In-House Counsel Forum on

Medical Device Pricing & Reimbursement

A Comprehensive Guide To Current Procedures and Proposed Changes Impacting Manufacturers, and Public and Private Payors

June 15-16, 2010 | The Sutton Place Hotel, Chicago

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Leading experts in device pricing, coverage, and reimbursement will address all major hot button concerns affecting the medical device industry today and help you:

- **PREDICT** industry trends for a time of contemplated **health care/ insurance reform**
- **COORDINATE FDA approval** and **CMS coverage** efforts to save time and money
- **EXPLORE** the link between **comparative effectiveness** and **device pricing** and **reimbursement**
- **SET pricing** and **SEEK reimbursement** for **new medical technologies**
- **EXAMINE** reimbursement of **capital** and **single use** equipment

PRE-CONFERENCE WORKSHOP: JUNE 14, 2010

A Device Pricing and Reimbursement Boot Camp: A Primer on the Present and Evolving Landscape of Reimbursement, Coverage, Pricing, and Payment

POST-CONFERENCE WORKSHOP: JUNE 17, 2010

B Addressing Reimbursement Concerns in Foreign Nationals

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Prepare now for contemplated changes affecting pricing, reimbursement and payment in the Medical Device Industry

Understand how proposed reforms will factor into the existing regulatory schematic.

ACI's Medical Device Pricing and Reimbursement conference is the one event that will provide you with a comprehensive understanding of the ever-changing pricing and reimbursement landscape impacting the device industry. At present, all eyes are on Washington, as the industry ponders the fate of health care/insurance reform and how its possible ratification will impact current device pricing and reimbursement practices. Other industry concerns loom over FDA approvals and how possible revisions to the 510(k) and PMA processes may affect CMS determinations regarding reimbursement. In light of this evolving landscape, it is increasingly important for medical device manufacturers to understand the contemplated new guidelines and how to best develop new reimbursement strategies.

Position your company's devices for optimum reimbursement rates without compromising the quality and integrity of the product

Our faculty of in-house counsel and leading law firm attorneys will provide you with the practical, real-world solutions you need in order to develop reimbursement strategies and set device prices. This conference will feature speakers from both large device manufacturing companies and smaller device companies. You will also hear from the attorneys who counsel these manufacturers.

Register now to ensure your place at what is sure to be a sold-out event. Call **1-888-224-2480**, fax your registration form to **1-877-927-1563**, or register online at **www.americanconference.com/devicepricing**

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Co-Chairs:

John Ridge
Director, Reimbursement Services
Ventana Medical (Tuscon, AZ)

Steven Stranne, M.D.
Partner, Bryan Cave LLP
(Washington, DC)

Speakers:

Michael Beebe
Vice President
HillCo Health (Washington DC)

Charles Carignan, MD
President & CEO
NinePoint Medical, Inc.
(Boston, MA)

Mark Domyahn
Global Director of Market Access and Reimbursement
Zimmer, Inc. (Minneapolis, MN)

Brian French
Partner
Nixon Peabody LLP (Boston, MA)

Rosemary Gammon
Director of Reimbursement & Payer Policy
Xoft, Inc. (Sunnyvale, CA)

Max Gill
Global Director Health Economics and Reimbursement
Covidien (Bedford, MA)

Ryan M. Graver
Global Director of Market Access and Health Economics
Zimmer, Inc. (Minneapolis, MN)

Elliott Gruskin, Ph.D.
Vice President, Research & Development
Synthes (West Chester, PA)

Eric D. Hargan
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(Chicago, IL)

Becky Jackson
Senior Legal Specialist
Medtronic (Minneapolis, MN)

Christopher J. Kutner
Partner
Farrell Fritz, P.C. (Uniondale, NY)

Laura Loeb
Partner
King & Spalding LLP
(Washington, DC)

Mark E. Lutes
Member
Epstein Becker Green
(Washington, DC)

Amy B. Manning
Partner
McGuire Woods LLP (Chicago, IL)

Christine Maroulis
Director, Health Economics & Reimbursement
Johnson & Johnson (Chicago, IL)

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Senior Policy Specialist
Foley Hoag LLP (Boston, MA)

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Partner
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Kathleen Schaum
Reimbursement Director
Healthpoint (Lake Worth, FL)

Esther Scherb
Partner
Latham & Watkins LLP
(Washington, DC)

Allison Shuren
Partner
Arnold & Porter (Washington, DC)

Judith Waltz
Partner
Foley & Lardner LLP
(San Francisco, CA)

Monday, June 14, 2010 | Pre-Conference Workshop

1:00 p.m. – 4:30 p.m. (registration begins at 12:00 p.m.)

