Morgan Lewis

FAST BREAK: NEW CONSIDERATIONS IN NEGOTIATING CIAs

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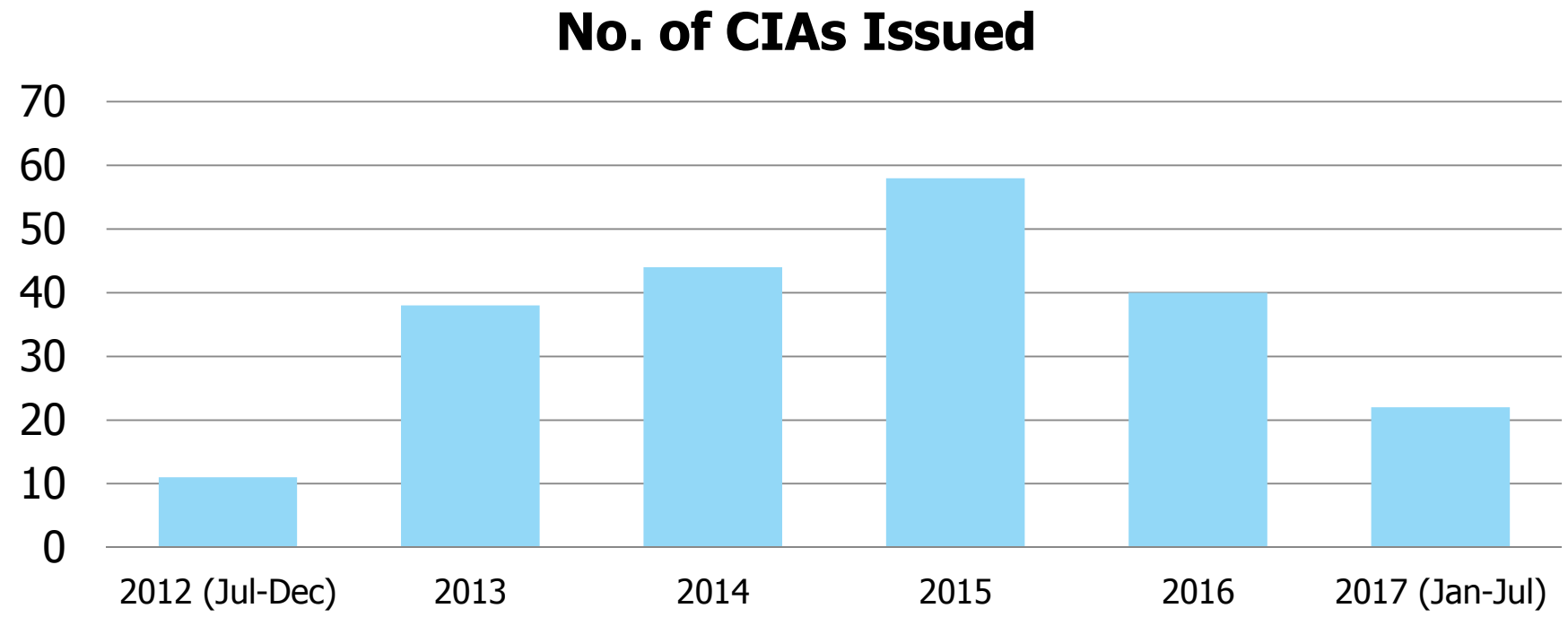
July 27, 2017

Agenda

- Recent Changes, Trends and Observations
- Evolving Government Perceptions
- Negotiation Strategies
- Implementation Strategies

RECENT CHANGES, TRENDS AND OBSERVATIONS

CIA Volume: July 2012- July 2017



Recent Trends: July 2015 – July 2017

- 86 CIAs executed in the last 24 months
- 14 have been 3-year CIAs
  - 1 PT practice;
  - 3 dentists;
  - 11 physician practices
- 71 have been 5-year CIAs

Recent Trends: July 2015 – July 2017 (cont.)

