Weill Cornell Medicine

Research Billing Compliance Handbook

OFFICE OF COMPLIANCE

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INTRODUCTION

Weill Cornell Medicine ("WCM") is committed to conducting research in compliance with Good Clinical Practices and in a manner that upholds the highest ethical standards, ensuring the protection of the rights and welfare of research participants.

The Office of Compliance ("OOC") at WCM provides oversight and guidance to ensure that research-related services are billed appropriately, in accordance with the Center for Medicare & Medicaid Services ("CMS") guidelines, including the National Coverage Determination (NCD) for Routine Costs in Clinical Trials.

This Research Billing Compliance Handbook is designed to:

- Distinguish between research billing compliance and general billing compliance.
- Provide current CMS and WCM policies governing the billing of research-related services.
- Offer step-by-step instructions on billing clinical services related to clinical trials and other research studies, to facilitate accurate coverage analysis, preparation, and interpretation.
- Help identify common coding and documentation errors related to research services.

Please note that billing regulations and institutional procedures are subject to change.
This handbook will be reviewed and updated annually, or as needed, to reflect current policy and regulatory requirements.

It is essential that this information be shared with all employees involved in research studies. Research participants must clearly understand which clinical services will be covered by the research study, which may be billed to their insurance, and/or which may become their personal responsibility (i.e., co-payments and/or insurance deductibles). These distinctions must be clearly communicated to research participants through the Informed Consent Form ("ICF").

BILLING COMPLIANCE

Weill Cornell Medicine faculty engaged in clinical practice are subject to specific legal and regulatory requirements regarding the billing of their professional services. General billing compliance is inherently complex due to the evolving nature of federal and state regulations governing professional fee reimbursement.

To address this complexity, WCM has established a Clinical Compliance Oversight Committee (CCOC) and adopted a Clinical Compliance Program Plan (the "Plan"). The Plan sets forth a comprehensive approach to ensure accurate and compliant billing practices, including those related to the supervision of post-graduate trainees. It provides a consistent framework for interpreting and applying Medicare, Medicaid, and other third-party payor billing requirements for professional fee reimbursement.

RESEARCH BILLING COMPLIANCE

The purpose of the research billing compliance program is to ensure that clinical services provided in connection with a research study are billed appropriately—avoiding duplicate billing to patients or third-party payers—and in alignment with all applicable regulations, including the CMS NCD for Routine Costs in Clinical Trials.

This program promotes institutional integrity and regulatory adherence by helping to:

- Reduce billing risks related to distinguishing between research-related services from routine standard-of-care services.
- Prevent inappropriately billing research participants and/or third-party payers.
- Promote consistency in the assignment of payment responsibility across all study documents (e.g., ICF, coverage analyses, budgets, and billing grids).
- Ensure appropriate recovery of clinical research study costs while maintaining compliance with billing requirements.

WHY IS RESEARCH BILLING COMPLIANCE IMPORTANT?

Adhering to research billing compliance is critical to maintaining ethical, legal, and financial integrity. Key reasons include:

- **Regulatory Requirement**: The CMS developed NCD 310.1, the Clinical Trial Policy, in response to President Clinton's Executive Memorandum dated June 7, 2000. This policy defines coverage requirements for routine costs in qualifying clinical trials. It also clarifies which services are reimbursable under Medicare and emphasizes the importance of properly classifying trial-related versus routine care services.
- **Prevention of "Double Billing":** Billing Medicare or another third-party payer services already covered by a research sponsor or grant is considered fraud and can trigger enforcement actions under the False Claims Act (FCA). Accurate billing ensures that services are not inappropriately billed twice.
- **Proper Cost Attribution**: Clearly distinguishing between "routine/standard of care" services and "research only" services is essential. This determination ensures that each service is billed to the appropriate payer—whether that be Medicare, a private insurer, the research sponsor, or the participant.

RESEARCH-RELATED SERVICES COVERED BY MEDICARE

The Medicare program is a federal health insurance plan that covers medically necessary diagnostic and therapeutic health care services related to the illness or injury of a specific beneficiary. For research participants, Medicare provides coverage for medically necessary routine/standard of care services rendered as part of a qualified clinical trial, provided those services would ordinarily be covered outside the context of the research and are not paid for or otherwise provided by the research study sponsor.