A Device Pricing and Reimbursement Boot Camp: A Primer on the Present and Evolving Landscape of Reimbursement, Coverage, Pricing, and Payment

Understanding medical device pricing and reimbursement can be a daunting task. Because there are so many different components involved, attorneys and device manufacturers need to keep abreast of changing policies, while understanding the complex foundation of the pricing and reimbursement rubric. Although each medical device is unique in nature, there are universal issues that each company faces and general strategies that can be applied to best position your company.

This program will serve as a primer to those who are new to this area and a refresher to more experienced pricing professionals. This workshop will cover the following:

- Examining the key concepts of device pricing and reimbursement
- Defining coverage, coding and payment
- How CMS designates codes for different devices
- Securing a CPT code assignment for a new or existing medical device
  - obtaining a new CPT code when an existing code does not apply to the device
- How is the price of a device determined?
- How coding relates to the classification of devices
- Explaining how different medical device classification levels impact the rate of reimbursement and coverage

Tuesday, June 15, 2010

7:30 **Registration and Continental Breakfast**

8:30 **Co-Chairs' Opening Remarks**

John Ridge
Director, Reimbursement Services
VENTANA MEDICAL (Tuscon, AZ)

Steven Stranne, M.D.
Partner
BRYAN CAVE LLP (Washington, D.C.)

The Politics and Policies of Device Pricing & Reimbursement

8:45 **Policy Considerations and Predicted Industry Trends for A Time of Contemplated Health Care/Insurance Reform**

Mark E. Lutes
Member
EPSTEIN BECKER GREEN (Washington, DC)

- How pending health care reform legislation is affecting the device industry and current views concerning device pricing and reimbursement
  - provisions in proposed health care/insurance reform legislation that expressly impact devices
    - o taxes
    - o calculation of tax
    - o deductibility
- Policy Considerations
  - rise in cost of insurance vs. decrease in covered services
- Understanding how contemplated cuts in device reimbursement may influence the decisions of health care professionals
  - effect on provider buying power and choice of device preference
  - impact on purchasing decisions and procurement at hospitals and patient care facilities
  - fraud and antitrust considerations relative to device purchasing decisions
- Establishing how proposed legislation will affect decisions made by both private payors and the government relative to new technologies
  - techniques for having new technologies reimbursed at higher rate than those which already exist

10:00 **Morning Coffee Break**

10:15 **The Evolving Roles of Comparative Effectiveness and Clinical Research in Coverage and Reimbursement Strategies for Medical Devices**

Laura Loeb
Partner
KING & SPALDING LLP (Washington, DC)

Steven Stranne, M.D., J.D.
Partner
BRYAN CAVE LLP (Washington, DC)

- Focusing on how provisions concerning comparative effectiveness as outlined in the Stimulus Bill and proposed health care/insurance reform legislation will affect device pricing and reimbursement
- Discerning the government's role in the analysis of the relative efficacy of different products
- How will comparative effectiveness be used as a way to deny coverage for some products?
- Using clinical trials to show how long-term patient outcomes are better in view of new technology
  - evaluating concerns that doctors have little or no solid evidence of the value of certain treatments
  - analyzing evidence of improved effectiveness as a way for new technologies to be reimbursed
  - knowing when to put a greater premium on evidence-based trials

11:30 **Outpatient vs. Inpatient Device Reimbursement, *i.e.*, Site of Service Payments**

Kathleen Schaum
Reimbursement Director
HEALTHPOINT (Lake Worth, FL)

Christopher J. Kutner
Partner
FARRELL FRITZ, P.C. (Uniondale, NY)

- Proving the efficacy of a device in order to get reimbursement
  - correlating reimbursement to the site of service
    - o how inpatient services are billed under Medicare Part A
- Determining what services are covered in an inpatient setting
  - getting increased payments for more extreme procedures and devices
  - assessing the impact of the proposed device tax on inpatient services
- Exploring the affect of the ACE program on payment and reimbursement in a hospital setting
- Understanding the differentiation in payment for outpatient services vs. inpatient services
  - identifying day-to-day challenges associated with coverage, coding, and payment of outpatient services
  - how outpatient services are currently billed under Medicare Part B
- Comprehending the implications of price bundling on hospitals and healthcare service providers
  - strategies to avoid purchasing decisions based on quantity and not quality

