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APPENDICES: THE FOLLOWING APPENDICES CAN BE FOUND ON THE CLINICAL TRIALS COMMUNITY PAGE ON PULSE UNDER DOCUMENTS. IF YOU ARE NOT ALREADY A MEMBER PLEASE SIGN UP ON THE ORA WEBSITE.

- APPENDIX 1: MCA SERVICES
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Clinical Trial Budgets

Budgeting for clinical trials requires a two-part process. The first part of the process is to conduct a Medicare coverage analysis. The second part is to create and negotiate the clinical trial budget. The Medicare coverage analysis is intended as a general guideline for use in determining which items and services may be billed to Medicare and private insurance based upon current Centers for Medicare and Medicaid (CMS) benefit policies, coverage determinations, coverage decisions, and federal guidelines. All items and services that are billed to Medicare must be supported by medical necessity. The billing grid will be used as a roadmap against which billing will be monitored and audited. This analysis also helps to determine the best possible budget proposal and aids in negotiating the budget with the funding sponsor.

I. Medicare Coverage Analysis

The Office of Research Administration (ORA) conducts Medicare coverage analyses for industry sponsored clinical research protocols at Thomas Jefferson University.

ORA identifies items and services that can be billed to Medicare based on:

- CMS national and local coverage determinations;
- Clinical trial billing rules;
- Medicare Benefit Policy Manual;
- Medicare Claims Processing Manual;
- "Routine care" as determined by PI to be reasonable and necessary for diagnosis and treatment and to prevent or detect complications

A Medicare coverage analysis (MCA) is required for all clinical trials in which tests, procedures and interventions associated with a clinical trial, are invoiced to insurance. Preparing an MCA involves determining the underlying eligibility of the study for Medicare coverage and reviewing clinical events specified in the protocol to determine which can be reimbursed by Medicare. ORA consults with investigators while preparing Medicare coverage analyses so that PI expertise and insights are reflected in the final outcome. This policy applies to all drugs, other agents, procedures, rehabilitation and device trials funded by industry sponsors.

When the analysis is complete, the investigator will receive a study-specific billing summary that lists all items and services to be provided as part of the clinical trial. This summary notes which items and services should be charged to study fund (and/or invoiced to the sponsor) and which item and services can be billed to Medicare. These billing grids are a valuable tool to ensure appropriate billing to Medicare and as expected by private insurance.

Disagreements about billing:

A. ORA billing grid indicates "acceptable to bill Medicare and the PI does not want to bill Medicare:

- 1) A PI may choose not to bill Medicare (or insurance) for items and services provided in the context of a clinical trial. The PI should notify ORA who will note the PI's decision in the comments section of the billing grid. ORA will ensure that the billing grid reflects that billing Medicare is not prohibited, but the PI has decided that Medicare will not be billed.
- 2) ORA will negotiate with the sponsor to ensure that projected research expenses will be covered by revenue from the sponsor.

B. PI disagrees with ORA assessment that a specific item or service cannot be billed to Medicare:

1) The PI will be asked to provide objective evidence such as journal articles and/or the US Pharmacopeia that a specific item or service is routine. Medicare will not accept hospital or department protocol as objective evidence. In this respect, there is no such thing as "our" standard of care.

- ✓ Having billed item or service in the past is not sufficient rationale for billing under current CMS policies or Fiscal Intermediary (FI) position.
- ✓ Given risk tolerance of Jefferson billing entities, questions will be resolved with the intent of maintaining low billing risk.
- ✓ If objective evidence is provided, then ORA will adjust the billing grid.
- ✓ It is important that the PI documents that any routine care billed is medically necessary.
- ✓ If no objective evidence is provided and the PI still disagrees, then ORA Contracts Director will approve any revisions to the billing grid.

II. Medicare Petitions for Device Studies

Medicare allows coverage for certain medical devices that are studied as part of a Food and Drug Administration (FDA) regulated clinical trial. A Medicare petition to our Fiscal Intermediary (FI), Highmark Inc., is generally only required an investigational device is studied under an Investigational Device Exemption (IDE). The IDE may stand alone or it may support a pre-market approval (PMA) application or pre-market notification (510k) submission to the FDA. Note that certain post-market and post-extension significant risk



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device studies may also require a petition. It is highly recommended that the Medicare petition be submitted prior to study initiation.

