
Criminal Actions	77	71
OI Civil/CMPL Actions	17	24
OCIG Civil/CMPL Actions	3	3
Total Civil/CMPL Actions	20	27
OI Expected Receivables	$367,331,695.00	$214,057,753.00
OCIG Expected Receivables	$4,777,140.00	$237,916.66
Total Expected Receivables	$372,108,835.00	$214,295,669.66
Exclusions	110	125

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Key Compliance Risk Areas

- Lack of medical necessity of skilled services (all providers & disciplines and)
- Lack of eligibility for the Medicare/Medicare benefit (*i.e.*, medical necessity; therapy goals, homebound status for HH)
- Documentation insufficiency and non-compliance with Federal health care program requirements
- Coding: inappropriate ICD-10 or CPT codes--upcoding
- In appropriate financial relationships with referral sources
- Marketing practices that encourage inappropriate referrals
- Issues with Face-to-Face (continues to be an issue of focus for Home Health and Hospice)
- Employment of Excluded Individuals
- Credentialing /Certification

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Quality of Care Corporate Integrity Agreements

- When a False Claims Act settlement resolves allegations of fraud that impact the quality of patient care, OIG may enter into a "quality-of-care" Corporate Integrity Agreement (CIA) with the settling provider. Under this type of CIA, OIG requires that the provider retain an entity with clinical expertise to perform quality-related reviews. For example, some CIAs require the provider to retain an independent quality monitor that will look at the entity's delivery of care and evaluate the provider's ability to prevent, detect, and respond to patient care problems. Other quality-of-care CIAs require the provider to retain a peer review consultant to evaluate the provider's peer review and medical credentialing systems. Agreements may also require the provider to retain a clinical expert to review the medical necessity and appropriateness of certain admissions and medical procedures. If you or your organization are interested being an independent quality monitor, please see the OIG's Notice for Potential Monitors for Quality-of-Care Corporate Integrity Agreements.
- Not an admission of substandard care or worthless services

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Examples of Quality of Care CIA

- There are seven Quality CIAs listed on the OIG website; most recent are:
- 2015: CF Watsonville East, LLC
- 2014: Extendicare Health Services (EHSI) and The Progressive Step Corporation (ProStep)
- 2014: Foundation Health Services
- 2014: St. Joseph Health System, Inc. D/B/A Saint Joseph London
- 2013 and older…

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Basic Requirements of CIAs

Seven Elements of a Compliance Program

1. Policy/Procedure/Written Code
2. Compliance Officer/Committee
3. Training/Education
4. Communications/Anonymous
5. Auditing Monitoring ---- External monitoring by experts (Attorney Client Privileges issues/ethics)
6. Disciplinary Measures
7. Disclosure /Timely Investigations and Reporting

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Other CIA Enforceable Requirements

- **Management Certifications:** Training for staff in high risk areas: Human Resources; Marketing (Anti-kickback); Billing (False Claims); Clinical Documentation (Regulations re: eligibility & medical Necessity; care plan goals, therapy).
- **Governing Board Education and Consulting Experts**
- **Annual IRO Audits and Claims Reviews (usually for five years) under an OIG Monitor Attorney**
- **Contract Arrangement Review**
- **Annual Internal Audit Plan**
- **Annual Compliance Program Risk/Effectiveness Assessment**
- **Reporting Overpayments**
- **Coding**
- **Annual Reports to the OIG Monitor**

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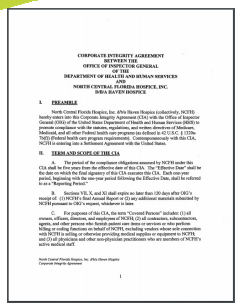
Lessons from Recent CIAs



CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
NORTH CENTRAL FLORIDA HOSPICE, INC.
D/B/A HAVEN HOSPICE

I. PREAMBLE

North Central Florida Hospice, Inc. d/b/a Haven Hospice (collectively, NCFH) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, NCFH is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assessed by NCFH under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) NCFH's final annual report; or (2) any additional materials submitted by NCFH pursuant to OIG's request, whichever is later.