- Recent 5-Year CIAs:
  - 1 Diagnostic Imaging
  - 1 EMS
  - 1 Lab
  - 1 Native American Tribe (youth counseling)
  - 1 Nutritional Supplement Provider
  - 2 Medicare Advantage Plans
  - 2 Pharmacies
  - 3 Health Tech.
  - 3 LTC/CCRC
  - 3 Pharmaceutical Manufacturers
  - 3 Staffing Companies
  - 4 Hospices
  - 5 Medical Supply/Device Entities
  - 6 Home Health
  - 6 Rehab Service Providers
  - 6 SNFs
  - 11 Physician Practices
  - 12 Hospitals

Recent Trends

- More innovation and customization
- Newer model, more streamlined CIA
- Greater flexibility in implementing and operating under a CIA
- The most obvious changes
  - Requirements for Written Standards
  - Training and Education Requirements
  - IRO Claims Reviews

Recent Trends

Medicare Advantage Organization and Former Chief Operating Officer to Pay $32.5 Million to Settle False Claims Act Allegations

Freedom Health Inc., a Tampa, Florida-based provider of managed care services, and its related corporate entities (collectively "Freedom Health"), agreed to pay $31,695,593 to resolve allegations that they violated the False Claims Act by engaging in illegal schemes to maximize their payment from the government in connection with their Medicare Advantage plans, the Justice Department announced today. In addition, the former Chief Operating Officer (COO) of Freedom Health Siddhartha Pagidipati, has agreed to pay $750,000 to resolve his alleged role in one of these schemes.

networks and their patients' health," said Chief Counsel to the Inspector General Gregory Demske of the Department of Health and Human Services Office of Inspector General (HHS-OIG). "OIG will investigate and hold managed care organizations accountable for fraud. Moving forward, the innovative CIA reduces the risks to patients and taxpayers by focusing on compliance issues unique to Medicare Advantage plans."

Recent Trends

Electronic Health Records Vendor to Pay $155 Million to Settle False Claims Act Allegations

One of the nation's largest vendors of electronic health records software, eClinicalWorks (ECW), and certain of its employees will pay a total of $155 million to resolve a False Claims Act lawsuit alleging that ECW misrepresented the capabilities of its software, the Justice Department announced. The settlement also resolves allegations that ECW paid kickbacks to certain customers in exchange for promoting its product. ECW is headquartered in Westborough, Massachusetts.

"Electronic health records have the potential to improve the care provided to Medicare and Medicaid beneficiaries, but only if the information is accurate and accessible," said Special Agent in Charge Phillip Coyne of HHS-OIG. "Those who engage in fraud that undermines the goals of EHR or puts patients at risk can expect a thorough investigation and strong remedial measures such as those in the novel and innovative Corporate Integrity Agreement in this case."

Recent Changes – Written Standards

Previous State:

Alliance Rehabilitation LLC
March 7, 2014

B. Written Standards

1. *Code of Conduct*. Within 90 days after the Effective Date, each of the Providers shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Each of the Providers shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The

1. *Code of Conduct*. Within 90 days after the Effective Date, each of the Providers shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Each of the Providers shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

3

2. *Policies and Procedures*. Within 90 days after the Effective Date, each Provider shall implement written Policies and Procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Provider's compliance with Federal health care program requirements.

