Reimbursement in the Pay for Performance Era

Jeffrey Bush
Director, Corporate Reimbursement
Becton, Dickinson and Company (BD)
AGENDA

• Alphabet Soup
• Pay For Performance (P4P)
  – CMS Hospital Quality Initiative
  – PVRP Transition to PQRI
  – CMS/Premier Hospital Quality Incentive Demo (HQID)
  – Next Gen: Value-Based Purchasing (VBP)
• Tying It All Together: Implications for Manufacturers
<table>
<thead>
<tr>
<th><strong>Needles</strong></th>
<th><strong>Syringes</strong></th>
<th><strong>Diagnostics</strong></th>
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<tbody>
<tr>
<td>Vacutainer Blood Collection Systems</td>
<td>Culture Media Molecular</td>
<td>Environmental Monitoring</td>
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<tr>
<td>Centrifuges</td>
<td>BGM</td>
<td>Flow Cytometry</td>
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<td>Ace Bandages</td>
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<td>BioCoats</td>
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<tr>
<td>Surgical Blades</td>
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<td>Research</td>
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<tr>
<td>Radiology &amp; Biopsy</td>
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<td>Antibodies</td>
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<td>Thermometers</td>
<td>Ophthalmic Blades</td>
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<td>Immunizations</td>
<td>Clontech</td>
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<td></td>
<td>Catheters</td>
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</tbody>
</table>
Pay for Performance (P4P)

What is P4P?
- Initiatives Authorized by Congress
- Launched by CMS (Medicare/Medicaid Admin)
- Designed to Link Payment with Performance in Healthcare Settings
  - Hospitals
  - Physicians

- Purpose of P4P
  - Getting the Biggest “Bang” for the “Buck”
  - I.e., Maximum Benefit @ Minimum Cost
Pay for Performance (P4P)

Ultimate Purpose of P4P

EBM Guidelines → Clinical Practice → Outcomes → CE

Not Necessarily Cost Savings
Medical Device Paradigm Shift

Clinical Decision-Making → EBM

BD
Helping all people live healthy lives
Pay for Performance (P4P)

• The P4R Paradigm
  – Payment Not Yet Linked to Clinical Performance
  – Payment Based only on Measurement/Reporting

• E.g., Providing Aspirin to Suspected MI Patient
  – Hospital A shows 0% compliance
  – Hospital A reports 0% compliance to CMS
  – Hospital A gets full payment update for year
  – Hospital B shows 100% compliance, but doesn’t report
  – Hospital B gets update reduced by .4% (2% in 2006/2007)
  – **But, both hospitals’ data become public information**
Pay for Performance (P4P)

- CMS/Congress P4P Goals for Future
  - Actual payment based on measurement against guidelines; Maybe peer comparison too
  - E.g., Providing Aspirin to Suspected MI Patient
    - Hospital A shows 50% compliance
    - Hospital A reports 50% compliance to CMS
    - Hospital B shows 90% compliance
    - Hospital B reports 90% compliance to CMS
    - Hospital B Gets Higher Payment than A for All Services, or at least for Services Related to MI
## P4P Hospital Measurements

The Hospital Quality Alliance (HQA) Ten Measure "Starter Set" 2004-2007

### Measure Build Out Table

<table>
<thead>
<tr>
<th>Measure Category</th>
<th>Measure Description</th>
<th>11/04 <em>Starter Set</em></th>
<th>4/1/05 7 New Measures</th>
<th>9/1/05 3 New Measures</th>
<th>2006 1 New Measure</th>
<th>2007 15 New Measures (anticipated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Myocardial Infarction (AMI)</td>
<td></td>
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<tr>
<td>AMI-1</td>
<td>Aspirin at arrival</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>AMI-2</td>
<td>Aspirin prescribed at discharge</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td>AMI-3</td>
<td>ACE inhibitor (ACE-I) or Angiotensin Receptor Blocker (ARBs) for left ventricular systolic dysfunction</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>AMI-4</td>
<td>Adult smoking cessation advice/counseling</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td>AMI-5</td>
<td>Beta blocker prescribed at discharge</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>AMI-6</td>
<td>Beta blocker at arrival</td>
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<tr>
<td>AMI-7</td>
<td>Thrombolytic agent received within 30 minutes of hospital arrival</td>
<td>✓</td>
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<tr>
<td>AMI-8</td>
<td>Primary Percutaneous Coronary Intervention (PCI) received within 120 minutes of hospital arrival</td>
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<td>✓</td>
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<tr>
<td>AMI-8a</td>
<td>30-day AMI mortality</td>
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<tr>
<td>Heart Failure (HF)</td>
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<tr>
<td>HF-1</td>
<td>Discharge instructions</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>HF-2</td>
<td>Left ventricular function assessment</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>HF-3</td>
<td>ACE inhibitor (ACE-I) or Angiotensin Receptor Blocker (ARBs) for left ventricular systolic dysfunction</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>HF-4</td>
<td>Adult smoking cessation advice/counseling</td>
<td>✓</td>
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<tr>
<td>HF-5</td>
<td>30-day HF mortality</td>
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<tr>
<td>Pneumonia (PN)</td>
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<tr>
<td>PN-1</td>
<td>Oxygenation assessment</td>
<td>✓</td>
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<tr>
<td>PN-2</td>
<td>Pneumococcal vaccination status</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>PN-3a</td>
<td>Blood culture performed in emergency department before first antibiotic received in hospital</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>PN-4</td>
<td>Adult smoking cessation advice/counseling</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>PN-5b</td>
<td>Initial antibiotic received within 4 hours of hospital arrival</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>PN-6</td>
<td>Appropriate initial antibiotic selection</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>PN-7</td>
<td>Influenza vaccination status</td>
<td>(Collected but not reported earlier due to vaccine shortage in 2008)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>PN-8</td>
<td>30-day Pneumonia mortality (pending NOF endorsement)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical Care Improvement/Surgical Infection Prevention (SCIP/SIP)</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>SCIP-Inf-1</td>
<td>Prophylactic antibiotic received within 1 hour prior to surgical incision</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>SCIP-Inf-2</td>
<td>Prophylactic antibiotic selection for surgical patients</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>SCIP-Inf-3</td>
<td>Prophylactic antibiotics discontinued within 24 hours after surgery end time</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>SCIP-VTE-1</td>
<td>Surgery patients with recommended venous thromboembolism prophylaxis ordered</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td>SCIP-VTE-2</td>
<td>Surgery patients with recommended venous thromboembolism prophylaxis received within 24 hours prior to or after surgery</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Hospital CAHPS (HCAHPS) -- Patient perspectives on hospital care