The FI requires we submit the following information and documents obtained from the sponsor:

- A copy of the most recent FDA-approval letter sent to sponsor or manufacturer of device. The IDE number must be included in the letter.
- Name of device (both trade, common or usual and classification name, if available).
- Any action taken to conform to any applicable IDE special controls
- A narrative description of the device that tells how the device is similar or different from other comparable devices.

The FI requires we submit the following information and documents:

- Indicate if device will be used in outpatient or inpatient setting
- IRB approved study protocol and/or IRB approval letter
- IRB approved Consent form
- Provider's NPI number (both TJU and PI)

We will request copies of these documents from the PI or study staff. Please contact ORA if you have any questions about your device study or how to determine if a petition is required.

PLEASE NOTE: Although the petition system grants approval for Medicare subjects, subjects with other insurance may require pre-approval before the insurance company will provide payment. It is the PI's responsibility to seek and gain these pre-approvals.

III. Clinical Trial Budgets

A. Overhead policy for clinical trials.

- a. The overhead rate for clinical trials is applied to the Total Direct Cost (TDC) base
- b. Overhead is generally not applied to the following:
 - i. Fees charged by the IRB
 - ii. Pass-thru costs defined as follows:
 - a) TJU submits invoice to sponsor who in turn pays vendor directly (i.e. advertising).
 - b) Other examples include:
 - a. Subject stipend paid directly from sponsor (i.e. gift card).
 - b. Direct reimbursement for travel.
- c. See price list in appendix for this fiscal year's overhead rate.

B. Administrative start-up

- a. Salary effort for the following activities is requested to be paid upon execution of contract
 - i. IRB preparation and submission.
 - ii. Gathering documents and signatures (1572, CVs, W-9, Consent Document, etc.).
 - iii. Training.
 - iv. Study initiation.
 - v. The amount request is dependent on the type of study and the salary of the Study Coordinator and/or PI.
- b. See price list in appendix.

C. IRB fees

- a. Per IRB policy, certain charges will apply for industry initiated clinical trials:
 - i. IRB initial review
 - a) Full
 - b) Expedited
 - ii. IRB continuing review
 - a) Full
 - b) Expedited
 - c) Note: Per IRB discretion, continuing review may occur more than just annually for certain studies.
 - iii. IRB amendment review
 - a) Full
 - b) Expedited
- b. See price IRB Fees for Commercially Sponsored Studies at <http://www.jefferson.edu/ohr/irb/IRBfeeschedule.cfm>

D. Research Costs

- a. Facility charges (Charge Description Master - CDM)
 - i. A research discount is applied to the CDM charge.
- b. Lab charges
 - i. A research rate is calculated on the lab charges. The rate is based on the fiscal year's Medicare payment schedule + negotiated mark up for the fiscal year.
 - ii. These rates are calculated in the price list provided to ORA
- c. JUP Fees
 - i. A research rate is calculated on the JUP charges. The rate is the Medicare payment schedule + negotiated mark up for the fiscal year.
 - ii. These rates are calculated in the price list provided to ORA
 - iii. This list contains both the technical and professional fees
 - iv. Technical fees from JUP are used in budgeting if the service takes place in an outpatient clinic or physicians office. Otherwise, the technical fee is most likely incurred by the facility (hospital) and the CDM is referenced.

- v. Professional fees from JUP are included when applicable and regardless of where the service is performed.
- d. See price list in appendix for this fiscal year research rates and discount.

E. Research Pricing

- i. The strategy we try to take with clinical trials budgeting is to charge the sponsor a fee between the maximum charge and the research rate (minimum charge).
- ii. We try to create margin to offset future price increases and any unforeseen or hidden expenses not uncovered during the budget development and negotiation process.

F. Figuring hourly rates for salary effort calculations

- a. The fiscal year fringe rate is added to all employee salaries.
- b. See price list in appendix for this fiscal year rates and charges.

G. Investigational Drug Service (Clinical Trials involving drugs and other agents)

- a. A budget from the investigational drug service (IDS) is required for clinical trials requiring the subject to be admitted to the hospital as an inpatient.
- b. ORA will contact the staff pharmacist who will drives the IDS budget.

H. Bed charges

- a. A research subject may also be an inpatient or outpatient and occasionally require a hospital bed. If this is not care the patient would have received anyway or covered by CMS Clinical Trial policy, then it needs to be covered by the sponsor (i.e. some phase one trials).
- b. An inpatient is generally defined as someone *admitted to and staying at* the hospital more than 24 hours. Inpatients usually stay overnight in a designated inpatient bed. Rates are charged daily.
- c. An outpatient is generally defined as someone *registered and visiting* the hospital, clinic or physicians office for less than 23 hours. Outpatients are occasionally assigned to a routine post-operative recovery (RPPR) bed (usually 8 hours or less) and/or observational bed (usually 23 hours or less). Rates are charged by the hour.
- d. An emergency patient is generally defined as someone visiting the emergency department. These patients sometimes roll over to an outpatient or inpatient status.

