KING & SPALDING

Best Practices: Compliance for Medicare Coverage, Reimbursement and Beyond

Clinical Trials: Emerging Legal Threats

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Overview

- HIPAA Privacy
- FDA standards differ from CMS standards
- Understanding 2007 CMS Clinical Trial Policy
  - Qualifying Trials
  - Routine Costs
  - Coverage with Evidence Development

Overview (contd.)

- Registration with www.clinicaltrials.gov under FDAAA 2007
- Risk Areas
- Enforcement Trends and Compliance Tips

Brief HIPAA Privacy Overview for Clinical Research

- The Privacy Rule permits a covered entity to use or disclose PHI for research in certain cases, including:
- If the subject of the PHI has granted specific written permission through an Authorization that satisfies section 45 C.F.R. 164.508
- For reviews preparatory to research with representations obtained from the researcher that satisfy section 45 C.F.R. 164.512(i)(1)(ii)
- For research solely on decedents' information with certain representations and documentation obtained from the researcher that satisfies section 45 C.F.R. 164.512(i)(1)(iii)
- If the covered entity receives appropriate documentation that an IRB or a Privacy Board has granted a waiver of the Authorization requirement that satisfies section 45 C.F.R. 164.512(i)
- If the information is released in the form of a limited data set, with certain identifiers re-moved and with a data use agreement between the researcher and the covered entity, as specified under section 45 C.F.R. 164.514(e)

Brief HIPAA Privacy Overview for Clinical Research

- Additional resources available at HHS Office of Civil Rights Web Site:
  - http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/

Clinical Trial Strategy
FDA and CMS Regulatory Expectations

- **1976 Medical Device Amendments** – FDA risk-based regulation of devices
  - Premarket Approval ("PMA") for Class III (highest risk) devices: "**reasonable assurance of safety & efficacy**"
  - Premarket Notification for Class I and II devices: "Substantial equivalence" to a device already marketed
- **Social Security Act Section 1862(a)(1)(A)** – CMS National Coverage Decision
  - Determination on a national level of items and services that are "**reasonable and necessary**"

Clinical Trial Strategy: FDA and CMS Regulatory Expectations

- FDA "reasonable assurance of safety and efficacy" determination does *not* equal:
  - CMS determination of "reasonable and necessary" under Section 1862(a)(1)(A) of Social Security Act
  - CMS determinations can differ from the FDA-approved labeling
    - CMS permits certain off-label coverage and reimbursement as well:
      - drugs prescribed for "medically accepted uses" supported in recognized compendia
      - For example, investigational drugs that have received an FDA reviewed IND application or are IND exempt, or IDE devices

Highlights of Revised Medicare Clinical Trial Policy

- Revised Medicare Clinical Trial Policy issued October 17, 2007
  - ❖Minor revisions of original 2000 Medicare Clinical Trial Policy
    - ✓Clarification of payment for "routine" costs that are studied (investigational item or service) in a clinical trial
    - ✓Added Coverage with Evidence Development (CED) to Medicare Clinical Trial Policy

Revised Medicare Clinical Trial Policy

- Medicare will cover routine cost of qualified clinical trials, including:
  - Deemed clinical trials
  - Clinical trials that have certified (by principal investigator) that they meet qualifying criteria
  - Clinical trials required under National Coverage Determination process

    (* new coverage)

Revised Medicare Clinical Trial Policy

Routine costs include:

- all items and services that are otherwise generally covered by Medicare (e.g., conventional care)
  - items and services covered by Parts A, B
  - items and services not otherwise excluded by statute (e.g. cosmetic items) or excluded under national coverage decision (i.e., noncoverage decision)
- investigational item or service itself if Medicare would "[cover] outside of the clinical trial"

  (* new clarifying language)

Revised Medicare Clinical Trial Policy

Routine costs also includes:

- Conventional patient care covered by Medicare, including medically reasonably and necessary care arising from use of the investigational item or service
- Items or services used to administer the item or service studied (e.g. administration of experimental drug or implantation of experimental medical device)
- Clinically appropriate monitoring or prevention of complications from clinical trial

Revised Medicare Clinical Trial Policy

Routine Costs DO NOT include:

