Swapping, Kickbacks, Fair Market Value: Risks for a Post-Acute Provider

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Agenda

- Overview of anti-kickback statute and other fraud and abuse laws
- Swapping and fair market value
- Post-acute care bundling and coordinated care arrangements

*OIG guidance for post-acute care compliance officers throughout*
Purpose of the Anti-kickback Statute

AKS designed to prevent improper referrals, which can lead to:

- Overutilization
- Increased costs
- Corruption of medical decision-making
- Patient steering
- Unfair competition

Anti-kickback Statute Overview

Prohibits asking for or receiving anything of value to induce or reward referrals of Federal health care program business
**Statutory Elements 42 U.S.C. 1320a-7b(b)**

Anti-kickback Statute prohibits:

- Knowingly and willfully
- Directly or indirectly offering, paying, soliciting, or receiving
- Remuneration
- In order to induce or reward the referral or purchase of (or arranging for the purchase of) items or services for which payment may be made by a Federal healthcare program

**Penalties for Kickbacks**

- Criminal fines up to $25K; prison up to 5 years
- Civil Money Penalty exposure, fines, program exclusion
Exceptions and Safe Harbors

- Statutory exceptions (Congress) / regulatory safe harbors (OIG)

- Transactions satisfying all elements of Safe Harbor will not be prosecuted. Transactions not satisfying all elements are not per se illegal, but are subject to a facts-and-circumstances analysis.
**OIG Fraud Alerts, Special Advisory Bulletins, Compliance Program Guidance**

**Searching OIG Website**
Other Fraud and Abuse Laws: Stark

<table>
<thead>
<tr>
<th>Anti-kickback Statute 42 USC 1320a-7b(b)</th>
<th>Physician Self-referral Law (Stark) 42 USC 1395nn</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referrals from everyone</td>
<td>Referrals from a physician</td>
</tr>
<tr>
<td>Any items or services</td>
<td>Designated health services</td>
</tr>
<tr>
<td>Intent required (knowing and willful)</td>
<td>No intent standard for overpayment (strict liability)</td>
</tr>
<tr>
<td></td>
<td>Intent required for civil monetary penalties for knowing violations</td>
</tr>
<tr>
<td>Criminal and civil penalties</td>
<td>Not criminal</td>
</tr>
<tr>
<td>Voluntary safe harbors (if not in safe harbor, may still be legal)</td>
<td>Mandatory exceptions (if not excepted, illegal)</td>
</tr>
<tr>
<td>OIG advisory opinion process</td>
<td>CMS advisory opinion process</td>
</tr>
</tbody>
</table>

April 18, 2016

Other Fraud and Abuse Laws: Beneficiary Inducement CMP

Section 1128A(a)(5) of the Social Security Act provides that:

- any person who offers or transfers remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services may be liable for civil money penalties of up to $10,000 for each wrongful act.

Certain exceptions, e.g., Non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts; Incentives to promote the delivery of preventive care

http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf
"Swapping" - typically arrangements in which providers and/or suppliers give discounts on Medicare Part A services in exchange for referrals on Part D or Part B business

Example: an LTC Pharmacy offers below market/discounted prices to SNF’s on Part A drugs, which the SNF is responsible for paying for, in exchange for an agreement to provide access to higher paying reimbursable business on the SNF’s Part D or B patients.

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Red Flags to Look For:

- Rates below total costs of providing services suggest provider may swap these below-cost rates in exchange for separately billable, non-discounted Federal health care program business.

- Discounted prices to one buyer that are lower than the prices the provider offers to other buyers with similar volumes but no separately billable Federal health care program business.

- Discounts coupled with exclusive provider agreements or other agreements to refer Federal health care business.
**OIG Advisory Opinion 10-26**

- **Unfavorable**
- Proposed payment plans for emergency and non-emergency transportation services provided for Medicaid-covered residents of skilled nursing facilities
- Additional guidance cited: reference to swapping discussions in 2003 Compliance Program Guidance (CPG) for Ambulance Suppliers and 2008 Supplemental CPG for Nursing Homes

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**OIG Advisory Opinion 12-09**

- **Favorable**
- Reduced-rate arrangements for the provision of therapy services at state-operated veterans' homes
- Additional guidance cited: footnote reference to 1999 and 2000 OIG letters on swapping arrangements - available on OIG website; see also ad ops 99-2 & 99-13
“Swapping” Hypothetical

