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Maximizing clinical research billing compliance: One site's journey to success

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Research billing compliance is a critical facet of the healthcare landscape, playing a pivotal role in ensuring ethical and transparent financial practices within the realm of medical research. At its core, research billing compliance refers to the adherence to regulatory standards and guidelines governing the billing and financial aspects of clinical trials and research studies. This compliance is essential to maintain the integrity of research findings, protect the rights of study participants, and uphold the trust of the public and funding bodies.

In 1995, the Centers for Medicare & Medicaid Services (CMS) issued a national coverage determination (NCD) related to routine costs associated with clinical trials.[1] This decision expanded Medicare coverage for certain routine patient care costs incurred during participation in clinical trials, recognizing the importance of clinical research and the need to facilitate patient access to innovative treatments. In 2000, CMS further refined its policy by issuing an additional NCD regarding the coverage of routine costs in clinical trials.[2] This decision aimed to clarify and broaden the coverage of items and services provided to Medicare beneficiaries participating in clinical trials. The intent was to encourage broader participation in clinical trials and ensure beneficiaries could access promising treatments without facing financial barriers.

NCDs reflected a growing recognition of the role clinical trials play in advancing medical knowledge and improving patient care. By providing coverage for certain costs associated with participation in trials, CMS aimed to support the inclusion of Medicare beneficiaries in clinical research studies. Furthermore, as of July 2007, Medicare covers the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in clinical trials.[3] The coverage requirements for routine costs of qualifying clinical trials services are found as part of the NCD guidelines.[4] These steps further align healthcare policy with the evolving landscape of medical research and treatment development.

Noncompliance with research billing regulations can have serious implications. It may result in financial penalties, loss of research funding, legal consequences, and damage to an institution's reputation. Additionally, investigators and institutions could face audits, investigations, or suspension from participating in federally funded research programs.[5] It is crucial to adhere to billing compliance to ensure ethical and legal conduct in research activities. Indeed, several organizations have faced legal action under the False Claims Act for issues related to clinical research billing.[6] One notable example is Duke University, which settled a case in 2019 for $112.5 million. The settlement resolved allegations that Duke submitted falsified data to the National Institutes of Health and the Environmental Protection Agency for research grants.[7] It is crucial to note that legal cases and

settlements can vary; organizations may take corrective actions to prevent future violations.

Setting

Stamford Health initiated a request for proposal for an external review of its research program in 2014 to perform a gap analysis to assess the current state of investigator-led and resident research; oncology clinical trials; gaps in policies and procedures for research and the institutional review board; research billing and compliance; HIPAA regulations; and conflicts of interest policies and practices. The company chosen was retained as it was deemed most capable of the expertise to thoroughly review billing compliance and grant budgeting processes and recommend software infrastructure needed for future growth. The company was tasked to identify gaps and develop recommendations that would both address current research needs and help guide the hospital in its efforts to expand research activity across different disciplines, such as cardiology, neuroscience, and other departments—including nursing and medical education.

Five dimension areas were assessed: governance and structure, people, process, compliance, and technology. While many excellent recommendations were made across the research program, the compliance observations and proposed recommendations are included for the purpose of this report. Key observations indicated that research billing compliance processes and controls were highly variable across the program, and the hospital's revenue cycle staff desired additional education and training on federal requirements as well as clarity on how study teams are ensuring the identification and flagging of research charges. In addition, gaps in policies and procedures existed, and organizational training and education on research billing compliance requirements were needed to drive awareness and accountability. Proposed recommendations included:

1. **Conducting a detailed billing compliance process assessment**. Stamford Health engaged a firm specializing in audit, tax, and advisory services to conduct a review of the accuracy of claims submitted for reimbursement through insurance for research participants at Stamford. The firm reviewed selected relevant clinical trial agreements and clinical study protocols and assessed the appropriateness of payments received. In total, five non-oncology studies (20 research subjects) and 42 oncology studies (113 research subjects) were reviewed, and consistent with our compliance program, refunds for any incorrect payments were made.

2. **Focusing the assessment on the gaps in the process and determining the efficacy of existing controls**. To address gaps in knowledge, Stamford Health engaged a consulting group specializing in research compliance to educate and train staff on various clinical research billing-related topics to implement new processes in response to identified gaps noted in the clinical research billing review. Included in the scope of the mandatory training sessions were discussions of the current regulatory environment and why this is important to Stamford Health, clinical research basics, Medicare billing basics, Medicare clinical trials policy, the device billing regulations for clinical trials, conducting a coverage analysis, and other related issues including Medicare claims processing guidance.

3. **Addressing key findings from the assessment and implementing those recommendations across the research program**. A research billing committee was created in 2016 to ensure research compliance and billing risk mitigation. This working group provided and continues to provide oversight, guidance, and decision-making support to the department of research and innovation, clinical research billing (CRB) enterprise. This working group first focused on developing, improving, and/or validating business processes critical to ensuring efficiency, financial accountability, and compliance with federal, state, and local guidelines on clinical research billing. Critical processes included identifying research subjects and encounters in the billing system/revenue cycle, tracking research subjects through the revenue cycle, segregating billable from nonbillable research charges, applying diagnosis codes, modifiers, and condition

codes appropriately, seeking reimbursement, and managing denials.

The executive director of the research and discovery department leads this working group. Working group membership consists of individuals from the organizational components representing Stamford Health's CRB process areas, including patient access services, health information management, practice administrators, billing and reimbursement managers, patient accounts, information services, revenue cycle management, professional billing operations manager, and ad hoc members when appropriate and pertinent issues arise.

The outcomes of the success of this program have not previously been reported on. Here, we present the findings of creating an efficient, harmonized process assigning accountability to the most appropriate owners and responsible parties to strike an appropriate balance between responsibilities to minimize error rates.