Corporate Integrity Agreement Developments- Understanding the Government's Expectations

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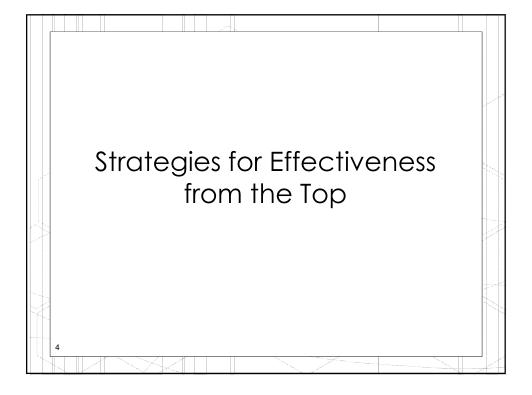Quest Advisory Group, LLC

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Disclaimer

The following information has been prepared based on current available information as of the date of this presentation.

Attendees should be aware that regulatory, coding, and billing information changes frequently, and the information contained in these slides may become outdated quickly.

This information is not intended to replace job specific training and should only be used as a reference after confirming the accuracy and applicability of the information based upon current published laws, statutes, regulations, and guidelines.

We have provided links to several source agencies to assist in locating current information after the date of this presentation.

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Agenda

- Strategies for Effectiveness from the Top
- Promoting Compliance and Mitigating Risk
- Summary and Recommendations

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Strategies for Effectiveness from the Top

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Effectiveness from the Top

- Board / Board committee
- Program oversight and fiduciary duties
  - Care
    - Reasonable inquiry
      - "Best knowledge" – meeting Federal program requirements
  - Loyalty
- Board education
  - Industry risks
  - Regulatory requirements/new guidance
  - CP effectiveness
- Compliance Expertise
  - "On" vs. "To"

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Effectiveness from the Top

- Senior leadership
  - Clarity of oversight role
  - Demonstrated commitment to CP
    - Trained on compliance issues and risks arising in scope of authority
    - Incentives and comp claw-back
  - Accountability
    - Issues arising under leader
    - Implementation and monitoring of corrective action

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Effectiveness from the Top

- Compliance Committee
  - Charter
  - Chaired by CO
  - Meeting at least quarterly
  - Composition – billing, clinical, HR, audit, operations
  - Sufficient minutes to reflect items considered
  - Self assessment

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Effectiveness from the Top

- CO independence and autonomy
  - Reporting structure
  - Member of senior management
  - Direct access to Board
  - Routine reporting to Board
  - Executive session
  - CO authority to engage outside SME

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Promoting Compliance and Mitigating Risk

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Promoting Compliance and Mitigating Risk-Generally

- CIAs have always been a good resource for modeling compliance programs. They offer valuable insight into the government's expectations of an effective compliance program.
- Reviewing CIAs of similar organizations can provide guidance for purposes of implementing an effective compliance program.
- The revisions to the standard CIA language signal that a more sophisticated model is needed in most provider organizations.
- They also indicate that providers should be having very serious discussions with executive leadership and counsel regarding the ever expanding compliance obligations and expectations.

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Mitigating Risk-Generally

- The OIG has indicated that when they are negotiating a CIA they often attempt to accommodate and recognize many of the elements of a pre-existing voluntary compliance program.
- When the worst case scenario happens, the more robust your program, the greater likelihood of a less cumbersome CIA or no CIA at all.
- Things to review/consider:
  - Does your compliance program have the infrastructure to cover the basic 8 components that would be required under a CIA?
  - Do your auditors maintain the current nationally recognized coding credentials than an IRO would possess?
  - Are your audits as comprehensive as they would be under a CIA? Do they evaluate the medical necessity of items and services as well as coding and billing accuracy?
  - Does your audit team include a nurse or physician who has the expertise to review medical necessity?

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Promoting Compliance and Mitigating Risk

- Effective compliance programs are not one size fits all. You can achieve an effective program through many different approaches.
  - Your program should be customized and scaled based on your size and risk.
  - Compliance resources should be appropriate based on your size and risk.
- It is appropriate to consider all options for assessing your compliance program before deciding what works best for your organization.
  - Surveys
  - Tests
  - Employee/Departmental competitions
- It is also important to make sure all employees have a voice in compliance since non-executives generally have the best understanding of the day to day.
  - They may often tell you that what is written in the policies and procedures is not how truly how the daily operations work.

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Promoting Compliance and Mitigating Risk

- It is important to remember in the rapidly changing enforcement environment, that the best defense is a good offense.
- Having an effective, VOLUNTARY, compliance program is your best defense against false claims allegations and onerous, mandatory CIAs.
- In March 2017, the Office of Inspector General (OIG) released a document outlining strategies for evaluating your compliance program's effectiveness.
- The intent of the document is to provide multiple strategies for evaluating the effectiveness of each compliance program element as addressed in the OIG's Compliance Program Guidance.
- The questions provide great insight in the expectations of the OIG and offer a great tool for self-evaluation of your compliance program efforts.
- The document clearly demonstrates that in order to have an "effective" compliance program, you must continually audit and revise your program.

