# CMS' Clinical Trial Policy – So Where Are We Now?

## The Trial Sponsor's Perspective

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# Current Policy is Inequitable

- Different treatment of drugs and devices
  - If IND trials deserve “deemed qualified” status, why not IDE trials?
- Some device trials covered under NCD, others covered under “Category B” reg., and others cannot be covered
  - Different coverage/payment formulas
- Basis goal – get new tech to beneficiaries – merits uniform policy implementation

# Current Policy is Confusing

- Definition of “covered services” is ambiguous
  - No mechanism for protocol review and preauthorization
  - No guarantee of uniform coverage across FIs under NCD
  - No guarantee of any coverage across FIs under regulation
- Severely complicates contracting with clinical sites

# July 19 Proposal was Improvement

- Qualifying criteria uniform under NCD
  - Self-certification under reasonably clear guidelines
- Narrowed the areas of service coverage ambiguity
- Removed most egregious payment flaw
  - Would pay for items/services covered outside a trial
- Failed to address some other critical flaws

# Should Trial Subjects Pay?

- Traditionally, they are spared any cost
  - Ethics: No promise of clinical benefit
  - Praxis: Why would they be willing to pay?
- IRBs and trial consent forms have typically enforced a “no cost to patient” rule
- Contracts between sponsors and sites have assumed no subject payment
- Medicare rules say otherwise

# Patient Financial Obligation in a Medicare Covered Trial

- The patient is responsible for normal copayment and/or deductible amounts
  - Fraud and Abuse rules forbid waiver by clinical site
    - No “safe harbor” for clinical research
  - Medicare Secondary Payer rules forbid sponsor from covering the obligation
    - A promise to pay “uncovered amounts” would make the sponsor primary payer
    - Work-arounds are clumsy and of dubious worth

# A Perfect “Catch-22”

Medicare desires to fund clinical research to make new technologies available more quickly to beneficiaries;

Ethics and common practice demand that clinical trial subjects be shielded from costs;

But

The available tools to shield the patient are either judged to be illegal or have the effect of eliminating Medicare funding

# These Issues Could Be Resolved

- Beyond the province of the Coverage group
- Require a coordinated Agency initiative
- DHHS General Counsel should review current interpretation re: secondary payer
- OIG could provide a supportive Advisory Opinion and/or a Safe Harbor for waiver of patient obligation in Medicare-covered research
- Nothing forthcoming as yet

# Sponsors and Sites Need to Contract

- Medicare support for clinical trials must allow for contract negotiation
- Requires clear and rational policies
  - Uniform principals for coverage qualification
  - Consistent and predictable coverage of services within trials
  - Program integrity rules that make sense for research settings
    - Safe harbor for sites for waiver of patient financial obligation
    - Allow sponsors to cover that obligation without further financial jeopardy

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