- The investigational item or service, itself, unless Medicare would cover outside of trial;
- Items and services for which there is no benefit category;
- Items and services, which are statutorily excluded;
- Items and services for which there is a national non-coverage decision;

Revised Medicare Clinical Trial Policy

Routine Costs DO NOT include (contd.):

- Items and services 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);
- Items and services customarily provided by the research sponsors free of charge; and
- Items and services provided solely to determine trial eligibility

Revised Medicare Clinical Trial Policy

Routine costs must be incurred during a qualifying clinical trial

I. Elements of Qualifying Clinical Trial:

- Trial evaluates an item or service in Medicare benefit category and is not statutorily excluded
- Trial has therapeutic intent and must not be designed exclusively to test toxicity or disease pathophysiology
- Trial of therapeutic intervention must enroll patients diagnosed with disease rather than healthy volunteers; trial of diagnostic intervention may enroll health control group of patients

Revised Medicare Clinical Trial Policy

II. Elements of Qualifying Clinical Trial (contd.)

1. Principal purpose is to test whether treatment will improve health outcomes
2. Well-supported by scientific and medical information or intended to clarify or establish health outcomes of comment treatment
3. No unjustifiable duplication of existing studies
4. Trial design is appropriate to answer research question asked

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Revised Medicare Clinical Trial Policy

II. Qualified clinical trial (contd.)

5. Sponsored by credible organization or individual capable of successfully completing trial
6. Comply with 45 C.F.R. Part 46 HHS human subject protection regulations
7. Conduct trial according to appropriate standards of scientific integrity

Qualification Process for Clinical Trials

Sponsor must:

- Enroll trial at www.clinicaltrials.gov
  - Failure to do so may lead to denied claims, and, in worse case scenario, government enforcement action to recover claims paid
- Notify clinicaltrials@cms.hhs.gov
- Satisfy remaining qualification criteria
  - For example, meet any specific coverage criteria established by local Medicare contractor
  - Medicare contractor discretion unchanged by revised Medicare Clinical Trial Policy

Automatically Qualified or "Deemed" Clinical Trials

Deemed Trials:

1. Funded by:
   - ✓ Agency for Healthcare Research and Quality (AHRQ)
   - ✓ Centers for Disease Control and Prevention (CDC)
   - ✓ Centers for Medicare & Medicaid Services (CMS)
   - ✓ Department of Defense (DOD)
   - ✓ Department of Veterans Affairs (VA)
   - ✓ National Institutes of Health (NIH)
2. Supported by center or cooperative groups funded by any of the above agencies

Automatically Qualified or "Deemed" Clinical Trials (contd.)

Deemed Trials (contd.):

3. Trials conducted under an Investigational New Drug (IND) application reviewed by FDA or IND exempt trials
   - 21 C.F.R. 312.2(b)
   - Sponsors of IND or IND exempt trial must identify trial by email to clinicaltrials@cms.hhs.gov

Investigational Devices Used In Clinical Trials

- **FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices – September 15, 1995**
  - Joint Agency Agreement between HCFA and FDA resulted in devices being categorized as Category A or Category B
  - Medicare would extend coverage to Category B devices that are being studied as part of a FDA approved clinical trial, but have not been approved for marketing

Intent of Agreement

- Medicare beneficiaries be assured greater access to the latest advancements in medical technology
- May help to improve the quality of clinical studies by ensuring that the Medicare patient population is included in the studies and the devices are being tested on the appropriate patient population
- The change in policy will facilitate enrollment into clinical trials
- Clarify Medicare coverage of reasonable and necessary medical services during trials for investigational devices

Investigational Devices

- Medicare contractors consider information about the device's use within the context of the FDA-approved clinical trial and patient protocols
- Medicare contractors consider whether the device use is:
  - medically necessary for the particular patient;
  - whether the amount, duration, and frequency of use or application of the service are medically appropriate; and
  - whether the device is furnished in a setting appropriate to the patient's medical needs and condition

Investigational Device Exemption Requests Category A

- Unchanged by revised Medicare Clinical Trial Policy
  - Category A (FDA Class III or experimental) where FDA has not determined device is safe and effective
  - Medicare covers routine costs of qualifying clinical trials using IDE Category A devices, on or after Jan. 1, 2005, but before Jan. 1, 2010
  - Category A device used in trial is intended for diagnosis, monitoring or treatment of an immediately life-threatening disease or condition
    - Immediately life-threatening disease or condition as "a state of a disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely to occur without early treatment"
  - Category A device is not covered