Within 90 days after the Effective Date, the Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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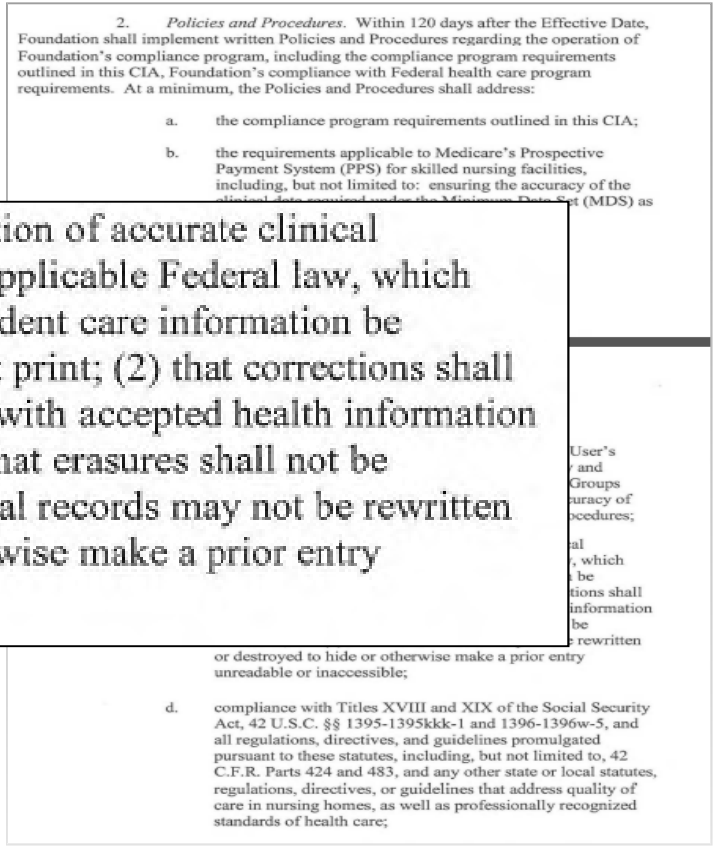
Recent Changes – Written Standards

Previous State:

American Family Services, Inc.
June 10, 2014



2. *Policies and Procedures.* Within 120 days after the Effective Date, Foundation shall implement written Policies and Procedures regarding the operation of Foundation's compliance program, including the compliance program requirements outlined in this CIA, Foundation's compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

a. the compliance program requirements outlined in this CIA;

b. the requirements applicable to Medicare's Prospective Payment System (PPS) for skilled nursing facilities, including, but not limited to: ensuring the accuracy of the clinical data required under the Minimum Data Set (MDS) as

c. compliance with the completion of accurate clinical assessments as required by applicable Federal law, which shall include: (1) that all resident care information be recorded in ink or permanent print; (2) that corrections shall only be made in accordance with accepted health information management standards; (3) that erasures shall not be allowable; and (4) that clinical records may not be rewritten or destroyed to hide or otherwise make a prior entry unreadable or inaccessible;

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or destroyed to hide or otherwise make a prior entry unreadable or inaccessible;

d. compliance with Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5, and all regulations, directives, and guidelines promulgated pursuant to these statutes, including, but not limited to, 42 C.F.R. Parts 424 and 483, and any other state or local statutes, regulations, directives, or guidelines that address quality of care in nursing homes, as well as professionally recognized standards of health care;

Recent Changes – Written Standards

2017:

A. Written Standards

Within 90 days after the Effective Date, the Company shall develop and implement written policies and procedures regarding the operation of its Compliance Program, including the Compliance Program requirements outlined in this CIA and the Company's compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of this CIA, the Company shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons.

At least annually (and more frequently, if appropriate), the Company shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

Recent Changes – Training and Education

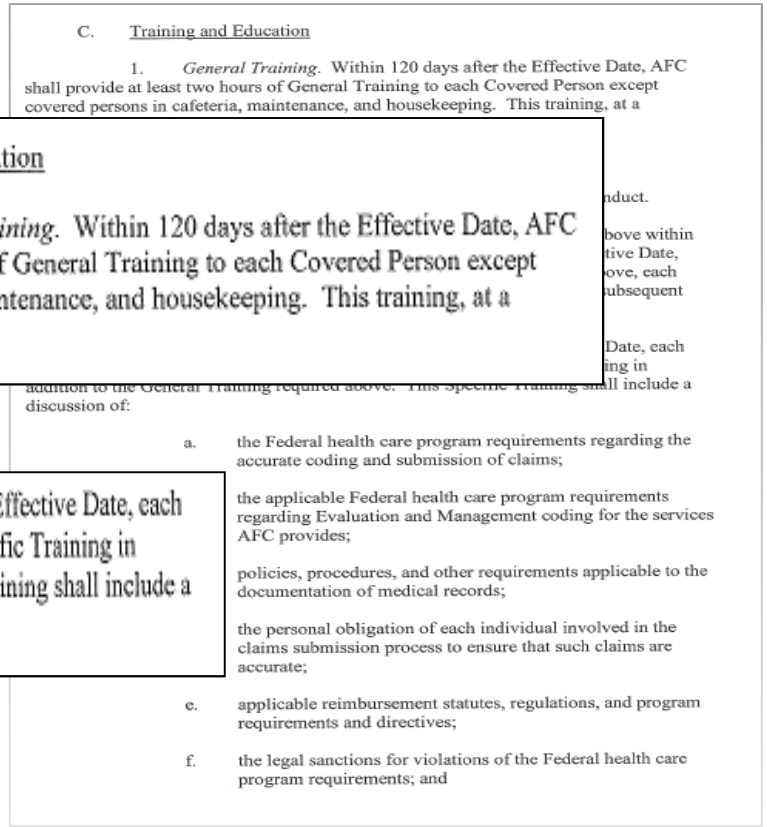
Previous State:

American Family Care, Inc.
March 12, 2014

C. Training and Education

1. *General Training*. Within 120 days after the Effective Date, AFC shall provide at least two hours of General Training to each Covered Person except covered persons in cafeteria, maintenance, and housekeeping. This training, at a minimum, shall explain AFC's:

2. *Specific Training*. Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least three hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of: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1. *General Training*. Within 120 days after the Effective Date, AFC shall provide at least two hours of General Training to each Covered Person except covered persons in cafeteria, maintenance, and housekeeping. This training, at a

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addition to the General Training required above. This Specific Training shall include a discussion of:

a. the Federal health care program requirements regarding the accurate coding and submission of claims;

the applicable Federal health care program requirements regarding Evaluation and Management coding for the services AFC provides;

policies, procedures, and other requirements applicable to the documentation of medical records;

the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;

e. applicable reimbursement statutes, regulations, and program requirements and directives;

f. the legal sanctions for violations of the Federal health care program requirements; and

Recent Changes – Training and Education

Previous State:

American Family Care, Inc.
March 12, 2014

1. "Covered Persons" includes:

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

   b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of AFC, excluding vendors whose sole connection with AFC is selling or otherwise providing medical supplies or equipment to AFC and who do not bill the Federal health care programs for such medical supplies or equipment.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

Recent Changes – Training and Education

Previous State:

Park Avenue
July 8, 2013

4. *Specific Training for Covered Behavioral Health Providers*. Within 90 days after the Effective Date, each Covered Behavioral Health Provider shall receive at least one hour of Specific Training for Covered Behavioral Health Providers in addition to the General Training and the Specific Training for Covered Health Care Practitioners required above. This Specific Training shall include a discussion of:

b. new and revised CPT codes, including during the first Reporting Period CPT codes 90791 and 90792;

c. criteria for providing psychotherapy to patients who have a diagnosis or are suspected of dementia or another cognitive deficit, including the use of the appropriate diagnostic tool; and

New Covered Behavioral Health Providers shall receive this training within 30 ... vered Behavioral Health ... er is later.

After receiving the initial Specific Training described in this subsection, each Covered Behavioral Health Provider shall receive at least one hour of Specific Training for Covered Behavioral Health Providers, in addition to the General Training and the Specific Training for Health Care Practitioners, in each subsequent Reporting Period.

Recent Changes – Training and Education

2017:

B. Training and Education

1. *Covered Persons Training.* Within 90 days after the Effective Date, Company shall develop a written plan (Training Plan) that outlines the steps Company will take to ensure that (a) all Covered Persons receive at least annual training regarding Company's CIA requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute, the Stark Law, and the False Claims Act and (b) all Relevant Covered Persons receive adequate training regarding the Federal health care program requirements that govern their professional responsibilities, including but not limited to, accurate submission of claims, medical necessity, and the legal actions for violations of the Federal health care program requirements.

