

Potential Effects of Healthcare Reform Law on the Medical Device Industry and its Customers



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Presentation to
Management by Objectives Meeting

Impact of Healthcare Reform Law

- Healthcare Reform Law (Patient Protection and Affordable Care Act of 2010, as amended by the Health Care Education Reconciliation Act of 2010) will significantly affect device manufacturers, in particular through impacts on their customers.
- Significant increase in population covered by health insurance (approx. 30 million) will result in substantial focus on cost-containment, including through administrative agency mechanisms.

Impact of Healthcare Reform Law

- Provisions directly affecting the device industry:
 - Excise tax
 - Transparency requirements
 - Fraud and abuse
 - Comparative effectiveness
 - Expanded coverage of preventative services
 - Coverage of costs for certain clinical trials
 - New FDA Office of Women's Health Issues

Device Excise Tax

- 2.3% excise tax beginning January 1, 2013
- Applies to sales of devices intended for human use
 - Exemption for eyeglasses, contact lenses, hearing aids, and other devices “generally purchased by the general public for retail or individual use”
 - Device leases also will be considered taxable events under the Internal Revenue Code

Transparency Requirements for Manufacturers

- Section 6002 – Physician Payment Sunshine provisions
 - Device and medical supply manufacturers required to report payments and other transfers of value to physicians and teaching hospitals of \$10 or more or \$100 in aggregate per calendar year
 - Device and medical supply manufacturers and GPOs also required to report any ownership or investment by physicians
- First report due March 31, 2013 for payments and investment interests from prior calendar year
- Limited preemption for previously enacted state physician payment reporting laws
- Reported information to be made publicly available in searchable website

Fraud and Abuse Program Integrity Provisions

- Healthcare Reform Law contains over 30 provisions related to healthcare fraud and abuse and program integrity, e.g.:
 - Anti-Kickback Statute is amended to relax the specific intent requirement and to provide that a violation of the statute constitutes a false or fraudulent claim under the False Claims Act
 - Section 6402 provides that identified overpayments must be reported and returned within 60 days to the applicable government contractor, intermediary, or carrier
 - Any delay in processing known overpayments creates the potential for False Claims Act liability
- Consequently, changes in fraud and abuse provisions create additional risks of government investigations and litigation

Comparative Effectiveness Research

- Healthcare Reform Law contains provisions supporting the development of comparative effectiveness research (CER) concerning healthcare products and services
- Section 6301 establishes the Patient-Centered Outcome Research Institute to assist in conducting CER and disseminating research findings
 - The Institute is to identify national priorities, establish a methodology committee, and establish a research project agenda
- The Institute is required to ensure that CER “findings not be construed as mandates for practice guidelines, coverage recommendations, payment, or policy recommendations”
 - Private payers can use such findings as a basis for their product or service approval or reimbursement decisions
 - Note that Wellpoint released standardized CER guidelines on May 19, 2010 for use in evaluating drug coverage. (Pharmaceutical Law & Industry Report, May 25, 2010)
- Potential for controversy - note rejection of 2009 recommendations by U.S. Preventive Services Task Force to end routine mammograms for women in their forties

Comparative Effectiveness Research

- Healthcare Reform Law allows CMS to use CER results to make a determination concerning Medicare coverage if such use is through an iterative and transparent process and a determination to deny coverage is not based solely on CER
 - Note that the Agency for Healthcare Research and Quality is considering use of “academic detailing” to disseminate CER to healthcare providers ([Pink Sheet](#), April 26, 2010)
- Significant practical limitations on use of CER including absence of accepted protocols, lack of historical CER studies for comparison, and controversy as to interpretation of results

Comparative Effectiveness Research

- Consider adding comparative effectiveness and cost effectiveness evaluations to R&D program
 - Increasing importance of inclusion of economic considerations at clinical trials stage
 - E.g., first comparative effectiveness trial of two pioneer drugs by National Institutes of Health currently being conducted
 - Comparative trial of two Genentech drugs (Lucentis - \$2,000/dose and Avastin - \$40/dose)
 - Potential for impact on medical device access and reimbursement
 - Note new study on Australian drug market by Tufts University Center for the Study of Drug Development, concluding that “comparative effective research severely restricts access to drugs not deemed cost-effective.” (Life Sciences Law and Industry Report, July 16, 2010)

