

Children's Hospital and Health System, Inc.
Administrative Policy and Procedure
Children's Research Institute

SUBJECT: Billing in Clinical Research Studies

POLICY

The protocol for a clinical research trial/study may include routine clinical services as part of managing a study subject's medical condition while participating in the study. Routine clinical services are defined as those services, items, and drugs that are provided consistent with the usual and customary standard of care including the type and frequency of any diagnostic modality.¹ Excluded from routine clinical services is the service, item, or investigational drug that is the subject of the study or any services, items, or drugs provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the subject's medical condition. Typically, routine clinical services provided to a patient enrolled in a clinical study are billable to third party insurers such as Medicare and Medicaid, or private insurance companies. However, when the sponsor of the study provides funding for these services these costs may not be billed to Medicare, Medicaid, other third party insurers, or the research subject.

In addition to routine clinical services, a clinical research study will have a service(s), item(s), or drug(s) that is the subject of the study which is considered the investigational or experimental aspect of the study. As a general rule, costs for items and services that are investigational or experimental – not considered medically necessary, safe, and effective – are not billable to Medicare, Medicaid, or other third party insurers. Securing funding of costs for services, drugs, devices, tests, and associated professional fees that are investigational or are needed solely to satisfy data collection and analysis needs is the responsibility of the principal investigator. Sources of funding may include industry, governmental agency, non-profits, or departmental funds. If funding is not secured, the study subject is then responsible for payment of these items and must be made aware of out-of-pocket costs through the informed consent process. Under limited circumstances, as provided in law and regulation, costs for experimental services or items required as part of a clinical research study may be billed to a third party payer.

It is policy that the study Principal Investigator has the ultimate responsibility for all aspects of the conduct of clinical investigation under his/her control. This includes the responsibility to ensure that all costs, incurred in the conduct of clinical studies are billed as appropriate, in compliance with relevant laws and regulations.

I. Identify All Billable Events for a Clinical Study

As of the effective date of this Policy, each clinical study with billable events will be conducted pursuant to a documented billing plan (as part of the IRB submission process) that:

1. Identifies the services, drugs, devices, and tests to be rendered in the context of the clinical study.
2. Identifies services, drugs, devices and tests indicated as necessary for the conduct of the study, but which would normally occur as routine clinical care for the underlying condition regardless of study participation.
3. States which party is responsible for paying for each service, drug, device or test.
4. Indicates an individual on the study team who will communicate with Children's Hospital and Health System (CHHS) Patient Accounts and/or the Medical College of Wisconsin (MCW) Billing and Collections for processing of research costs.

Clinical research studies without any billable events (for example: non-interventional chart reviews) are exempt from this procedure and do not require billing plans.

II. Resources for Compliance with this Policy

Investigators and research staff are encouraged to consult with CHHS Research Compliance and CHHS Finance for assistance in budget analysis and coverage determinations. Specific contact information for assistance in this area and information on the coverage determination process can be found on the Children's Research Institute (CRI) website. Budget development tools, billing matrix template, and instructions are also available in IRBnet and on the CRI Website.

III. Reporting Research Events – Billing Resolution

The Principal Investigator or research staff must ensure that CHHS Patient Accounts, and when necessary, MCW Billing and Collections, are properly notified of every subject enrolled into protocols with billable events, and all study visit specific charges are reported within 24 hours of the event. Once this information is provided, CHHS Patient Accounts and MCW Billing and Collections are responsible for reviewing the study patient/subject bill, and re-directing study specific charges to the appropriate payer.

Templates, forms, and contact information necessary for this process can be found on the CRI Website.

IV. Non-Children's Hospital of Wisconsin Professional Charges

Any study specific professional fees generated and billed through the Medical College of Wisconsin must be arranged with MCW Billing and Collections. If an agreement to waive a professional fee is has been arranged with a non-investigator healthcare provider, it should be documented and signed by the provider waiving his or her fees, and MCW Billing and Collections must be made aware of the agreement. Subject to an Investigator's departmental policy, Investigators may have the prerogative to waive their professional fees for research, and do not require any written documentation of this decision. Please note: Investigators and research staff may not waive any CHW fees.

References:

¹Wisconsin Legislative Council Act Memo 2005 Wisconsin Act 194
Medicare Clinical Research Policy

Approved by:

Peggy Troy, President of CHHS