



**The New Model Corporate Integrity
Agreement: Plusses and Pitfalls**

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Nashville Regional HCCA Compliance Conference
Friday November 16, 2018

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Session Objective



Implications of recent changes to Corporate Integrity Agreements

- Anti-Kickback Statute / Stark related
- False billing related



**Anti-Kickback Statue and Stark
Related Corporate Integrity
Agreement Changes**

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CIA: AKS / Stark Changes



- Centralized risk assessment
- Training
- Certifications
- Required procedures and expanded tracking
- Expanded IRO arrangements review
 - Expanded systems review procedures
 - Expanded transactions review procedures
 - 90% threshold and “Additional Transactions Review”

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CIA: AKS / Stark Changes (cont.)



- Centralized risk assessment; Internal review process*
 - A process for identifying and prioritizing potential risks;
 - Develop internal audit work plan related to risks;
 - Implement work plans;
 - Develop corrective action plans related to results; and
 - Track corrective action plans to assess effectiveness.
- Required for all risks associated with Federal health care programs, not just those associated with AKS / Stark.*

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CIA: AKS / Stark Changes (cont.)



- Compliance training plan*
 - Annual written training plan
 - Entity customized arrangements and covered persons training
 - Board member training 2+hours
 - Training records

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CIA: AKS / Stark Changes (cont.)



- Compliance committee (of management)
Minutes of the Compliance Committee meetings made available to the OIG upon request.
- Certifying employees
...Chief Nursing Officer; Chief Quality Officer; Chief Information Officer; Chief Human Resources Officer; Chief Information Officer; Presidents; Executive Vice Presidents; and Executive Directors.
- Management certifications
-I have been trained on and understand that compliance requirements and responsibilities as they relate to [department], an area under my supervision.

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CIA: AKS / Stark Changes (cont.)



- Management certifications (cont.)
-My job responsibilities include ensuring compliance with regard to the [department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and [entity's] policies.
-I have taken steps to promote such compliance.
-To the best of my knowledge, the [department] of [entity] is in compliance with all applicable Federal health care program requirements and the obligations of the CIA.
-I understand that this certification is being provided to and relied upon by the United States.

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CIA: AKS / Stark Changes (Cont.)



- Process for management certifications

Within 90 days after the Effective Date, [entity] shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

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CIA: AKS / Stark Changes (cont.)



- Compliance Officer* and CEO certifications
 - to the best of his or her knowledge, except as otherwise described in the report, [entity] is in compliance with all of the requirements of this CIA*;
 - to the best of his or her knowledge, [entity] has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, including the Focus Arrangements Procedures required in Section III.D of the CIA;
 - to the best of his or her knowledge, [entity] has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.D.2 of the CIA;

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CIA: AKS / Stark Changes (cont.)



- Compliance Officer* and CEO certifications (cont.)
 - he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful*; and
 - he or she understands that the certification is being provided to and relied upon by the United States.

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CIA: AKS / Stark Changes (cont.)



- Board oversight*
 - Meet Quarterly to review CCO and Compliance Committee
 - Submit to OIG a description of documents reviewed and steps taken to oversee the compliance program (in support of Resolution)
 - Adopt Resolution

The Board of Directors has made a reasonable inquiry into the operations of [entity]'s Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, [entity] has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.

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CIA: AKS / Stark Changes (cont.)



- Compliance with AKS and Stark procedures
 - Focus arrangement tracking system (FATS) must be expanded to include not only the new or renewed arrangements, but also five (5) additional elements.
 1. Names and positions of Arrangements Covered Persons involved in the negotiation, review, and approval of all Focus Arrangements
 2. Remuneration* ...to ensure that the parties are complying with the financial terms and that [they] are commercially reasonable

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CIA: AKS / Stark Changes (cont.)



- 3. Documentation of Fair Market Value including key dates and the names of individuals/entities that determined FMV and names and positions of the Cover Persons involved.
- 4. Service logs*
- 5. Monitoring of space and materials*
- Ensuring that all existing Focus Arrangements are subject to a written review and approval process (legal, business need, FMV)

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CIA: AKS / Stark Changes (cont.)



- IRO arrangements systems review provisions
 - Documenting names and positions of involved arrangements covered persons
 - Parties' compliance with financial terms and commercial reasonableness
 - Key FMV dates and the names of individuals / entities that perform the assessment and the names / positions of involved management members
 - Process for determining and documenting business need or business rational

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CIA: AKS / Stark Changes (cont.)