Investigational Device Exemption Requests Category B

- Category B (FDA Class I, II or III, non-experimental) devices have no initial questions about safety or efficacy
  - usually updates to or evolution of proven technology
- Medicare covers Category B devices if they are considered reasonable and necessary, AND if all other applicable Medicare coverage requirements are met

Application for Medicare Coverage of Investigational Device

- Providers must furnish Medicare contractor with the following information **prior to** submission of a claim for payment:
- For Category B devices submit
  - Copy of FDA approval letter furnished to sponsor
  - name of the device (both trade, common or usual and classification name)
  - action taken to conform to any applicable FDA special controls
  - narrative description of the device to enable payment determination

Application for Medicare Coverage of Investigational Device (contd.)

- Providers must furnish Medicare contractor with the following information **prior to** submission of a claim for payment:
- For Category B devices submit (contd.)
  - statement indicating how device is similar to and/or different from other comparable products, and
  - provider's protocol for obtaining informed consent from clinical trial subjects (informed consent document approved by Institutional Review Board)

Application for Medicare Coverage of Investigational Device (contd.)

- Providers must furnish Medicare contractor with the following information **prior to** submission of a claim for payment:
- For Category A devices submit
  - in addition to the items listed for Category B devices (*e.g.*, FDA approval letter etc.)
  - information necessary to review the clinical trial to determine whether the device is being used for the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition *(e.g.*, the study protocol, etc.)

Application for Medicare Coverage of Investigational Device (contd.)

- Application information should be sent to:
  - Contractor Medical Director
  - Attn: IDE applications
- Providers may bill for either an Investigational Device Exemption or a clinical trial, **but not both**
- Check local Medicare contractor (Fiscal Intermediary, Carrier or Medicare Administrative Contractor) Policy for specific coding and billing guidance

Coverage with Evidence Development Added to Medicare Clinical Trial Policy

- What is Coverage with Evidence Development?
  - Medicare coverage conditioned on the collection additional evidence (evidence development):
  - through National Coverage Determination process
  - may be required for items and services used in clinical trials when there is some evidence of significant medical benefit, but insufficient evidence to support a “reasonable and necessary” determination
  - conditional upon meeting standards of patient safety and clinical evidence, items and services not otherwise covered
  - would be considered “reasonable and necessary” in the context of a clinical trial

Routine Costs in Clinical Trial Conducted Under Coverage with Evidence Development

- Routine costs covered
- Item or service studied is not covered
- Clinical trial must meet specific requirements under Coverage with Evidence Development National Coverage Decision
- No guarantee of favorable coverage determination at conclusion of clinical trial

Coverage with Evidence Development

- Coverage with Study Participation
  - requires another clinical trial
- Coverage with Appropriateness Determination
  - requires data submission to registry
- Medicare coverage of routine costs in clinical trial or registry, but administrative costs and cost of item or service studied generally not covered

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National Coverage Decisions Requiring Coverage with Evidence Development

- Chemotherapy for Colorectal Cancer (Clinical Trial), NCD 110.17
- Positron Emission Tomography (Fluoro-D-Glucose) (PET (FDG)) for Dementia and Neurodegenerative Diseases (Clinical Trial), NCD 220.6.13
- Home Use of Oxygen in Approved Clinical Trials, NCD 240.2.1
- PET (FDG) for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung and Testicular Cancers (Registry), NCD 220.6.14
- Implantable Cardioverter Defibrillators (ICDs) (Registry or Clinical Trial), NCD 20.4
- Artificial Hearts (Clinical Trial), CAG-00322N, May 1, 2008 (Decision Memo: http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=211)

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Medicare Clinical Trial Billing Tips

- Comply with Medical Records Documentation Requirements (not required with claim, but make available on request)
  - Beneficiary records must include trial name
  - Sponsor; and
  - Sponsor-assigned protocol number

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Medicare Coverage and Reimbursement Tips (contd.)

