

**Health Care Compliance
Association (HCCA)**

**4th Annual Healthcare Enforcement
Compliance Conference
November 4-7, 2018
Washington D.C.
Grand Hyatt Washington**

YOUR SPEAKERS



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**P6 Enforcement & Compliance
Home Health, Hospice and
Nursing Homes**

Identify	Identify what's hot in the enforcement environment for post-acute care providers
Learn	Learn the life cycle of a Corporate Integrity Agreement (CIA); initiation, negotiation, implementation, management and graduation
Discuss	Discuss requirements for an Independent Review Organization (IRO) and roles of the provider, outside counsel and the IRO
Examine	Examine potential impacts of a CIA on the provider's financial and clinical operations, its compliance activities and the post-graduate effects

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What's heating up and what's hot...

- ▶ Government Auditing and Investigations – including Targeted Probe and Educate audits.

Home Health Focus:

Medical Necessity, Homebound Status, Face-to-Face, Therapy.

Hospice Focus:

Eligibility; Levels of Care: General Inpatient Care and Continuous Home Care; Long Length of Stays, Patients in nursing homes or ALF.

Skilled Nursing Facilities:

Quality of Care, Therapy Medical Necessity, OIG probe on staffing records.

Assisted Living Communities:

Quality of Care, lack of consistency with reporting deficiencies and Government Accountability Office (GAO) findings.

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Overview of Risk Areas & Risk Mitigation for Post-Acute Care Providers

- ▶ Medical Necessity of Services
- ▶ Incident to Billing/Unsupervised Services
- ▶ Services ordered but not performed
- ▶ Kickbacks/Inappropriate Referrals
- ▶ Overbilling/Up-coding/OASIS/ICD-10/MDS
- ▶ Therapy Manipulation
- ▶ Insufficient Documentation
- ▶ Staff Training/Education
- ▶ Credentialing/Certification
- ▶ Exclusions- Monitoring and prebill auditing



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Government Audits

- ▶ Medicare Administrative Contractors (MACs).
- ▶ Zone Integrity Program Contractors (ZPICs) – Focus on Fraud.
- ▶ United Integrity Program Contractors (UPICS).
 - ▶ Replacing the ZPIC, PSC and other.
 - ▶ Seven initial contracts.
 - ▶ Advance Med Corp (\$76.8 million task order – first under the UPIC).
 - ▶ Other Medicare Contractors: TriCenturion, Inc.; StrategicHealthSolutions LLC; Noridian Healthcare Solutions, LLC; IntegriGuard LLC d/b/a/ HMS Federal; Health Integrity, LLC.
 - ▶ Medicare and Medicaid audits (replace MIC).

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Government Audits (Continued)

- ▶ HHS OIG: Hospices Inappropriately Billed Medicare Over \$250 Million for General Inpatient Care. March 2016.
- ▶ Office of Inspector General (OIG) Office of Audit Services (OAS).
 - ▶ Audit agencies with intent to publish findings.
 - ▶ Sample size
 - ▶ Example:
 - ▶ Hospice of New York, LLC, Improperly Claimed Medicare Reimbursement for Some Hospice Services - June 2015.
- ▶ RACS – created administrative backlog.
- ▶ Comprehensive Error Rate Testing (CERTS).

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Targeted Probe and Educate (TPE)


- ▶ MACs Medical Review Program.
- ▶ MACs must develop an annual Improper Payment Reduction. Strategy (IPRS)—required by CMS.
 - ▶ Data is analyzed by provider, services and beneficiary.
 - ▶ Historical claims data.
 - ▶ Use of patterns/trends; high volume/cost and change in frequency/outliers.
 - ▶ Comparative billing reports: state, regional and national.
 - ▶ CMS Reports and other government reports (OIG/GAO).

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TPE: What Providers Need to Know

- ▶ Once the MAC identifies your risk, claims review is initiated.
 - ▶ Validate issue.
 - ▶ Target and Probe of 20-40 claims.
 - ▶ Selected Sample of 20-40.
 - ▶ Initial request for records may be a smaller number of patients if agency has small census (but a total of 20-40 for round one is still applicable).
 - ▶ Benchmarks established.
 - ▶ One on one provider education.
 - ▶ Providers with high error rates will continue to second and possibly third rounds.



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Why and when are Home Health & Hospice providers targeted for focused audits?

- ▶ The home health & hospice benefit is costly and will continue to increase with increase of Medicare Beneficiaries.
- ▶ Fraud and abusive practices is real.
- ▶ Mandates under the Patient Protection and Affordable Care Act (ACA).
- ▶ Government Initiatives.
 - ▶ Medicare Strike Force -- established in 2007 (OIG, DOJ, U.S. Attorneys, FBI, and local law enforcement).
- ▶ Government reports for patterns of potential or actual abusive practices.
- ▶ Data Analytics -- state, regional, MAC jurisdiction, national.
 - ▶ PEPPER Data; claims, quality, and beneficiary data.

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Actions to take when you receive notice of an audit or a clinical record request

- ▶ Identify the contractor of the audit request (MAC, ZPIC, UPIC, OIG...).
- ▶ Do not panic...
- ▶ Do not ignore the letter or let the letter sit on your desk -- or any desk!
- ▶ Take immediate action:
 - ▶ Notify your compliance officer.
 - ▶ May wish to engage legal counsel and outside consulting firm to assist ...
 - ▶ Organize records for ease of auditor review; submit timely.
 - ▶ Consider Appeals process if denials (see next slide).