Medicare does not reimburse or subsidize the cost of conducting research for its own sake. Specifically, Medicare does not pay for:

- Investigational items or services that are solely for research purposes.

- Items or services that are paid for by a research sponsor or other third party.
- Services provided solely to collect data or for administrative research needs.

To ensure compliance:

- All billed services must be supported by documentation and aligned with CMS guidelines, including the applicable NCD.
- Research-related services must be carefully reviewed to determine whether they qualify as routine/standard-of-care or are study-specific and sponsor-funded.
- Items or services that are deemed standard-of-care may be billable to Medicare, provided they meet all CMS requirements and are not covered by the research sponsor.

Because research protocols often include a combination of standard-of-care and research-driven services, the billing process can be complex and prone to errors. To mitigate risk:

- Researchers and study staff must be knowledgeable about CMS regulations, WCM billing policies, and research billing compliance procedures.
- Proper cost attribution must be established during the preparation of the budget and coverage analysis.

Accurate billing protects the institution from regulatory enforcement, helps maintain patient trust, and ensures financial integrity in clinical research.

Documentation requirements for research patients

Specific documentation requirements ensure accurate and complete documentation of the clinical research-informed consent process and research-related activities in each subject's electronic medical records (EMR).

All clinical research activities involving human subjects must be appropriately documented in the EMR. Proper documentation serves multiple critical functions:

- Ensures the clinical care provided to research participants is visible to all treating providers.

- Provides evidence of compliance with billing requirements and supports claims submitted to third-party payors.
- Protect the institution in the event of regulatory audit or inquiries.

Documentation Key Requirements

Documentation of Clinical Research Services must be recorded as clinical encounters or research notes within the EMR and is subject to compliance with legal, regulatory, and institutional requirements. These notes must accurately reflect the Clinical Research Services provided and include key elements related to the research study, including the Informed Consent process.

Documentation of the Informed Consent Process

All potential research subjects must receive Informed Consent before any Clinical Research Services commence. The current IRB-approved Informed Consent form must be used. For clinical research studies that involve clinical services, the Informed Consent process must be documented in the EMR and include the following required elements:

- A summary of the discussion with the research subject regarding the study's purpose, procedures, risks/benefits, and alternatives.
- Confirmation that the research subject had an opportunity to review the Informed Consent form and ask questions.
- Verification that the research subject's voluntary agreement to participate in the study was obtained.
- Confirmation that the research subject received a copy of the signed Informed Consent form.

For additional information regarding the Informed Consent process, please reference the Joint Clinical Trials Office Policy Rs02 - Informed Consent. Epic tools are available to facilitate the documentation process using the ".StudyConsent" smart phrase.

Documentation of Clinical Research Services/Provider Visits

For each clinical research visit, an Epic clinical encounter/research note and research-related orders must be linked to the study. Documentation of the research-related clinical services shall be written in a clinical encounter/research note and must contain the following:

- Study Reference, for example, [SHORT TITLE] or [IRB NUMBER].
- Visit Reference: Visit [#]/Day [#].
- An accurate reflection of the research subject's condition and care provided.
- Core documentation requirements supporting the services billed, including CPT/HCPCS codes, modifiers, ICD-10 codes, place of service, and units of service posted for each encounter; and
- Encounter type (e.g., Research, Progress Note, Procedure Note)

Documentation of Non-Provider Research Visits for Data Collection Only

For each Non-Provider Research Visit for Data Collection Only (not on the provider's schedule), an Epic chart note/Allied Health note can be created. Documentation on the research-related data collection only events shall be written in the note and must contain the following:

- Study Reference, for example, [SHORT TITLE] or [IRB NUMBER].
- Visit Reference: Visit [#]/Day [#], and
- An accurate reflection on the research activities that were fulfilled during the visit

Note: The chart note encounter type can be closed without a CPT/HCPCS code.

SERVICES RENDERED TO RESEARCH PARTICIPANTS

Routine/Standard of Care

Medicare's Coverage Decision for Clinical Trials states that the definition of standard of care includes research protocol items and services that are ordinarily covered outside of a trial per coverage guidelines and are provided for any of the following reasons:

- Direct clinical management of the patient
- Conventional care
- Clinically appropriate monitoring of the effects of the investigational item or service
- Services required for prevention, diagnosis, or treatment of complications
- Provision/administration of an investigational item or service (e.g., infusion administration services and supplies)

Routine/standard-of-care services may include blood tests to measure tumor markers, office visits for follow-up of chronic conditions, or imaging tests for implanted devices. In some clinical trials, the sponsor may agree to cover all services, including those that are customarily considered part of the standard of care. In those cases, these services should not be billed to the patient and/or the patient's insurance.