The Training Plan shall include information regarding the following: training topics, categories of Covered Persons or Relevant Covered Persons required to attend each training session, length of the training session(s), schedule for training, and format of the training. Company shall furnish training to its Covered Persons and Relevant Covered Persons pursuant to the Training Plan during each Reporting Period.

Recent Changes – IRO Systems Review

Previous State:

Amedisys, Inc
April 22, 2014

4. *Systems Review*. If Amedisys's Discovery Sample identifies an Error Rate of 5% or greater, Amedisys's IRO shall also conduct a Systems Review. The Systems Review shall consist of the following:

a. a review of Amedisys's billing and coding systems and processes relating to claims submitted to Federal health care programs (including, but not limited to, the operation of the billing system, the process by which claims are coded, billing; and procedures to identify and correct inaccurate coding and billing);

b. for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall review the system(s) and process(es) that generated the claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

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Recent Changes – IRO Systems Review

2017:

APPENDIX B

CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review. . . .

2. *Claims Review Sample.* The IRO shall randomly select and review a sample of 100 Paid Claims from Population 1 (Claims Review Sample 1) and 100 Paid Claims from Population 2 (Claims Review Sample 2). The Paid Claims shall be reviewed based on the supporting documentation available and applicable Medicare and state Medicaid program requirements to determine whether the items and services furnished were medically necessary and appropriately documented, and whether the claim was correctly coded, submitted, and reimbursed. For each claim in the Claims Review Samples that resulted in an Overpayment, the IRO shall review the system(s) and process(es) that generated the claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

Recent Changes – IRO Claims Review

Previous State:

Amedisys, Inc
April 22, 2014

2. *Discovery Sample.* The IRO shall randomly select and review a sample of 30 Paid Claims from each of the Subject Facilities, for a total of 300 Paid Claims (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available to Amedisys or under Amedisys's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

If the Error Rate (as defined above) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, the Discovery discretion and as analyze or le or any other

t the Error Rate s from the hods. The Paid ng pplicable billing correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. The findings of the Full Sample shall be used by the IRO to estimate the actual Overpayment in the Population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from Amedisys to the appropriate Federal health care program payor (e.g., Medicare contractor), for appropriate follow-up by that payor.

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Recent Changes – IRO Claims Review

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3. *Full Sample.* If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims from the Subject Facilities (Full Sample) using commonly accepted sampling methods. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available to Amedisys or under Amedisys's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. The findings of the Full Sample shall be used by the IRO to estimate the actual Overpayment in the Population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate.

Recent Changes – IRO Claims Review

2017:

APPENDIX B

CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review. . . .

4. *Repayment of Identified Overpayments.* Company shall repay within 60 days the Overpayment(s) identified by the IRO in the Claims Review Samples, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. § 401.301-305 (and any applicable CMS guidance) (the "CMS overpayment rule"). If Company determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, Company shall repay that amount at the mean point estimate as calculated by the IRO. Company shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor. OIG, in its sole discretion, may refer the findings of the Claims Review Samples (and any related work papers) received from Company to the appropriate Medicare or state Medicaid program contractor for appropriate follow up by the payor.

Recent Changes – IRO Claims Review

- Must return any identified overpayments within sample (~100 claims), and then determine whether additional sampling/extrapolation is necessary under 60-day rule
- Places responsibility under 60-day rule entirely on entity - RISK
  - Facts and circumstances *could* justify the decision not to extrapolate, but must be evaluated carefully

Recent Changes – IRO Claims Review

- New "rules," but OIG willing to engage in discussions about specific sample parameters
  - Smaller claims populations "allows for more targeted reviews and allows submissions of subsets of claims" – OIG
- Get expert assistance to guide you in negotiating claims review
  - Know what inferences might be drawn from the sample: Is it statistically significant? To what population of claims could you reasonably extrapolate?
  - Structure sample to target specific categories of claims (e.g., CPT code, geographic region, facility, patient population, etc.) in order to limit potential universe of implicated claims

