

Commissioners and staff

**October 5-6, 2017**

The Horizon Ballroom

Ronald Reagan Building

International Trade Center

1300 Pennsylvania Avenue, N.W.

## Thursday, October 5, 2017

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Time	Topic <i>(staff contact)</i>
9:00 AM – 11:00 AM	Next steps for the Merit-based Incentive Payment System <i>(Kate Bloniarz, David Glass)</i>
11:00 AM – 12:00 PM	Physician-owned distributors and the Stark Law <i>(Brian O'Donnell)</i>
12:00 PM – 12:15 PM	Public comment
1:15 PM – 2:45 PM	Paying for sequential stays and aligning regulatory requirements in a unified payment system for post-acute care <i>(Carol Carter, Dana Kelley)</i>
2:45 PM – 3:45 PM	Mandated report: Telehealth services – observations from site visits and focus groups <i>(Evan Christman, Andy Johnson, Amy Phillips)</i>
3:45 PM – 5:15 PM	Mandated report: Coverage of telehealth services under commercial insurance plans <i>(Zach Gaumer, Amy Phillips)</i>
5:15 PM – 5:30 PM	Public comment

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**2017 Public Meetings**

<b>October 5-6, 2017</b>	<b>Ronald Reagan Building, Int'l Trade Center Horizon Ballroom 1300 Pennsylvania Avenue, NW</b>
<b>November 2-3, 2017</b>	<b>Ronald Reagan Building, Int'l Trade Center Horizon Ballroom 1300 Pennsylvania Avenue, NW</b>
<b>December 7-8, 2017</b>	<b>Ronald Reagan Building, Int'l Trade Center Horizon Ballroom 1300 Pennsylvania Avenue, NW</b>
<b>January 11-12, 2018</b>	<b>Ronald Reagan Building, Int'l Trade Center Horizon Ballroom 1300 Pennsylvania Avenue, NW</b>
<b>March 1-2, 2018</b>	<b>Ronald Reagan Building, Int'l Trade Center Horizon Ballroom 1300 Pennsylvania Avenue, NW</b>
<b>April 5-6, 2018</b>	<b>Ronald Reagan Building, Int'l Trade Center Horizon Ballroom 1300 Pennsylvania Avenue, NW</b>
<b>September 6-7, 2018</b>	<b>Ronald Reagan Building, Int'l Trade Center Horizon Ballroom 1300 Pennsylvania Avenue, NW</b>

**Commission members**

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*Palo Alto, CA*

**Jon B. Christianson, Ph.D., Vice Chairman**  
*University of Minnesota School of Public Health  
Minneapolis, MN*

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*Express Scripts  
St. Louis, MO*

**Kathy Buto, MPA**  
*Arlington, VA*

**Alice Coombs, M.D.**  
*South Shore Hospital  
Weymouth, MA*

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*UnityPoint Health  
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**Pat Wang, J.D.**  
*Healthfirst  
New York, NY*

## Physician-owned distributors and the Stark law

Brian O'Donnell  
October 5, 2017

MEDPAC

### Roadmap for this presentation

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

MEDPAC

## Background – implantable devices and Medicare

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- 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

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- 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

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- 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

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- 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

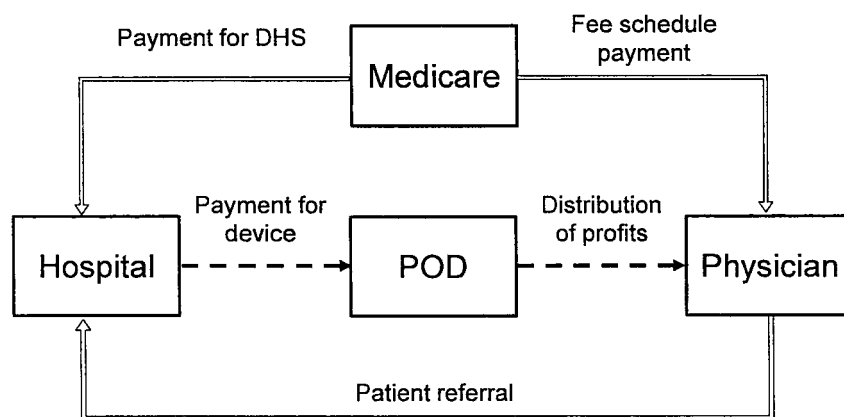
## Key Stark law concepts

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- 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

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## PODs might qualify for indirect compensation exception

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- 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

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- 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

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- 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

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- 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

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- 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

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- 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

