AdventHealth

POLICY

Policy #	Policy Name
CW AHC 106	Billing Compliance in Clinical Research Policy
Policy Location	**Responsible Department**
*Company-Wide Policies	Research Services
Executive Owner	**Original Creation Date**
Executive Director of Research Services	01/18/2022
Policy Effective Date	**Policy Review Date**
08/16/2023	08/16/2023

I. SCOPE: This policy applies to all employees and agents of AdventHealth and AdventHealth Medical Group (AHMG) who conduct human subjects research, provide Billable Patient Care Items or Services related to a research study protocol, or perform clinical research billing. That includes, but is not limited to, Research Services Personnel, Research Personnel, clinical providers serving as research investigators, employees involved in the registration of research participants, ordering, coding, or billing of research related Billable Patient Care Items or Services.

II. PURPOSE: This policy establishes AdventHealth's requirements to facilitate compliant clinical research billing, including appropriate billing of human subject's research that may potentially generate claims to participants or third-party payers for Billable Patient Care Items or Services designated as part of a research protocol.

III. POLICY: To ensure that Billable Patient Care Items or Services associated with the conduct of human subject's research are billed, in compliance with applicable laws, regulations, the Centers for Medicare & Medicaid Services (CMS) requirements, as well as institutional policies and procedures, study related documents, and grant and contractual obligations.

IV. PROCEDURE/GUIDELINES:

A. Billing for all Billable Patient Care Items or Services related to a human subject's research study and has Institutional Clearance must be:
   1. Consistent with CMS billing rules (including, but not limited to, requirements for billing "routine care services" to Medicare) or billing requirements of any other third-party payer being billed, including without limitation the application of National Clinical Trials (NCT) identifier numbers, as well as appropriate research-related modifiers and codes on Medicare claims.
   2. Consistent with any grant provisions or contractual obligations entered into by AdventHealth.
   3. Represented consistently across all study-related documents, including but not limited to the study protocol, grant agreement, contract, internal budget, Coverage Analysis (CA) or Billing Grid, and informed consent.
   4. Consistent with applicable AdventHealth policies and procedures.

B. AdventHealth research billing compliance training requirements are defined per the CW AHC 106 Research Billing Compliance SOP, including the following:
    1. Individuals required to complete training
    2. Method of training required based on role
    3. Frequency of training
C. All individuals with a role or responsibility under this policy will receive education and training regarding this policy.
D. For human subjects research in which there are Billable Patient Care Items or Services, and AHRI's Office of Sponsored Programs (OSP) determines, during the study start up process, the study qualifies for Medicare coverage of routine costs, a CA is required. AHRI may utilize an external vendor with expertise in clinical research CA development to conduct the CA. The CA establishes and documents billing decisions for each clinical research study prior to patient enrollment and is critical to determining accurate research billing. The CA must be referenced when reviewing research related encounters and all billing decisions must match the decisions documented in the CA for the related study. In the event OSP and the clinical research team is not in agreement regarding CA decisions (such as if items/services are considered routine care), OSP will request additional justification from the individual who developed the CA and the principal investigator supporting their opinions for discussion to resolution. If no resolution is reached, the decision may be escalated to the Director OSP.
E. To ensure research billing compliance, the following must be completed:
    1. A CA risk assessment must be completed for all human subjects research and documented in the study specific research budget template. This process will identify which research studies require a CA to be completed.
    2. All new clinical research studies including Billable Patient Care Items or Services must be communicated to all applicable parties per the approved workflow process for your AdventHealth division prior to recruitment to ensure any necessary research accounts are created for research charge delineation. For those divisions in Epic EMR the research study guarantor account creation is triggered automatically during the study build process or when the first hospital charges assigned to the research study are posted. For those studies, including non-AdventHealth providers, the study team must communicate with the providers office per the CW AHC 257 Research Billing Compliance SOP.
    3. Upon consenting a patient to a clinical trial the patient enrollment steps as outlined in the CW AHC 257 Research Billing Compliance SOP must be completed in order to hold research patient charges and drive those charges to the Epic report titled "Patients Needing Research Billing Review". These steps include linking the patient to the applicable research record in Epic by 7:00 pm local time. After informed consent is obtained, all research subjects must also be entered into the clinical trial management system (CTMS) as soon as possible.
    4. All research subject study visits and study visit elements must be completed in CTMS as soon as possible, but no later than 48 hours post visit completion.
    5. Research study and patient statuses must be maintained per the CW AHC 257 Research Billing Compliance SOP.
    6. To satisfy CMS billing requirements to include the trial name, sponsor, and sponsor-assigned protocol number in the medical record, the signed informed consent form

