Allina Health

System-wide Policy:
Research Billing Compliance Policy

Reference #: SYS-ADMIN-RA-200

Origination Date: April 16, 1999
Next Review Date: February 2020
Effective Date: March 1, 2017

Approval Date: February 20, 2017
Approved By: Research Oversight Committee

{Please utilize these definitions}

System-wide Policy Ownership Group: Research Operations

System Policy Information Resource: Manager of Research Operations

Stakeholder Groups
Research Oversight Committee
Research Operations
Research Compliance
Research Directors

SCOPE:

Sites, Facilities, Business Units	**Departments, Divisions, Operational Areas**	**People applicable to** (Physicians, NP, Administration, Contractors etc.)
System Wide	System Wide	Any person or entity, internal or external, involved in the conduct of research within an Allina 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 regulations and guidance, internal processes and policies, and contractual obligations.

All personnel involved in the conduct of research at Allina Health including but not limited to registration of research participants, ordering of research items and services, coding research services, and/or billing for research items and services are shall comply with this policy.

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 billing of research 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: (Optional)

PROCEDURES:

Research Oversight Committee will:

1. Provide policy direction and oversight to the Research Billing Compliance Program.

Research Compliance will:

1. Provide policy guidance
2. Provide guidance regarding research billing compliance regulation and laws
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 research community
4. Coordinate the investigation and resolution of alleged research billing noncompliance.
5. Develop and maintain billing compliance metrics
6. Provide regular reports at Research Oversight Committee meetings on the status of overall compliance activities at the business units.
7. Interact with Government Payers according to Compliance Policy 402-01.14 as it relates to research billing inquiries.

Allina Health Researchers will:

1. Understand and adhere to Allina Health research billing procedures and guidelines,
2. Participate in required training
3. Report research billing compliance concerns
4. Respond in a timely manner to requests for information associated with internal reviews or investigations.

PROTOCOL:
Not applicable.

FORMS:
Not applicable.

ALGORITHM:
Not applicable.

ADDENDUM:
Not applicable.

FAQs:
Not applicable.

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: (optional)

Clinical Trial Billing

Allina Health Regulatory Education Grid:
Not applicable.

RELATED POLICIES/DOCUMENTS:

Name of Policy	Content ID	Business Unit where Originated
Compliance Program	SYS-402.01.01	Corporate Compliance
Interactions with Government Payers for Policy or Coverage Determinations	SYS-402.01.14	Corporate Compliance
Requirement for Complying with Sponsored Programs Review Process	RES 300.00	Office of Sponsored Programs
Written Agreements and Contracts for Research	RES 301.00	Office of Sponsored Programs
Research Site Responsibility for Identification of Non-Billable Items and Services	RES 303.00	Office of Sponsored Programs

POLICIES/DOCUMENTS REPLACING:

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