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Complete Healthcare Compliance Manual 2024
Clinical Research: Medicare Clinical Trial Policy

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What Is the Medicare Clinical Trial Policy?

Clinical trial billing is one of the highest priorities for research sites that are doing therapeutic trials. This process is defined as a review of all documentation to create a coverage analysis to validate what can be billed out to commercial and government payers on a claim. It includes the coverage analysis with a convergence of documentation within the budget, contract, and consent. After a patient is identified as one who has consented to a particular study, tracking that patient throughout the life cycle of the study to ensure proper billing within the clinical trial policy and rules is best practice.

The clinical trial policy was enacted by President Bill Clinton in October 2000 to enable seniors to have more opportunity to participate in clinical trials.[2] Information gained from important clinical trials is used to inform coverage decisions, so Medicare was instructed to revise rules to expand benefits for qualifying clinical trials.

The types of trials that are of highest importance for compliance are the investigational device exemption (IDE); drug; and coverage with evidence development (CED) studies. The role of the Medicare's National Coverage Determination (NCD) and how it affects a site varies among different institutions. Because of the variety of tasks and responsibilities related to the clinical trial billing process, institutions often need several specialized individuals to maintain all aspects of compliance in billing Medicare and other types of health insurance. Establishing a billing compliance program takes not only expertise in the Centers for Medicare & Medicaid Services' (CMS) National Coverage Determination for Routine Costs in Clinical Trials (NCD 310.1), but also a significant commitment.[3] Finding expertise in this area can be extremely difficult. The breadth of employees who are involved in the process reach across an institution or site. It will include a principal investigator and research team, the finance staff, and coding department.

Formulations of how this work is performed at each site are based on the electronic medical record, physician–investigator relationship to the site and practice group ownership, a clinical trials management system, the institutional review board's views on identifying costs to patients, and the varying risk profile of the research portfolio. Staff must dedicate significant focus to billing compliance: by not having a solid program, a site can have true risks. By not having an effective program fully implemented, those risk increase. The roles and responsibilities defined by the U.S. Department of Justice Criminal Division's *Evaluation of Corporate Compliance Programs* in June 2020 should be configured by solid policies, procedures, and defined responsibilities of the compliance team.[4]

NCD 310.1 is an established policy that even after 20 years can be difficult to absorb. In order to cover conventional care, and the expanded benefits to monitor and prevent toxicities, one must understand the type of trial that is being done. Sites must designate who will perform the qualifying status and billing nature of the tests and procedures on the schedule of events in a clinical trial protocol. It takes careful review to ensure that all of the items eligible for billing Medicare and commercial insurance are correct and validated. This tedious process is called a coverage analysis. Within the study calendar, the items must be itemized as they will show up on a claim

for justification of billing. Reviewing published evidence-based guidelines provides direction on the billing process before the study starts and helps ensure compliant billing once patients are enrolled.

The risk of not providing a coverage analysis and review can lead to liability under the False Claims Act.[5] These risks were brought to national attention when Rush University Medical Center entered into a million-dollar settlement agreement with the Department of Justice in 2005 for clinical trial billing errors in cancer research. This included overpayments related solely to the NCD 310.1. Rush's settlement with the federal government was the first to focus on a clinical trial policy.[6] The potential for noncompliant billing in clinical research became noticeable for sites across the country after the Rush settlement. Many sites began conducting more intense evaluations of qualifying status and determining routine costs. The risks of vague budgets without coverage analysis guidance became more evident as auditing moved forward. The coverage analysis became a powerful, necessary tool. Recognizing the application of NCD 310.1 to research studies as a priority in the study start-up process has become increasingly more important throughout the last 20 years.