C. For purposes of this CIA, the term "Covered Persons" includes: (1) all owners, officers, directors, and employees of NCFH; (2) all contractors, subcontractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of NCFH, excluding vendors whose sole connection with NCFH is selling or otherwise providing medical supplies or equipment to NCFH; and (3) all physicians and other non-physician practitioners who are members of NCFH's active medical staff.

North Central Florida Hospice, Inc. d/b/a Haven Hospice
Corporate Integrity Agreement

1

- *Risk Assessment and Internal Review Process*
  - Centralized, annual process to identify and address risks associated with participation in the Federal health care programs
  - Requires input from compliance, legal, and department leaders
  - Includes development and implementation of internal audit work plans, creation of corrective action plans to address deficiencies, and tracking of CAPs

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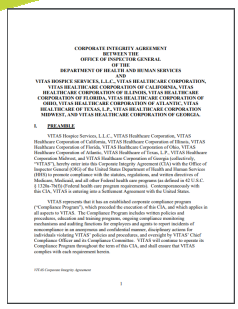
Lessons from Recent CIAs



CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
VITAS HOSPICE SERVICES, L.L.C., VITAS HEALTHCARE CORPORATION, VITAS HEALTHCARE CORPORATION OF CALIFORNIA, VITAS HEALTHCARE CORPORATION OF ILLINOIS, VITAS HEALTHCARE CORPORATION OF FLORIDA, VITAS HEALTHCARE CORPORATION OF ATLANTIC, VITAS HEALTHCARE OF TEXAS, L.P., VITAS HEALTHCARE OF TEXAS, L.P., VITAS HEALTHCARE CORPORATION MIDWEST, AND VITAS HEALTHCARE CORPORATION OF GEORGIA,

I. PREAMBLE

VITAS Hospice Services, L.L.C., VITAS Healthcare Corporation, VITAS Healthcare Corporation of California, VITAS Healthcare Corporation of Illinois, VITAS Healthcare Corporation of Florida, VITAS Healthcare Corporation of Ohio, VITAS Healthcare Corporation of Atlantic, VITAS Healthcare of Texas, L.P., VITAS Healthcare of Texas, L.P., VITAS Healthcare Corporation Midwest, and VITAS Healthcare Corporation of Georgia, (collectively, "VITAS"), hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, VITAS is entering into a Settlement Agreement with the United States.

VITAS represents that it has an established corporate compliance program ("Compliance Program"), which preceded the execution of this CIA, and which applies to all aspects to VITAS. The Compliance Program includes written policies and procedures, education and training programs, ongoing compliance monitoring mechanisms and enabling functions for employees and agents to report incidents of suspected misconduct and violations of compliance policies and procedures by individuals violating VITAS' policies and procedures, and oversight by VITAS' Chief Compliance Officer and its Compliance Committee. VITAS will continue to operate its Compliance Program throughout the term of this CIA, and shall ensure that VITAS complies with each requirement herein.

VITAS Corporate Integrity Agreement

1

- *Management Certifications*
  - Require key management-level employees to certify that their areas of oversight and authority are in compliance with applicable Federal health care program requirements and the CIA
  - Employees unable to furnish the certification must provide a written explanation of the reasons why
  - One CIA in particular requires certifications from management of both the operating entities *and* the parent company

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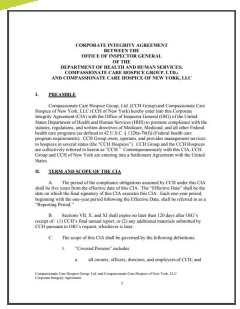
Lessons from Recent CIAs



CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
COMPASSIONATE CARE HOSPICE GROUP, LTD.,
AND COMPASSIONATE CARE HOSPICE OF NEW YORK, LLC

