

# **Billing Third-Party Payors for Services to Patients/Subjects in Clinical Trials:**

## **Compliance Obstacles in Academic Medical Centers**

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# Agenda

- Background of Medicare Regulations relating to Billing for Clinical Trial Services
- Compliance Ambiguities: Pending Critical Unresolved Issues in the Medicare Regulations
- Compliance Obstacles Posed by AMC Organization and Structure

# Background of Medicare Regulations

- Old “Research Costs Regulation” governs the preparation of cost reports for facilities: reimbursable/recoverable costs of clinical trials are all those that do not exceed standard of care
- Old “Non-Covered Services Rule”: services that are required for delivery of a non-covered service or item are themselves not covered and not reimbursable by Medicare
- 1995: Regulations for reimbursement of clinical trials services in significant risk device trials: Category A (experimental) and Category B (investigational) devices

\*Now Centers of Medicare and Medicaid Services (CMS)

\*\*Now Medicare Evidence Development & Coverage Advisory Committee (MedCAC)

# Background of Medicare Regulations

- June 7, 2000 Executive Memorandum, issued by President Clinton, requiring Medicare to pay for “routine care costs” in clinical trials
- HCFA implemented a Clinical Trial NCD on September 9, 2000, with trial eligibility requirements and new coding requirements for clinical trial services billed to Medicare under the NCD
- 2006-2008: CMS reconsiders the Clinical Trial Policy NCD: goes nowhere, no substantive changes, despite many unresolved issues

# Clinical Trial Policy NCD

## Coverage for Services Rendered in Clinical Trials

- Medicare covers the **routine costs** of **qualifying clinical trials**, as well as **reasonable and necessary** items and services used **to diagnose and treat complications** arising from participation in **all clinical trials**.
- Primary change from old Medicare law is abrogation of the “Non-Covered Services Rule” in clinical trial context, for qualifying clinical trials
  - Bottom line: under old Medicare law, if service or item being tested is itself non-covered, all services in the trial are also non-covered
  - Under 2000 NCD, such services in these trials ARE covered

# Clinical Trial Policy NCD

## Coverage – Key Tests

- **What are the Key Tests to Determine if the Costs of a Trial are Coverable?**
  - Is it a qualifying clinical trial?
  - Are the items and services routine costs?
  - Are the routine costs reasonable and necessary? (i.e., does Medicare generally cover the services outside a clinical trial?)

# Clinical Trial Policy NCD

## Coverage – Is the trial a qualifying clinical trial (QCT)?

- Any clinical trial, to receive Medicare coverage of routine costs, must meet the following four requirements:
  1. Subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
  2. Trial must have therapeutic intent. It cannot be designed to test toxicity or disease pathophysiology, exclusively. **[BIG PROBLEM]**
  3. Trials of therapeutic interventions must enroll patients with diagnosed disease. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.
  4. The clinical trial must be "deemed" to have "desirable characteristics," e.g., solid scientific design, not duplicative of previous trials, protection of human subjects, conducted by reputable institution and investigator, etc.

# Clinical Trial Policy NCD

## Coverage – Is the trial a qualifying clinical trial (QCT)? (Cont'd)

- A trial is “deemed” to have the desirable characteristics if it is:
  - funded by NIH, CDC, AHRQ, CMS, DOD, or the VA;
  - supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD or the VA;
  - conducted under an investigational new drug application (IND) reviewed by the FDA; or
  - a drug trial that is exempt from having an IND under 21 CFR 312.2(b)(1).

# Clinical Trial Policy NCD

## Coverage – Are the items and services routine costs?

- Routine costs in clinical trials include items and services:
  - For which there exists a benefit category;
  - That are coverable by Medicare outside of a clinical trial;
  - That are typically provided absent a clinical trial (e.g., conventional care);
  - Required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
  - Needed for reasonable and necessary care arising from the provision of an investigational item or service--in particular, for the diagnosis or treatment of complications.

# Clinical Trial Policy NCD

## Coverage – Are the items and services routine costs? (Cont'd)

- Routine costs in clinical trials exclude items and services:
  - That are investigational, *unless otherwise covered outside of the clinical trial*;
  - That are statutorily excluded;
  - For which there is a national non-coverage decision;
  - Provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
  - Provided by the research sponsors free of charge for any enrollee in the trial.

# Clinical Trial Policy NCD

## Coverage of Complications of Clinical Trials

- Even if Medicare offers limited or no coverage of services related to a clinical trial, Medicare will **ALWAYS** cover treatment of complications, as long as the treatment items and services are generally covered by Medicare.