must be scanned into the electronic medical record (EMR) for each subject enrolled in a clinical research study that includes Billable Patient Care Items or Services.

F. All study specific information and documents necessary for complete and accurate research billing compliance and invoicing must be made available to all parties involved in ensuring the processes are performed correctly, as needed. Including, but not limited to the study protocol, informed consent, clinical trial agreement, CA risk assessment, CA and Billing Grid, study type as defined in Epic, employment status of providers participating in study activity, physician payment letters, and Schedule As.
G. Compliance with this policy and associated CW AHC 257 Research Billing Compliance SOP. will be subject to auditing and monitoring activities by ORIC and Corporate Compliance.
H. Violations of the requirements of this policy may result in one or more of the following (without limitation):
   1. Human subjects research that does not comply with this policy, may not receive Institutional Clearance and may not begin the study or utilize hospital services in support of the study.
   2. AdventHealth or reviewing Institutional Review Board (IRB) suspension or hold of associated study(ies) involved.
   3. Employee discipline or other administrative actions as appropriate.
   4. Requirement to develop and complete a corrective and preventative action (CAPA) lead by the AHRI compliance team. Additional training and education may be required as part of the CAPA.

V. DEFINITION(S):

For abbreviations not defined in this policy, refer to CW AHC 102 Abbreviations in Research.

Billable Patient Care Items or Services: Those items, procedures, and services with Current Procedural Terminology (CPT), Healthcare Common Procedural Coding System (HCPCS), Diagnosis-Related Group (DRG), and International Classification of Diseases (ICD) codes, billable to Medicare, other third-party payers, or to research.

Billing Grid: Documentation of billing decisions for research study that may or may not include Billable Patient Care Items or Services without detailed billing justifications for studies not determined to qualify for Medicare coverage of routine costs, for example; purely observational research with no protocol required items/services (conventional care), studies that are funded in full by research Sponsor or Funder and no Billable Patient Care Items or Services will be billed to Medicare or a third party payer.

Coverage Analysis (CA): A systematic review of research-related documents to determine the Medicare qualifying status of (1) the study itself, and (2) the Medicare billing status of the items/services provided to the research subjects over the course of the research. The CA is the mechanism for compliance with the Medicare billing rules.

Institutional Clearance: Action required and provided by the Office of Sponsored Programs (OSP) in order to initiate a research project.

Research Services Personnel: Individuals involved in the oversight of research.

Research Personnel: Individuals involved in the design, conduct, or reporting of research.

Schedule A: Documentation of specific tasks and compensation related to time and effort of an Investigator or sub-investigator.

VI. EXCEPTION(S): See CW AHC 101 Research Oversight

VII. REFERENCE(S):

Federal False Claims Act, 31 U.S.C. §§ 3729 – 3733

Anti-Kickback Statute, 42 U.S.C. § 1320a- 7b(b)
Physician Self-Referral Law, 42 U.S.C. §1395nn

Medicare Clinical Trials Policy - National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) (https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&fromdb=true)

Medicare Benefit Policy Manual, Ch. 14; https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c14.pdf

CMS Coverage with Evidence Development (CED), https://www.cms.gov/medicare/coverage/coverage-with-evidence-development/

Mandatory Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials
https://www.medicaid.gov/federal-policy-guidance/downloads/smd21005.pdf

VIII. RELATED DOCUMENT(S) / ATTACHMENT(S):

- Research Services Account Notification Form
- Research Oversight
- Abbreviations in Research
- Informed Consent Process and Written Documentation of Informed Consent
- SOP CW AHC 106257 Research Billing Compliance