Clinical Research Billing: EHR Optimization
Recommendations for Non-Academic Medical Practices

American College of Medical Practice Executives
Professional Paper – FOCUS

Submission Date: June 11, 2018

Paper being submitted in partial fulfillment of the requirements for election to Fellow
Introduction

Physicians have historically engaged in clinical research for a variety of patient- and non-patient-focused reasons, including patient treatment benefit, specialty-specific scientific advancement, professional and personal interest, and research sponsor remuneration. Physicians routinely find that the availability of funding and other support resources is dependent on the specific investigational drug or device research topic, and they may initiate their own studies, collaborate with industry or non-industry sponsors, or engage with colleagues from other institutions to advance their interests and expertise in clinical research. When physicians in small practices engage in clinical research activities, they have traditionally dedicated minimal administrative and revenue cycle support to those efforts, typically maintaining clinical research activities separately from daily revenue cycle workflows. Practices have also historically used “shadow medical charts” and other tools to distinguish clinical research services from routine, non-research treatment services for research-enrolled patients. The manual processes have traditionally met the needs of the practices and research sponsors, since the sponsors typically prefer reports and unique invoices rather than industry-standard claim forms. Such parallel workflows were relatively easy to accommodate in a paper medical record environment.

The advent of complex electronic health record (EHR) systems in physician practices requires the incorporation of the clinical research workflows into those systems. Parallel paper workflows are discouraged, and healthcare organizations and practices that performed clinical research services in a non-EHR environment cannot readily transfer those manual workflows into an EHR environment. The translation of past workflows into a new EHR environment is not intuitive, and
practice operations teams require guidance and support in that effort. The incorporation of clinical research billing processes within general operational and revenue cycle workflows ensures that clinical care is effectively coordinated for each research-enrolled patient, whether or not each encounter includes research-related services. The merger of clinical research and non-clinical research billing workflows increases efficiency for the practice team members, allowing the team to fully leverage the established EHR system to support all clinical activity. It also ensures billing accuracy to research sponsors, government payers, insurance payers, and patients, regardless of whether research-related charges appear on a sponsor invoice, insurance claim form, or patient statement.

The research methodology for this paper consists of a review of governmental regulations and guidelines specific to clinical research billing, as well as the application of practical knowledge gained in working within multiple healthcare practice settings and EHR environments. This paper will review the historical background of medical billing for clinical research activities and the impact of EHR utilization on research billing operations. This paper will also provide workflow optimization recommendations that result in greater accuracy and efficiency in clinical research billing. While each EHR system houses its own proprietary architecture and uses product-specific terminology, some general infrastructure concepts apply to all EHRs that can be used for clinical research billing adaptation. Healthcare managers at all levels, particularly those employed in non-academic settings, will gain mastery in clinical research practice and revenue cycle operations, resulting in greater financial and resource preparedness to support clinical research in their own specific medical practice settings.

**Background**

References to clinical research activities date to biblical times. (King James Bible, Book of Daniel, ch 1 v 12-15), and physicians and their patients have jointly engaged in clinical research activities for millennia. Clinical research financial management in the United States has
undergone significant changes in the past few decades. Prior to the mid-1990s, clinical research study financial management was characterized by manual and labor-intensive workflow processes. Clinical researchers and study teams typically managed their enrolled participant activities via spreadsheet or other basic tools, and those tracking tools did not interface with billing support departments or systems. Information was not easily accessible to physicians or patients regarding best practice research study financial management, and billing compliance issues were common, typically due undocumented services delivered, unbilled charges, erroneously billed charges, and/or claim form errors. Such errors resulted in inaccurate billing to sponsors, government payers, insurance payers, and patients, resulting in significant risk management challenges and dissatisfaction for numerous clinical research stakeholders.

Since the mid-1990s, three federal government regulations were enacted to address clinical research patient access, funding, and management. Those developments continue to impact daily physician practice operations. Those regulations have also continued to evolve, increasing the operational complexity of clinical research billing activities.

