

<b>Applicability:</b>	UW Medicine
<b>Policy Title:</b>	Budgeting and Billing Requirements for Human Subjects Research Using UW Medicine Faculty, Facilities or Services
<b>Policy Number:</b>	COMP.202
<b>Date Established:</b>	April 25, 2005
<b>Date Effective:</b>	July 8, 2024
<b>Next Review Date:</b>	July 8, 2027

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### **PURPOSE & APPLICABILITY**

This policy outlines standards and activities required for accurate human subject research billing. For purposes of this policy, individuals who receive billable services, items or tests while participating in a human subjects research study<sup>1</sup> are generically referred to as “study participants” or “study subjects.”

This policy applies to the following:

- All human subjects research studies (hereafter referred to as “studies”) utilizing services, items or tests furnished by a UW Physicians (UWP) provider, regardless of the site of practice.
- All studies with services, items or tests provided by a facility that generates financial transactions through UW Medicine Patient Financial Services (PFS) or Clinical Trials Office (CTO), whether these services are billed to study participants, their insurance providers or study budgets. See [202.G1 Billing Entity by Site of Practice](#).
- Principal Investigators (PIs), study teams, departments and offices collaborating on any research activities pertaining to the studies described above.

### **POLICY**

Complex federal and private payer rules and regulations govern the conditions under which services, items and tests performed in a study can be billed to study sponsors, study subjects or their insurance providers. Accurate study billing depends on planning and collaboration between the PI, their study team, and other individuals and institutional offices before, during and after the study is initiated. The purpose of this policy is to establish enterprise-wide standards, activities, and documentation requirements for accurate research billing, as well as to identify when studies require pre-implementation review by the UW Medicine CTO. Additionally, this policy outlines escalations and remedial actions when standards are not met or activities required by the policy are not performed.

### **Study Activities & Procedures**

The following list shows activities and procedures throughout the study lifecycle that generally affect research billing compliance and are governed by this policy. Other activities, not listed below, may also be required as determined by the institutional clinical trials governance bodies.

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<sup>1</sup> This includes, but is not limited to, clinical trials and clinical research studies, such as Investigational New Drug (IND) studies, Investigational Device Exemption (IDE) studies, CMS-approved Coverage with Evidence Development (CED) studies, subject registries, etc.

Note: Study teams must complete all required activities and procedures that are flagged with a “\*” in the section below.

- Pre-implementation:
  - Study document submission\*
  - Study entry into the OnCore Clinical Trial Management System (OnCore CTMS)
  - OnCore CTMS calendar build
  - OnCore CTMS calendar review\*
  - Procedural coding of study-related services, items or tests
  - Coverage analysis
  - Billing Grid (BG) review\*
  - Compliance review
  - Pricing finalization
  - Finalization of Informed Consent Form (ICF) in accordance with the BG\*
  - Receiving IRB approval of study protocol and finalized ICF\*
  - Budget development and negotiation in accordance with the BG\*
  - OnCore CTMS budget entry
  - Summary review (document congruence)
  - PI approval of final budget and BG\*
  - Receiving fully executed Clinical Trial Agreement (CTA or contract) with budget and payment language as approved by CTO during Summary review\*
  - Study activation in Epic Electronic Medical Record (EMR or Epic) system and other study implementation activities
  - Opening study to subject accrual in OnCore CTMS
- Post-implementation:
  - Enrollment entry and updates in OnCore CTMS\*
  - Submitting Medicaid Attestation<sup>2</sup> form\*
  - Study timeline management in Epic\*
  - Epic encounter linking to a study time point\*
  - Appropriate visit status and visit variation documentation in OnCore CTMS and Epic LAR (Epic study participant record)\*
  - Research billing review and charge routing in Epic
  - Invoicing study sponsor\*
  - Study amendments\*
    - Amendments or changes to the study that do not meet the Amendment Exclusion List and affect the BG or the budget require institutional REDCap intake submission, following an established process.<sup>3</sup>
  - Study closeout in Epic

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<sup>2</sup> 2021 federal legislation requires Medicaid Attestation for studies considered to be a “qualifying clinical trial” (QCT); this is a separate requirement from the Medicare Clinical Trial Policy. Specifically, both the PI and the study subject’s healthcare provider (HCP) must attest to the appropriateness of the subject’s participation in the QCT by submitting the WA State Health Care Authority (HCA) “Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial” prior to enrolling any study subjects with any Medicaid coverage (i.e., “traditional” such as WA State’s Apple Health program or Managed Medicaid coverage).

- If the PI is the same person as the HCP, then only the PI’s signature is necessary for the Medicaid Attestation form.
- If the PI is not the same person as the HCP, then separate signatures from both the PI and HCP are necessary.

<sup>3</sup> The Amendment exclusion list is located at <https://www.iths.org/ctms/ctms-submissions/study-amendments/>, and the study-specific survey queue link for submission is found in **OnCore > PC Console > Documents/Info > FAQs > Answer** to follow the “Changes to my Study What Next?” survey.