EVOLVING GOVERNMENT PERCEPTIONS

Evolving Government Perceptions

- CIAs have been around for many years and have evolved over time
- Corporate Compliance Programs have matured
  - Query whether a higher degree of sophistication is now expected
- Most corporations and their compliance counsel are very familiar with the template, boilerplate provisions of the recent past and how they operate
- No size fits all – but we mean it this time
  - OIG can provide greater flexibility with respect to certain requirements that allow a corporation to design program elements that make the most sense and will result in the highest level of compliance
- Risk spectrum concept

NEGOTIATION STRATEGIES

Negotiation Strategies

- The scope and intensity of CIAs vary substantially
- OIG considers the same criteria it contemplates in determining whether to exclude/impose integrity obligations in deciding appropriate degree of oversight
- Establish trustworthiness/make your case:
  - Effectiveness of existing compliance program
  - previous conduct
  - egregiousness of underlying misconduct alleged
  - successor status

Negotiation Strategies – Confines of Template CIA

- Differing degrees of flexibility
  - Limited/no flexibility as to management certifications, reporting structure, disclosure program, reporting obligations, audit/inspection rights, and more administrative provisions
  - Substantial flexibility as to training, written policies, monitoring/auditing, IRO review (the substance)
- Navigating the bureaucracy
  - "I understand your arguments, but the position of the Office is firm on this"
  - Reviewer, and Reviewer's Reviewer: Request an in-person meeting with the chain of command.
  - "Cold Comfort" letters/email with notice to monitor

IMPLEMENTATION STRATEGIES

Implementation Strategies – Flexibility and Risk

- Greater flexibility = greater risk
  - E.g., whether to make an extrapolated overpayment based on IRO Claims Review
- Coordinate closely with business functions and involve them in designing Compliance Program elements
- Work to establish a good relationship with your OIG monitor
- Transparency is key
- Get OIG buy-in, *even if not required*
  - Policies and procedures (overpayment policy, reportable event policy)
  - Training plan
  - Design of Claims Review Sample if you have ability to customize

Thanks!

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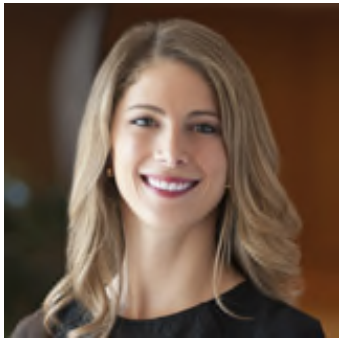
Click Here for full bio

Scott represents life sciences and healthcare organizations in government and internal corporate investigations; civil, criminal, and administrative enforcement actions by government agencies; and complex civil and criminal litigation. Scott handles a range of fraud, abuse, and compliance matters involving the False Claims Act, the Anti-Kickback Statute, the Stark Law, off-label promotion, government reimbursement, and quality of care for global pharmaceutical and medical device manufacturers; healthcare providers, suppliers, and payors; biotechnology companies; contract research organizations; diagnostic testing facilities; and laboratory equipment manufacturers.

Scott also routinely assists clients with government self-disclosures and assesses, designs, consults on and implements mandatory and voluntary compliance and integrity programs, including negotiating and implementing Corporate Integrity Agreements with the US Department of Health and Human Services, Office of Inspector General.

Thanks!



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Click Here for full bio

Holly C. Barker counsels clients on US federal and state healthcare fraud and abuse enforcement and regulatory matters, primarily defending companies in False Claims Act (FCA) actions. Holly represents pharmaceutical and medical device manufacturers, hospital systems, long–term care facilities, clinical laboratories, physicians, and senior healthcare executives in complex criminal, civil and administrative fraud and abuse matters before US Attorneys' Offices, the HHS Office of Inspector General, and state MFCUs.

Holly also handles Medicare claims disputes in administrative proceedings. Her cases typically involve alleged violations of the Anti-Kickback Statute, the FCA, the Federal Food Drug and Cosmetic Act, and the Stark law.

Join us next month!

Please join us for next month's webinar:

"*Fast Break*: ERISA Update for Health Care Providers"

Featuring Jeremy Blumenfeld and Brian Ortelere

- August 31, 3:00 PM (EST)