# Coverage of Services Rendered in Trials of Medical Devices

- 1995 regulations for services rendered to patients/subjects in clinical trials of significant risk devices remain effective and are independent of 2000 NCD
- Category A and Category B device trials coverage is allowed by CMS and FDA on case by case basis at time IDE is issued, but coverage can only be decisively determined by local Medicare intermediary and carrier
- Before billing ANY Category A or Category B device trial services to Medicare, intermediary and carrier must be informed and **MUST** approve
- This required practice has not been uniformly respected

# Critical Unresolved Issues: What is “therapeutic intent”?

- A study must have therapeutic intent to be a qualifying clinical trial under the NCD.
- CMS statements:
  - “The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.”
  - “The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes.”

# Critical Unresolved Issues: What is “therapeutic intent”?

- These questions are not academic; they have direct impact on drug studies that are Phase I and Phase II that may measure therapeutic benefit as a secondary objective but not a primary objective.
  - Impacts going-forward budgeting for research costs in such trials
  - Impacts potential past liability for claims already made and collected
- Cancer studies have the most at stake, since most Phase I drug studies may have therapeutic benefit as one objective, but not primary objective.

# Critical Unresolved Issues: CMS Commentary on Therapeutic Intent

- June 2006 Conference: At Forum on Regulation of the Association of Academic Health Centers (AAHC), CMS official states that in order to meet the therapeutic intent standard, the **“primary objective” of the research study must be measurement of therapeutic benefit**
- December 2006 MedCAC Hearing: “...there is in general the assumption that **many Phase Ones, if not most Phase Ones, currently aren’t covered in the clinical trial policy.**” Steven Phurrough, MD, Director of CMS Coverage & Analysis Group (CMS Transcript, p. 182)
- August 2007 Open Door Forum: [In response to a question on the therapeutic intent standard] “For those trials that are currently under way, they will have to live under whatever confusion they think there is around the current policy, the 2000 and the July 9th policy, and we will not attempt to clarify that any more than it is currently clarified.” Dr. Phurrough (CMS Audio recording)

# Critical Unresolved Issues: Local Medicare Contractor Role in Interpreting Therapeutic Intent

- Various local Medicare contractors have applied the “primary objective” test
- In the absence of clarity from CMS, local Medicare medical directors have the authority to interpret and make “reasonable and necessary” determinations
- October 17, 2007 CMS FAQ # 4: A provider with “trials that do not meet the existing criteria for deemed trials should contact their local Medicare contractors to determine whether items and services will be covered in that geographic area.”
- **VERY ALARMING:** we never before had to seek “preapproval” for coverage under the NCD!

## Critical Unresolved Issues: Coverage for Trials that are non-Device, non-NCD Trials

- We have historically billed for non-device, non-NCD trials under the old Medicare laws and regulations
- Basic billing standard has been: do NOT bill any costs that exceed “standard of care,” but ok to bill up to and including “standard of care” services
- This was not addressed or disputed at time of 2000 NCD
- But in the 2006-2008 discussions, CMS began to suggest that if a trial is non-device, non-NCD, then **NOTHING** in the trial can be billed to Medicare
- This has been shocking to the entire academic medical community, and remains unresolved and unclarified

# Critical Unresolved Issues: Medicare as Secondary Payor

- April 2004 letter from MSP regional authority indicated that if a private sponsor of a clinical trial had agreed in CTA to cover any costs of subject injuries that were denied by third-party payors (including Medicare and Medicaid), then that sponsor was committing itself to be the primary payor for these services
  - Rationale: Medicare and Medicaid are ALWAYS secondary payors, not primary payors
- This would mean that all claims previously submitted to Medicare that were related to subject injuries in trials with such CTA provisions were likely bad or false claims

# Critical Unresolved Issues: Medicare as Secondary Payor

- This would upset decades of CTA template practices, especially if the logic of this letter ruling applied to ALL clinical trial services, not just services related to subject injuries
- In 2008, in informal verbal comments, CMS has backed off the logical extension of the letter ruling, and has indicated that it will confine the ruling to CTA provisions relating to subject injuries only

