

The Evolving Legislative & Regulatory Environment for Medical Device Manufacturers

Thomas C. Novelli
Medical Device Manufacturers Association
tnovelli@medicaldevices.org

Medical Device Manufacturers Association

- National trade association focusing on regulatory, legislative and legal issues for medical device companies
- Over 270 member companies

Health Care Reform

Goals of Health Reform

- Increase and extend health insurance coverage
- Improve efficiencies throughout health care system
- Reduce costs and fraud, waste and abuse

Health Care Reform

Initial Top 5 Concerns for industry

1. Transparency/sunshine
2. Comparative effectiveness research
3. Medicare Commission
4. Payment bundling
5. Shared-savings/accountable care organizations

Health Care Reform

Top 5 Concerns Post-Senate Finance Committee Bill

1. Device tax
2. Device tax
3. Device tax
4. Device tax
5. Device tax

Medical Device Tax

Start date	2013
Assessment	2.3% deductible excise tax
Exemptions	Certain devices including eyeglasses, contact lenses, hearing aids products sold at retail IRS currently soliciting comments on exemptions
Small Business Provision	None

Physician Payment Sunshine

- Congress concerned about potential conflicts/inappropriate relationship with manufacturers
- Sunshine law requires the disclosure of most payments made to physicians and other providers
- Concerns remain about relation to state laws

Physician Payment Sunshine

Start date: March 31, 2013 for payments made in 2012

Payments to: Physicians, teaching hospitals

Threshold: \$10/transfer or \$100 aggregate over year

Delayed disclosure : (1) FDA clearance/approval OR (2) 4 years post transfer

Preemption: Preempts similar state law; does not preempt requirements outside Federal law

Independent Payment Advisory Board (IPAB)

- Independent board with one goal: reducing costs in Medicare program; Commission nominated by the President
- Recommendations become effective absent Congressional action overturning Commission recommendations (30 days)
- Nothing prevents the Board from cutting the price or beneficiary access to certain items or procedures, or from changing long-standing statutory or regulatory policy

Comparative Effectiveness

- Comparative effectiveness research studies the effectiveness of competing therapeutic treatments
- Can lead to coverage decisions based on “most effective treatment”
- Industry concern regarding cost-effectiveness

Comparative Effectiveness

Health Care Reform

- Patient-Centered Outcomes Research Institute established as nonprofit corporation
- \$360M annually for CE research, funded through Medicare and tax on insurers (separate from insurance industry fee)
- Focuses CER on “clinical” comparative effectiveness

Accountable Care Organizations

Health Care Reform

- Collaborative organizations between physicians and surgeons intended to improve the coordination for care
- Shared savings component: physicians share in savings for reduced costs
 - Incentive to use lowest-cost products?
 - How are “savings” calculated

Action Steps

Health Care Reform

- Device tax: Engage Congress
 - Impact on jobs
 - Impact on innovation
- Device Tax: Prioritize
 - Impact on R&D development?
 - Build into pricing model?

Action Steps

Health Care Reform

- **Sunshine Laws: Start now!**
 - Track payments early, if not already
 - Data management systems
- **Comparative Effectiveness**
 - What will make your product different, more effective?
 - Innovative - “me too” era likely over

FDA Reform

- High profile medical device safety issues changing the debate in Washington
 - Congress playing a more active role
 - Contributing factor towards potential 510(k) overhaul
 - Oversight efforts include investigations into:
 - Stents
 - Defibrillator leads
 - Pacemakers

FDA Reform

Congressional Oversight

- Congress focusing primarily on the FDA approval process and potential conflicts/inappropriate relationship(s) with manufacturers
- Impact:
 - Negative publicity for manufacturer
 - Potential increased scrutiny from regulators
 - Potential financial impact from investors
 - Corrective legislative action
 - Referrals to appropriate regulators/enforcement agencies (DOJ/HHS OIG)

FDA Reform

- Ongoing review of the 510(k) clearance process
 - FDA Townhall Meetings
 - Institutes of Medicine Report (due 2011)
 - Public meetings - Summer 2010

- FDA Recommendations
 - Released January 2011
 - Potentially impactful measures deferred to the IOM

FDA's Impact on Innovation

- Extensive survey by Stanford University
 - Supported by MDMA, NVCA
- FDA **NEGATIVELY** impacted >75% of companies
 - 50% had review staff/branch chief change
 - >30% state appropriate FDA staff/consultants not present at meetings
 - >90% state FDA has become much more risk-averse in last decade
 - >80% state FDA has difficulty dealing with novel technologies and/or indications

FDA's Impact on Innovation

- Avg. cost of 510(k) & PMAs significant increased by FDA delays
 - Avg. 510(k) cost: \$31 million (\$24M or 77% on FDA related activities)
 - Avg. PMA cost: \$94 million (\$75M or 80% on FDA related activities)
- Patients in U.S. wait an average **2** years longer than Europeans to access US technologies
- Venture capital moving away from med-tech
- Impact on jobs, economy, patient care, innovation

Questions?

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