From a patient access perspective, information about clinical trials was not widely transparent or available. Patients who wanted to participate in clinical research studies generally coordinated enrollment with their individual physicians, and neither physicians nor patients could easily learn about active research studies. Physicians and patients affiliated with academic medical research institutions, typically located in large metropolitan areas, could more readily engage in research studies, thus gain access to perceived better clinical care, than those individuals without such access. Restricted access resulted in physicians and researchers who could not readily encourage research participation for their patients, restricting the participant pool for active drug and device studies. The restricted patient access resulted in an adverse impact to the health of American citizens and medical science advancements.

In 1997, the Food and Drug Administration Modernization Act (FDAMA) required the U.S. Department of Health and Human Services (HHS) and National Institutes of Health (NIH) to
develop a publicly available registry of industry- and non-industry-funded research studies. (NIH, Clinical trials background). This registry, at the www.ClinicalTrials.gov website, was activated in February 2000, and was designed to provide transparency to independent researchers, physicians, patients, and other stakeholders regarding funded clinical studies for a variety of medical conditions. Each registered study has a unique assigned National Clinical Trial (NCT) number, used as a search parameter and reportable on claims. The registry initially focused on NIH-funded studies and did not mandate researcher participation (NIH, Clinical trials history). As of September 2016, all NIH-funded studies require registration on ClinicalTrials.gov. The registration mandate was further expanded for certain clinical trials of drug and device products effective January 18, 2017, with the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR part 11) (Federal Register, Clinical trials registration).

While the United States federal government worked to increase patient access to federally funded clinical research studies, it also coordinated efforts to provide funding for research-related clinical services. Prior to 2000, government and insurance payers did not reimburse for research-related medical services, which discouraged participation in clinical research studies. Historically, three responsible parties paid research-related costs; they were absorbed by the physician/medical practice, billed to a third-party who served as a sponsor for the research topic, or billed directly to the patient. The cost challenges had a particularly adverse impact on elderly patients, who are most likely to suffer from illness and disease (CMS, Medicare coverage).


The Health Care Financing Administration (HCFA, now the Centers for Medicare and Medicaid Services, CMS) issued a clinical trial policy National Coverage Determination (NCD), effective September 19, 2000. (CMS, Medicare coverage database). That NCD, (National Coverage
Determination (NCD) for Routine Costs in Clinical Trials (310.1)), was effective until 7/9/2007, and clarified the clinical trial characteristics and specific clinical services eligible for Medicare reimbursement.

Policy 310.1 was reviewed and revised in July 2007, and it clarified that a) items that are covered outside the trial are also covered inside the trial, and b) coverage would be provided for services eligible within a new Coverage with Evidence Development (CED) category. (CMS, Regulations and guidance). Effective January 1, 2008, with an implementation date of April 7, 2008, CMS also updated the CMS Manual to clarify claims processing requirements. (CMS, Regulations and guidance). The new policy implemented two new charge-specific Healthcare Common Procedure Coding System (HCPCS) modifiers for inclusion on applicable claim forms, as well as other charge-specific and claim-specific codes and processing requirements, which inform Medicare of the specific billable research-related services included on each claim form. Non-governmental payers adopted similar guidelines to their own enrolled member populations.

While new governmental regulations facilitated clinical research enrollment from the perspectives of patient access and funding, the federal government also developed programs to encourage healthcare facilities and providers in their adoption of advanced medical billing and EHR systems. The Health Information Technology for Economic and Clinical Health (HITECH) Act was enacted in 2009, which implemented Medicare and Medicaid incentive payments to encourage the meaningful use of EHR technology and improve existing information privacy and security policies and practices. (CMS, Fact sheet). The legislation has impacted every area of clinical care delivered to the United States patient population, including clinical research.

The significant developments regarding clinical research patient access, funding, and EHR interoperability have converged to increase patient demand for clinical research participation, resulting in a higher volume of clinical research activities at practice sites. Physicians and researchers need to leverage highly complex available technology to manage their clinical research line of business. While many physicians and their healthcare organizations have
continued to use parallel paper or rudimentary medical billing systems to perform the required billing functions, it is inefficient and exposes them to significant compliance risk. In an attempt to compromise, physicians and their care teams may attempt to transfer their existing manual workflows into their newly advanced technical environment, which also results in inefficiencies and deficient care coordination when they do not leverage the full scope of their available tools. Clinical research billing must specially designed for, and fully incorporated within, the overall revenue cycle processes, engaging multiple stakeholders from clinical, business operations, information technology, finance/revenue cycle, and compliance teams to ensure coordinated clinical care and compliant financial management for each enrolled patient.