Research Protocol-Driven Services

Protocol-driven services are those explicitly rendered for data collection and would not be provided if the patient were not enrolled in the study. These services are performed simply because of the protocol requirement and not because the patient's medical condition warrants it.

Research protocol-driven items or services can be:

- An investigational item or service (whatever is being studied).
- Items or services rendered solely for research purposes (i.e., data collection).
- Items or services rendered solely to determine trial eligibility.
- Items or services paid for by the grant or research sponsor.
- Items or services are promised "free" in the ICF because the sponsor has made special arrangements, such as using an outside lab or providing investigational drugs or equipment.

CLINICAL TRIAL BILLING POLICY

The Compliance Plan addresses the parties responsible for overseeing the billing activity for research patients in all clinical trials conducted at WCM, regardless of payer.

The Clinical Trial National Coverage Determination issued by CMS serves as the principal billing rule for services rendered during a clinical research study. The policy is intended to encourage Medicare beneficiaries to participate in clinical trials without penalties. As of September 2000, Medicare explicitly authorized payment for routine/standard-of-care costs, as well as costs associated with medical complications from participation in a qualifying clinical trial.

CMS Guidelines

Medicare is considered the "gold standard" for determining healthcare coverage policies, and many third-party payors base their own coverage decisions on Medicare rules, including those governing clinical research services.

According to CMS NCD 310.1, Medicare provides coverage for:

- Routine costs associated with qualifying clinical trials, and
- Reasonable and medically necessary items and services required to diagnose or treat complications that arise from participation in a clinical trial.

"*Medicare covers the routine costs of qualifying clinical trials, as well as reasonable and medically necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.*"

To qualify for Medicare coverage, a clinical trial must meet specific criteria outlined by CMS, including the purpose of the trial, trial design, and beneficiary protections. Additionally, routine costs must be clearly distinguishable from investigational services and those covered by the research sponsor.
All other applicable Medicare billing rules—including medical necessity, provider qualifications, and proper documentation—must be followed.

COVERAGE ANALYSIS

WCM Policy

At WCM, institutional policy requires completing a coverage analysis of all research studies involving patient services related to research. This analysis must be conducted in conjunction with the initial IRB submission and updated as needed throughout the life of the study.

Building a coverage analysis involves reviewing the protocol requirements to determine whether study-related services are billable to the patient's insurance as medically necessary routine/standard-of-care or to the study sponsor. When finalized and approved, the coverage analysis serves as the official source for identifying the appropriate dispositions for each clinical service associated with the study.

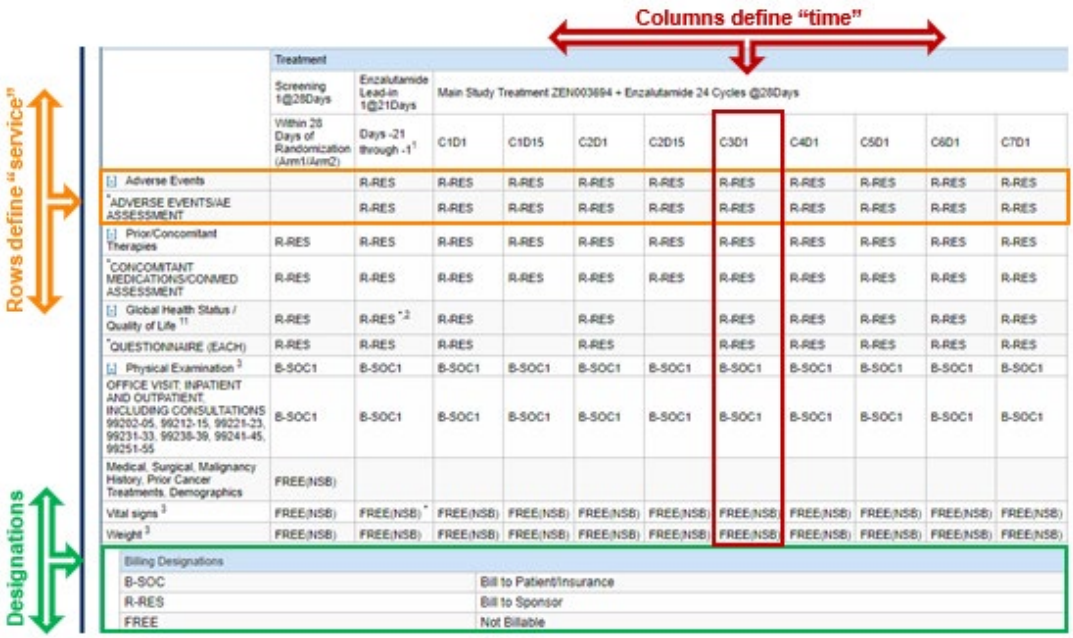
Principal Investigator ("PI") Responsibilities

