Coordination Between FDA and CMS:
Strategic Considerations for Medicare
Coverage and Payment, and the Growing
Impact of CMS in the Marketplace

Kirk L. Dobbins
Hyman, Phelps & McNamara, P.C.
Washington, D.C.
www.hpm.com
The Nation’s Health Dollar, CY 2000

Medicare, Medicaid, and SCHIP account for one-third of national health spending.

Income Sources:
- Private Insurance: 34%
- Other Public: 12%
- Other Private: 6%
- Medicaid and SCHIP: 15%
- Out-of-pocket: 15%
- Medicare: 17%

Total National Health Spending = $1.3 Trillion

1 Other public includes programs such as workers’ compensation, public health activity, Department of Defense, Department of Veterans Affairs, Indian Health Service, and State and local hospital subsidies and school health.
2 Other private includes industrial in-plant, privately funded construction, and non-patient revenues, including philanthropy.

Note: Numbers shown may not sum due to rounding.

Personal health care expenditures, 2003
Expenditures $1.4 trillion

Source of funds
- Private health insurance
- Federal Government
- Out-of-pocket
- State/local govt.
- Other private funds

Type of expenditures
- Hospital
- Physician
- Nursing home
- Prescription drugs
- Other

SOURCE: Centers for Disease Control and Prevention, National Center for Health Statistics, Health, United States, 2005, figure 9.
Medicare’s Impact on the Health Care Market

- In Fiscal Year 2005, CMS “outlayed” $484.3 billion.
- CMS is one of the largest purchasers of health care in the world.
- Medicare and Medicaid represent 33 cents of every dollar spent on health care in the United States.

Source: CMS Financial Report, FY 2005
Medicare Part D Bolsters CMS’s Influence on the Health Care Market

<table>
<thead>
<tr>
<th>Plan Type</th>
<th>Enrollment</th>
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</thead>
<tbody>
<tr>
<td>Stand-Alone Prescription Drug Plan (PDP)</td>
<td>10.00</td>
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<tr>
<td>Medicare Advantage with Prescription Drugs (MA-PD)</td>
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<tr>
<td>Medicare Retiree Drug Subsidy (RDS)</td>
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<td>Medicare-Medicaid (Automatically Enrolled)</td>
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<td>FEHB Retiree Coverage</td>
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<tr>
<td>TRICARE Retiree Coverage</td>
<td>5.00</td>
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<tr>
<td>TOTAL</td>
<td>30.00</td>
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Note: Enrollment figures are approximate and subject to change based on data availability.
Difference between FDA and CMS Regulatory Review

- **FDA: Safe and Effective**
- **CMS: Reasonable and Medically Necessary for Medicare Population:**
  - Data showing improved health outcomes for Medicare beneficiaries over existing treatment or technology
- **CMS: Implicitly looks for value gained from new technology in improving health outcomes for Medicare beneficiaries**
Medicare Coverage, Coding, Payment
When Is a Device or Drug Eligible for Medicare Coverage?

- FDA cleared or approved devices or drugs are “eligible” for Medicare coverage
- Class I or II, Category B device (non-experimental/investigational)
- Class III, Category A device, possibly, if used in “diagnosis, monitoring, or treatment of an immediate life-threatening disease or condition”
- FDA-approved drugs for treatment of covered illness in Medicare benefit category (Part A or B)
Statutory Coverage Standard

- “Reasonable and Necessary” (42 USC 1395y(a)): no payment for items . . . which are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member.
What Is “Reasonable and Necessary?”

- No statutory or regulatory definition of “reasonable and necessary.”
- CMS has generally interpreted “reasonable and necessary” to mean that the item should improve health outcomes overall for Medicare beneficiaries.
What Guides Coverage and Payment Decisions?

- Legislation
- CMS
- Regulations
- Medicare Program Manuals
- Contractor Policies (LCD, Articles, Internal Guides)
Strategic Considerations for Medicare Coverage

- National Coverage Determination (NCD) versus Local Coverage Determination (LCD)
- Evidence/Clinical Data that shows improvement in health outcomes for Medicare beneficiaries
- Show “value” to Medicare
- Early planning for Medicare coverage
- Assess current Medicare coverage, coding and payment
NCD Versus LCD: Which Is Better?

