Recent Developments in Stark and Anti-Kickback Statute Enforcement

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Agenda Overview

- Lessons learned from recent case law
- Early experience with the Stark Self-Referral Disclosure Protocol
- Potential impact of ACO Stark and kickback waivers
Recent Cases of Interest

- Tuomey
- Bradford
- Halifax Hospital
- Kosenske

U.S. ex. rel. Drakeford v. Tuomey Health System

- Part-time employment agreements between hospital subsidiary and surgeons covered only surgeries performed in hospital
- Physicians received allegedly rich bonuses based on their professional component revenues
- Key Stark issue is whether the bonuses created an indirect compensation arrangement under Stark
- ICA exists when physician receives aggregate compensation that varies with the volume or value of referrals or other business generated (no express FMV test)
- 4th Circuit says compensation above FMV can vary with volume or value of referrals (even if not directly linked to DHS) and thereby create ICA
U.S. ex. rel. Kosenske v. Carlisle

HMA

- Original exclusive inpatient anesthesiology staffing agreement extended to pain clinic, arguably without written amendment
- Pain clinic is hospital-based
  - Hospital bills technical component and group bills professional component
  - No exchange of compensation by parties
- 3rd Circuit nonetheless states that pain clinic arrangement must be at FMV and there is no support for an FMV determination


Regional Medical Center

- Hospital subleases nuclear camera from physician group
- Sublease requires hospital to cover cost of master lease plus pay $23,655 per month for “other rights,” including a non-compete
- W.D. Pa. says there is indirect compensation arrangement because sublease above FMV
- Court states lease payments linked to DHS referrals because appraiser’s report considered expected flow of business due to non-compete
U.S. ex. Rel. Baklid-Kunz v. Halifax Hospital Medical Center

- Medical oncologists employed by hospital entitled to bonus if professional revenues of all oncologists exceed a threshold -- each oncologist receives “equitable portion” of the bonus pool
- Government argues that oncologists’ compensation violates Stark even though bonus pool includes only professional revenues (bonus must be based on personal productivity)
- Motion to dismiss pending before M.D. Fla.

Lessons Learned From Recent Cases

- The False Claims Act has become the primary vehicle for enforcing Stark and the AKS
- A third party appraisal does not insulate providers against FMV claims
- Indirect compensation arrangements likely to be viewed similarly to direct ones
- Courts/government may take expansive view of when compensation takes DHS referrals into account
- Exclusivity and non-competes may receive heightened scrutiny
- Part-time employment may raise risk level
The Rationale for the Self-Referral Disclosure Protocol

- Stark requires refunding of “tainted claims” – this could amount to millions of dollars for minor, technical violations
- CMS historically took the position it could not settle claims for less than full refund amount
- Providers settled Stark claims through the OIG self-disclosure protocol, but OIG began to reject Stark-only disclosures in March 2009
- The SRDP was created under the ACA to give CMS authority to enter into reasonable settlements for Stark violations

Submissions Under the SRDP

Types of Providers Making Submissions

- Hospital: 125
- Labs: 11
- Group Practice: 8
- Other: 6


Status of Submissions

- Under CMS Review: 51
- Referred to Law Enforcement: 3
- Withdrawn: 0
- Settled: 6
- Administrative Hold: 20
- Additional Information Requested: 61
- Pending: 0

Announced Settlements to Date

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/10/11</td>
<td>Hospital in MA failed to satisfy personal services exception for department chiefs and coverage arrangements.</td>
<td>$579,000</td>
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<tr>
<td>07/11/11</td>
<td>Physician group in OH failed to satisfy in-office exception for two claims.</td>
<td>$60,000</td>
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<tr>
<td>11/09/11</td>
<td>Hospital in MS failed to satisfy personal services exception for hospital-based MDs.</td>
<td>$130,000</td>
</tr>
<tr>
<td>01/05/12</td>
<td>Hospital in CA exceeded non-monetary compensation exception for one physician.</td>
<td>$ 6,700</td>
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<tr>
<td>01/05/12</td>
<td>Hospital in GA exceeded non-monetary compensation exception for two physicians.</td>
<td>$ 4,500</td>
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<tr>
<td>03/09/12</td>
<td>Physician group in IA failed to satisfy employment exception for several physicians.</td>
<td>$74,000</td>
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Feedback From CMS

- Many disclosures do not include adequate legal analysis, sufficient financial information or complete documentation
- Quality of submissions improving over time
- SRDP being used frequently by hospitals on the verge of being sold as means of extinguishing uncertain liabilities
Recent FAQs From CMS Clarify Look-Back Period

- SRDP regulations indicated look back period is entire period of non-compliance.
- Recent FAQs from CMS state:
  - Period of noncompliance may be different from the 4-year time frame for reopening determinations at 42 C.F.R. § 405.980(b).
  - A hospital may disclose the total amount of remuneration received by a physician and the claims paid to the hospital based upon reopening period.
- This guidance can vastly mitigate potential exposure for longstanding non-compliance.