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Promoting Compliance and Mitigating Risk

- Emphasis should be targeted around the following areas:
  - Culture
  - Employee and vendor screening
  - Access to policies and procedures
  - Comprehension and understanding
  - Accountability
  - Appropriate resources (budget and staffing)
  - Clear reporting and oversight
  - Quality
  - Ongoing audits/assessments
  - Appropriate mitigation and corrective action plans
  - Ongoing training
  - Competency
  - Consistent enforcement/discipline
  - Incentives
  - Reliance on outside expertise
- Documenting your efforts in a way that is producible.

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Promoting Compliance and Mitigating Risk-Generally

- The OIG resource addresses each of the following in great detail:
  - Standards, Policies and Procedures
  - Compliance Program Administration
  - Screening and Evaluation of Employees, Physicians, Vendors, and Other Agents
  - Communication, Education and Training on Compliance Issues
  - Monitoring, Auditing, and Internal Reporting Systems
  - Discipline for Non-Compliance
  - Investigations and Remedial Measures

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Mitigating Risk-Billing

- Questions to ask:
  - Does everyone fully understand and agree upon your responsibilities under the "overpayment rule"?
  - How do you apply the overpayment rule and guidelines to your current audit processes?
  - What is your current policy/process pertaining to the calculation of financial error rates?
    - Do you net overpayments and underpayments?
    - Knowing what we know now, should you continue that practice?
    - How will you handle statistical sampling and extrapolation of overpayments?
      - What about underpayments?
      - Lower-bound versus the mid-point?
      - The OIG and some contractors differ from the Program Integrity Manual.

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Mitigating Risk-Quality

- Do you monitor quality of care delivered?
- Do your processes prevent, detect and respond to patient care issues?
- Do you evaluate peer review and credentialing processes?
- Do you monitor risk arising from alternate payment models?
- Do you validate Quality measures?
- Do you monitor Open Payments?

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Mitigating Risk-Arrangements

- Do you have central tracking of all agreements/contracts?
- For new/renewed arrangements do you have:
  - Clear and specific business rationale?
  - Well documented FMV and commercial reasonableness?
  - Compliance sign off?
  - Pre-approved agreements for common contracts?

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Mitigating Risk-Arrangements

- Annual evaluation of processes to approve/renew arrangements
- Ensure sufficiency of training for individuals developing, approving and managing arrangements
- Routing monitoring for ongoing contract adherence

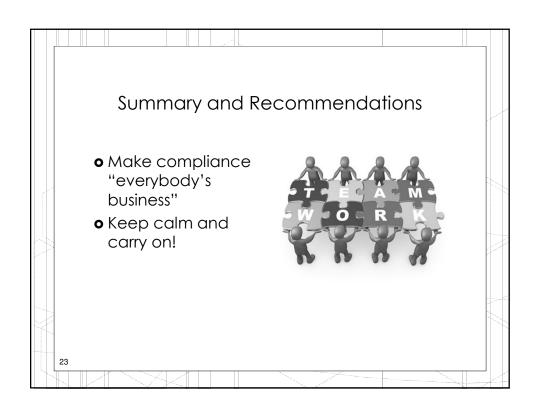19

Summary and Recommendations
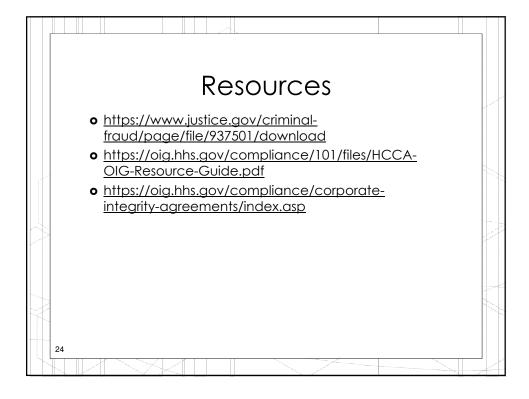
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Summary and Recommendations

- With increased transparency in government enforcement, the expectations for effective compliance programs has never been greater.
- Evaluate your program through the eyes of the DOJ or OIG.
  - Be proactive, not reactive.
  - Identify areas of need and opportunity.
    - Prioritize based on risk.
  - Consider new or more efficient ways to audit/assess your program elements.
  - Document your efforts!
  - Challenge all employees to become part of the solution.
  - Partner with external experts on an as-needed or supplemental basis.

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Summary and Recommendations

- Keep abreast of CIAs within your sector
- Continuous improvement in your program
  - Resources
  - Operational and service line changes
- Periodic program effectiveness reviews
- Risk assessment
- Excluded party monitoring
- Policies and procedures
- Training
  - Initial, ongoing, role based
- How can you demonstrate effectiveness?

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Summary and Recommendations

- Make compliance "everybody's business"
- Keep calm and carry on!

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Resources

- https://www.justice.gov/criminal-fraud/page/file/937501/download
- https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf
- https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp

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