12:45 **Networking Lunch**

2:00 **Antitrust Concerns in Medical Device Pricing and Reimbursement**

Amy B. Manning
Partner
MCGUIRE WOODS LLP (Chicago, IL)

- Exploring common antitrust implications for medical device pricing
- Pricing concerns under the Robinson-Patman Act
- How bundled discounts on certain medical devices may violate antitrust laws
- Understanding why certain payments made by medical device companies to group purchasing organizations are viewed as kickbacks and a form of anticompetitive conduct

3:00 **Afternoon Refreshment Break**

3:15 **The Role of Market Access in Medical Device Pricing and Reimbursement**

Mark Domyahn
Global Director of Market Access and Reimbursement
ZIMMER, INC. (Minneapolis, MN)

Ryan M. Graver
Global Director of Market Access and Health Economics
ZIMMER, INC. (Minneapolis, MN)

- The growing trend in developing health economics/reimbursement departments
- The impact of reimbursement and clinical strategies on global market access
- Developing and executing global strategies that inform and support medical device value positions
- Recognizing the role of price in reimbursement and clinical evidence development strategies
- Securing access to global markets through the utilization of clinical data

4:15 **Using the Competitive Bidding Process for Durable Medical Equipment to Your Advantage**

Carolyn J. McElroy
General Counsel
PACIFIC PULMONARY (Mountainair, NM)

- Overview of the competitive bidding process for DME
- Examining the company selection process for the Competitive Bidding Program
  - evaluation of pilot program – cost savings
  - weighing concerns that competitive bidding has shut out certain suppliers
- Setting price strategies of DME in line with successful bids in pilot program
- Reviewing increased government scrutiny of DME reimbursement
  - strategies to avoid such scrutiny
- Comprehending how government auditing of DME companies have resulted in decreased reimbursement amounts
- What reimbursement lessons can manufacturers of implantable devices glean from the DME bidding process

5:45 **Conference Adjourns to Day 2**

Wednesday, June 16, 2010

8:00 **Continental Breakfast**

9:00 **Co-Chairs' Remarks**

9:15 **Coverage, Coding and Payment: A Re-Examination of the Basics in View of New Devices and Technologies**

Michael Beebe
Vice President
HILLCO HEALTH (Washington, DC)

John Ridge
Director, Reimbursement Services
VENTANA MEDICAL (Tuscon, AZ)

Bruce Quinn
Senior Policy Specialist
FOLEY HOAG LLP (Boston, MA)

- Assigning a CPT or HCPCS to new medical devices/new technological advances
  - how does this code assignment impact device reimbursement?
  - special considerations for "me too" devices
- What evidence does CMS require for reimbursement approval
- How is the reimbursement of new medical technologies influenced by less expensive devices within the same product category?
- Understanding how the classification of a medical device impacts its reimbursement
  - which class of devices is open to the most rigorous clinical trial requirements
- Identifying required mechanisms to get a device covered and paid

10:15 **Morning Coffee Break**

10:30 **Exploring the Relationship Between the FDA Approval and CMS Payment Processes**

Elliott Gruskin, Ph.D.
Global Vice President, Research and Development
SYNTHES (West Chester, PA)

James R. Ravitz
Partner
ARENT FOX LLP (Washington, DC)

Esther R. Scherb
Partner
LATHAM & WATKINS LLP (Washington DC)

- Understanding how the scrutiny of the 510(k) clearance and PMA processes connect with reimbursement
  - comparing and contrasting the 510(k) and PMA processes for device clearance/approval
- Analyzing changes that the FDA is proposing to create a more stringent and vigorous clearance process in view of perceived abuses
- Reviewing industry strategies for remedying perceived abuses in the 510(k) clearance and PMA processes
  - expanded clinical trials
- Comprehending policy changes at FDA and CMS relative to approvals and reimbursements
  - how AHRQ is working in tandem with CMS in regard to product coverage

11:45 **Payment and Reimbursement From the Perspectives of Both Private and Public Payors**

Rosemary Gammon
Director of Reimbursement & Payer Policy
XOFT, INC. (Sunnyvale, CA)

Christine Maroulis
Director, Health Economics & Reimbursement
JOHNSON & JOHNSON (Chicago, IL)