- Medicare Coverage Database and contractor websites may contain updated coding and billing requirements:
- For example, effective January 1, 2008:
  - CMS is discontinuing QA, QR, and QV, Health Common Procedure Coding System Code modifiers to identify investigational and routine clinical services used in qualifying clinical trials
  - Implementation date no later than April 7, 2008
  - CMS Transmittal 1418, Change Request 5805

Medicare Coverage and Reimbursement Tips (contd.)

- Q0 - Investigational clinical service furnished in qualified/approved clinical trial
  - Investigational clinical services are items/services that are investigated as an objective within the study
  - Q0 replaces
    - » QA (FDA Investigational Device Exemption) and
    - » QR (item/service furnished in a Medicare specified study)
- Q1 - Routine clinical service furnished in qualified/approved clinical trial
  - Routine clinical services
  - Q1 replaces
    - » QV (routine care item/service furnished in a qualifying clinical trial)

Medicare Secondary Payer Law

- Medicare Secondary Payer law (42 U.S.C. 1395y(b)(2)(A)(ii) (amended by MMA § 301(b)(1)): "business . . . professional entity 'deemed' to have a 'self-insured plan' if it carries its own risks, whether by failing to obtain insurance or otherwise"
- CMS interpretation in April 2004 letter: Statement by trial sponsor that it would "pay for medically necessary services" for complications related to clinical trial considered "insurance" for primary payment responsibility

Medicare Secondary Payer Law (contd.)

- Medicare is payer of last resort, not clinical trail sponsor, when sponsor guarantees payment for patient care arising from clinical trial complications
  - No clarification in Revised Medicare Clinical Trial Policy
  - Addressed further in MLN Matter SE0822 Revised:
    - "If the routine costs of the clinical trial are not billed to indigent non-Medicare patients because of their inability to pay (but are being billed to all the other patients in the clinical trial who have the financial means to pay even when his/her private insurer denies payment for the routine costs), then a legal obligation to pay exists. Therefore, Medicare payment may be made …. "
- Requires careful language in trial agreements and in discussions with clinical trial participants
- Need CMS or Congress to clarify whether policy reflected in April 2004 letter is consistent with Congressional intent of Medicare Secondary Payer law

Medicare Secondary Payer Law (contd.)

Section 111 of Medicare, Medicaid, and SCHIP Extension Act of 2007

- Potentially creates a reporting obligation for clinical trial sponsor, principal investigator, or clinical trial site
  - Based on April 2004 CMS letter, clinical trial sponsor who guarantees payment for trial-related complications in trial agreement is a guarantee of insurance and therefore a self-insured plan that is primarily responsible for payment for medical costs incurred to treat injured participants for trial complications
  - Medicare payment is secondary

Medicare Secondary Payer Law (contd.)

Section 111 of Medicare, Medicaid, and SCHIP Extension Act of 2007

- Requires on or after the first day of the calendar quarter that is 18 months after enactment of Act (*i.e.*, July 1, 2009)
  - Submission of certain information by, or on behalf of applicable plans, including self-insurance
    - Determination of whether a patient is entitled to Medicare benefits
    - Information, including patient identity, and other information deemed necessary for coordination of benefits to the HHS Secretary
- Failure to meet reporting requirement is subject to civil monetary penalty of $1000 per day of noncompliance
- Potential prosecution for the submission or causing the submission of false claims in violation of federal False Claims Act

Food and Drug Administration Amendments Act of 2007

- CMS is reviewing clinical trial-related provisions and will issue additional rules or guidance:
  - "We are working to develop clearer standards for Medicare-covered trials that will be consistent with the FDA AA 2007, which was enacted after the NCD public comment period expired. CMS is reviewing this legislation to ensure that we are not imposing duplicative or inconsistent standards."
  - "Final Decision for Clinical Trial Policy Qs and As" available at http://www.cms.hhs.gov/determinationprocess/downloads/id210qa.pdf

Clinical Trial-Related Provisions of FDAAA

- Requires registration of trials for all diseases and conditions at www.ClinicalTrials.gov including:
  - Summary and title intended for lay public
  - primary purpose
  - primary disease or condition studied
  - intervention
  - start date and expected completion date
- Clinical Trial Registry database must be searchable and user-friendly to public

Clinical Trial-Related Provisions of FDAAA (contd.)