Comparative Effectiveness Research (Con't)

- Monitor assessments by the U.K.'s National Institute for Healthcare and Clinical Excellence
 - NICE recently denied use by the National Health Service of two leukemia products, Sprycel and Tasisna, on the basis of clinical effectiveness and cost concerns ([Pink Sheet](#), Feb. 15, 2010)

Coverage Issues

- Expanded coverage for preventative services
 - Potential market opportunity for diagnostic products
- Coverage of costs for certain clinical trials
 - Prohibits health plans from denying coverage of certain routine patient costs associated with participation in “approved clinical trials”
 - Includes trials that are:
 - For the prevention, detection, or treatment of cancer or other life-threatening diseases or conditions, and
 - Federally funded or conducted pursuant to an investigational new drug application (IND) or exemption (e.g., for drug-device combination products)

Women's Health

- New FDA Office of Women's Health established within the Office of the Commissioner
 - **Responsibilities include:**
 - Reporting to the Commissioner information related to women's participation in clinical trials
 - Establishing FDA goals and objectives for issues concerning women's health
 - Providing information to women and healthcare providers on those areas in which differences between men and women exist
 - Consulting with stakeholders on women's health policies
 - **May result in increased FDA focus on approval of products/therapies targeted to women**

Environment Affecting Service Providers

- Healthcare Reform Law is a major event for most healthcare providers, affecting their medical device industry suppliers
 - *See Congressional Research Service, Medicare Provisions in the Patient Protection and Affordable Care Act (PPACA): Summary and Timeline (June 30, 2010), for a review and summary.*
- Important to separate evaluation of short-term, mid-term, and long-term trends and changes
- Nature of impact still evolving and will continue to evolve over course of Law's implementation

Environment Affecting Service Providers

Factors in assessing impact on customers:

- Will Healthcare Reform Law significantly impact payor mix for providers? Reduce number of uninsured? When?
- Who are the newly covered? What will they be covered for (new benefits packages)?
- How will an increase in insured affect private insurers' relationships with providers?
- Medicare provider payment changes
- Quality requirements and impact on providers
- Medical necessity determinations/comparative effectiveness
- Compliance/enforcement environment

Coverage Increases – Impact on Healthcare Providers?

Individual insureds

- Mandate begins in 2014, penalty through income tax if not covered
- Premium subsidies on sliding scale for 133%-400% of Federal Poverty Level (FPL)
- New individuals will access coverage mainly through state-operated exchanges
- Individuals will enroll in “qualified” private plans with “essential health benefit” packages
- Some exchange requirements will affect plan/provider relationships (e.g., out of network providers)

Coverage Increases – Impact on Healthcare Providers?

Employer requirements

- Immediate/near-term employee benefit changes (e.g., dependent coverage)
- Most employer requirements begin in 2014
- Pay (penalty) or play (offer coverage) or both
- Small employer exceptions to penalty structure
- Small employer access to state-operated exchanges

Coverage Increases – Impact on Healthcare Providers?

Medicaid

- Medicaid eligibility streamlining – will it add predictability for providers? Decrease administrative costs? Increase number of Medicaid patients?
- Medicaid expansion
 - Up to 133% of Federal Poverty Level
 - All individuals under age 65
 - Benchmark benefit package (at least essential health benefits)
 - Limited provider payment relief (primary care)

Coverage Increases – Impact on Healthcare Providers?

Interaction of expanded coverage

- Expansion of Medicaid - new coverage or replacement coverage? Or both?
- Expansion of coverage through exchanges - new coverage or replacement coverage? Or both?
- Coverage changes likely to have biggest impact on providers with high percentage of uninsured patients
- Near term disproportionate share hospital (DSH) payment decreases

Coverage Increases – Impact on Healthcare Providers?

