

Clinical Research Policies and Operational Procedures

Clinical Research Billing Remediation Policy

Policy Number: 2

Effective Date: December 19, 2007

Review Date: December 19, 2007

Introduction

Audits of clinical research billing activities may be initiated in response to external or internal complaints and inquiries, or conducted as part of the UW Medicine Compliance (UWM-C) audit program. When billing errors are identified during the course of those audits, UW Medicine is obligated to engage in timely, effective remediation activities. For purposes of this policy, remediation activities include, but are not limited to the following:

- Repayments (such as those to Medicare and Medicaid, 3rd party commercial payors and patients who self-pay)
- Adjustments to research study and patient accounts
- Disclosures to appropriate contractors and regulators
- Education and re-training of research, hospital and billing staff
- Modification of operational processes when necessary to prevent future errors

Although the hospitals and practice plans have primary accountability for establishing their own internal processes to track effectively, resolve, and report entity-specific billing errors, remediation activities associated with most clinical research billing errors require coordination among various offices and entities.

Purpose and Scope

The purpose of this policy is to establish standards by which hospitals and clinics owned or operated by UW Medicine, the physician practice plan, patient financial services, and clinical research budget and billing office will complete remediation activities when clinical research billing errors are determined to have occurred.

This policy applies to remediation activities carried out by the following UW Medicine offices¹:

- UW Medicine Compliance (UWM-C)
- UW Medical Center Compliance (UWMC-C)
- Harborview Medical Center Compliance (HMC-C)
- UW Medicine Patient Financial Services (PFS)

¹ The Seattle Cancer Care Alliance (SCCA), carries out oncology research activities which may involve pro-fee and facility billing processed by UW Medicine. The SCCA has its own clinical research auditing program and internal processes for remediating their audit findings.

- University of Washington Physicians Compliance (UWP-C)
- School of Medicine Clinical Research Budget and Billing Office (CRBB)

Policy Statements

1. Unlike routine clinical services billing errors that often require corrections and recharges to be submitted at the hospital or clinic service center level, corrections for clinical research billing errors will be submitted as described in this policy by the applicable Compliance Office staff member.
2. Medicare/Medicaid repayments and adjustments should be completed within 30 days of receipt by PFS, UWP-C, and CRBB.
3. When Medicare/Medicaid repayments and adjustments are required in audit findings, the appropriate entity Compliance Officer shall make timely disclosures to the appropriate contractor in accordance with applicable notification criteria.
4. All other remediation activities involving repayments and adjustments will be completed within 90 days after auditor notification to PFS, UWP-C, and CRBB.
5. When other disclosures or notifications to regulatory agencies are deemed necessary, the appropriate entity Compliance Officer shall make the disclosure or notification in a timely manner in accordance with applicable notification criteria.

Roles, Responsibilities, and Procedures

Roles of Compliance Offices and Auditing Staff:

UWM Compliance is responsible for establishing and implementing the UW Medicine clinical research billing audit program, monitoring timely completion of remediation activities, and overseeing the work of UW Medicine clinical research billing audit staff. UWM Compliance audit staff are responsible for conducting audits initiated as part of the UW Medicine audit program.

Entity Compliance Office staff (UWMC-C, HMC-C, UWP-C) are responsible for conducting audits in response to complaints or inquiries received by or specific to the entity.

All compliance staff who conduct audits involving clinical research billing are responsible for completing work in a timely manner and maintaining audit documentation in the Risk Master database. They are also responsible for the following:

- Notifying the affected Principal Investigator (PI), study staff and department or division upon initiation of the audit about the reason for the audit, the process and timeline and documentation requirements.
- Maintaining effective communication with the PI and study staff throughout the audit process.

- Reviewing audit results and recommended remediation activities with the affected PI, and/or study staff before finalizing remediation activity spreadsheets².
- Notifying the Department Director or Division Administrator if remediation activities will impact the future conduct of the research study or involve repayments, adjustments and disclosures.
- Submitting remediation activity spreadsheets to the PFS Manager, the CRBB Director, and the following designated authorities:
 - When remediation involves UWMC billing: UWMC Compliance Officer
 - When remediation involves HMC billing: HMC Deputy Compliance Officer
 - When remediation involves professional fee billing: UWP-C Director of Compliance.
 - Upon completion of audits they perform, UWM-C audit staff will provide a copy of the audit report to the appropriate entity compliance office (UWMC-C, HMC-C, and/or UWP-C).

Responsibilities of Compliance Officers:

Entity Compliance Officers and their designees are responsible for developing effective processes for completing the entity's remediation activities (including operational modifications), monitoring timely completion of entity-specific activities associated with each completed audit (including process improvement projects), and making timely disclosures to the Medicare contractors or other appropriate oversight agencies in accordance with the entity's requirements for such notifications.

Procedures³ - Patient Financial Services:

As they correct billing errors, PFS staff will complete the appropriate section of the remediation activity spreadsheet.

PFS will provide an electronic copy of the completed remediation activity spreadsheet to both the CRBB Director and the applicable auditor to confirm that PFS has completed its required remediation activities and, if necessary, to notify CRBB that it may re-bill or credit research charges to the appropriate budget source.

Procedures - University of Washington Physicians:

As they correct billing errors, UWP-C staff will complete the appropriate section of the remediation activity spreadsheet.

UWP-C will provide an electronic copy of the completed remediation activity spreadsheet to both the CRBB Director and the applicable auditor to confirm that UWP-C has completed its required

² see templates - Attachments 1-4

³ See Research Billing Audit Remediation Flow Sheet, Attachment 5

remediation activities and, if necessary, to notify CRBB that it may re-bill or credit research charges to the appropriate budget source. Additionally, UWP will provide a copy of the completed spreadsheet to the applicable SoM Department Administrator.

Procedures - CRBB:

As they complete study account rebilling and crediting, CRBB staff will complete the appropriate section of the remediation spreadsheet. When CRBB staff discover an inactive or expended AAA account, they will notify the appropriate entity Compliance Officer and the PI's Department Director/Division Administrator to determine options for payment resolution.

When study account rebilling has been completed, the CRBB Director will provide an electronic copy of the completed remediation activity spreadsheet to the applicable auditor to confirm completion of the remediation process.

Summary of Audit Notifications:

At the completion of each research billing audit, the following offices/staff will receive a copy of the audit report from UW Medicine Compliance or the entity Compliance Office depending upon who has initiated the audit:

- Principal Investigator
- Study Coordinator
- SoM Department Chair/Division Head
- SoM Department Director/Division Administrator
- Applicable entity Compliance Officer

For each research billing audit that requires remediation, the following offices will receive copies of the UW Medicine Research Audit Remediation Spreadsheets from UW Medicine Compliance or the entity Compliance Office depending upon who has initiated the audit:

- Principal Investigator
- Study Coordinator
- Applicable entity Compliance Officers
- Patient Financial Services
- Clinical Research Budgeting and Billing Office
- SoM Department Administrator

Compliance Officer: _____ Date: _____

Sue Clausen
Associate Vice President/Chief Compliance Officer
