An overview of the medical device industry

Brian O’Donnell
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Presentation overview

- Background
- Unique device identifiers (UDI)
- Gainsharing in Medicare
- Price transparency for implantable medical devices (IMD)
- Physician-owned distributorships (POD)
- Discussion of commissioner interest in potential policies and/or future work
Background

- Wide variety of medical devices
- Role of the Food and Drug Administration (FDA)
  - Premarket requirements
  - Postmarket surveillance
- Role of Medicare
  - No direct payments to device companies; providers are reimbursed when they use devices to deliver care
  - Payments for devices often bundled with other inputs
- Overall size and composition of medical device industry
  - Estimates of industry size vary – $119 billion in 2011 to $172 billion in 2013
  - Many small firms and a few large, diversified firms
Background

- **Industry profitability**
  - Small, publicly-traded firms often not profitable
  - Large firms consistently profitable (20% - 30% EBITDA margins)

- **Hospitals spent $24 billion on IMDs and supplies for Medicare-covered services in 2014**
  - $14 billion on IMDs
  - $10 billion on medical supplies
  - 15% of total hospital costs
  - Average annual IMD spending growth faster than supplies from 2011-2014 (4.7% vs. 2.4%)

- **Medicare also pays for devices in other settings**
  - Ambulatory surgical centers
  - Physician offices

Data are preliminary and subject to change
Unique device identifiers

- UDIs are alphanumeric codes assigned to each device
- Use of UDIs by manufacturers being phased in by 2020; use not mandatory for providers
- UDIs consist of two parts
  - Device identifier (DI) – manufacturer and model
  - Production identifier – lot number, date of manufacture, etc.
- Current proposal to add DI field to claim forms; some disagreement among stakeholders
  - Modified claim forms likely effective in 2021 or 2022
  - Proponents want to leverage the scale, availability, and longitudinal nature of administrative claims data
  - Others suggest costs too high, DIs not needed on claims
Unique device identifiers

- Some potential benefits of UDIs
  - Provide critical information for providers at point of care
  - Improve postmarket surveillance and recall implementation
  - Improve adherence to Medicare’s current device credit policy
  - Improve tracking of failed devices’ costs; aid cost-recovery efforts
  - Enable value-based purchasing

- Potential policies for Commission consideration
  - Require providers to retain and use UDIs
  - Require DIs on claims
  - Explore a “device failure penalty” to compensate Medicare and beneficiaries for costs of failed devices and related costs
Gainsharing in Medicare

- Physician and hospital incentives often misaligned
  - Hospitals pay for devices
  - Physicians influence choice of device

- Gainsharing aligns incentives by allowing hospitals to share cost savings with physicians

- Some concerns about poorly-designed gainsharing programs: stinting, inappropriately quick discharges, and induced demand

- Gainsharing can violate federal law; programs involving Medicare FFS beneficiaries generally limited to:
  - OIG-approved gainsharing programs
  - Demonstrations where fraud and abuse laws are waived
Gainsharing in Medicare

- Empirical research largely supports notion that gain-sharing can reduce costs, improve/maintain quality
- Relatively new quality programs could help ensure quality under gainsharing arrangements
  - e.g., Hospital Readmissions Reduction Program could help guard against inappropriate discharges
- Potential policy for Commission consideration
  - Reiterate Commission’s 2005 recommendation that Congress grant the Secretary authority to allow hospital-physician gainsharing and regulate arrangements to protect quality of care and minimize financial incentives affecting physician referrals
IMD price transparency

- Limited price competition in IMD market
  - Manufacturers often compete on differentiated products rather than price
  - Limited number of competitors (e.g., four firms account for ~95% of knee/hip implants)

- IMDs are often technologically advanced and expensive; purchase price of IMD can equal 30%-80% of insurer’s payment to hospital for a procedure

- IMD pricing is opaque
  - Hospitals often unaware of what others paid for same device
  - Patients/physicians often have limited knowledge of device prices and limited incentive to seek prices
  - Manufacturers enforce price confidentiality through confidentiality clauses in contracts and lawsuits
IMD price transparency

- Current IMD purchasing system results in wide variation in IMD prices across purchasers

- Limited empirical evidence on effects of price transparency in analogous markets
  - Some contend enhanced price transparency could reduce price variation and increase hospital negotiating leverage
  - Others concerned price transparency could lead to higher prices

- Potential policy for Commission consideration
  - Explore how to implement a price transparency program for IMDs, coupled with other reforms to encourage price competition (e.g., gainsharing)
Physician-owned distributorships

- PODs are companies that profit when their physician-owners order devices through PODs; common POD models include the “distributor,” “manufacturer,” and “GPO” models.

- A POD’s physician-owners could have a financial incentive to perform more and potentially inappropriate surgeries.

- OIG found that nearly 1 in 5 spinal fusion surgeries used devices from PODs in 2011:
  - Evidence of induced demand
  - Per unit device cost similar or more expensive when acquired through a POD.
Physician-owned distributorships

- 2013 OIG Special Fraud Alert (SFA) – PODs “inherently suspect” under anti-kickback statute; but POD prosecutions have been limited
- Some hospitals restricted dealings with PODs after SFA
- Minimal POD reporting under Open Payments
  - Some PODs may not be required to report or have changed structure to avoid reporting
  - Some PODs may also fail to report when required to do so
- Potential policies for Commission consideration
  - Improve Open Payments reporting
  - Require hospital-level POD policies
Discussion topics

- Unique device identifiers
  - Require providers to retain and use UDIs
  - Require DIs on claims
  - Explore a “device failure penalty”

- Gainsharing – reiterate support for Commission’s 2005 recommendation on hospital-physician gainsharing

- Price transparency – explore how to implement a price transparency program for IMDs

- PODs
  - Improve Open Payments reporting
  - Require hospital-level POD policies

- Other device policies of interest to Commission