**Challenges**

The current challenges regarding clinical research billing are numerous and can discourage well-meaning efforts to comply with clinical research billing rules in a sophisticated EHR environment. Those challenges include infrastructure support needs, clinical and study documentation quality, and interpretive variation minimization. The effective navigation of those risk areas is critical for success in an EHR environment.

Infrastructure support needs – Clinical research service delivery typically involves performing services in a non-traditional manner, or outside a typical schedule or standard, for patients who may otherwise be ineligible candidates for those services. A multidisciplinary team dedicated to clinical research operations is required to ensure common understanding and coordinated operational oversight, and to effectively communicate workflow issues and problems before they expand. From a clinical perspective, the physician researcher and care team must have a solid base of knowledge regarding the nature of the study and the specific services to be provided. The business operations team must have a clear understanding regarding patient registration, scheduling, and charge flow processes. A team of information technology analysts must have a thorough understanding of the medical billing or EHR system and provide technical expertise in the translation of clinical research concepts within the application. A team of credentialed coding
and billing analysts is required to ensure accurate charge direction, full coding and billing compliance, and metrics tracking and reporting. Active engagement by compliance experts is also required, to assess risk potential and provide guidance as required.

Clinical and study documentation quality - As a clinical research billing best practice, whether a practice participates in one or many studies, each research study requires study documentation to ensure a common and comprehensive understanding of study requirements. Each study should have a completed coverage analysis document, which assesses the study components against Medicare coverage requirements and documents funding eligibility from governmental, commercial, and sponsor sources (Piatt, D. and Willenberg, K., 2013 April, Compliance today, p. 37).

Each study should also have a billing grid, which can consist of a simple spreadsheet, or a complex, multi-arm document that resides in a separate clinical trials management system (CTMS). The billing grid specifies the particular services to be performed within the context of the study, the timepoints for completion, and the designated eligible payer for each service. When delivering research-related services to research-enrolled patients, the physician must document the nature of the services and their relationship to the study in each clinical note. This ensures clear and comprehensive understanding regarding the services performed and payer charge direction requirements.

Study-specific and patient-specific documentation components serve to inform the study team, coding/billing team, and other multidisciplinary stakeholders of the appropriate charge direction and billing requirements for the charges at issue. Those components also ensure full compliance with all billing rules and regulations. The technical and operational stakeholders can use the information to assess whether automated EHR solutions can be implemented to ease the workflow for physicians or support staff. From a technical perspective, such options include special reports or worklists, research-specific visit types, automated order sets, and alerts.
regarding potential missing associated charges. Operationally, a practice could develop more efficient study-specific service delivery workflows.

Interpretive variation minimization - Significant interpretive diversity exists regarding research-related terminology and billing policies. While such diversity is common in every healthcare specialty, the experimental nature of clinical research compounds the complexity level. CMS billing rules are not clearly defined, and differences of opinion are common between payers, research sponsors, and participating providers and institutions regarding responsible financial party. One example involves charge direction - many research stakeholders perceive a binary charge direction option (“bill to research study” or “bill to insurance/standard of care”). In reality, charges for enrolled patients can actually be directed in one of three ways: (Note that “standard of care” is a commonly used term by clinical researchers and is not a billing term, thus cannot be translated effectively into a billing direction.) The three charge direction options are as follows:

- Research-related, bill to study – services are required by the sponsor in relation to the study, and the charges are billable to sponsor via invoice.

- Research-related, bill to patient/government/insurance payer – services are required by the sponsor in relation to the study, but are not billable to the study, for certain Medicare-qualified studies. The charges are billable to the patient, or their designated government or insurance payer, and they require research-specific codes and modifiers at the charge and claim level to comply with billing guidelines.