Lessons Learned From Early SRDP Experience

- The process usually moves very slowly but a high-quality submission may expedite the process and lead to better results.
- The early settlements have involved modest amounts but it is difficult to draw conclusions as to the degree of CMS “leniency”:
  - Unclear if CMS has been settling the easiest cases first
  - Unclear what maximum liability was in these cases
  - Unclear what type of cases have been referred to law enforcement or put on hold
ACO Fraud and Abuse Issues

- Stark
- Anti-Kickback Statute
- Anti-inducement provisions of CMPL
- Prohibition on physicians limiting covered services

Fraud and Abuse Issues in ACO Employment Model
Fraud and Abuse Issues in ACO Joint Venture Model

- **CMS**
  - Shared savings payments

- **Hospital/Physician Jointly Owned ACO**
  - Performance based compensation
  - Same issues as in employment model.
  - Kickback issues relating to distributions.
  - Stark/kickback issues raised by hospital investment in infrastructure and care management

- **Physician Owners**
  - Shared savings/surplus distributions

- **Hospital Owners**
  - Start-up capital and care management support
  - Shared savings/surplus distributions

- **Private Payers**
  - Performance based compensation

Scope of Proposed OIG/CMS Waivers

<table>
<thead>
<tr>
<th>Law</th>
<th>Waivers</th>
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<tr>
<td>Stark</td>
<td>Distribution of CMS shared savings payments by ACO to ACO participants, providers and suppliers for activities related to ACO’s participation in MSSP.</td>
</tr>
<tr>
<td>Anti-Kickback</td>
<td>Same as Stark waiver, Any relationship directly related to ACO’s participation in MSSP that satisfies Stark exception</td>
</tr>
<tr>
<td>Inducements to Physicians to Limit Services</td>
<td>Distribution of CMS shared saving payments by ACO to physician if not knowingly made to limit medically necessary services.</td>
</tr>
<tr>
<td>Beneficiary inducements</td>
<td>None</td>
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Elements of Joint Venture Model Not Protected by Proposed Waivers

- Investments by hospital in ACO start-up infrastructure (planning, legal, contracting, information technology, etc.)
- Hospital payment for care managers and other staff supporting physician practices
- Distribution of shared savings or other incentives from payers other than Medicare

Revised Waivers in Interim Final Rule

- ACO Pre-participation Waiver
- ACO Participation Waiver
- Shared Savings Distribution Waiver
- Compliance With Stark Exception Waiver
- Waiver for Patient Incentives
ACO Pre-participation Waiver

- Covers “start up arrangements” pre-dating MSSP participation agreement
- Good faith intent to participate in MSSP
- Diligent steps to develop ACO in target year
- Bona fide determination by ACO governing body that arrangement “reasonably related to purposes of MSSP”
- Documentation
- Public disclosure

ACO Participation Waiver

- ACO participates in MSSP
- ACO satisfies MSSP governance and management rules
- Bona fide determination by ACO governing body that arrangement “reasonably related to purposes of MSSP”
- Documentation
- Public disclosure
Shared Savings Distribution Waiver

- Tracks shared savings distribution waiver in initial CMS/OIG proposal
- Does not cover distribution of shared savings or incentives paid by commercial insurers
- Commercial insurer payments may be protected under ACO participation waiver or existing Stark and anti-kickback exceptions

Compliance With Stark Law Exception Waiver

- Tracks similar waiver in initial CMS/OIG proposal
- Precludes need to comply with anti-kickback safe harbor
- Probably of limited value given other waivers
Waiver for Patient Incentives

- Covers free or below FMV items or services (but not cash or cost sharing waivers)
- ACO participates in MSSP
- Reasonable connection between items or services and beneficiary’s medical care
- Items or services are:
  - For preventive care (undefined)
  - To advance adherence to treatment, drug regime or care plan, or chronic disease management

Questions and Answers

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