



Advising the Congress on Medicare issues

An overview of the medical device industry

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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

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