For any study involving billable clinical services:

- The PI must generate a coverage analysis as part of the IRB application process.
- The analysis must be updated when there are amendments to the protocol, ICF, or at the time of IRB renewal.
- The coverage analysis must mirror the study schedule of events and align with the services listed in the research protocol and/or informed consent.

Completing the coverage analysis requires a thorough understanding of the protocol and funding source, as well as considering whether the clinical services are medically necessary, routine/standard of care, and whether each service would have been rendered to the patient regardless of enrollment in the research study. It also requires knowing the extent to which the sponsor pays for clinical services.

The Department Compliance Liaison (for the PI) and/or a designated OOC manager is responsible for reviewing and approving the coverage analysis once the calendar is complete and the budget has been approved. The designated OOC Manager will initiate approval for those departments that don't have an active Compliance Liaison. Therefore, research billing compliance personnel must know how to read a coverage analysis, which is defined by columns of time and rows of services. The figure below depicts an example of a portion of a completed coverage analysis.



The **column** headings are service intervals defined by the investigator (days, weeks, months, cycles, etc.) to reflect the planned timing/interval of when services will be rendered after enrollment in the study. The **row** headings are service categories defined and organized by the PI. Individual CPT codes accompany services listed under each row heading. The grid **billing designation** codes are added to complete the grid. Currently, **only two (2)** codes are used, which are defined below.

- **B-SOC** indicates that the service is medically necessary, routine/standard-of-care, and may be billed to the patient or their insurance. It is essential to ensure the patient is aware of their responsibility to pay, even though this is specified in the informed consent. Depending on individual patient circumstances, an Advanced Beneficiary Notice (ABN) may be required for Medicare patients, and a Notification of Non-Covered Services may be necessary for other patients. Notification is essential for transparency and protection from surprise billing from an out-of-network provider at a participating hospital.
- **R-RES** indicates that the research sponsor, private, or internal funds pay for services designated in the protocol or contract, and these are not to be billed to the patient or their insurance.

The compliance designee will review the coverage analysis and the study protocol, paying particular attention to the schedule of events, informed consent, and budget when applicable. Once the guidelines are followed and the coverage analysis is approved for sign-off by the Department Compliance Liaison (for the PI) and/or a COO manager (on behalf of the department), it is used to create a billing grid that facilitates the routing of research charges for billing in the Practice Management System ("Epic").

- Studies originating before 7/1/2021 should have included the submission of a Human Research Billing Analysis Form ("HRBAF"). Since the use of the HRBAF is phased out, those still active studies will continue to use the HRBAF for the lifecycle of the research study.
- Studies with billing risk originating after 7/1/2021 require a coverage analysis to be generated in the clinical trials management system, OnCore.

QUALIFYING CLINICAL TRIAL

A qualifying clinical trial is a trial that MUST satisfy the three "necessary requirements" AND be deemed CMS to have the 7 "desirable characteristics."

The three (3) "necessary requirements" are:

1. The study must investigate an item or service in a Medicare benefit category.
2. The study must enroll patients with diagnosed diseases rather than healthy volunteers.
3. The study must have therapeutic intent – it must not be designed solely to test the safety or toxicity of the investigational item or service.

The seven (7) "desirable characteristics" are:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes.
2. The trial is well-supported by available scientific and medical information or intended to clarify or establish the health outcomes of interventions already in common clinical use.
3. The trial does not unjustifiably duplicate existing studies.