- Not research-related, bill to patient/government/insurance payer – services are not required by the study or related to the study, but they were potentially performed on the same date of service as research-related services. The charges do not require research-specific codes and modifiers, and they process via usual patient billing and claim processing workflows.
As an example, a research-enrolled patient may arrive to a practice for research-related reasons and receive three different services: a scheduled X-ray Chest, a scheduled Current Procedural Terminology (CPT) Evaluation and Management (E&M) visit, and an unscheduled flu shot.

- X-ray Chest – the study’s billing grid clearly indicates that this service is required by the sponsor for the research study and will be paid by the sponsor. The charge is designated as research-related, bill to study. It is billed to the sponsor via a sponsor invoice. It is not billed to a different payer via a claim form or patient statement.

- CPT E&M – the billing grid clearly indicates that this service is required by the sponsor, but the service is typically paid by the patient/government/insurance payer due to the patient’s active clinical condition. The charge is designated as research-related, bill to patient/government/insurance payer. It is billed to the patient/government/insurance payer via a claim form or patient statement, with research-related codes and modifiers. It is not billed to the sponsor via a sponsor invoice.

- Flu shot – the billing grid does not include this service, and it is not related to the research study. The charge is designated as not research-related, bill to patient/government/insurance payer. It is billed to the patient/government/insurance payer via claim form or patient statement, without research-related codes and modifiers. It is not billed to the sponsor via a sponsor invoice.

A clear and comprehensive approach to addressing support infrastructure, clinical and study documentation, and interpretive variation serves as a strong foundation for the incorporation of research billing operations in a complex EHR system.

Recommendations
The construction of an effective clinical research billing system includes a thorough current state assessment of the medical billing or EHR system. Critical architectural decisions are required to ensure effective workflow processes and stakeholder satisfaction.

An advanced EHR application must be thoroughly analyzed to identify system-level opportunities and limitations for clinical research billing. (Willenberg K., 2014 November, Twelve tips for clinical trial billing compliance. Compliance Today, p. 57). A current state assessment must effectively identify how facility and professional charges flow through the system, from every servicing department, given that charges billable to research may be generated from any and every servicing area. Due to the three research charge direction options, an EHR system must include functionality that allows for charge direction to different research study accounts for sponsor billing, which may be separate and different from the architecture for the usual billing to patient or government/insurance payers. Within some EHR systems, each research study account may have its own established guarantor, payer plan, or contract, or each research study account may utilize a completely different methodology within the EHR system. New worklists and reports may be required to ensure timely and accurate charge processing.

An evaluation of how research-related codes and modifiers will be applied to charges and claims is required. An EHR system must incorporate the specific billing rules particular to clinical research services. Specific codes and modifiers must be added at the charge level and at the claim level for certain eligible studies and services, and the EHR architecture must be sufficiently flexible to address those needs.

The system must also be tested with samples of studies, enrolled patients, charges, and claims to ensure the workflow operates as intended and is corrected as required. Claims production and patient statement generation workflows must be thoroughly tested and optimized. A small, representative sample of studies and patients can be used to test newly constructed architecture and workflows. Such an effort will also increase stakeholder confidence within the research.
community, ensuring effective engagement in the process and encouraging active participation in optimization efforts.

**Discussion**

Clinical research billing has historically been a highly specialized area of the revenue cycle, primarily leveraged by large academic research institutions, due to their traditional role as clinical research innovators. Resource and access constraints typically restricted small physician practices from engaging in clinical research activities, resulting in limited experience with clinical research workflows. In the past few years, a variety of regulatory and technical developments have converged to increase the likelihood that a physician practice may need to become involved in clinical research management and billing activities. The construction of effective workflow processes and incorporation of them within a medical billing or EHR system minimizes compliance risk and increases workflow satisfaction by physicians, patients, and support teams. Non-academic physician practices can leverage their internal resources to effectively engage in clinical research activities, to the benefit of their patients, physicians, and research sponsors.
References

https://www.kingjamesbibleonline.org/Daniel-Chapter-1/