- It depends . . . .
National Coverage Decision

- Medicare Program Integrity Manual, Chapter 13
- National scope/jurisdiction
- NCD (+ or -) = no contractor discretion
- May be initiated internally by CMS or on request
- NCDs binding on: contractors, providers, and ALJs on claims appeals
Local Coverage Decision

- Medicare Program Integrity Manual, Chapter 13
- Focus on what is “reasonable and necessary”
- Limited Scope/Jurisdiction (several states)
- Often reactive rather than proactive: utilization, denial of claims or new technology
- Can Be Overruled by Administrative Law Judge
Premarket Considerations for Medicare Coverage

- Early Planning: Phase I-III
  - Include Medicare population in clinical studies
  - cost effectiveness endpoints
- FDA Clearance or Approval: 510(k) versus Premarket Approval Application (PMA) review
- Meet with CMS
Premarket Considerations for Medicare Coverage

- 510(k) may: preclude new HCPCS code; place device in existing payment categories; significantly limit payment; or preclude coverage
- PMA may allow you to get separate code, which may lead to better reimbursement
- Informal meeting with CMS may provide guidance: clinical trials and data should show efficacy for Medicare population
Other Coverage Considerations

- Even if no data on effectiveness for Medicare population, there are options:
  - Coverage with Evidence Development:
    - New Coverage Pathways:
    - Coverage with Appropriateness Determination
    - Coverage with Study Participation
  - FDA Phase IV
Coding Considerations

- Healthcare Common Procedure Coding System (HCPCS) Codes: Level I and II
- HCPCS Level I: AMA (five digit code)
- Category III Current Procedural Terminology (CPT-4) Codes: medical procedures and services performed by physicians and other healthcare providers
- CPT Coding Process By AMA: 1+ year process unless your product is covered by an existing code
Coding Considerations

- **HCPCS Level II: CMS** (five position alphanumerical code)
- **Certain medical equipment, drugs, and services** when used outside physician’s office and not otherwise described in CPT-4 codes
- **Examples**: C-codes (C2625) (stent); L-codes (L8699) (prosthetic implant n.o.c.); J-codes (J3499)
- **Fairly well-defined applications process**, but need three months of marketing experience prior to requesting code; exemption for drugs
- **HCPCS Application Process by CMS: strategic timing issues**
Payment

CMS Payment Systems:

- Prospective Payment Systems
- Fee Schedules
- New Technology Considerations
Payment

- Inpatient Hospital Prospective Payment System (IPPS)
- Diagnosis Related Groups (DRGs)
- Drugs included in DRG
- New technology add-on
Payment

■ IPPS special add-on for new technology:
  - CMS must determine that new device is a substantial clinical improvement over current treatments.
  - Significant changes likely due to proposed changes to DRGs.
Payment

- Hospital Outpatient Prospective Payment System (OPPS) transitional pass-through payment or new APC category for new devices:
  - CMS must determine that new device is a substantial clinical improvement over current treatments.
Payment

- **New Technology APC:**
  - Intended to provide payment under the OPPS for complete services or procedures that cannot be appropriately billed under an existing HCPCS code or APC.
  - Must be “truly new,” i.e., inability to describe appropriately, and without redundancy, the complete service with a current individual HCPCS code or combination of codes.
  - Must be distinct procedure with a beginning, middle, and end.
Payment

- **New outpatient prescription drugs:**
  - Pass-through payment (generally ASP + 6%, unless covered by competitive acquisition contract)
  - Pass-through for 2, but no more than 3 years
  - News drugs that do not qualify for pass-through payment, i.e. nonpass-through, (95% average wholesale price)
Payment

- **Medicare Part B: Average Sales Price Methodology for outpatient prescription drugs (generally, ASP + 6%)**
- **Specified Covered Outpatient Drugs (generally ASP + 6%)**
  - Radiopharmaceuticals
  - Drug receiving pass-through payments prior to 2003
- **Part D voluntary prescription drug benefit:**
  - Government payment to plans
  - Premiums paid by Medicare beneficiaries
  - Part D effect on prescription drug market
Conclusion

Effective Early Planning

Coverage, Coding

Medicare Payment
Thank you!

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