ABC Rx is a long-term care institutional pharmacy. ABC Rx is growing rapidly and they badly want to enter into a long term contract with LTC, Inc., a large post-acute care provider. Currently, the LTC, Inc. nursing homes are paying for their Medicare Part A drugs at the state Medicaid allowable price. The LTC, Inc. nursing homes are also paying their current pharmacy for consulting pharmacists at $30.00 per hour. ABC Rx offers to sell LTC, Inc. its Medicare Part A drugs at 95% of the state Medicaid allowable price and offers to provide consulting pharmacists at $25.00 per hour. The ABC Rx offer is made with the expectation that ABC Rx will be the exclusive provider of institutional pharmacy services for all of the LTC, Inc. nursing homes, subject to patient choice, and would obtain all of the nursing homes’ separately billable business, e.g., under Part B and Part D. At these rates, ABC Rx has a positive gross margin for the Medicare Part A drugs but ABC Rx pays its consulting pharmacists $30.00 per hour. However, overall, ABC Rx would make a small profit on the arrangement, even if ABC Rx does not also become the exclusive provider of the nursing homes’ separately billable business.

Affordable Care Act (ACA) and Coordinated Care Initiatives

• The CMS Innovation Center was created by §3021 of the ACA (amending §1115A of the SSA)

• For purpose of testing “innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care.”

• Model must either reduce spending without reducing the quality of care, or improve the quality of care without increasing spending, and must not deny or limit the coverage or provision of any benefits.
ACA and Coordinated Care Initiatives

- **CMS Innovation Center**
  https://innovation.cms.gov/initiatives/index.html#views=models

- **Past and Present Innovation Center Programs:**
  - Nursing Home Value-Based Purchasing Demonstration
  - Physician Group Practice Transition Demonstration
  - Comprehensive Primary Care Initiative
  - Accountable Care Organizations (ACO)
  - Bundled Payments for Care (BPCI)

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The ACA Established ACOs

- **ACO** - An organization of health care providers that agrees to be:
  - Accountable for the quality, cost, and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it
  - Share in the savings such activities generate for Medicare
  - Financially responsible should costs exceed certain benchmarks

- **Examples:**
  - Pioneer ACO Model
  - MSSP ACO Model
  - Next Generation ACO Model
Overview of Bundled Payments

**Bundled Payment** - Medicare offers a single lump sum for an entire episode of care related to a treatment or condition and that sum is then divided among all parties who provide services during that episode of care.

- 1991: coronary artery bypass graft surgery demo (CABG)
- 2009: Acute Care Episode (ACE)
- 2016: Oncology Care Model (OCM)

Bundled Payment v. ACO

**Bundled Payments**
- Specific patients
- Budget determined by hospital
- Specific conditions
- Specialist Focused
- Organization keeps all savings
- Payment from contracted org.
- Less money (pilot project)
- Up and Downside Risk

**ACO**
- Every patient
- Budget determined by CMS
- All conditions
- PCP Focused
- Savings shared with Medicare
- Payments from Medicare
- More money involved
- Up and Downside Risk
## Bundled Payment for Care Improvement (BPCI) Models

<table>
<thead>
<tr>
<th>Model</th>
<th>Episode</th>
<th>Services Included in the Bundle</th>
<th>Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>All DRGs; all acute patients</td>
<td>All Part A services paid as part of the MS-DRG payment</td>
<td>Retrospective</td>
</tr>
<tr>
<td>2</td>
<td>Selected DRGs; hospital plus post-acute period</td>
<td>All non-hospice Part A and B services during the initial inpatient stay, post-acute period and readmissions</td>
<td>Retrospective</td>
</tr>
<tr>
<td>3</td>
<td>Selected DRGs; post-acute period only</td>
<td>All non-hospice Part A and B services during the post-acute period and readmissions</td>
<td>Retrospective</td>
</tr>
<tr>
<td>4</td>
<td>Selected DRGs; hospital plus readmissions</td>
<td>All non-hospice Part A and B services (including the hospital and physician) during initial inpatient stay and readmissions</td>
<td>Prospective</td>
</tr>
</tbody>
</table>


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## Comprehensive Care for Joint Replacement (CJR) Model

**On November 16, 2015, CMS finalized regulations regarding the Comprehensive Care for Joint Replacement (CJR) Model**

- Acute care hospitals in 67 MSAs will receive retrospective bundled payments for episodes of care for lower extremity joint replacement or reattachment of a lower extremity (LEJR).
  - MS-DRG 469 (Major joint replacement or reattachment of lower extremity with major complications or comorbidities)
  - MS-DRG 470 (Major joint replacement or reattachment of lower extremity without major complications or comorbidities)
  - Separate episode target prices for MS-DRGs 469 and 470
- All related care (Part A and B) within 90 days of hospital discharge from the LEJR procedure will be included in the episode of care, including hospital care, post-acute care and hospital services, with certain exclusions.
- Begins April 1, 2016.
- Repayment Risk: Y1 (0%) Y2 (5%) Y3 (10%) Y4-5 (20%)
- Gain Share Opportunity: Y1 (5%) Y2 (5%) Y3 (10%) Y4-5 (20%)

Fraud and Abuse Waivers

- **Shared Savings Program Waivers** (Section 1899(f) of SSA)
  - Secretary may waive certain fraud and abuse laws *as necessary* to carry out the provisions of the Medicare Shared Savings Program.
  - October 29, 2015: OIG and CMS jointly published the Medicare Program; Final Waivers in Connection with the Shared Saving Program Final Rule.

