BRIGHAM HEALTH
BWH BRIGHAM AND WOMEN'S HOSPITAL

COMPLIANCE PROGRAM GUIDELINE: Clinical Research Billing Audit Program

Effective Date:
Last Updated:

I. Reference Guidance

Clinical research may take place separately from, but is often provided in conjunction with, the provision of usual and customary clinical care of patients. To ensure that the billing of research-related clinical services is handled in compliance with regulatory requirements, and in accordance with study's Informed Consent Form (ICF) and agreement with the sponsor, all Brigham and Women's Health Care human subject research protocols are subject to periodic research billing audit. The research billing specialists in the BWHC Office of Billing Compliance are responsible for identifying protocols for review, conducting research billing audits of patient care charge activity associated with those protocols, providing post-audit feedback and education to Principal Investigators (PIs) and study staff, monitoring timely and accurate corrections of any identified research-related patient care billing errors, and perform re-evaluations for audits determined to present significant billing risk.

II. PROCESS (see Attachment B for further details)

The research billing compliance auditor:

1. Identifies type of audit to be performed (see Attachment A).
2. Identifies the human subject research protocol to be audited.
3. Notifies the Principal Investigator (PI) of the intent to conduct a research billing audit and identifies study documents required to be provided by the PI/study team.
4. Reviews all pertinent study documents (pulled from the Partners Electronic Research Administration Portal and/or supplied by the PI/study team).
5. Sets the audit scope.
6. Utilizes the institution's current and/or legacy patient care billing system to review all charge activity for services provided to subjects within the audit scope (supporting documentation [e.g., visit notes and test reports, research association applied to encounters in the Electronic Medical Record system] is also reviewed).
7. Prepares preliminary findings reports and notifies the PI of the preliminary audit completion. A meeting is set with the PI and study team to review findings, verify accuracy,

and provide education and guidance.

8. Prepares the final audit reports and sign-off document, which may include follow-up actions required by the PI/study team to correct charge errors and/or address workflow concerns.
9. Obtains receipt of the fully executed audit sign-off document, signifying completion of the required follow-up actions by the PI/study team, and marks the research billing audit as complete.
10. Completes audit follow-up, escalation, and re-auditing, if applicable.

III. PURPOSE

The purpose of the research billing audit is to provide an internal mechanism for quality assurance, quality improvement, and education pursuant to research financial compliance and clinical research billing. In addition, BWH research billing compliance provides support in complying with all institutional policies, federal, and state laws and regulations, while protecting research participants and the institution from research-related misbilling.

IV. REFERENCES

- ✓ Medicare Claims Processing Manual, chapter 32
- ✓ 21 CRF 50.25 (b) (3): FDA Regulation on Human Subjects, Informed Consent
- ✓ 45 CFR 46.116(b) (3): Department of Health and Human Services (DHHS) Regulations on the Protection of Human Research Subject
- ✓ American Medical Association (AMA) Current Procedural Terminology (CPT)
- ✓ American Medical Association (AMA) Evaluation and Management Services Documentation Guidelines
- ✓ Centers for Medicare and Medicaid Services (CMS) National Coverage Determination for Clinical Trials 310.1
- ✓ False Claims Act, 31 U.S.C 3729
- ✓ Federal Register 65-Office of Inspector General (OIG) Compliance Program Guidance for Third Party Medical Billing companies, Hospitals, Individuals and small group Physician Practices
- ✓ Office of Inspector General; Office of Management and Budget Circular A-100, A-21
- ✓ Patient Protection and Affordable Care Act (PPACA), HR 3590, 2709. Coverage for Individuals Participating in Approved Clinical Trials
- ✓ President Bill Clinton's Executive Memorandum directing Medicare to revise reimbursement for all Routine Patient Care associated with research
- ✓ Social Security Act Reasonable and Necessary 1862

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Attachment A

TYPES OF RESEARCH BILLING AUDITS

Research billing audits may be classified as routine or non-routine. Regardless of classification, the purpose of a research billing audits is to confirm that all charges for research-related patient care services are directed in compliance with regulatory requirements, in accordance with study's Informed Consent Form (ICF) and sponsor agreement.

Routine Research Billing Audits

Routine research billing audits are categorized into two subtypes: routine billing audits and targeted routine billing audits.

1. Routine billing audit: Protocol selection is random; not driven by previous research billing activity or inclusion in a known set of billing risk variables.
2. Targeted routine billing audit: Protocol selection is in response to study and or study team's inclusion in a known set of higher billing risk variables.

Non-routine Research Billing Audits

Non-routine research billing audits (also called "probe" audits) are initiated in response to known, current billing error/errors, the investigation into which produces evidence that a broader examination of the protocol's research billing activity is warranted.