Benefits

- What will newly insured be covered for?
- Defined benefits - “essential health benefits package” for “qualified” health plans statutory list with HHS implementation
- Broad statutory list would be positive for most providers
- Statutory list includes Rx drugs

Coverage Increases – Impact on Healthcare Providers?

Provider/Payor relationships

- How to analyze the impact of coverage changes on provider/payor relationships?
- Which private payors will continue in or enter Medicaid market (Medicaid managed care)?
- Which private payors will opt to participate in exchange coverage? Which payors have relevant experience for this newly regulated market?
- Significant overlap and/or consolidation of payors in Medicaid and exchange markets?
- Post-2014 analysis very speculative

Medicare Provider Payment Changes

Impact on Hospitals

- Increased financial pressure on hospitals as a result of multiple payment changes in Healthcare Reform Law
- Payment constraints and incentives
 - Market basket (MB) update for IPPS and outpatient prospective payment system (OPPS) hospitals subject to cuts beginning FY/CY 2010
 - Productivity adjustment to be applied to MB update for IPPS and OPPS hospitals beginning FY/CY 2012
 - Medicare DSH payments reduced 75% beginning in FY 2014

Medicare Provider Payment Changes

Impact on Hospitals (con't)

- Payment changes (budget neutral) based on value based purchasing (VBP) performance standards beginning FY 2013
- 1% payment reduction to inpatient prospective payment system (IPPS) hospitals in top quartile for hospital-acquired conditions (HACs) beginning FY 2015
- Payment adjustments for high hospital readmission rates beginning in FY 2013
- Changes to graduate medical education (GME) payments for academic medical centers beginning July 1, 2011
- How will these payment cuts offset the expected improved payor mix?

Medicare Provider Payment Changes

Physicians and other providers

- Physicians - still no long term Medicare resolution
- Physician Fee Schedule reform
- This year
 - The Sustainable Growth Rate (“SGR”) patch became particularly contentious due to health reform and deficit concerns

Medicare Provider Payment Changes (Con't)

Physicians and other providers

- This year (cont'd)
 - Physician groups and others pressed for the inclusion of a permanent SGR repeal in health reform. This was ultimately removed due to costs.
 - Congressional leaders assured physician groups that they would pass a repeal separately. However, attempts to do so have languished in the Senate.
 - Instead, Congress has passed four short term patches to the 2010 SGR. Delayed action on these bills caused disruptions to physician payment.

Medicare Provider Payment Changes

Physicians and other providers

- This year (cont'd)
 - The current course is unsustainable as the deficit increases, and an SGR fix becomes more expensive.
 - If Congress does not intervene, CMS will reduce 2011 physician payments by an estimated 27%, up from 21.2% in 2010.

Medicare Provider Payment Changes

Physicians and other providers

- VBP for other providers
- Payment cuts to most Medicare providers

Medicare Provider Payment Changes

Independent Payment Advisory Board (IPAB)

- Significant new 15-member IPAB that will present Congress with proposals to reduce costs and improve quality for entire Medicare program
- May address both products and services
- IPAB cannot make proposals to ration care, raise taxes or Part B premiums, or change Medicare benefit, eligibility, or cost-sharing standards
 - PhRMA intends to attempt to limit IPAB's potential power to make cuts in Medicare. ([Inside Health Policy Daily News](#), July 14, 2010).

Delivery System Changes – Impact on Providers

- Accountable Care Organizations (to be established January 1, 2012)
 - HHS to establish Medicaid Shared Savings Plan, to allow groups of providers who form ACOs to share in cost savings
 - Eligible MCOs could include group physicians' practices, partnerships or joint ventures between hospitals and physicians, and practice networks
- Bundled Payments
 - HHS required to develop a national, voluntary bundled payment pilot program to provide incentives for healthcare providers to coordinate care more efficiently, effective 2013.

Quality Requirements – Impact on Healthcare Providers?