- **Waivers for Innovation Center Models** (Section 1115A(d)(1) of SSA)
  - Secretary may waive certain fraud and abuse laws *as necessary* solely for purposes of testing payment and service delivery models developed by the Center for Medicare and Medicaid Innovation.
  - As of early March 2016: Six groups of waivers issued, including those for the BPCI models and CJR.

- Keep in Mind: A waiver will apply to the arrangement(s) only if the individuals/entities seeking its protection are eligible to use the waiver and all conditions of the waiver are met.

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Fraud and Abuse Waivers v. Program Waivers

[Link](https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html)
### Waivers for BPCI Models

**Sept. 13, 2012:** OIG and CMS jointly issued waivers for specified arrangements involving BPCI Model 1 Participants.

- Waiver of the AKS and physician self-referral law in connection with:
  - Incentive payments - sharing of cost savings earned pursuant to CMS-approved gainsharing methodology and conditions set forth in Waiver Notice and Participation Agreement between the hospitals and CMS.

**July 26, 2013:** OIG and CMS jointly issued waivers for specified arrangements involving BPCI Models 2, 3, and 4 Participants.

- Waiver of the AKS and physician self-referral law in connection with:
  - Savings Pool Contribution - Internal Cost Savings contributed by Episode-Integrated Providers (EIPs)
  - Incentive Payments - certain distributions from the BPCI Savings Pool
  - Gainsharing Payments - made by Gainsharer Group Practice to Gainsharer Group Practice Practitioners
- Waiver of the AKS and CMP prohibiting beneficiary inducements in connection with:
  - Patient engagement incentives - in-kind items or services provided by a Model Awardee, EIP, or Gainsharer to a Model Beneficiary
- Waiver of AKS:
  - Professional Services Fee - for Model 4 only, payments from hospitals to physicians and non-physician practitioners for professional services furnished to hospital inpatients
  - Each pursuant to conditions set forth in the applicable Waiver Notice and Participation Agreement

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### Waivers for BPCI Models


Waivers for CJR

November 16, 2015: OIG and CMS jointly issued waivers for specified arrangements involving CJR Model participants.

- Waiver of the AKS and physician self-referral law in connection with:
  - Certain gainsharing and alignment payments between hospitals and providers or suppliers
    - Protects hospitals that share payments from CMS and hospital internal cost savings with other providers and suppliers.
  - Certain payments from a physician group practice (PGP) to members of the physician practice
    - Protects arrangements in which a PGP that received a gainsharing payment from a hospital in the CJR model distributes a portion of those funds to its practice collaboration agents.
    - Each subject to certain conditions, including compliance with program rules.
  - Waiver of the AKS and CMP prohibiting beneficiary inducements in connection with:
    - Certain patient engagement incentives that promote preventive care or certain clinical goals
      - Allows participant hospitals to provide in-kind items and services to beneficiaries in CJR model episodes.
    - Incentives must comply with applicable program rules and waiver conditions.


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"Bundling" Hypothetical

ABC Hospital System ("ABC") is a large tertiary hospital system in Cleveland, Ohio. ABC has issued a request for proposal ("RFP") to post-acute care providers to participate in a comprehensive post acute care bundling arrangement. ABC has stated in the RFP that it will not contract with every post acute care provider and is looking for one comprehensive post acute care solution for its proposed bundling arrangement. The RFP states that, among the criteria that ABC intends to use are quality of care, pricing, patient outcomes and rehospitalization rates. LTC, Inc. is a large post-acute care provider in the Cleveland, Ohio market. They own and operate nursing homes, home health agencies and hospices. LTC, Inc. wants to win the RFP and is considering the following alternatives:

1. LTC is willing to offer its nursing home services with a per diem pricing that represents a significant discount from LTC’s standard pricing. LTC is willing to offer a less significant discount on its home health services. The LTC nursing home services proposal, standing alone, will cause LTC to lose money. However, when combined with the home health services, LTC expects to break even or generate a small profit.

2. LTC is considering proposing a shared savings arrangement pursuant to which LTC will receive thirty percent (30%) of the savings generated from a selected baseline year and will also be obligated to pay thirty percent (30%) of the losses if the post acute care costs exceed the baseline year costs.

3. ABC acknowledges that the bundling arrangement cannot be optimized without dedicated patient navigators. However, ABC cannot afford to hire these navigators. LTC is considering offering to provide the navigators to ABC for free as part of the overall proposal.
Conclusion

Questions