

## Billing Compliance in Clinical Research

Policy Number: 01

Effective Date: April 25, 2005

Revised: November 1, 2006

### **Purpose and Scope**

The purpose of this policy is to clarify compliance requirements governing research studies contracted through the University of Washington when they include clinical services, items or tests that are potentially billable through Seattle Cancer Care Alliance, UW Medicine Patient Financial Services (PFS)<sup>1</sup> or University of Washington Physicians (UWP).

### **Introduction**

Numerous rules promulgated by federal and private payors govern the conditions under which clinical services, items and tests associated with a research study can be billed to subjects or their insurers. Operating procedures, tools and resources to guide researchers through the process of analyzing and applying billing regulations, National Coverage Decisions<sup>2</sup>, registering studies, developing budgets, registering subjects, managing the billing and reconciliation process, and closing out studies continue to be developed and refined in order to help ensure compliance with the policy statements that follow.

The complexity of the rules and established procedures requires that UW Medicine investigators, administrators and staff work collaboratively with study sites and the practice plans to ensure that costs associated with clinical studies are billed in compliance with relevant laws and regulations.

### **Policy Statements**

1. All professional and facility fees billed to Medicare, Medicaid, other third party insurers or research subjects that are associated with participation in a clinical research study must be:
  - consistent with applicable **billing rules** of the third party payor being billed,
  - consistent with any contractual obligations entered into by UW Medicine or study sites ,
  - represented consistently across all study related documents, including the grant, contract, billing plan and Informed Consent Document, and

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<sup>1</sup> PFS bills facility fees, and at times professional fees, for Harborview Medical Center and UW Medical Center.

<sup>2</sup> Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category). National Coverage Decisions (NCDs) are made through an evidence-based process, with opportunities for public participation. In the absence of a national coverage policy, an item or service may be covered at the discretion of the Medicare contractors based on a Local Coverage Decision (LCD).

- consistent with UW Medicine procedures that establish safeguards to prevent billing mistakes.
2. Costs to the research subject associated with participating in the research study will be disclosed in the Informed Consent Document signed by the research subject.
  3. Each **clinical research study that has potentially billable patient services will be registered** with the Clinical Research Budget and Billing office (CRBB) in advance of initiating the study.
  4. Each clinical research study that has potentially billable patient services will be conducted pursuant to a documented **billing plan** that serves as a guide for appropriately directing charges to the study account, the research subject or a third party insurer.
  5. Each **research subject** who participates in a clinical research study that has potentially billable patient services will be reported to the CRBB.
  6. All research subjects receiving care at UW Medicine hospitals and clinics will be registered as subjects/patients under the procedures applicable at each site.

## **Roles and Responsibilities**

### **General Responsibilities**

All **UW Medicine faculty, staff and trainees** are individually responsible for understanding and adhering to UW Medicine's policies and procedures, participating in required training, fulfilling recordkeeping requirements, reporting compliance concerns, seeking clarification when questions arise and responding in a timely manner to requests for information associated with internal audits or investigations.

Persons in **management or supervisory positions** have additional responsibilities, including communication of compliance and operational expectations, ensuring that appropriate training is taken, implementing and enforcing policies, and monitoring compliance.

Persons in **executive leadership positions** are accountable for the successful implementation and sustenance of compliance and related operational programs within their specific areas of oversight, and are responsible for participating in the development and implementation of UW Medicine-wide systems.

The Vice President for Medical Affairs has delegated additional specific authorities for the following positions:

- The Associate Vice President for Compliance (AVPC) develops UW Medicine-wide policies, establishes roles and responsibilities, educates faculty and staff, oversees the audit program, and coordinates the investigation and resolution of alleged noncompliance.

- The Associate Vice President/CFO (AVP-CFO) oversees the development and implementation of process improvement projects, convenes related oversight committees, and facilitates the commitment of institutional resources that may be necessary to satisfy compliance and operational priorities.
- The Vice Dean for Research and Graduate Education (VD-RGE) leads process improvement teams, provides leadership and oversight for the Clinical Research Billing and Budget office (CRBB), and serves as the School of Medicine's liaison with UW research offices to ensure effective coordination of shared concerns.
- The Vice Dean for Clinical Affairs (VD-CA) serves as chief medical advisor to the CRBB for resolving issues related to conventional vs. experimental care and participates in the identification of tools and resources necessary to help ensure compliance with established policies and procedures.
- The Vice Dean for Administration and Finance (VDAF) works closely with the AVPC to establish and communicate the compliance and operational expectations for School of Medicine chairs and administrators.
- Compliance Officers at the medical centers, School of Medicine and practice plan work closely with the CRBB, study sites, practice plans and operational departments to develop procedural safeguards; receive and investigate allegations of noncompliance; conduct audits; and participate in the development and delivery of compliance training.

## Operational Responsibilities

The **Principal Investigator (PI)** has primary accountability for all aspects of the clinical research projects operating under his/her name. Specific responsibilities include the following:

- Work closely with the study team and appropriate individuals<sup>3</sup> throughout the conduct of the study in order to ensure compliance with applicable billing rules as required by policy statement #1 above.
- Register each clinical research project that has potentially billable patient services in advance of initiating the study using procedures established by the CRBB.
- Register each subject enrolled in any study that has potentially billable patient services using procedures established by the CRBB.
- Develop a billing plan using procedures established by the CRBB.
- Ensure that services for patients enrolled in research studies are billed in accordance with the billing plan and adhere to the billing requirements of National Coverage Decisions involving clinical research (e.g., coverage of routine costs of in clinical trials and Category A devices).
- Report billing questions and concerns to billing staff for review and/or correction.
- Follow related clinical research implementation and billing procedures specific to each practice plan and study site.
- Conduct periodic reconciliation of charges to the billing plan.

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<sup>3</sup> A wide range of individuals may need to be involved throughout the conduct of the study, including but not limited to departmental administrators; budget and billing specialists in the CRBB, the practice plans or the study sites; clinic managers; compliance officers at the research billing sites; and coding specialists.

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- Ensure that appropriate documentation exists in the medical record when Medicare coverage is allowed under the CMS National Coverage Decision for Routine Costs in Clinical Trials of 2000.
- Adhere to UW Medicine records retention requirements.  
(<http://www.washington.edu/admin/recmgmt/uw.gs7.html>)

The **Clinical Research Budget and Billing office (CRBB)** (<http://www.uwmedicine.org/Research/ResearchBudgetBilling/>) provides centralized support for PIs and is responsible for the following:

- Establishing and maintaining procedures for clinical research budgeting and billing
- Providing education and outreach regarding clinical research billing procedures
- Providing technical assistance, advice, tools and resources to PIs, study coordinators, staff at study sites and department administrators regarding third party payor reimbursement, budget development and billing
- Allocating study charges to research study accounts
- Reporting unresolved billing concerns to appropriate compliance offices

**Study site personnel** (including patient service representatives, billers, coders, clinic administrators and service providers) are responsible for working with the Principal Investigator to ensure that services for patients enrolled in research studies are billed and recorded in accordance with the billing plan, and seeking clarification when questions arise.

**Offices that bill facility and professional fees** are responsible for establishing business practices and systems that support compliance with research billing policies and procedures.