- IRO arrangements transactions review provisions
 - Verify names and positions of involved arrangements covered persons are included in the FATS
 - Verify parties' performance requirements are included in the FATS
 - Verify remuneration determined in accordance with entity policy regarding FMV
 - Verify compliance with financial terms
 - Verify business need or business rationale is specified and consistent with entity policies

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CIA: AKS / Stark Changes (cont.)



- IRO arrangements transactions review prov. (cont.)
 - Expanded procedures for non-compliant areas in the transaction review (ie: interviews, documentation)
 - New 90% compliance threshold for each element of the transaction review
 - OIG may require the IRO to select an additional sample for an "Additional Transactions Review" within 60 days

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False Billing Related Corporate Integrity Agreement Changes



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CIA: False Billing Changes



- Overpayment provisions
- Medical necessity
- Quality indicator requirements
- Annual report requirement: Summary of audits
- IRO claims review provisions
 - IRO team
 - IRO Risk based population determination
 - IRO quantitative results / Overpayment calculations

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CIA: False Billing Changes (cont.)



- Overpayment provisions
 - Adopts the definition from the CMS rule (but CIA overpayment provisions are applicable to overpayments from all Federal health care programs)
CMS overpayment rule more expansive than CIA terms
 - Requires development of policies to ensure compliance with requirements of the CMS overpayment rule (and available for submission to OIG)
Provider is in the best position to determine the appropriate process

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CIA: False Billing Changes (cont.)



- Overpayment provisions (cont.)
 - Overpayment obligations connected to reportable events requirements (substantial overpayments)

-a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;

-a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;

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CIA: False Billing Changes (cont.)



- Medical necessity requirement in IRO claims review
 - Coding, billing, and claims submission
 - Medically necessary and appropriately documented
- Quality indicator requirements in IRO claims review

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...to determine whether the items and services furnished were medically necessary, medically appropriate, and appropriately documented, and whether the claim was correctly coded, submitted, and reimbursed.

CIA: False Billing Changes (cont.)



- Annual report requirement: Summary of audits
- Requirement to provide annually a summary of audits conducted by Medicare or Medicaid program contractor or any government entity or contractor
 - Requirement to provide the related audit response and corrective action plans
 - Potential source of risk identification for limiting the population in the IRO claims review from all claims to targeted locations and claims types

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CIA: False Billing Changes (cont.)



- IRO team expanded to include medical professionals

...assign licensed nurses or physicians with relevant education, training and specialized expertise (or other licensed health care professionals acting within their scope of practice and specialized expertise)...

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CIA: False Billing Changes (cont.)



- IRO claims review population is now risk based versus all paid claims
 - More dynamic and changes from year to year
 - IRO and management may collaborate to limit the population
 - Best practice is to relate to risk assessment process

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CIA: False Billing Changes (cont.)



- IRO claims review population (OIG pre-approval)
-In OIG's discretion, OIG may limit the Population to one or more subset(s) of Paid Claims to be reviewed and shall notify [entity] and the IRO of its selection of the Population at least 30 days prior to the end of each Reporting Period.
-In connection with limiting the Population, OIG also may select the Covered Facilities that will be subject to the Claims Review in each Reporting Period.
-In order to facilitate OIG's selection, at least 90 days prior to the end of the Reporting Period, [entity] shall furnish to OIG the following information for each Covered Facility for the prior calendar year: (1) Medicare program revenues, (2) Medicare program population, and (3) Medicare program payor mix.

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CIA: False Billing Changes (cont.)



- IRO discovery sample and full sample removed
 - Full Sample 5% threshold no longer applicable
 - Systems Review 5% threshold no longer applicable
- IRO quantitative results
 - Sample overpayments related to documentation errors
 - Sample overpayments related to medical necessity
 - Error rate defined and no longer net of underpayments
 - Calculation of population overpayments based upon mean point estimate

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CIA: False Billing Changes (cont.)



- IRO calculation of repayment of identified overpayments changed
 - Repayment based upon errors calculated from mean point estimate within 60 days instead of from discovery sample and extrapolated error in the full sample within 30 days.
 - Management now more directly follows the CMS overpayment rule.

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Additional Questions



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