- Communication with Doctors (composite) – Dec
- Communication with Nurses (composite) – Dec
- Responsiveness of Hospital Staff (composite) – Dec
- Cleanliness and Quietness of Hospital (composite) – Dec
- Pain Control (composite) – Dec
- Communication about Medicines (composite) – Dec
- Discharge Information (composite) – Dec
- Overall Rating of Hospital Care – Dec
- Overall Recommendation – Dec

**TOTALS** 10 17 20 21 36

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*Measure revised to incorporate ARBs, per joint agreement of the Center and Medicaid Services (CMS) and the Joint Commission on Accreditation Organizations (JCAHO) issued on November 15, 2004.*
PVRP

- Physician Voluntary Reporting Program
- Similar Evolution to HQI
- Low Participation
- Basic Measures (74 in 2007)
## Physician Voluntary Quality Measures

### AMI-Related
- Aspirin at arrival for AMI
- Beta blocker at arrival for AMI

### Pneumonia-Related
- Antibiotic admin timing for patient hospitalized for pneumonia

### Diabetes Related
- Hemoglobin A1c control
- LDL control
- High BP control

### Other Myocardial
- Angiotensin-converting enzyme inhibitor or angiotensin-receptor blocker therapy for left ventricular systolic dysfunction
- Beta-blocker therapy for left ventricular systolic dysfunction
- Beta-blocker therapy for patient with prior myocardial infarction
- Antiplatelet therapy for patient with coronary artery disease
- LDL control in patient with coronary artery disease
- Warfarin therapy in heart failure patient with atrial fibrillation
Pay for Performance (P4P)

- Other “P4P” Initiatives
  - Gainsharing
  - Transparency in Purchasing
  - Value-Based Purchasing in DRA of 2005
  - MedPAC: Lab Results on Bills
  - Hospital Acquired Infections in DRA of 2005
PQRI

- Physician Quality Reporting Initiative
- Replaces PVRP
- Another P4R Opportunity
- Established in Tax Relief and Healthcare Act of 2006 (TRHCA)
- Provides for a 1.5% Incentive Payment for Physicians to Report Quality Data
  - New Money to the PFS System
• Reporting on Regular Claims

• Must Report Applicable Designated Measures (74) for Period July 1 to December 31, 2007

• Payment will be in a lump sum in mid-2008

• Must report each measure in 80% of cases wherein measure is reportable on at least 3 of measures reported (exceptions)
CMS/Premier HQID

• Raised overall quality by 11.8% in 2 yrs
• Variation between top and bottom performers shrinking
• Estimate 1,284 MI patients saved
• $8.7MM incentive payments to top 20% performing hospitals in each of 5 clinical areas ($744K top pmt)

• Leslie Norwalk: “The Premier hospital alliance is showing that even limited additional payments, focused on supporting evidence-based quality measures, can drive across-the-board improvements in quality, fewer complications and reduced costs.”
P4P Implications for MD Manufacturers

- For Diagnostics, Evidence Becomes More than Sensitivity/Specificity
- For Other Medical Devices, Evidence is More than Safety/Efficacy or Proof of Concept
- Going Forward, A Device’s Value to the Healthcare System Must Be Established
P4P Implications for MD Manufacturers

• As Device Manufacturers, We Must:
  – Consider Early & Often How We Will Demonstrate the Value of Our New Tech
  – Incorporate as Much Data Collection as Possible in Initial & Pivotal Trials
  – Work with Healthcare Economists to Derive Value Long Before We go to Market
In Summary

- Begin to Think About Reimbursement & Needed Evidence Long Before Trials
- Plan to Incorporate Data Collection into Clinical Trials that will Feed Outcomes Analyses
- Focus on Value to Payers (or the HC System)
- If Possible, Establish Link to Existing Quality Measures or Determine Pathway to Creation of New Quality Measures
THANK YOU!!!!