- Understanding how Medicare sets the standard for both public and private payors for payment and reimbursement of devices
- Exploring criteria which private payors use for payment and reimbursement other than those set by Medicare
- Lobbying the government for favorable reimbursement decisions
- Comprehending how negative national coverage decisions affect local reimbursement
- Analyzing the advantages of Medicare centralized coverage and reimbursement decisions

12:45 **Networking Luncheon**

2:00 **Setting Price and Seeking Reimbursement for New Medical Technologies Under Current Protocols and Proposed Reforms**

Charles Carignan, MD
President & CEO
NINEPOINT MEDICAL, INC. (Boston, MA)

Allison Shuren
Partner
ARNOLD & PORTER LLP (Washington, DC)

- Navigating the payment and reimbursement strategies for new medical technologies
- Using medical evidence in the approval of new devices
- How do new and innovative devices receive approval?
  - overcoming obstacles for fitting new medical technologies into existing codes
- Identifying common struggles and proposing solutions to coding dilemmas in new technologies
- If new technology does not fit into an existing code, how do device manufacturers obtain a new code
- Evaluating the link between cost and coverage relative to new technologies
- Factoring reimbursement into the design and execution of new medial technologies
- Conducting an early product reimbursement assessment to determine the feasibility of a new device
- How do device manufactures think about reimbursement when evaluating whether to develop a new technology?

3:15 **Afternoon Coffee Break**

3:30 **Current Trends in Government Investigations and Enforcement Actions Concerning Medical Device Pricing and Reimbursement**

Becky L. Jackson
Senior Legal Specialist
MEDTRONIC (Minneapolis, MN)

Brian French
Partner
NIXON PEABODY LLP (Boston, MA)

Judith Waltz
Partner
FOLEY & LARDNER LLP (San Francisco, CA)

- Identifying fraud and abuse concerns in device coverage, pricing and reimbursement
- Avoiding anti-kickback violations for physicians and hospitals
  - Stark Law implications
- Pinpointing scenarios where hospitals, physicians, and ASCs have been implicated for device reimbursement fraud by the government
- What are device manufacturers doing to prepare the sales force to speak to the government and private payors?
- Assessing the impact of the AdvaMed Code of Conduct on reimbursement and pricing protocols
- Exploring gain sharing concerns relative to pricing and reimbursement
  - common triggers for gain sharing investigations
    - o adopting a preference for one medical device over another in order to get a larger volume discount when ordering the device
    - o sharing savings between hospitals and doctors
  - reviewing gain sharing program by the Inspector General's Office at HHS

4:45 **Conference Concludes**

Thursday, June 17, 2010 | Post-Conference Workshop
9:00 a.m. – 12:00 p.m. (registration begins at 8:15 a.m.)

B Addressing Reimbursement Concerns in Foreign Nations

Max Gill
Global Director Health Economics and Reimbursement
COVIDIEN (Bedford, MA)

In this global economy, it is more important than ever for medical device companies to think not only about domestic pricing and reimbursement strategies, but international strategies as well. This workshop will address the "nuts and bolts" of pricing and reimbursement in foreign countries. Points of discussion will include:

- Reimbursement strategies for different countries.
  - EU
  - Emerging markets
- Compliance challenges of introducing domestic (U.S.) device products into foreign countries
- Understanding how FDA and CMS look at the approval and reimbursement for devices that come from outside the U.S.
- Exploring the link between research and development, price setting and reimbursement in foreign countries
- Strategies for cost containment of clinical research in view of different requirements in different countries for device reimbursement
- Comprehending the impact of government relations on reimbursement strategies around the world

- From medical device companies:
  - In-house Counsel having responsibility for:
    - o Reimbursement
    - o Medicare/Medicaid
    - o Government Contracts
  - Officers and Directors, and Managers for:
    - o Pricing, Contracts and Reimbursement
    - o Medicaid/Medicare Rebate
    - o Government Affairs
    - o Healthcare Economics
    - o Compliance
- Law firm attorneys with practice areas in:
  - Medical Device Reimbursement
  - FDA and Food and Drug Regulatory Law
  - Government Contracts

In-House Counsel Forum on

Medical Device Pricing & Reimbursement

A Comprehensive Guide To Current Procedures and Proposed Changes Impacting Manufacturers, and Public and Private Payors

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A **Device Pricing and Reimbursement Boot Camp: A Primer on the Present and Evolving Landscape of Reimbursement, Coverage, Pricing, and Payment**

Or Post-Conference master class on June 17, 2010:

B **Addressing Reimbursement Concerns in Foreign Nations**

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