For all studies covered by this policy as described in the **PURPOSE & APPLICABILITY** section on page 1:

1. Each study must be:
  - a. Reviewed by CTO to approve the congruence of the study budget as well as contractual and ICF language with the coverage analysis and the BG in advance of opening the study to subject accrual; *and*
  - b. Conducted pursuant to the study's CMS coverage analysis and approved BG (performed and generated by CTO) that appropriately direct charges to the study sponsor, the study subject or the study subject's insurance provider.
2. For industry and non-federally funded (i.e., Non-profit, Foundation, Association, etc.) studies contracted through UW, the final negotiated study budget must be submitted to CTO prior to CTA execution to verify its alignment with the BG.
3. All clinical services, items or tests which generate a charge in Epic, whether billable to the study sponsor, study subject, or study subject's insurance provider, must be fully documented by the relevant healthcare provider of those services, items or tests in the medical record in a manner consistent with:
  - a. UWP and UW Medicine policies that establish documentation requirements for such items, tests and/or services;
  - b. UW Medicine policies and procedures that establish safeguards to prevent billing errors; *and*
  - c. Any grant provisions or contractual obligations entered by UW Medicine or study sites.
4. Potential costs to the study subject or their insurance provider while participating in the study must be:
  - a. Clearly disclosed and agreed to by the study subject during the informed consent process; *and*
  - b. Represented consistently across all active and approved study-related documents, including but not limited to the protocol, grant award, contract, budget, payment terms, BG and ICF. Study documents must not contain any language (including subject injury) that implies that a study subject or their health insurance program (government-funded or private) be charged first and the study sponsor pay the remaining balance not covered by insurance. Such language may implicate federal laws (e.g., Medicare Secondary Payer provisions) and could result in a False Claims Act violation by UW Medicine. In addition, any "carve-out" language that implies any variations in routing charges based on the study subject's insurance provider (or lack of insurance) runs counter to the principle of promoting equitable access to research regardless of study participant's insurance status and should not be accepted.
5. Studies are **prohibited** from reimbursing study subjects for any portion of their costs owed from a study visit (including co-pays, deductibles and coinsurance amounts after their insurance provider has been billed) **unless the study team has completed all of the following steps prior:**

- a. Obtain approval from the appropriate entity leader/financial official in accordance with the requirements of UW Medicine Compliance policy [COMP.205 \(Applying Charge Waivers and Discounts to Patient Accounts and Balances\)](#) and/or the equivalent UWP policy;
- b. Ensure this reimbursement option is disclosed in the IRB-approved ICF; *and*
- c. Work with CTO to appropriately document the reimbursement in the study-related documents.

These steps are crucial for UW Medicine complying with the False Claims Act by preventing subjects' insurance providers from being inappropriately billed for costs covered by study funding.

6. Study teams must ensure the following:
  - a. All study subjects are registered as patients of every UW Medicine hospital or site where study-related services will be delivered according to the procedures applicable at each site.
  - b. All study subjects have appropriate information about their research participation documented in their medical record in accordance with the policies of the study site as detailed in #3 of the current policy section.
  - c. All study subjects have their initial study enrollment and all status changes recorded in OnCore CTMS within **one (1) business day**.
  - d. All enrolled study subjects who meet study screening requirements have a study timeline in Epic. The "study timeline" is based on the study's Billing Calendar being "pushed" to Epic from OnCore CTMS and is individualized based on the specific study subject's visit schedule.
  - e. All research-related encounters, inpatient or outpatient, for enrolled study subjects are linked to their Epic study record and to the appropriate time point on the study timeline at the time of scheduling, prior to subject's arrival, or at notification of admission (whenever possible). "Research-related encounters" and "study time points" are those discretely called out in the OnCore CTMS Billing Calendar (e.g., Cycle 1 Day 1, Visit 2, 3 Week Follow Up, End of Treatment, etc.).
  - f. For studies that generate research-related charges in Epic or require research-related orders, study teams must record any visit procedure variations or exceptions to the approved Billing Grid in Epic LAR (enrollment comment field). This must be completed within **three (3) business days** of the date of service when a variation or exception occurred.
7. Studies testing a device under an Investigational Device Exemption (IDE) where any study-related services, items or tests are billed to study subjects or their insurance providers must be reviewed and approved by the Centers for Medicare and Medicaid Services (CMS) and/or its designated Medicare Administrative Contractor (MAC). The MAC must provide written confirmation that the study has been entered into its Medicare claims processing system. This review and approval process is coordinated by CTO and must be completed prior to CTO activating the study's Epic research account and the commencement of study subject enrollment.

8. When a study ends (i.e., all study subjects have received all services in the study BG), all study billing has been completed, and all study balances have been paid, study teams must update OnCore CTMS Protocol Status to IRB Study Closure and complete other steps under the Study Billing Closeout Process.