- Must certify compliance with the clinical trial databank requirements at 42 U.S.C. 282(j)(5)(B) using FDA form to include:
  - National Clinical Trial (NCT) numbers
  - Certification must accompany submission to FDA on or after December 26, 2007

Clinical Trial-Related Provisions of FDAAA (contd.)

- Effective April 1, 2008, Medicare began encouraging voluntary submission of NCT numbers on claims
  - Transmittal 310, January 18, 2008
    - MLN Matters MM5790
  - CMS will use this number to identify all items/services furnished to beneficiaries during clinical trial

Clinical Trial-Related Provisions of FDAAA (contd.)

- Voluntary, so claims submitted without the clinical trial number will be paid the same as claims containing a number
- CMS has not indicated whether it plans to implement mandatory NCT number reporting

Compliance Risk Areas

- Ineffective oversight and tracking of Medicare routine costs and “free” items and services
- Consider: OIG Draft Model Guidance for PHS Research Awards:
  - http://oig.hhs.gov/publications/docs/press/2006/ResearchCPG-finalrelease06072006.pdf
- OIG 2009 WorkPlan:
  - **Financial Conflicts of Interest in Research Funded by the National Institutes of Health**
    - OIG will review NIH’s oversight of grantees’ compliance with financial conflicts-of-interest requirements
  - **Colleges’ and Universities’ Compliance With Cost Principles**
    - OIG will review colleges’ and universities’ compliance with selected cost principles governed by OMB Circular A-21, Cost Principles for Educational Institutions
  - **Use of Data and Safety Monitoring Boards in Clinical Trials**
    - OIG will review the extent to which Data and Safety Monitoring Boards (DSMB) monitor data in clinical trials consistent with June 1998 NIH Policy for Data and Safety Monitorin
- NIH Time and Effort Reporting
  - ensure that institution has implemented effective measures to ensure researchers do not bill for more effort than is possible
- Charge Allocation to Grant Awards
  - implement effective accounting systems to properly allocate funding by source
- Cost transfers
  - ensure that cost transfers comply with NIH requirements, including supporting sufficient supporting documentation

Compliance Risk Areas (contd.)

- False Claims Act
  - Certain clinical research areas are at risk for FCA liability:
    - fraudulent Medicare billing, e.g. billing for “free” items and services, and double billing
    - scientific misconduct: United States ex rel. Condie v. Regents of the University of California, 1993 U.S. Dist. LEXIS 21384 (N.D.Cal. 1993); United States ex rel. Milam v. Regents of University of California, 912 F. Supp. 868 (D. Md. 1995)
    - grant fraud, e.g. submission of false information on grant applications (misrepresentation of PI identity): United States ex rel. Wu v. Thomas Jefferson University (settled 2000); see also United States ex rel. Cantekin v .University of Pittsburgh, 192 F. 3d 402 (3rd Cir. 1999), cert. denied, 531 U.S. 880 (2000)
    - cost allocation fraud

Best Practices for Compliance

- Engage in discussions with major payers in area, including Medicare, regarding streamlining decisions regarding coverage during clinical trials
  - *Example, ensure that you notify Medicare Contractor Medical Director describing trial involving Category B device and obtain notification that coverage requirements are met before billing for device and routine costs*
  - Need to develop process for identifying services provided in a clinical trial
- Need to review protocols to determine which services should and shouldn't be billed and audit to ensure billing rules followed
- Ensure compliance with billing requirements in
  - Medicare Claims Processing Manual, Chap. 32, Section 68 and 69, as applicable
  - NCD Manual, Section 310.1

Best Practices for Compliance (contd.)

- Ensure compliance with federal grant authorities:
  - NIH Grants Policy Statement (Dec. 2003)
  - NIH Office of Extramural Research, Financial Questionnaire: Evaluation of Management Systems
  - OMB Circular A-21 - Cost Principals for Educational Institutions
  - OMB Circular A-110 - Uniform Administration Requirements for Grants and Agreements with Higher Education Institutions, Hospitals, and Other Non-Profit Organizations
    - 45 C.F.R. Part 74
  - OMB Circular A-133 - Audits of State, Local Governments, and Non-Profits
  - PHS Form 398, Application for PHS Grant

Thank You

Questions?