4. The trial design is appropriate to answer the research question being asked in the trial.
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully.
6. The trial complies with Federal regulations relating to protecting human subjects.
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

Qualifying Clinical Trials: "Deemed Trials"

CMS does not automatically designate all clinical trials as "Deemed Trials." Instead, it identifies specific trials that meet the required characteristics, ensuring they align with CMS criteria for coverage. Not all studies qualify—only those demonstrating the necessary elements to be deemed eligible under CMS guidelines.

Clinical trials deemed by CMS to have the seven (7) desirable characteristics are:

- Trials funded by certain government agencies: National Institute of Health (NIH), Centers for Disease Control ("CDC"), Agency for Healthcare Research and Quality ("AHRQ"), CMS, Department of Defense ("DOD"), and the Veterans Administration("VA").
- Trials funded by centers or cooperative groups that receive funding from the government agencies noted above.
- Trials conducted under an Investigational New Drug application ("IND") reviewed by the FDA.
- Drug trials are exempt from having an IND under 21 CFR 312.2(b)(1).

DEVICE TRIAL

Medicare coverage for Investigational Devices and services "related to" the use of those devices is limited to those being studied by an FDA-approved clinical trial. Examples of services "related to" the use of the devices include hospital stay, the surgeon's and anesthesiologist's fees, and other professional/technical fees for services required during the device's implantation.

FDA categorizes all Investigational Device Exceptions (IDE) applications into two categories:

Category A: Innovation devices for which the 'absolute' risk of the device has not been established (i.e., initial questions of safety and effectiveness have not been resolved). CMS does not cover Category A devices under Medicare because they do not meet the statutory requirement for Medicare to pay for devices deemed reasonable and necessary. The study designed for this type of device would most likely examine its safety and effectiveness.

Category B: Non-experimental and/or investigational devices where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. CMS will cover Category B devices if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met.

However, there is an exception for devices deemed reasonable and necessary for rare diseases, where it would be challenging to gather enough clinical evidence to meet the FDA standard for safety and effectiveness. This regulatory pathway was created for humanitarian medical devices intended to benefit patients in diagnosing and treating rare diseases that affect less than 8,000 individuals in the United States annually.

CMS Policy on Device Trial Billing

The CMS does not cover Category A devices because they do not satisfy the statutory requirement that Medicare pays only for items and services determined to be reasonable and necessary. However, CMS will cover Category B devices if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met.

Medicare's approval process for device trials involves a two-part authorization request submitted by the study PI to the fiscal intermediary (National Government Services/NGS).

HOW ARE RESEARCH PATIENTS FLAGGED IN ONCORE?

Weill Cornell Medicine policy mandates that each research study participant who signs an ICF must be registered in OnCore. The study team must enter the date of consent and upload the signed ICF into OnCore for review by the central registration team. After that, the registrar enters the eligible status and 'on study" date if the consent is valid.

If the participant consented to a study involving billing services, the participant's medical chart is flagged in Epic, creating a patient-study association ("study record"). This association will allow study-related information and/or activity to be documented, encounters and/or orders to be linked, and ultimately, study-related charges to be routed to the research workqueues for review. This "study record" can be found in the patient's medical chart under the tab 'Research Studies' and includes the study title, the type of study, the start date, the IRB, and the NCT number. If Medicare and/or a third-party insurance payer requests a medical review, this study information must be provided. A copy of the participant's signed ICF must also be available if the participant requests a medical review.

RESEARCH IDENTIFIERS USED FOR RESEARCH BILLING

Weill Cornell Medicine policy requires that the correct research modifier and research diagnosis code be appended to all claims billed to the patient and/or their insurance.

When conducting research billing compliance audits, the OOC reviews a sample of research participants' billing activity for their routine/standard-of-care services associated with clinical trials conducted at WCM to ensure they are submitted with the correct modifier and diagnosis code.

All research services must be posted with a valid CPT code and linked to the appropriate fee schedule (No dummy code (99999) OR $0.00 fee should be posted in Epic).

Research Modifier ("BG")

BG (Billable to Grant) is a modifier used in the Epic system to identify services paid by the sponsor/study. This internal modifier, unique to WCM, prevents a bill associated with the charge from being released to the patient or the patient's insurance.