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Provider Appeal Rights

- ▶ 1. Redeterminations Conducted by the MAC.
- ▶ 2. Reconsiderations (Qualified Independent Contractors -- QICs) Second level of appeal filed to QIC.
- ▶ 3. Administrative Law Judge (ALJ).
- ▶ 4. Medicare Appeals Council (DHHS).
- ▶ 5. Judicial Review - U.S. District Court.



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Case Law and Pending Litigation

- ▶ Escobar
- ▶ Aseracare; Vista Hospice
- ▶ Brookdale
- ▶ Consulate
- ▶ LifeCare; Signature; Manor Care

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Life Cycle: Corporate Integrity Agreement (CIA)

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



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Corporate Integrity Agreements

- ▶ Medicare/Medicaid Provider entities under investigation for alleged fraud or abuse may enter into a settlement agreement with DHHS OIG.
- ▶ In addition to the Settlement Agreement, the OIG may require mandatory compliance with a second agreement – Corporate Integrity Agreement (CIA).
- ▶ The Provider agrees to the CIA and the OIG agrees *not* to exclude Provider entity/C-Suite/owners from Medicare/Medicaid and other Federal programs.



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Insights/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 may identify sample to be audited.
 - ▶ Specific issues such as medical necessity or eligibility, coding.

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CIAs Require Providers to have 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
- ▶ 8. NY OMIG: A Policy of Non-Intimidation and Non-Retaliation



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Other CIA Enforceable Requirements

- ▶ **Management and Board 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**
- ▶ **Contract Arrangement Review**
- ▶ **Annual Internal Audit Plan**
- ▶ **Annual Compliance Program Risk/Effectiveness Assessment**
- ▶ **Reporting Overpayments**
- ▶ **Coding**
- ▶ **Annual IRO Audits and Claims Reviews (usually for five years) under an OIG Monitor Attorney**
- ▶ **Annual Reports to the OIG**



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Requirements of Annual Audits

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CIA Breaches

- ▶ Breach provision - provider's failure to comply with its CIA obligations “may” lead to OIG demanding penalties (dollar amounts could be stipulated in the CIA).
- ▶ *U.S. ex rel. Boise v. Cephalon, Inc.* (July 21, 2015) - relators stated a claim under the 31 U.S.C. 3729(a)(1)(G)—“reverse false claims” provision of the FCA—based on alleged violations of a Corporate Integrity Agreement (CIA).
- ▶ Alleged off-label medication promotion and paid unlawful kickbacks in violation of the CIA (entitling the OIG to stipulated penalties), failed to report the violations and making false certifications of compliance.
- ▶ Improperly avoided its obligation to pay penalties violated of § 3729(a)(1)(G).

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CIA Enforcements

- ▶ December 29, 2016 - CF Watsonville East, LLC and Watsonville, West, LLC (Watsonville) paid a stipulated penalty of \$70,000 for failure to notify OIG of adverse final determinations made by the California HHS.
- ▶ September 13, 2016 - Kindred Healthcare, Inc. paid a stipulated penalty of \$3,073,961.98 (largest for CIA violation) for failure to correct improper billing practices in the 4th year of the 5 year agreement.
- ▶ September 18, 2014 - OIG demanded a \$25,000 stipulated penalty against Foundation Health Services, Inc. (Foundation) for its failure to timely retain an Independent Quality Monitor as required by its CIA with the OIG. Foundation appealed to an ALJ and the stipulated penalty was later withdrawn after Foundation retained a Quality Monitor and agreed to a 2 month extension of its CIA.

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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.
 - Threats to Independence - self-review and management participation.
- 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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IRO Objectivity

- ▶ Independent in fact and appearance when providing audit and attestation engagements.
- ▶ Maintain attitude of impartiality.
- ▶ Free of conflict of interests.



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Principles of Independence

- ▶ **Yellow Book:**
 - ▶ Audit organizations must not provide non-audit services that involve performing management functions or make management decisions.
 - ▶ **EXAMPLE**
 - ▶ Audit organizations must not audit their own work or provide non-audit functions where the functions are significant or material to the subject matter of the audits...
 - ▶ Non-audit services: do not impair independence; must implement supplemental safeguards; no impairment to independence.

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Potential Impacts of a CIA on Provider: Financial, Clinical, Operations, Compliance...

- ▶ IRO is greatest "hard" cost - "soft" costs include required training time, maintaining process to collect and present required reports, staff reaction to additional oversight.
- ▶ Done properly, implementation of a CIA should improve or maintain clinical and operational excellence.
- ▶ CIA can be an opportunity to elevate internal view of Compliance.
- ▶ However - risk that existence of CIA will be viewed as a "scarlet letter" hindering network and contracting opportunities; risk of (baseless) third party claims.

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Post Graduate Effects of a CIA

- ▶ Accountability
- ▶ Best Practices
- ▶ Consistency and Collaboration with Compliance throughout.

Compliance is everyone's job!

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Practice Tips for Attorneys, Compliance Officer and Providers

- ▶ Educate clients/employees/vendors/contractors on fraud and abuse laws....compliance & ethics programs... and re-educate...
 - ▶ Impart the importance of a live and evolving compliance program.
- ▶ Assist clients in the development and implementation of compliance program.
- ▶ Encourage clients to obtain external baseline audits/compliance risk & effectiveness assessments.
- ▶ Engage their C-Suite and Governing Board in Quality and Compliance initiatives.

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QUESTIONS



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THANK YOU!

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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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