The Role of Medicare National Coverage in the Regulatory Process

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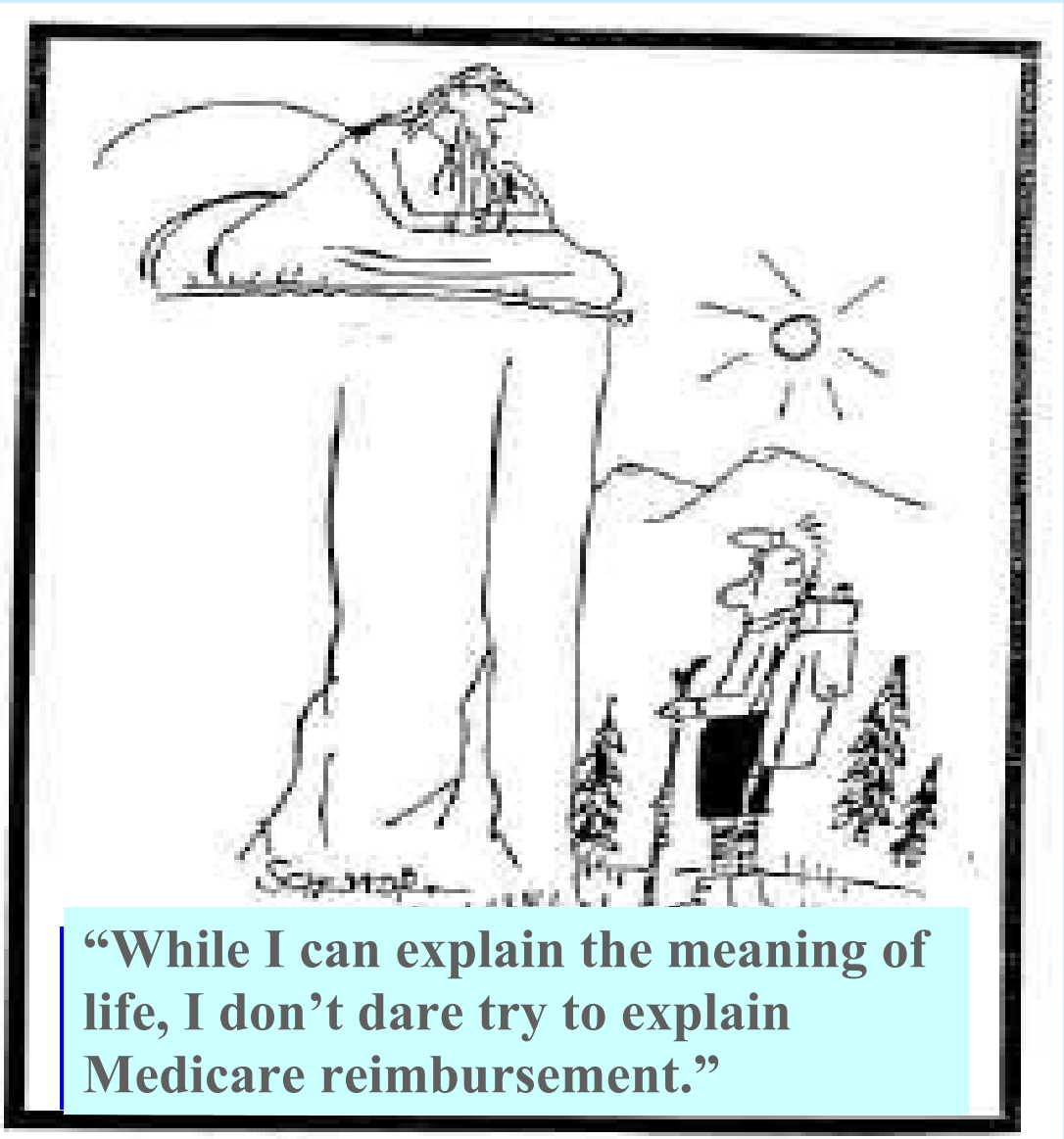
"Today more than ever, we must get more for what we spend on health care. We've got to generate valuable innovation in medical products to reduce errors, complications, and unnecessary care while improving quality. All that's necessary to understand how urgent this is to consider the alternative: crude forms of cost cutting, in ways that reduce the incentives for medical progress while doing nothing to make our fragmented system work better. We owe it to the patients we serve to be more clinically sophisticated than that."

Mark McClellan, September 2004



“While I can explain the meaning of life, I don’t dare try to explain Medicare reimbursement.”

Steps to Coverage Determination and Payment

Outside of CMS:

- Congress determines benefit categories
- FDA approves drugs/devices for market

Within CMS:

