Physician-owned distributors and the Stark law

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Roadmap for this presentation

- Background
- Application of the Stark law to PODs
- Policy approaches to limit the use of PODs through the Stark law
- Summary and discussion
Background – implantable devices and Medicare

- **Role of Medicare**
  - No direct payments to device companies; providers reimbursed when they use devices to deliver care
  - Payments often bundled with other inputs

- **Hospitals spent $24 billion on devices and supplies for Medicare-covered services in 2014**
  - $14 billion on implantable medical devices
  - $10 billion on medical supplies
  - 15% of total hospital costs

- **Hospitals face challenges in purchasing devices efficiently, such as**
  - Restrictions on hospital-physician collaboration (e.g., gainsharing)
  - PODs
Background – defining PODs

- PODs allow physicians to profit from the sale of devices they use.
- PODs are entities that derive revenue from selling, or arranging for the sale of, devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients.
- Three common POD models:
  - Distributor
  - Group purchasing organization (GPO)
  - Manufacturer
Background – implications for Medicare

- In 2013, OIG found some evidence of induced demand and equal or higher device costs associated with PODs
  - Rate of spinal surgery grew faster for hospitals that began buying devices from PODs compared with all hospitals (16% vs. 5%)
  - None of the devices was less costly when supplied by a POD; spinal plates averaged $845 more when supplied by a POD ($2,475 vs. $1,630)

- Court case reveals instances of patients being referred for surgery unnecessarily to increase POD profits

- Senate Finance Committee report: PODs operating in at least 43 states as of November 2015

- In 2013, OIG found that:
  - 1 in 5 Medicare spinal fusions used POD-supplied devices
  - 1 in 3 hospitals purchased spinal devices from PODs
Applying the Stark law to PODs

- Principle: physicians’ decisions should be based on clinical considerations, not financial ones

- The Stark law is designed to regulate potential conflicts of interest like those created by PODs

- The Stark law (1) prohibits a physician from referring designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare for those referred DHS, unless an exception applies
Key Stark law concepts

- **Designated health services (DHS)**
  - E.g., hospital inpatient services

- **DHS entity**
  - E.g., hospital

- **Financial relationships** (can be direct or indirect)
  - Ownership/investment
  - Compensation

- **Exceptions**
  - E.g., rural, employment, etc.
Indirect compensation relationship between a hospital and a physician-owner of a POD

- Payment for device
- Distribution of profits
- Patient referral
- Medicare
- Fee schedule payment
- Payment for DHS
PODs might qualify for indirect compensation exception

- If an indirect compensation arrangement exists between hospital and physician, referrals are prohibited, unless an exception applies.

- Key exception: indirect compensation exception. One of the criteria for exception is that:
  - Compensation received by the physician from the POD does *not* take into account the volume/value of referrals from the referring physician to the hospital.

- Because physician-owners’ *aggregate* compensation increases as volume/value of referrals increase, relationship would appear not to qualify for the exception.

- However, “per unit of service” rule deems the compensation not to take into account the volume/value of referrals if the compensation *per unit* is fair market value and (2) does not vary during the course of the arrangement.
Policy approaches to limit the use of PODs through the Stark law

- **Approach 1:** eliminate the application of the “per unit of service” rule to PODs, thereby removing PODs from indirect compensation exception.

- **Approach 2:** make PODs DHS entities, thereby prohibiting physician ownership of PODs.
Defining PODs in Stark law or regulations

- Stark law or regulations do not currently define what constitutes a POD, so definition is needed. Definition could be:
  - An entity that receives any of its revenue from selling or arranging for the sale (including through contractual arrangements such as group purchasing organization contracts) of medical devices ordered by a physician-owner for use in procedures performed by a physician-owner.

- Additional language could be added to prevent PODs from changing their structure to avoid being classified as a POD and regulated under the Stark law.

- Potential problem with POD definition: some entities not generally thought of as PODs might be included (e.g., device manufacturer with some physician ownership).
Industry concern about medical device innovation

- Physician ownership of device manufacturers not uncommon, especially in start-ups

- Stark law changes could prevent physicians from referring patients for hospital procedures if the manufacturer in which they have an ownership stake supplies the devices

- Industry concern that prohibiting such referrals and forcing physicians to be compensated in ways other than ownership stakes could provide a disincentive for physicians to innovate

- Self-referral could be allowed in certain circumstances
  - If certain criteria are met (e.g., 40% or less of POD business generated by physician-owners)
  - Large, publicly traded companies
Transparency of POD-physician relationships

- Hospitals will have a strong incentive to monitor their supply chain if Stark law changes are made because of possible denial of claims and False Claims Act liability.

- Some PODs are likely to exist even if Stark law changes are made:
  - PODs would still be able to sell to non-DHS entities such as ambulatory surgical centers.
  - If self-referral is allowed in certain cases to protect device innovation.

- Current POD reporting under Open Payments program is minimal:
  - Not all PODs are currently required to report.
  - Some PODs that are required to report fail to do so.
Summary and discussion

- Reiterate Commission’s past recommendations to (1) more broadly allow hospital-physician gainsharing in Medicare and (2) regulate those arrangements to protect quality of care and minimize financial incentives that could affect physician referrals.

- Modify Stark law to limit the use of PODs
  - Approach 1: eliminate application of the “per unit of service” rule to PODs
  - Approach 2: make PODs DHS entities

- To ensure device innovation is not harmed by Stark law changes
  - Exception for large, publicly traded companies, and/or
  - Exception for PODs if certain criteria are met (e.g., 40% or less of POD business generated by physician-owners)

- Require all PODs to (1) report under Open Payments program and (2) identify as PODs.