Any charge posted with the BG modifier will be suspended in a charge review work queue for dispositioning either as research-related standard of care or billed to insurance. This suspension only occurs when the participant is *not yet registered* in OnCore; once registration is complete, the BG modifier allows the charge to route according to the participant's coverage designation.

Research Modifiers ("Q1" and "Q0")

The Q1 modifier is used to identify items and services that constitute medically necessary routine/standard of care or treatment of complications arising from a Medicare beneficiary's participation in a Medicare-covered clinical trial. The Q1 modifier is the provider's attestation that the service meets the Medicare coverage criteria (i.e., was furnished to a beneficiary participating in a Medicare qualifying clinical trial and represents routine/standard patient care, including complications associated with qualifying trial participation).

The Q0 (numeral 0 versus the letter o) modifier is used for investigational clinical service provided in an approved clinical research study. Investigational clinical services refer to the items and services being investigated as an objective within the study. Investigational clinical services may include items or services approved, unapproved, or otherwise covered (or not covered) under Medicare.

Research Diagnosis Code ("Z00.6")

The research diagnosis code Z00.6 is used to identify a participant in a clinical trial. It is appended as a secondary diagnosis code (or in the primary position if the participant is a healthy control group volunteer). All claims submitted with modifier Q1 or Q0 require using the diagnosis code Z00.6.

Mandatory Reporting of National Clinical Trial ("NCT") Identifier Numbers on Medicare Claims

CMS requires WCM to include NCT identifier numbers on all claims forms for items and services provided in clinical trials. The NCT number is used only if the clinical services are associated with the clinical trial. CMS uses the NCT number to identify all items and services provided to beneficiaries during their participation in a clinical trial, clinical study, or registry. Epic has been updated with the NCT numbers for each corresponding protocol with billable clinical services.

How Research Indicators Are Applied to Claims

When a patient is enrolled in a research study, Epic prompts users to answer three research-related billing questions to determine whether the services are study-related or standard care.

Based on these responses, Epic automatically applies or removes research billing indicators on claims, ensuring accurate classification for tracking and compliance.

This process differentiates between billable routine costs covered by insurance (for qualifying clinical trials) and research-funded expenses, helping maintain billing integrity and regulatory compliance.

RESEARCH BILLING COMPLIANCE MONITORING

Research Billing Compliance Audit Program

The audit program aims to confirm that clinical services associated with a clinical research study are appropriately billed to patients and third-party payers, and to ensure adherence to all regulations governing medical billing practices related to clinical research, including but not limited to the CMS National Coverage Decision.

As an essential component, the OOC conducts routine internal reviews of professional fee billing for clinical services provided to research subjects enrolled in clinical trials or other human-subject research

studies. These reviews are designed to validate that clinical services associated with research studies are billed accurately and in accordance with applicable federal guidelines. The reviews follow the annual research billing compliance audit workplan schedule.

As part of this process, the audit program evaluates a sample of studies rather than all research clinical services at WCM. This approach helps identify knowledge gaps, assess billing practices, and recommend corrective actions to ensure compliance and accuracy.

The research billing compliance audit program uses audits and other evaluation techniques to monitor compliance and implement corrective action when necessary. Specifically, the program aims to:

- Ensure consistent payment responsibility for clinical services across all study documents.
- Reduce billing risks between research and routine standard-of-care services.
- Reduce the risks of inappropriate billing to research participants and/or third-party payers.
- Ensure appropriate recovery of clinical service costs associated with clinical research studies, and
- Ensure Principal Investigators (PIs) and their study teams implement the corrective actions for issue(s) identified during internal reviews to mitigate future risks.

When internal review findings require corrective actions, the respective PI and study team are responsible for implementing these actions.

Study Selection by the Research Audit Workplan

Studies to be Audits by the OOC are chosen through a comprehensive search conducted by the Joint Clinical Trials Office (JCTO). The resulting list of studies is then refined based on study billing risk, study type (e.g., interventional), current status (e.g., Open to Accrual), and protocol type (e.g., treatment or diagnosis). Studies that meet the criteria after filtering are included in the audit workplan for the fiscal year. This risk assessment helps inform the development of the research audit workplan.

A Guided Random Selection process is implemented to ensure equitable representation, and at least one study from each department and across divisions is included. If a department does not have a

study that meets the criteria for inclusion in the work plan, a "placeholder" is added to the workplan to accommodate any prospective study information if any were to prepare a coverage analysis for a new study within the fiscal year. Alternatively, a placeholder may be filled in for the work plan year by conducting a follow-up review of a previously audited study from the department to ensure that all corrective actions have been implemented.

