Louisiana State University
Health Care Services Division
Baton Rouge, LA

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Deputy Chief Executive Officer
LSU Health Care Services Division

2/15/17
Date

Chief Medical Officer
LSU Health Care Services Division

2/15/17
Date

Purpose and Scope:
The purpose of this policy is to establish minimum uniform billing requirements and conditions when a Louisiana State University Heath Care Services Division (HCSD) hospital is authorized to participate in research activities.

This policy applies to HCSD Headquarters, HCSD hospitals, employees and medical staff/faculty regardless of medical school affiliation (LSU, Tulane and Ochsner faculty, etc.) who conduct research in HSCD hospitals regardless of funding source.

Policy Statement:

a. It is the policy that HCSD hospitals faculty, providers and staff work collaboratively with the sites of practice plans to ensure that billing for costs incurred in the conduct of research activities occur only as appropriate

   i. Any billing to Medicare, Medicaid, another third party insurer, or to the research subject for professional or clinical services, drugs, devices or tests provided in the context of clinical research study must be:
   ii. consistent with the applicable billing rules of the third party payor being billed; this will be accomplished in coordination with the research staff and the Patient Accounting staff,
   iii. consistent with any contractual obligations entered into by HCSD or sites of practice, and
   iv. fully disclosed in the Informed Consent Document signed by the research subject.

b. It is the policy of HCSD that each clinical study will be charged and coded based on the actual services rendered. The billing plan developed as part of the detail study budget will serve as a guide of how charges will be directed to the appropriate responsible party (i.e. the sponsor or the patient).

The billing plan will:

1) Delineate the services, drugs, devices, and tests to be rendered in the context of the clinical study;
2) Identify which services, drugs, devices, and tests must be billed to the study, or which are appropriate to be billed to the patient or the patient's insurer (See Appendix B); and
3) Be updated and provided to appropriate billing staff at the appropriate site of practice if amendments are made to the contract or protocol.
4) It is the policy of HCSD that all study related documents will contain consistent statements with respect to the services that will be provided by the sponsor and which services will be billed to a third party payer or the research subject.
5) It is the policy of HCSD that all faculty, providers and staff shall follow the safeguards established by HCSD and each practice site to ensure that all rendered services and items are billed and reimbursed appropriately.

c. It is the policy of HCSD that all study subjects receiving procedures for clinical research purposes at any HCSD hospital are properly identified and classified for appropriate billing and reimbursement.

Procedure

The Principal Investigator (PI), department chair or designee and Research Oversight Committee will work collaboratively with staff at the Central Billing Office in order to ensure compliance with the rules for billing federally funded health programs and third party payers for services, drugs, tests and procedures rendered in the clinical research context. As individual facilities have unique operations, each site of practice is granted the right to develop its own written procedures to address how it will meet the requirements of this policy. It is the PI's responsibility to inquire about the particulars of that policy at the site of interest. The responsibilities of the PI, according to HCSD, are as follows:

- Develop a detailed budget (Appendix A) with billing plan (Appendix D) as aforementioned
- Ensure that all study related documents contain consistent language regarding which costs will be reimbursed by the study sponsor and which services will be billed to a patient or the patients insurer
- Establish safeguards to ensure that all charges are billed appropriately, including tracking all study related services and checking them against invoice reports prior to billing
- Report any billing concerns to the appropriate billing staff for review and/or correction.
- Follow all other clinical research implementation and billing procedures determined by the site of practice.

Audit & Compliance Requirements

It is the intent of HCSD and the sites of practice to bill clinical research activities appropriately. Therefore, alleged violations of this policy shall be reported to the Compliance office. This includes billing issues that have been reported but remain unresolved. Allegations will be addressed in a timely manner by the appropriate compliance office staff.

Failure to Comply

1. **Hospital**
   Failure to comply with this policy could result in the refund of current sponsored project money, as well as the loss of future clinical research opportunities.

2. **Principal Investigator**
   Failure to comply with this policy could result in the loss of research privileges at the sponsoring LSU-HCSD hospital. If the failure to comply with the policy reveals misconduct on the part of the PI, the matter will be referred to the hospital administrator and medical staff for disciplinary action up to and including the termination of medical staff privileges.

3. **Employees**
   Any employee, who is found to have intentionally violated this policy or the procedures of the hospital, as they relate to clinical trials /clinical research, may be subject to disciplinary action, up to and including termination of employment in accordance with hospital regulations, the rules of the Department of State Civil Service and/or LSU-HCSD policies.

Definitions:

A. Sponsored Project: Services/programs/activities underwritten by an external organization (governmental or nongovernmental). Awards can be "financial" or "non-financial," research or non-research, and are intended to fulfill a general purpose identified by the sponsoring agency.

B. Types of Sponsored Projects:
   - Grant: award for assistance to provide services, supplies, or equipment, to conduct research or for education purposes.
   - Sub-recipient Agreement: agreement with a primary grantee.
   - Interagency Transfer Agreement (IAT): agreement between two or more state agencies for the purposes of transferring funds, property or services
   - Intra-Agency Agreement: agreement within different entities in the same state agency.
   - Memorandum of Understanding (MOU): a simple agreement of cooperation between two organizations defining the roles and responsibilities of each organization in relation to the other
   - Contract: a written legal agreement, enforceable by laws and signed by two or more parties for the fulfillment of expressed obligations, including services to be provided, time periods, terms of payment, and other terms and conditions as are appropriate and which are mutually agreed upon.
   - Clinical Research: a clinical trial, study or other research sponsored by a private sponsor, nonprofit foundation, governmental agency, or other funding source, which is designed to test the safety, and/or therapeutic, diagnostic, or preventive interventions that may eventually be used in humans.
   - Gift: a donation of tangible or intangible property in which there is no expectation of a benefit to the donor.
   - Other: Any use of HCSD resources; staff, space, supplies, by any non-HCSD entity
     - Example:
       - Surveys
       - Data collection or reporting
       - Dedication of "in-kind" HCSD resources toward any project sponsored by a non-HCSD entity
       - HR services to hire staff and accounting services
       - Use of computer equipment
       - Use of state employee toward grant activities

C. Principal Investigator (PI)--in research, the person who directs a research project or program. The principal investigator (the PI) usually writes and submits the grant application, oversees the scientific and technical aspects of the grant, and has responsibility for the management of the research.
D. Bill –A bill is the actual claim presented to one or more sponsors for reimbursement. It may contain all the charges associated with the rendered services, or only some of them.
E. Charge-Each service or item in the hospital charge description master lists a price. Charges are those prices associated with the services rendered.
F. Clinical Research (as defined for this policy): A study designed to assess the safety and/or efficacy of drugs, devices, diagnostics, treatments, or preventative measures in humans.
G. Federal Health Care Programs: Any plan or program that provides health benefits whether directly, through insurance or otherwise, which is funded directly, in whole or in part, by the United States Government or a State health benefit program (with the exception of the Federal Employees Health Benefits Program) (section 112B(f) of the Act). The most significant Federal health care programs are Medicare, Medicaid, Tricare, and the Veterans programs.

References:

CMS National Coverage Decision for Routine Costs in Clinical Trials, 2000

Appendices

Appendix A Clinical Trial/Research Study Budget Worksheet

Appendix B HCSD Research Billing Plan Form