An overview of the medical device industry

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Overview of today's presentation

- Overall size and composition of medical device industry
- Development of new medical devices
- FDA regulation of medical devices
- Key features of medical device market
- How Medicare pays for medical devices
- Topics for discussion

Overall size and composition of medical device industry

- Recent estimates of total U.S. spending on devices range from $119 billion in 2011 to $172 billion in 2013
- Industry has 5,300 to 5,600 U.S. companies
  - Most companies are small firms that focus on developing new products
  - A small number of large, diversified companies account for most sales and employment
- Between 330,000 and 365,000 employees
- U.S. accounts for about 40% of global sales

Financial performance of medical device industry

- Largest medical device companies have been highly profitable
  - EBITDA margins in 20-30% range
  - Revenue growth dropped after the recession, but companies reduced costs to maintain margins
- Smaller publicly-traded companies are often not profitable
- No public information for privately-held startup device companies

Development of new medical devices

- Small companies focus on developing products in specific areas
- Large device companies often acquire small companies with promising products
- Large device companies account for majority of industry's research and development
- Venture capital funding for startup device companies has declined in recent years
- Device companies tend to make frequent, incremental changes to their products

FDA regulation of medical devices: premarket requirements

- Level of FDA scrutiny depends on the risk of the device
  - Class I devices: low risk, no prior review required
  - Class II devices: moderate risk, must be substantially equivalent to an existing device (510(k) clearance), review takes 3-6 months
  - Class III devices: high risk, must be found safe and effective (premarket approval), review can take 18-24 months
- Very few devices (about 1%) are required to use the premarket approval process

FDA regulation of medical devices: postmarket surveillance

- Manufacturers and providers must submit reports about adverse events to FDA
- Sentinel System uses electronic health data to better monitor safety of devices
- FDA can recall devices that pose a health risk
- Device manufacturers required to use unique device identifiers (UDIs); FDA and CMS support adding some UDI information to claims data

Key features of the medical device market

- Coverage determinations are an important issue for new technologies
- Group purchasing organizations (GPOs) help negotiate contracts for many providers
  - Account for about 75% of hospital purchases
  - Primarily used for more conventional devices
  - Largely used to buy conventional devices
  - Primarily funded by administrative fees paid by device companies and other suppliers
  - Safe harbor exception allows GPOs to collect fees

Extensive ties between device companies and physicians

- Device companies can have many kinds of relationships with physicians
  - Royalty payments
  - Consulting fees
  - Payments for promotional activities
  - Funding for research
- Device companies made at least $2.3 billion in payments to providers in 2015
- Financial relationships may improperly influence physicians' treatment choices

Implantable medical devices (IMDs)

- IMDs are often technologically advanced and can be expensive
- Several factors contribute to high prices
  - High barriers to entry
  - Product differentiation
  - Confidential prices
  - Influence of physician preferences
- Recent changes have given some hospitals greater ability to negotiate lower prices
  - Gainsharing arrangements can align incentives

How Medicare pays for medical devices

- No direct payments to device companies; providers are reimbursed when they use devices to deliver care
- Payments for devices are often bundled with payments for other inputs
- CMS uses a variety of methods to estimate cost of devices
- Hospitals spent $14 billion on implantable devices and $10 billion on medical supplies for Medicare services in 2014

Topics for discussion

- What is the Commission's level of interest in future work related to medical devices?
- Some possible issues to explore
  - Explore implications of adding UDIs to claims data
  - Reiterate prior recommendation that gainsharing arrangements should be permitted
  - Recommend ways to improve the usability of Open Payments data
  - Explore implications of greater price transparency for IMDs