Studies are prioritized for audit based on evaluating potential Impact, Vulnerability, and Speed of Onset factors. Annually, the audit schedule is established and initially presented to the Research Billing Compliance Audit Workplan workgroup for awareness and guidance. It is then presented to the CCOC and the Audit Risk and Compliance Committee of the Board of Trustees for acceptance.

In addition, to the workplan, compliance reviews can also be conducted via:

- A Probe review based on an alleged issue or concern, e.g., via the hotline or other report, insurance, sponsor, patient inquiry, or a pattern of payment denials.

Regardless of the review manner listed above, the formal, systematic two (2) stage audit review will be conducted to verify a consistent interpretation and effective application of study-related charges and to ensure that designated research billing systems are being utilized to the full extent and in adherence to all regulations governing medical billing practices related to clinical research.

Risk-Based Research Billing Compliance Audit

Each clinical trial selected for audit undergoes a systematic 2-step audit review:

1. Billing Grid Review: This review assesses the accuracy of the study's coverage analysis by performing a concordance review with the study protocol, informed consent, budget, and/or CTA.

2. Retrospective or Prospective Review: Following the Billing Grid Review, a sample of research subjects within the selected study is reviewed retrospectively or prospectively to ensure billing accuracy.

Before starting a scheduled audit, a Research Billing Compliance Audit Notice is sent to the Department's Chief Administrative Officer, compliance leader, and liaison. The notice outlines the

audit objective, explains the 2-step review process, and defines the scope. It includes a questionnaire that must be completed and returned to the OOC, along with the requested study documents, procedure information, and contact information of actively involved research staff.

A Probe Review differs from a Billing Grid and Retrospective/Prospective Review in that it is unannounced, unscheduled, and usually initiated based on an alleged issue or concern. The type of audit(s) conducted in response to a Probe Review depends on the specific content of the reported issue or concern.

Reporting audit results

For the Billing Grid Review, the department will receive an **Audit Memo** outlining findings and any required changes to the coverage analysis. Changes may include, but are not limited to:

- Adding or removing CPT codes.
- Correcting billing dispositions.
- Correcting the schedules of services or procedures.
- Adding footnotes to explain exceptional circumstances, and
- Outlining changes needed to resolve contradictions in the protocol, consent form, and/or the study budget or CTA.

For Retrospective or Prospective Reviews, a Compliance Audit Report (CAR) is issued to the Department. It outlines identified risks for incorrect billing (i.e., primary findings), other compliance issues (secondary or incidental findings), root causes of deficiencies or violations, and recommendations for corrective actions.

Primary findings of non-compliance indicate potential billing risk and include, but are not limited to:

- Double billing.
- Incorrect billing to the wrong payment source, where a service (s) is/are billed as standard-of-care (SOC) to the patient or their insurance, or SOC services are billed as research.
- Electronic Medical Record encounters for research-related services not linked to the study.
- Charges for research-related services were incorrectly dispositioned.

- Research-related services rendered but not billed/posted, and
- Research service posted with a $0.00 charge or deleted.

Secondary/Incidental findings of non-compliance may indicate a potential billing, coding, and/or documentation risk and include, but are not limited to:

- Lack of documentation of the informed consent process and/or failure to upload the signed consent (Rs02 – Informed Consent SOP) form to the participant's EMR;
- Documentation errors related to copying and pasting notes (OOC-C 400.61 Copy & Paste Restriction in the Electronic Medical Record), pre-charting, Epic template, or smart phrase usage;
- Missing "off-study" dates in OnCore for participants who completed the study protocol;
- Untimely completion of service notes documentation (3.07 Clinical Documentation: Timely Completion of Medical Record Entries);
- Absence of study-related documentation in the EMR.
- Reportable Events, as defined by the Institutional Research Board (IRB) (100.1 Human Research Protections Program).

Corrective Action Responses

In response to the Billing Grid Audit Memo and CAR, the Department must provide the OOC with a preliminary management response that includes a plan of action for resolving the identified risks, a completion timeline, and the identification of the action owner(s) responsible for implementation. If the OOC finds the preliminary management responses unsatisfactory, further discussion and cooperation must be undertaken to achieve an acceptable response within a reasonable period.

