Physician-owned distributors and the Stark law

Brian O'Donnell

October 5, 2017

MEDPAC

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

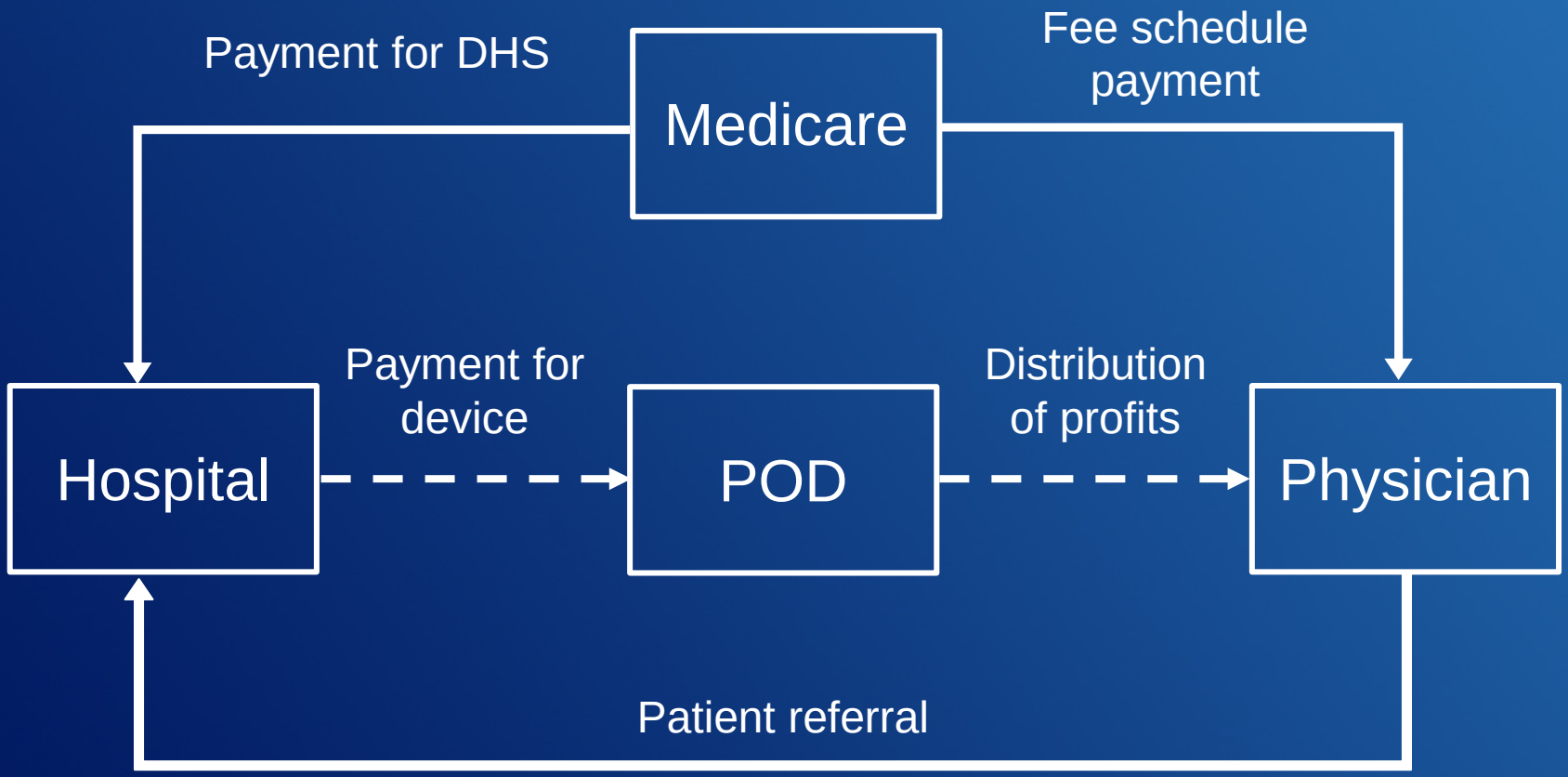
Applying the Stark law to PODs

- 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



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* (1) 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