### **Escalation Process for Policy Non-Compliance**

Study team failure to adhere to this policy will result in the following actions:

- First (1) violation: CTO will confirm with the study team member(s) and/or PI that they understand the requirements of the policy and offer specific guidance on the missed steps.
- Second (2) violation: study team member(s) and/or PI will be required to repeat training on applicable policies and/or workflows (e.g., Epic and OnCore CTMS workflows) and submit the completion certificate(s) to CTO.
- Third (3) violation: study team's department leadership will be informed regarding the recurring violations and the risk of the study team losing Epic and OnCore systems access. CTO will facilitate additional training.
- Fourth (4) violation: study team member's and/or PI's Epic and OnCore CTMS access will be suspended. Study team's department and UW Medicine Compliance will be notified. Another appropriately trained study team member will have to assume responsibilities to ensure continuity of research participation until system access is restored. Prior to regaining access, study team will be required to submit Corrective and Preventive Action (CAPA) plan to be approved by the department leadership in consultation with UW Medicine Compliance. Access will be restored upon completion of all aspects of the approved CAPA.
- Further violations may result in institutional audits of all studies conducted by the team and in permanent termination of Epic and OnCore system access.

### **DEFINITIONS**

See [UW Medicine Compliance Glossary](#).

### **REGULATORY/LEGISLATION/REFERENCES**

- Centers for Medicare and Medicaid Services (CMS), Medicare Claims Processing Manual, CMS Pub. 100-04, Chap. 32 (Rev. 12571, April 11, 2024); available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c32.pdf>
- CMS, Medicare Benefit Policy Manual, Chapter 14 – Medical Devices (Rev. 198, November 6, 2014); available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c14.pdf>
- CMS, Medicare National Coverage Determinations (NCD) Manual Pub. 100-03, Transmittal 74: Medicare Clinical Trial Policy (CTP), (September 7, 2007); available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R74NCD.pdf>
- CMS, Coverage with Evidence Development; available at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>
- Consolidated Appropriations Act of 2021 (Public Law 116-260); available at <https://www.congress.gov/116/plaws/publ260/PLAW-116publ260.pdf>
- Social Security Act, Title 18, Section 1862 (42 United States Code Section 1395y): Exclusions from Coverage and Medicare as Secondary Payer; available at [https://www.ssa.gov/OP\\_Home/ssact/title18/1862.htm](https://www.ssa.gov/OP_Home/ssact/title18/1862.htm)

- US Department of Health & Human Services, Office for Human Research Protections, Federal Policy for the Protection of Human Subjects ('Common Rule'); available at <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>

#### **PROCEDURE ADDENDUM(S) REFERENCES/LINKS**

- [UW Medicine Compliance Glossary](#)
- [202.G1 Billing Entity by Site of Practice](#)
- Epic Training Materials
- UWMC, Medical Director Policies and Procedures: Medical Record
- HMC, Medical Staff Organization Bylaws, Rules, and Regulations
- [Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial](#)

#### **Contacts and Resources**

UW Medicine Clinical Trials Office (CTO):

Main Office: 206.543.7774, [uwcto@uw.edu](mailto:uwcto@uw.edu)

Billing Team: 206.543.9006, [crbills@uw.edu](mailto:crbills@uw.edu)

<https://clinicaltrials.uwmedicine.org/>

UW Human Subjects Division:

Main Office: 206.543.0098, [hsdinfo@uw.edu](mailto:hsdinfo@uw.edu)

<https://www.washington.edu/research/hsd/>

UW Medicine Compliance:

Main Office: 206.543.3098, [comply@uw.edu](mailto:comply@uw.edu)

Toll-free line: 855.211.6193

Anonymous: 206.616.5248, 866.964.7744

<http://depts.washington.edu/comply/>

#### **ROLES AND RESPONSIBILITIES**

Each UW Medicine workforce member is 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 audits or investigations. The specific roles and responsibilities with regard to this policy are listed below.

- The PI has primary accountability for all aspects of the clinical research projects operating under their name. The PI may delegate responsibility for the procedures required by this policy to qualified and appropriately trained members of the study team.
- CTO provides centralized support for PIs and is responsible for maintaining operations and researcher training programs (in conjunction with OnCore CTMS, Research IT, etc.) to support proper budgeting and billing in clinical trials. This includes reviewing and advising on study budget development, as well as development of Medicare Coverage Analysis-compliant billing plans which help drive accurate billing to the right payer. CTO also coordinates the required communications with the MAC in advance of IDE device study commencement, as described in #7 under the POLICY section.

- Supporting clinical, administrative and IT personnel (including, but not limited to: patient service representatives, Epic application analysts, coders, billers, clinic administrators and service providers) are responsible for maintaining procedures and working with the PI and study team to ensure that services for patients enrolled in research studies are scheduled, coded, billed and recorded in accordance with instructions from the study team, 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.
- UW Medicine Compliance staff members work closely with CTO, study sites and operational departments to develop procedural safeguards; receive and investigate allegations of billing noncompliance; conduct audits; and participate in the development and delivery of compliance training.

**APPROVALS**

/s/ Beth DeLair  
Beth DeLair  
Chief Compliance Officer, UW Medicine  
Associate VP for Medical Affairs, UW

7/11/2024  
Date