Attachment B

AUDIT PROCESS

The research billing compliance auditor:

1. Determines which type of research billing audit is to be performed:
    A. Routine billing audit
    B. Targeted routine billing audit
    C. Non-routine (probe) research billing audit
2. Informs the PI, and cc'd research department administrator (if role absent, then department administrator), that his/her protocol has been selected for research billing audit.
    A. If a routine audit, this communication is initiated via email. A copy of the BWH/BWPO Research Billing Compliance Plan is provided with this communication.
    B. If a non-routine audit, the communication will occur during the course of the charge error investigation that prompted the audit's initiation. This communication may occur via email, telephone, or in person.
3. Specifies which study documents are to be provided by the PI/study team within ten days of the audit-initiation communication. These documents include (but may not be limited to):
    A. Completed Pre-Audit Questionnaire supplied with the initial email (routine audits only).
    B. Subject enrollment log, including medical record numbers and dates of all research-related services.
    C. Any pertinent study documents not found in the Electronic Research Administration Portal (ICF, agreement with the sponsor, Medicare Coverage Analysis [MCA], protocol).
4. Determines audit scope, upon receipt of the study documents from the PI/study team:
    A. Identify services deemed not billable to subject/insurance for audit.
    B. Determine number of subjects to be selected for audit (specific subjects are chosen via use of a random number generator).
5. Conducts the charge audit.
    A. Reviews all hospital and professional charges in the current and/or legacy patient care billing system, for each subject/service within the scope of the audit, to determine charge direction.
        i. If billed to the study fund, item is marked "Agree- No subject/insurance bill".

ii. If billed to the subject or insurance, item is marked "Disagree- Subject/insurance bill".

iii. If billed to an incorrect study fund, item is marked "Agree- No subject/insurance bill" and is not included in the findings of charges billed inappropriately to subject/insurance. However, the observation will be noted in the audit rationale for study team information/correction.

6. Prepares preliminary audit reports, including:

   A. Audit Findings Report: grid-based document detailing the findings for each service reviewed, by subject and study visit. For charges marked "Disagree- Subject/insurance bill", applicable CPT numbers and full charge amounts billed to subjects or insurance are included.

   B. Audit Rationale Report: descriptive accompaniment to the Audit Findings Report.

      i. The intention behind the research billing audit.

      ii. A description of the audit process.

      iii. The scope set for the audit being reported.

      iv. The findings, when applicable, including the number of subjects/accounts examined for each study visit and research service.

      v. The conclusion, including percentage of charges directed correctly for each study visit and research service.

7. Notifies PI via email, of preliminary audit completion.

   A. If no findings of charges billed inappropriately to subjects/insurance are observed: the preliminary Audit Findings and Audit Rationale reports are included with this communication. A meeting with the auditor is available, but not required. The PI may confirm agreement with the audit findings at that time, or may review with the auditor in more detail via email, telephone, or in person, at his/her discretion.

   B. If findings of charges billed inappropriately to insurance are observed: the Audit Findings and Audit Rationale reports are not included with the communication. A mandatory in-person meeting is set for the auditor to review the preliminary reports with the PI and study team.

8. Meets with PI/study team to review preliminary reports and provides guidance/education (meeting is optional if no findings of misbilled charges to subject/insurance are noted in the preliminary report).

   A. An in-person meeting is scheduled for the auditor to review the preliminary audit reports with the PI/study team.

   B. Findings of charges billed inappropriately to subjects/insurance are discussed in

detail. PI/study team comments or questions are encouraged to ensure accuracy of the findings. PI/study team input may affect the final audit findings (e.g., a subject's health status may have warranted the ordering of an otherwise research-related test or procedure as a part of their usual care, thereby rendering the test/procedure billable to subject/insurance).

C. Causes/sources of charge errors are identified (e.g., insufficient staff training, insufficient staff access to systems functionalities, inappropriate study team workflows, communication problems within study team or with other involved groups or departments, systems issues). Guidance is provided to correct problems and avoid future research billing errors.

D. PI/study team initiates Patient Care Corrections to redirect inappropriately billed research charges to the study fund. Education and guidance regarding the corrections process is provided by the auditor.

9. Prepares final audit report within 10 business days after preliminary review, which may include updated findings supplied to the PI. Follow-up actions required by the PI/study team to correct charge errors or address workflow concerns are included in an accompanying audit sign-off document. All noted follow-up actions must be completed, and fully executed sign-off document returned to the research billing compliance auditor, within 15 business days of the document's receipt (see Attachment C).
    A. Receipt of the signed audit sign-off document is confirmed by the research billing compliance auditor, and cc'd research department administrator (if role absent, then department administrator), signifying completion of the research billing audit.
    B. Auditor internally documents overall audit risk tolerance level (see Attachment C).

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Attachment C

EVIDENCE OF SIGNIFICANT OR CHRONIC NON-COMPLIANCE

If significant issues of non-compliance are revealed during or after the research billing audit process, or if repeat audits reveal chronic non-compliance by a PI or study team, a focused review will be implemented to address and correct this non-compliance.

Risk tolerance evaluations will be determined and recorded by the Research Billing Compliance Auditor post audit completion. Risk tolerance levels include: 0 (no risk observed); 1 (low risk observed); 2 (medium risk observed); and 3 (high risk observed). This scale will aid in future determinations of significant or chronic non-compliance.

Repeat audits of studies with assigned medium or high risk tolerance ranking will occur. If billing errors are identified, Patient Care Corrections must be submitted by PI/study team within identified timeframe. Dependent on results of the repeat audit or Patient Care Corrections non-compliance, an escalation process may be inacted.

Research billing compliance will provide all departments auditied with an annual report, breaking down: all audit results, education(s) provided, re-audit activity- when applicable, along with suggested areas of potential research billing practice improvements and other recomendations.