Allina Health

System-wide Policy:
Research Billing Compliance Policy
Reference #: SYS-ADMIN-RA-200

Origination Date: April 16, 1999
Next Review Date: December 2026
Effective Date: December 2023

Approval Date: December 11, 2023
Approved By: Research Advisory Council

System-wide Policy Ownership Group: Research Administration

System Policy Information Resource: Manager of Research Operations

Stakeholder Groups
Research Integrity
Research Directors
Revenue Cycle Management (RCM)

SCOPE:

Sites, Facilities, Business Units	Departments, Divisions, Operational Areas	People applicable to
System Wide Allina Health Group; Abbott Northwestern Hospital, Buffalo Hospital, Cambridge Medical Center, District One Hospital, Mercy Hospital, New Ulm Medical Center, Owatonna Hospital, River Falls Area Hospital, Regina Hospital, St. Francis Regional Medical Center, United Hospital; Allina Health Emergency Medical Services, Courage Kenny Rehabilitation Services; Allina Health System Office; All other business units	All	Any person or entity, internal or external, involved in the conduct of research within an Allina Health facility

POLICY STATEMENT:

It is the policy of Allina Health that all clinical services associated with research studies are billed appropriately and in compliance with applicable federal laws, regulations and guidance, internal processes and policies, and contractual obligations.

Examples of research related activities that affect billing compliance include scheduling or ordering research visits or procedures, linking research visits, or billing for items and services related to research. .

Researchers, research staff, and Allina Health employees involved in research activities at Allina Health are required to report any good faith belief of non-compliance with law or regulation related to research billing by Allina Health business units.

Failure to comply with this policy may result in corrective and disciplinary action including, but not limited to, suspension of study activities, suspension of billing to participants and third parties and reassignment of claims from billing entities to research accounts, and/or employment action.

DEFINITIONS: N/A

PROCEDURES:

Research Advisory Council (RAC) will:

1. Provide recommendations to Chair for consideration in policy direction and oversight for the Research Billing Compliance Program.

Research Integrity will:

1. Provide policy guidance.
2. Provide guidance regarding research billing compliance laws and regulations.
3. Provide direction and oversight related to any reports of non-compliance as requested by Research Operations.

Research Operations will:

1. Maintain policies for research billing compliance.
2. Document procedures and guidelines for clinical research billing compliance.
3. Provide research billing compliance education to the Allina Health research community.
4. Coordinate the investigation and resolution of alleged research billing noncompliance.
5. Develop and maintain billing compliance metrics.
6. Provide reports at Research Advisory Council meetings on the status of overall compliance activities at the business units.

Allina Health Researchers will:

1. Participate in required training.
2. Adhere to Allina Health research billing procedures and guidelines.

3. Report research billing compliance concerns to any of the below:
    a. Research Operations OSPBilling@allina.com,
    b. Research Compliance researchcompliance@allina.com,
    c. Compliance Billing Adjustment or Correction Report (CABE),
    d. Anonymous reporting available through Integrity Line 1-800-472-9301 or online report.
4. Respond in a timely manner to requests for information associated with internal reviews or investigations.

PROTOCOL:
N/A

FORMS:
N/A

ALGORITHM:
N/A

ADDENDUM:
N/A

FAQs:
N/A

REFERENCES:

Related Regulation and Laws: (not limited to the below)

Medicare Clinical Trial Policy

Affordable Care Act (ACA), Section 2709

42 CFR 405 Subpart B – Medicare IDE Coverage

Medicare Claims Processing Manual Chapter 32
- Part 68 – Investigational Device Exemption (IDE) Studies
- Part 69 – Qualifying Clinical Trials

Medicare Managed Care Manual
- Chapter 4, 10.7 – Clinical Trials
- Chapter 8, 40.4.3 – Special Rules for the September 2000 NCD on Clinical Trials & 40.4.4 – Category B Investigational Device Exemption (IDE) Trials

Medicare Benefit Policy Manual Chapter 14, Investigational Device Exemption

Alternate Search Terms:

Clinical Trial Billing

Allina Health Regulatory Education Grid:
N/A

RELATED POLICIES/DOCUMENTS:

Name of Policy	Content ID	Business Unit where Originated
Integrity and Compliance Program	SYS-COMPLIANCE 900	Integrity and Compliance
Use of Excellian (Epic) Research Functionality	SYS-ADMIN-RA-001	Research Administration
Requirement for Complying with Research Operations Review Process	SYS-ADMIN-RA 201.00	Research Administration
Research Agreements and Contracts	SYS-ADMIN-RA 202.00	Research Administration
Research Site Responsibility for Identification of Non-Billable Items and Services	SYS-ADMIN-RA 203.00	Research Administration

POLICIES/DOCUMENTS REPLACING:

Name of Policy	Content ID	Business Unit where Originated
Research Billing Compliance Policy	RES 101.00	Office of Sponsored Programs