I. Clinical Research Unit (CRU)

- a. The CRU can provide certain services and beds for research subjects who are also patients.
- b. When applicable, ORA will contact the CRU Director to request a budget. The CRU budget will be incorporated into the overall budget proposed to sponsor.

J. Radiology Charges

- a. Copies of films are de-identified and provided on CDs. There is no extra charge for a few additional copies.
- b. ORA may ask Radiology Director of Administrative Services to review the protocol to ensure there are no hidden charges in the protocol and the services are within those provided by Radiology.

K. Anesthesia Charges

- a. ORA may ask Anesthesia Senior Research Coordinator to review the protocol to confirm there are no hidden charges not described in the protocol and the services are within those provided by Anesthesia.

L. Pathology Standard Fees:

- a. Document processing, material retrieval and inventory contract
 - i. This is charged regardless of whether or not sufficient material collected or present.
- b. Unstained slides (pretreated)
- c. H&E stained slides
- d. Tissue core of tumor and/or normal tissue
- e. Paraffin ribbons = no charge
- f. ORA may ask the Pathology Supervisor to review the protocol to ensure there are no hidden charges in the protocol and the services are within those provided by Pathology.
- g. See price list in appendix for this fiscal year rates and charges.

M. Lab charges

- a. Some protocols require certain labs be drawn at Jefferson and sent to sponsor's designated central lab for analysis.
 - i. There is a charge for the blood draw and the preparation.
- b. On occasion, ORA may need to ask labs to review the protocol to confirm they can deliver the items described.
- c. See price list in appendix for this fiscal year's fees.

N. Professional fees

- a. Professional fees may be charged for certain services performed in an outpatient clinic, physician's office or hospital (i.e. EKG).

O. Record Retention Fees

- a. The FDA requires patient binders and study information to be retained by our institution for two years beyond the close out of the study.
- b. Occasionally, a sponsor might request that the documents to be stored for a longer period.
- c. See price list in appendix for this fiscal year rates and charges.

IV. ORA Process

- a. The Principal Investigator or study team member contacts a Contract Associate in ORA about an industry sponsored clinical trial and provides the following documents:
 - PTF/ePTF,
 - most recent version of the study protocol,
 - draft Informed Consent Document,
 - draft budget,
 - draft Clinical Trial Agreement (CTA),
 - FDA IDE letter, when applicable
- b. The Budget Specialist proceeds to contact PI, study or department staff to inquire if the PI plans to bill subject's insurance for routine care within the context of the study.
- c. If the PI does not plan to bill insurance, the Budget Specialist will provide a billing grid stating that all study-protocol assessments will be charged to the study fund. The PI will be asked to give approval either by email.
- d. If the PI does plan to bill insurance, the Budget Specialist will determine if the study is considered a qualifying clinical trial (or covered device trial) according to CMS. If the study does not qualify, the Budget Specialist will provide a billing grid stating that all study-protocol assessments will be charged to the study fund. If the study qualifies, then the Budget Specialist drafts a billing grid which states which procedures can be billed to Medicare and which can be billed to the study fund. The billing grid is then sent by email to the PI for approval.
- e. Once the billing grid is approved by the PI, the Budget Specialist proceeds to draft a budget. After consulting with the PI, the Budget Specialist will negotiate with the sponsor. After the budget meets with PI and sponsor approval, the Budget Specialist sends the negotiated budget and payment terms to the Contract Associate. At this time, a draft Proposed Budget Form (PBF) is also sent to the PI/Department for review. Once the Department approves the PBF, it is forwarded to the Contract Associate along with a partially AIM form and the approved billing grid.
- f. After all internal documents are received (i.e. PTF/ePTF, PBF, IRB approval letter), and the Contract is executed, ORA Post-Award will establish an account number specific to the study. The account number will be added to the billing grid. At this time the billing grid is considered final and will be disseminated to the following:
 - PI/Study team,
 - Department Administrator
 - Compliance Officer
 - JUP Business Services
 - i. Director
 - ii. Clinical Trials Biller
 - Hospital Billing Services.
 - i. Director
 - ii. Clinical Trials Biller