- Coverage
- Coding
- Payment

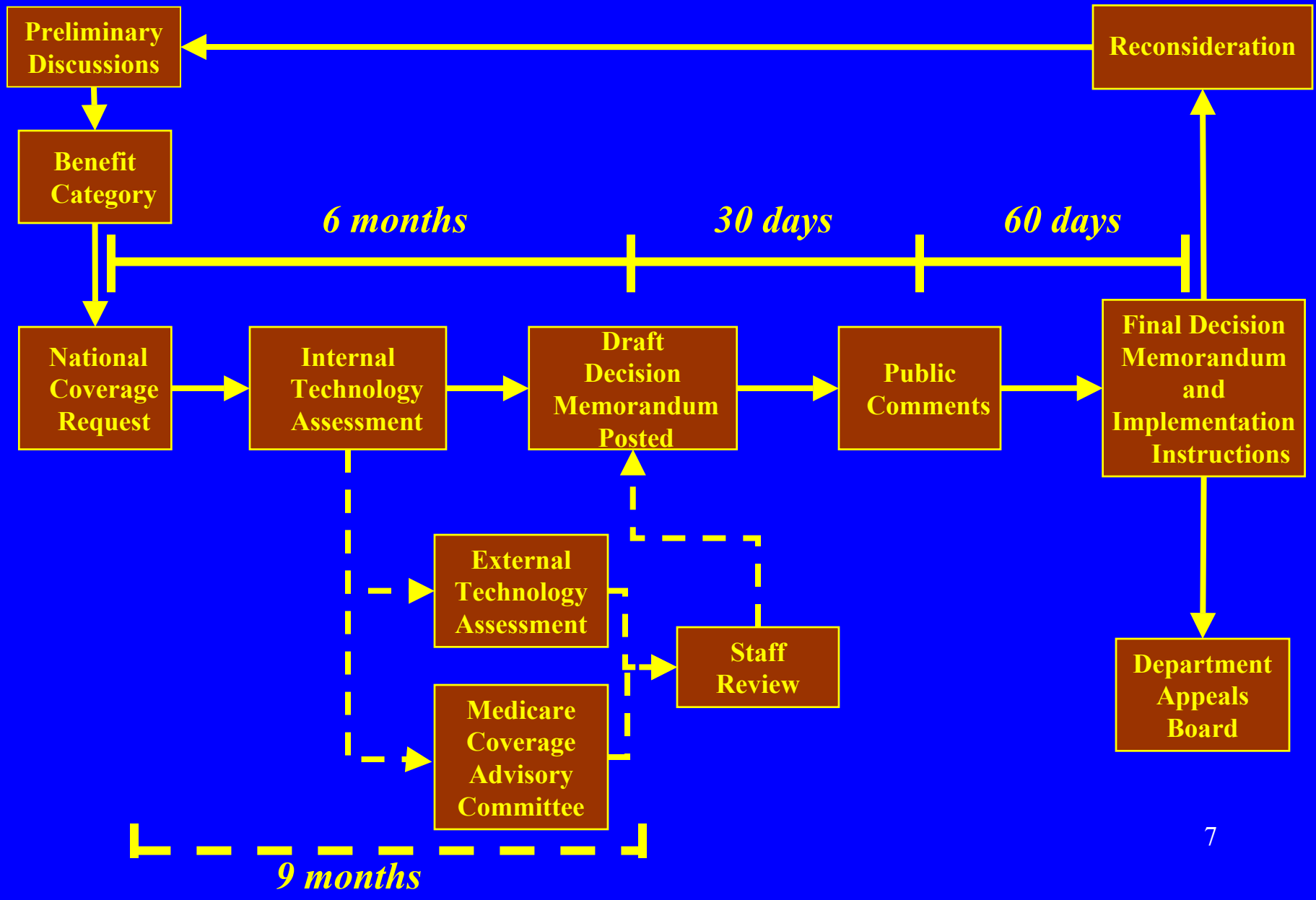
FDA

If the technology requires FDA approval, then that technology must have FDA approval for at least one indication.

Benefit Category Determination

- SSA 1861: Congress determines the services that CMS covers
- Examples:
  - Hospital services
  - Physician services
  - Colorectal cancer screening

MEDICARE NATIONAL COVERAGE PROCESS



Statutory Basis for Coverage

- Sec. 1862 (a)(1), Title 18, SSA
- ". . .no payment may be made. . .for expenses incurred for items or services. . . [which], except for items and services described in a succeeding subparagraph, are not ***reasonable and necessary*** for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Reasonable and Necessary

- Safe and effective (per FDA, if applicable)
- Adequate evidence to conclude that the item or service improves health outcomes
  - emphasis of outcomes experienced by patients
  - generalizable to the Medicare population
  - as good or better than current covered alternatives
- Future Agency action will provide greater detail on producing “adequate evidence”

Improved Health Outcomes

Evidence-based medicine

EBM: Definition

"...Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research."

Evidence-Based Medicine Working Group, JAMA (1992)

EBM

- Good Evidence
- Applicable Results

National Decisions

- National Coverage
- National Noncoverage
- National Coverage with restrictions
  - Specific populations
  - Specific facilities/physicians
  - Coverage with evidence development

Population Restrictions

Population in trial unless clear path to generalize results to Medicare population

Facility Standards

- Transplant centers
- Lung Volume Reduction Surgery
- Left Ventricular Assist Devices
- Carotid Stents
- Bariatric Surgery

Evidence Development

- Coverage with Appropriateness Determination

  R&N under 1862(a)(1)(A) but additional data needed to ensure the item or service provided in an R&N manner

- Coverage with Study Participation

  Not R&N under 1862(a)(1)(A) but R&N under 1862(a)(1)(E)

Recent Decisions

- ICDs
- PET scans for Alzheimer
- Colorectal Cancer drugs
- Cochlear implants
- PET scans for oncology indications
- Home Oxygen

"We will have to have more comprehensive and timely evidence on the value of new medical treatments. With this evidence, we could do a better job of helping patients find the right treatments for their needs and help health care providers make better use of quality measures and payment incentives. It would encourage the more rapid diffusion of new treatments that really are worthwhile. Together these steps will improve medical innovation, since it would be clearer to product developers that they will be rewarded when and only when their new treatments truly add value to patient care. We cannot get this valuable evidence unless more routine and extensive data collection and analysis tools are systematically built into our delivery of care."

Mark McClellan, Sept 2004

CMS/FDA

Part A&B: CMS coverage ≠ FDA approval

- Labeled indications may not be covered
- Unlabeled indications may be covered

CMS/FDA Cooperation

- Pre-approval & pre-coverage
- Postmarket surveillance

Contact Information

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