- Current trend of increasing payor quality requirements accelerates under Healthcare Reform Law
- Growing intersection between quality requirements and payment amounts
- Development of near-term Medicare value-based purchasing (VBP) program for physicians and other providers
- Establishment of hospital VBP program with payment modifications based on quality performance

Quality Requirements – Impact on Healthcare Providers? (Con't)

- Quality requirements may affect “physicians preference” items, such as stents or artificial joints, by intensifying cost pressures on hospitals leading to increases in standardization in purchasing and to device manufacturers being pressured to differentiate their products based on outcomes research.

Quality Requirements – Impact on Healthcare Providers?

- Potential impact of VBP and quality requirements on provider purchasing trends
- Public performance reporting of quality and resource use measures
- Center for Medicare and Medicaid Innovation and other pilot and demonstration projects
- Overall national quality improvement strategy - HHS, the Agency for Healthcare Research and Quality, and CMS to identify gaps and needed improvements

Medical Necessity and Comparative Effectiveness

Medical necessity for providers/products/services

- Current trend for more stringent medical necessity/coverage requirements in Medicare
- Scrutiny of provider ordering of items and services (e.g., “in-person” evaluation for DME)
- Trend will be enhanced by Healthcare Reform Law’s addition of comparative effectiveness research and review

Transparency Requirements for Providers

- New transparency requirements may provide another basis for fraud and abuse investigations
- Section 6001 – Requires hospitals to:
 - To disclose physician ownership or investment interests to HHS and on hospital website and advertising
 - To ensure physicians with hospital ownership/investment interests disclose such interests to patients
- Section 6003 – Requires physician to provide to patients referred for in-office ancillary services (radiology or imaging services) information on other suppliers who offer such services

Transparency Requirements for Providers

- Section 6101 – Requires nursing homes to disclose to HHS ownership and management information including:
 - Ownership interests
 - Members of governing body
 - Officers, directors and other managing employees
 - Individuals or entities that exercise operational, financial, or managerial control
 - Individuals or entities that lease or sublease real property to the facility
 - Individuals or entities that provide management or administrative services, clinical consulting, or accounting or financial services
- Section 6106 – Requires nursing homes to provide to HHS direct care staffing information; reported information to be included on Nursing Home Compare Website

Compliance / Enforcement Environment for Providers

- Multiple fraud and abuse and “program integrity” provisions imposed by Healthcare Reform Law
- Increased funding and penalties for fraud and abuse violations
- Stringent overpayment reporting requirements
- New healthcare provider compliance requirements and behavioral changes that emerge from new compliance environment could affect provider/manufacture relationships

Mandatory Compliance Programs Requirement

- Healthcare Reform Law for the first time mandates that suppliers, providers, and physicians adopt a compliance and ethics program
 - CMS will issue the mandatory compliance program requirements on a rolling basis among industry sectors
 - Likely to track the current OIG guidance document
 - States are required to extend the mandatory compliance programs requirement to Medicaid
- Requirements present new opportunity for regulatory investigations as well as potential False Claims Act liability for failure to prevent or identify improper claims or payments

Consequences of Healthcare Reform Law

- Healthcare Reform Law presents significant challenges for device companies
 - Potential for restrictions on Medicare or Medicaid coverage and reimbursement from comparative effectiveness research
 - Potential for adoption of mirror restrictions on coverage and reimbursement by private payers
 - Potential for expanded fraud and abuse investigations and litigation
 - Potential for adverse impacts on product suppliers from value-based purchasing and other requirements imposed on healthcare providers by the Healthcare Reform Law
 - Potential for adverse impacts on product suppliers from transparency reporting requirements of healthcare providers

Consequences of Healthcare Reform Law (Con't)

- Potential effects on device company sales and marketing
 - Potential increased consolidation among healthcare provider customers
 - Potential increased use of group purchasing organizations (GPOs)
 - Potential purchasing effects of development of accountable care organizations and bundled payment programs
 - Potential concerns regarding price differentials, and compliance issues under the Robinson-Patman Act concerning price discrimination
- Need to closely monitor FDA and CMS development of regulations and administrative application of Healthcare Reform Law as to potential effects on product development, marketing, and sales

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