



Reimbursement Dynamics

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Today's Reimbursement Dynamics



- Healthcare delivery in US is seriously flawed
 - Costs are excessive and growing
 - Quality is inadequate in average as well as highly variable
 - Large inequities in access to care
 - Cost of caring for uninsured passed on to taxpayers and insured patients
- Important changes occurring at two levels of government
 - CMS (Centers for Medicare and Medicaid Services) is implementing important changes in Medicare policy at the administrative level of Government
 - Congress is engaged in a major overhaul of overall US healthcare policy

New Healthcare Legislation



- Outcome uncertain and there is significant political opposition
 - Taxpayer concerns over cost of reform and who will pay for it
 - Medicare beneficiaries concerned about benefit cuts
 - Businesses that do not provide healthcare benefits
- Reform is supported by major stakeholders
 - Hospitals
 - AMA
 - Drug and device trade organizations
 - Businesses currently providing healthcare benefits

Legislation



- Major disagreement over a government-run plan
 - Those who think government is inherently inefficient
 - Those who think government will undercut private plans
 - Those who think government will ration care
 - Those who think that only government has sufficient power to force change
- Likely effects on industry
 - More covered lives will increase the amount of money flowing into providers and drug and device suppliers
 - Increased regulation and consolidation of private payers
 - Increased emphasis on “quality” and other reforms of “pay for service”
 - More “comparative effectiveness” studies

Pay for Service Issues



- The traditional payment model for healthcare and for insurance
- Examples:
 - Medicare “Part A” hospital inpatient
 - Medicare “Part B” physician and hospital outpatient services
 - Private insurance plans (except HMO)
- **Contribute to high cost, low quality**
 - Providers can be paid for “unnecessary” services
 - No quality control

Coverage Decisions are One Control



- Decisions are not made in Washington
- Rarely made in Baltimore
- Usually made at a regional level by contractors who also provide private health plans
- Medical Directors (who are MDs) of the contractors are responsible for them
- Cost is a consideration
- Clinical data is usually the key consideration for favorable decisions; default decision is usually “no”
- External technology assessments are a comparative effectiveness tool that is used when available

Medicare's Prospective Payment Systems Provide Cost Control



- PPS
 - Hospital Inpatient Prospective Payment System
 - Hospital Outpatient Prospective Payment System
- Principles of PPS:
 - Bundling of services
 - A single payment to the institution at discharge, based on diagnosis, severity and method of treatment
 - Coverage: only specific ICD-9 diagnosis and procedure code combinations are paid for
 - Additional treatments during a stay are not paid for (even if necessary)
 - Payment is approximately equal to National average cost of treatment (statistical data from previous claims and hospital cost reports)
 - The amount on the “hospital bill” is used only to gather statistical data
 - Hospitals make or lose money on each claim
 - Each hospital will make or lose money on Medicare patients

PPS Does Not Promote Quality



- Quality: defined as health of patient after discharge
- No incentive for quality
- Suboptimal outcomes result in readmissions
- Poor quality is actually rewarded
- Congress and others believe that poor quality is a major driver of high costs

Medicare's New Initiatives for Quality



- Healthcare IT to improve efficiency
- Promote comparative effectiveness research
 - Information: what works best for the patient
 - Risk: cost effectiveness considerations could lead to lower quality
 - However, low quality and arbitrary coverage limitations are already established fact; research is the only way forward
- “Pay for Performance”
 - Financial incentives for better outcomes
- Don't pay for avoidable complications
 - “Present on admission” indicators have been added to claim forms

How is New Technology Impacted?



- **Prospective Payment Systems**
 - PPS are a disincentive to a hospital to acquire new technology to improve outcomes
 - Pay for performance unlikely to provide sufficient incentives to adopt new technologies
 - Technologies that save hospital costs more easily adopted
 - Technologies that reduce nosocomial complications could be very valuable
- **Coverage**
 - New procedures are usually not covered, by default
 - Favorable coverage decisions usually require clinical data
 - Different from FDA requirements
 - Often impractical to collect, especially for small or emerging companies
 - Comparative effectiveness data doesn't exist for new technologies
- **New legislation is likely to augment these problems (unintentionally)**

New Tech Add-on Payments (Inpatient)



- CMS mechanism to encourage adoption of new technologies that improve patient outcomes but increase hospital costs
- Two to three year added payment for technologies that are:
 - New
 - FDA Approved
 - Provide significant clinical improvement
- Very selective program
 - Less than a dozen applications per year
 - Usually only one or two approvals

New Tech Add-on Payments



- A new ICD-9-CM procedure code is assigned in order to identify on claims the use of the new technology
- The two to three year period allows CMS to collect statistical data to determine the proper placement of the code in the permanent “MS-DRG” payment categories.
- The additional cost of the procedure must exceed a threshold published by CMS
- Payment is limited to half of the amount the hospital cost for the claim exceeds the MS-DRG payment
- Precedent for permanent coverage and payment
- “Significant clinical improvement” is based on FDA approval (usually PMA) and its clinical data

New Tech Add-on Process



- Request for new ICD-9-CM procedure code
 - Due 2 months before CMS' Fall "Coordination and Maintenance Committee" meeting.
 - If approved, goes into effect October 1 of following year
- New Tech add-on application
 - Due in November for the following October 1.
 - Three main components
 - Description
 - Clinical data
 - Economic data to show that the technology cost exceeds CMS' threshold
- FDA approval for the product is needed well before the IPPS final rule is published in the Federal Register (July).



The TherOx Experience with New Technology Add-on Payments