I. PREAMBLE

Compassionate Care Hospice Group, Ltd. (CCH Group) and Compassionate Care Hospice of New York, LLC (CCH of New York) hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). CCH Group owns, operates, and provides management services to hospices in several states (the "CCH Hospices"). CCH Group and the CCH Hospices are collectively referred to herein as "CCH." Contemporaneously with this CIA, CCH Group and CCH of New York are entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by CCH under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) CCH's final annual report; or (2) any additional materials submitted by CCH pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

a. all owners, officers, directors, and employees of CCH; and

Compassionate Care Hospice Group, Ltd. and Compassionate Care Hospice of New York, LLC
Corporate Integrity Agreement

1

- *Board Compliance Expert*
  - Engagement of expert in corporate governance and compliance to assist governing body in fulfilling its oversight function
  - Includes regularly meeting with governing body and preparation of compliance program review reports
- *Chief Quality Officer*
  - Member of senior management primarily responsible for monitoring day-to-day quality of care and patient safety activities
  - Reports to Compliance Officer, with authority to directly report to the governing body on QA matters

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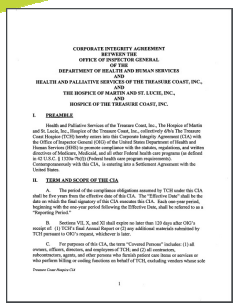
Lessons from Recent CIAs



CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
HEALTH AND PALLIATIVE SERVICES OF THE TREASURE COAST, INC.,
AND
THE HOSPICE OF MARTIN AND ST. LUCIE, INC.,
AND
HOSPICE OF THE TREASURE COAST, INC.

I. PREAMBLE

Health and Palliative Services of the Treasure Coast, Inc., The Hospice of Martin and St. Lucie, Inc., and Hospice of the Treasure Coast, Inc. (collectively, "Treasure Coast Hospice (TCH) hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements).
Contemporaneously with this CIA, is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by TCH under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) TCH's annual report, or (2) any additional materials submitted by TCH pursuant to OIG's request, whichever is later.

C. For purposes of this CIA, the term "Covered Persons" includes: (1) all owners, officers, directors, and employees of TCH; and (2) all contractors, subcontractors, agents, and other persons who perform billing or coding functions on behalf of TCH, excluding vendors whose sole

Treasure Coast Hospice CIA

1

- *Hospice CIA Claims Review*
  - Provides for both an Eligibility Review and Appropriate Level of Services Review
  - Beneficiary Population generally defined to include Medicare patients who received uninterrupted services for 210 days or more in Reporting Period
  - Also includes a review of the provider's systems and processes to identify specific problems or weaknesses that may have led to errors discovered by the IRO

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Lessons/Requirements of CIA

- CIAs based on allegations of false claims billed and paid will require annual clinical record and claims audits by an Independent Review Organization (IRO)
- CIAs based on allegations of violations of Anti-Kickback statute: require annual audits of contracts and "arrangements"
- Reporting Period Annually for three-five years: Date CIA fully executed through the next year
  - CIA will identify sample to be audited
  - Specific issues such as medical necessity or eligibility, coding

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Independent Review Organization

- **Definition: (IRO)**
  - A consulting, auditing or accounting firm that provides independent and objective reviews and analyses
  - Provides services to Medicare/ Medicaid Provider entities who are mandated to comply with a Corporate Integrity Agreement (CIA)
  - IROs are often full service consulting firms; however, they cannot provide similar or same services to companies for which they are providing services under the CIA ; neither can they provide *any* services that could jeopardize their objectivity

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IRO Standards

- OIG will *not* recommend or choose IRO for entity
- OIG provides guidance
  - *GOA Government Auditing Standards* sets forth standards (Also known as the "Yellow Book") for choosing IRO
    - www.gao.gov/yellowbook
    - Two core requirements:
      - Objectivity & Independence
- IRO accountable to OIG; OIG maintains the right to disapprove of IRO or require replacement of an IRO;
  - to access materials, meet with the IRO or to perform a Validation Review of IRO's work

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Types of IRO Reviews

- **System Reviews**
- **Transaction Reviews**
  - Clinical Record
  - Claims Audits
  - Cost Reports
  - Business Arrangements
  - Contracts
  - Other

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How do Attorneys Assist Clients with CIA Compliance?