Upon acceptance of the preliminary response, a final response can be submitted along with the signed attestation from the PI, attesting that they have reviewed and endorsed the final management response(s) and agree to apply the coverage analysis and retrospective/prospective recommendations to all other ongoing studies.

For the Billing Grid review, a revised coverage analysis must be completed and submitted to the OOC, Joint Clinical Trials Office (JCTO), and, if applicable, the Cancer Clinical Trials Office (CCTO).

For the Retrospective/Prospective Review, audit results will be reported to the department's Chief Administrator Officer, Compliance Leader and Liaison, the JCTO, and IRB if applicable (i.e., for reportable events). The Central Business Office (CBO) is notified when the audit results require a patient or insurance refund. Per CMS guidelines, all refunds must be processed within 60 days. However, the Department is responsible for initiating and confirming that corrections have been completed.

If, during the audit review, the OOC determines that a particular finding needs to be escalated before the report is issued, the finding will be shared with the researcher, department leadership, and/or research leadership as appropriate. Immediate and preventive corrective actions are monitored, and the nature of the follow-up depends on the seriousness and complexity of the deficiencies.

RESEARCH BILLING COMPLIANCE REPORTING

Quarterly Report

The COO issues Research Billing Compliance Quarterly Reports to ensure that all research billing activities at WCM are monitored and properly documented. This report is distributed with the General Billing Compliance Quarterly Report to each Department Administrator and Billing Compliance Liaison.

<u>The following items will be included in the Research Billing Compliance Quarterly Report:</u>

- The total number of active clinical trials
- The total number of active clinical trials with billing risk
- The number of PIs associated with those clinical trials at risk
- A summary page that contains information about research audit results and actions taken/pending by the Department to ensure compliance with the Research Billing Compliance Policies.

The purpose of the Research Billing Compliance Quarterly Report will be to facilitate a reconciliation process. For closed studies with open enrollment in OnCore, the department will be required to verify the study's closure. Departments should reconcile the list of all active studies and confirm studies with billing compliance risk (studies with clinical services vs. studies with no clinical services). Departments should also verify the enrollment of active research participants against the WRB-HS.

The department's compliance team will be asked to thoroughly review the report and the required actions for any discrepancies. Any questions and/or concerns can be discussed with their Billing Compliance Manager during their Quarterly Report Meeting, though a separate meeting is not required for this review.

Annual Report

With the addition of active research information, the quarterly reports will be compiled and summarized in each Department's annual compliance report, which must be presented during a scheduled meeting of the Clinical Compliance Oversight Committee.

WHAT CAN BE DONE TO ENSURE COMPLIANCE WITH RESEARCH BILLING REQUIREMENTS?

- Determine whether your clinical trial qualifies for Medicare coverage for the routine care costs associated with the clinical trial.
- Review all research documents for consistency (coverage analysis with the study protocol, the IRB application, informed consent, and budget).
- Ensure consistency of payment terms across the research documents.
- Ensure documentation to support each service billed appropriately.
- Ensure that participants are entered in OnCore and that encounters are linked in Epic.
- Ensure the informed consent process is documented and the signed consent is uploaded to the participant's EMR.
- Ensure research-related services are correctly dispositioned before billing.

- Ensure all paper and electronic documentation includes the protocol name and number.
- Endorse the proposed strategies for mitigating the identified risk trends in Research Billing Compliance Audit Reports and apply them to other ongoing studies.

CONTACT INFORMATION

If you have questions or concerns about Research Billing Compliance, please contact:

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REFERENCE LINKS IN TEXT

WCM Compliance Plan

CMS Fee Schedules

Joint Clinical Trials Office Policy Rs02-Informed Consent

Clinical Trials Policy/Clinical Trials National Coverage Determination

Clinical Documentation: Core Requirements in Clinical Research Services

Medicare's Coverage Decision for Clinical Trials/Qualified Clinical Trials

Coverage Analysis

Building a Coverage Analysis

Advanced Beneficiary Notice (ABN)

Surprise Medical Bills

Coverage Analysis Guidelines

Qualifying Clinical Trial

Humanitarian Medical Devices

National Clinical Trial (NCT) Identifier

CMS Manual

Audit Program

OOC Compliance Policies