The UT System Office of Health Affairs, in conjunction with the UT Systemwide Compliance Office, has developed the following Guiding Principles for Clinical Trial Billing for consideration with the UT System health institutions. The complexities of billing for clinical research are enormous and the UT health institutions must stay vigilant in the pursuit of excellence in the research and patient care enterprises.

Our hope is to continue a collaborative dialogue with the campuses on these issues and the best practices which may already be in place across the campuses. Representatives from Health Affairs and Systemwide Compliance have validated the appropriateness and reasonableness of these principles with representatives from each institution. The authoritative sources used to develop these guiding principles are included at the end of this document for your reference.

I. Support Structure
   a. Senior Level Champion – The ownership of the clinical trial billing process is (1) assigned and (2) openly acknowledged and accepted by a senior-level champion within the institution. This champion is empowered by the president and has sufficient influence and resources to assure accuracy of clinical trial billing across the enterprise.
   b. Oversight – The institution and the senior-level champion need a mechanism in place to oversee the detailed procedures which are completed in order to achieve the guiding principles. As part of this mechanism, appropriate roles and responsibilities are defined and assigned for oversight of the billing for clinical trials.
   c. Tracking/Management Tool – The institution should have a mechanism to register, record and/or track all clinical trials and trial participants at the institution (e.g., use of a clinical trial management system)

II. Policies and Procedures
   a. General - Appropriate policies and standards addressing the complexities of billing for clinical trials are established, followed and enforced through well-publicized disciplinary guidelines.
   b. Qualifying Clinical Trial - The Principal Investigator and the institution (i.e., the billing provider) certify the trial meets the requirements of a qualifying clinical trial and that the routine costs have been appropriately identified before billing occurs.
   c. Patient Trial Enrollment – Patients are not enrolled in a clinical trial until all financial agreements/documents have been finalized and reconciled against each other. These documents may include, but are not necessarily limited to, the sponsor contract or agreement, informed consent, cost/budget analysis or grid, schedule of events and the trial protocol (including when revisions are made).
   d. Regulatory/Billing Requirements – Clinical trials follow all pertinent laws and regulations for coverage and billing including, but not limited to the following:
      i. Services performed must meet the legal definition of medical necessity
      ii. There must be an effective process for seeking written approval from the local Medicare contractor for clinical device trials.
      iii. Condition code 30, ICD-9 code V70.7 and HCPCS modifiers Q0/Q1 are appropriately added to services at the claim and/or line-item level for patients in qualifying clinical trials.
      iv. Split billing occurs, as appropriate, for Medicare managed care enrollees in qualifying clinical trials.
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v. Providers' research and billing enterprises communicate effectively enough with one another to supply the 8-digit clinical trial number for qualifying clinical trials for which routine costs will be billed.

e. **Residuals** – Institutional policies should exist for handling residual amounts.
   i. Grant/contract residual practices should incentivize efficient use of resources and not incentivize the Principal Investigators and study teams to bill services to third-party payors instead of to research accounts.
   ii. Principal investigators and department leadership should be held accountable for appropriate billing practices and for subsidizing clinical trials which do not fully cover all the costs.

f. **Medical Records** - The billing provider must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information does not need to be submitted with the claim but must be provided if requested for medical review.

III. **Budget/Coverage Analysis**
   a. A financial coverage analysis should be performed for every clinical trial. This analysis should include:
      i. An accurate, comprehensive budgeting grid or other appropriate document detailing each service provided (including all billing codes) within the context of the clinical trial as well as the billing eligibility of each item.
      ii. Use of a standardized fee sheet, or standardized procedure to obtain and report appropriate prices/costs for the services to be performed during the clinical trial.
      iii. A Medicare coverage analysis that delineates the services covered/billable under the NCD/LCD, or via FI/MAC approval.
   b. The coverage analysis policies and procedures should be vetted through the oversight group to ensure that the best practice compliance standards outlined in these guiding principles are achieved.

IV. **Auditing & Monitoring**
   a. Appropriate internal auditing and monitoring of clinical trial billing occurs. This auditing and monitoring should include, but is not limited to:
      i. Reporting and allocation of residuals
      ii. Rebills of clinical trial accounts
      iii. Sponsor identified overpayments
   b. When problems are detected, any billing errors are rebilled and/or refunded appropriately, the appropriate compliance personnel/committee is notified, and prompt corrective action occurs.

V. **Education/Outreach**
   a. An education and training program for new and existing faculty and staff should exist to ensure all involved parties are knowledgeable about the governing laws, regulations, and rules.
   b. The education/outreach program should cover the relevant policies and procedures, as well as provide targeted compliance training to those individuals involved in operating and billing for the clinical trials at your institution.

Last updated October 2012
Revisions Approved by SECC 10/22/12
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Regulatory Guidance

- “FDA-Approved IDE and Clinical Trial Part A Billing Instructions,” TrailBlazer Health Enterprises, LLC., June 2009
- “FDA-Approved Investigational Device Exemptions (IDE) Pre-Approval Submission Checklist,” TrailBlazer Health Enterprises, LLC., March 2009
- 42 CFR 405.207; 42 CFR 405.209
- CMS One-Time Notification, Pub. 100-20, Transmittal 310, January 18, 2008
- Medicare Benefit Policy Manual Ch. 14
- Medicare Claims Processing Manual Ch. 32, Sec. 68.3-68.4; 69.3; 69.6;
- Medicare NCD for Routine Costs in Clinical Trials (310.1)
- MLN Matters: MM3548
- Social Security Act 1862(a)(1)(a); 1862(m)
- Medicare A/B Reference Manual: [Chapter 7 - Clinical Trials and IDE Requests], Novitas Solutions.

Best Practice Guidance (Scholarly journal articles, Subject matter expert presentations, etc.)

- “Clinical Trials Administration Toolkit,” The Association of Academic Health Centers, 2008
- Boyd, C. and Meade, R. “Clinical Trial Billing Compliance at Academic Medical Centers,” Academic Medicine, 2007; 82:646-653

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