- Attorneys usually work with clients to negotiate CIAs
- May be asked to assist with discussions and hiring of IRO (may consider an RFP)
- May assist with review of annual reports.
- Attorneys can assist providers to establish and maintain a solid *Compliance and Ethics Program* that includes the seven elements of a compliance program:
  - Written Policies and Procedures
  - Effective Oversight by Compliance Officer and governing body
  - Effective Reporting (anonymous hotline available)
  - Compliance Education on hire, annually and for high risk areas
  - Audits and systemic practices to monitor compliance with high risk areas
  - Consistent disciplinary measures to enforce standards of conduct
  - Effective policies for prompt reporting, investigations and corrective actions

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Compliance Program Best Practices

- Governing Board involvement and knowledge
- Executive Team involvement and knowledge: CEO, COO, CFO, CCO, CNO, other
- Marketing Team
- Human Resources
- Clinical Management and staff clinicians/care providers
- Revenue Cycle and Billing personnel
- Other (see recent CIA requirements)

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Compliance Program Best Practices

- **Human Resources:**
  - On hire & systematic monthly OIG Exclusion checks
  - Code of Conduct/Standards of Ethics: introduce on hire and signed by employees, independent contractors; vendor education
  - Annual employee attestation (and exit interview attestation) that employee is not aware of non-compliance with policy or violations of the law
  - Set up expectation of exit interview on hire
  - Disciplinary Practices
- **Marketing & Referral Sources**
  - Training and education
    - Role playing; case studies; use agendas & sign-in sheets

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Compliance Program Best Practices

- **Clinical/Documentation and QAPI & Compliance Committees**
  - Practical hands-on documentation (training and practice) consistent with regulations
  - Education on payment requirements
  - Physicians, nurses/practitioners, therapists/chaplains, MSW
  - QAPI/Compliance: Pre-Bill auditing and monitoring for eligibility/medical necessity/homebound and other technical documentation requirements such as ICD-10 Coding, CPT coding
- **Revenue Cycle and Billing**
  - EMR education/Billing education and implementation of pre-bill edits
  - Routine pre-bill reviews/audits of final claim ready to bill

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Compliance Program Best Practices

- Educate Governing Board & Executive Team
  - Private or Public: The government is looking to provider governing Boards for effective oversight of healthcare providers ---and to monitor company quality and compliance:
  - See "Practical Guidance for Health Care Governing Boards on Compliance Oversight" on OIG website
  - See also: "A toolkit for Health Care Board
  - Go to: www.oig/hhs/gov for additional resources and guidance for compliance related issues

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Compliance Resources

- U.S. Department of Justice, Criminal Division, Fraud Section:
  - February 21, 2017:
    - *Evaluation of Corporate Compliance Programs*
      - *Topics and Questions*
  - HCCA/OIG Document March 2017
    - Measuring Compliance Effectiveness

See https://oig.hhs.gov/compliance/compliance-resource-portal/

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Recoupments of Overpayments

- Adams EMS, Inc. V. Azar, No. H18-1443 (S.D. Tex, July 11, 2018) Centers for Medicare and Medicaid Services (CMS) cannot recoup monies until after Administrative Law Judge (ALJ) have been held.
- Family Rehabilitation, Inc. v. Azar, No. 17-1133 (5th Cir Mar. 2, 2018) CM cannot recoup monies from a home health agency until after hearings …by an administrative law judge

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Appeals and Case Law

Appeal Process takes years

- Redeterminations
- Reconsiderations (Quality Integrity Contractors (QIC)
- Administrative Law Judge (ALJ) Hearings on Overpayments
- Medicare Appeals Council

Evolving Case Law:

- 2018- Superior Home Health Serv., LLC v. Azar No.;1 CV-00663 Re: Extrapolation
- 2016 Escobar and aftermath of: materiality Issue implies certification
- 2015 – 2016 Aseracare Decisions
- Other developing case law on alleged overpayments and fraud

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QUESTIONS ?

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Education Purposes

This presentation is for education purposes only and should not be construed as providing legal advice.

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Driving Results

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