# Critical Unresolved Issues: Applicability to Medicaid

- Medicaid is a partially federally funded program, but CMS does not issue detailed coverage rules
- Rather, coverage rules are left to state Medicaid authorities
- Most Medicaid payment regulations are much less detailed than Medicare regulations, and no state appears to have adopted anything like the 2000 NCD or the 1995 medical device trial rules
- Medicaid regs most often just limit payment to “reasonable and necessary services” and exclude payment for “experimental” services

# Critical Unresolved Issues: Applicability to Medicaid

- Bottom line: strictly interpreted, Medicaid – except in some specific exceptions, as when a state legislature has adopted laws requiring, for example, Medicaid coverage for pediatric oncology trials – does NOT cover ANY services required to conduct a clinical trial
- Arguably NO coverage under Medicaid for trials of unapproved drugs or unapproved devices
- CMS has refused to comment on this discontinuity

# Critical Unresolved Issues: Applicability to Private Insurance

- Specific state laws or regulations sometimes apply to private, state-regulated health insurance, e.g., mandating coverage of services in oncology clinical trials or pediatric clinical trials
- Varies from state to state
- Many health insurance plans are exempted from state health insurance regulation by ERISA, due to self-funded status of the plans, so state laws and regs would not apply to those plans
- Private insurance and private managed care contracts may have specific provisions – in template contracts or as result of negotiations – that govern what will and will not be covered in clinical trials of eligibles/enrollees
- Is there coordination between billing compliance on these issues and the managed care contracting staff at the AMC?

# Managing Research Billing Compliance

- **Clinical research billing compliance involves:**
  - Identifying clinical research services that can or cannot be billed to third-party payors
  - Ensuring processes are in place to bill to third-party payors only services that can appropriately be billed
  - To the extent possible, distinguishing among payors: private managed care and private insurance and their varying contracts, Medicaid programs, Medicare
  - Harmonizing relevant portions of study documents (CTAs, study budgets, protocols, informed consent forms) in accordance with billing rules

# Managing Research Billing Compliance

## Coordination is Key to Compliance

1. Identifying patients who are research subjects and are receiving research services
2. The protocol's schedule of events: understanding and identifying what is standard of care and what is research
3. Distinguishing between those services already paid in grant or sponsored study agreement vs. those services that can and should be billed to third-party payors
  - Requires coordination of study team with grants and contracts office that negotiates study budgets
4. Distinguishing between beneficiaries/enrollees of Medicare, Medicaid and private insurance/managed care, if there are coverage differences in the same trial
5. The financial disclosure language of the study's informed consent: what is said to patients/subjects about their own payment obligations

# Research Billing Compliance Risks

- Ignoring clinical research billing rules can lead to:
  - Billing for services that are already paid by the sponsor (double billing)
  - Billing for services promised free in the informed consent
  - Billing for services that are for research-purposes only
  - Billing for services that are part of a non-qualifying clinical trial
  - Billing for services in device trial in which no intermediary or carrier has approved billing under the Category A and Category B device rules

# Compliance Barriers

- Division between billing systems of hospital and faculty practice(s)
- Divisions between pathology, radiology, anesthesiology and general facility billing systems
- Divisions among various departments in billing for professional services
- Lack of coordination between PI/study team and staff who negotiate CTA budget
- PI over-eagerness to classify trial-related services as “standard of care”
- Incentives created by grant/contract residual practices for PIs and study teams to bill services to third-party payors, and not to research accounts

## Compliance Barriers (cont'd)

- NIH and private sponsor refusal fully to fund research-only services that cannot legitimately be billed to third-party payors
- Inability to distinguish research vs. non-research patients at time of service
- Inability to remove charges from electronic billing system and direct charges to grant or contract account, at time of service
- Inability to direct charges, at time of service, based on payor class
- Restrictions on subject enrollment discrimination by payor class
- Emergency visits, or non-research-related visits, by research subjects
- Respecting Medicare coding requirements

# Take Away Points: Compliance Tasks

- **Develop a database of all research studies performed at or by the AMC**
- **Develop a database of patients who are enrolled in the research studies; identify at time of registration/appointment**
- **Require coverage analyses before research study budget has been negotiated, in order to determine whether the study is financially viable**
- **Require coverage analyses that determines “billability” of trial-related items and services, before billing for services is done**

# Take-Away Points: Compliance Tasks

- **Mechanisms to distinguish among payors, if payment policies among payors differ in the same trial**
- **Establish safeguards to ensure that claims are appropriately either directed to an internal research account or to third-party payor**
- **Develop an education program for investigators and study coordinators**
- **Develop an auditing and monitoring program that samples billing for services during research studies**

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