HURON

Clinical research billing: Optimize efficiency and compliance with technology tools

STREAMLINE PROCESSES AND REDUCE ERRORS

Why clinical research billing compliance matters

When executed correctly, research billing compliance offers multiple benefits for academic research institutions, including improved recruitment of and experiences for study participants. It also increases principal investigator satisfaction and trust and strengthens relationships with sponsors and payors.

Conversely, the impact of non-compliance can be substantial. Incorrect billing can lead to study participant and administrator stress, costly litigation, significant write-offs, and a breakdown in the relationship among the institution, participants, study teams, and principal investigators.

By leveraging technology and assessing operational workflows, institutions can help ensure clinical research billing is more accurate, efficient, and compliant.

IN BRIEF

- Compliant clinical research billing offers multiple benefits for academic research institutions. Conversely, the impact of non-compliance can be substantial.
- Technology tools, such as electronic health records (EHR), clinical trials management systems (CTMS), and claims-generating systems, can streamline processes and reduce manual interventions.
- Before implementing any significant system changes, be sure to assess current workflows, barriers to compliance, and define desired outcomes to yield the best results.

> "With high stakes for reputation and cost, research billing compliance is critical for any institution undertaking clinical research."

Leveraging academic research technology

Several crucial points exist in research clinical billing workflows where technology tools, such as EHR, CTMS, and claims-generating systems, can improve compliance. When combined, they can streamline processes and reduce manual interventions in multiple ways:

Identifying research patients. As a first step, study teams must identify and communicate to the billing department which patients are enrolled in research. Many EHRs allow a flag to be applied to research patient records, which can be used to create a bill hold for charge review. In some EHRs, this flag communicates clinically that a patient is also a study participant. Some CTMS systems can interface participant enrollment data to an EHR, decreasing study team double data entry for enrollment. The actual charge review may be manual or partially assisted by other billing tools provided by the EHR. Using a CTMS to document when invoiceable study activity occurs provides an additional reference point for manual charge review.

Flagging visits with research activity. Beyond identifying a research participant, some EHRs allow the flagging of research visits. Flagging a visit as having research-related activity enables a more targeted and efficient charge review. Additionally, some systems can be set to exclude non-research-related visits from the research bill hold. However, allowing this functionality requires consistent flagging in all visits with research activity.

Automating charge segregation. Some EHR and CTMS systems provide additional support for research billing review, such as holding, correctly segregating, and applying research charges to the research study, patient, or patient's insurance provider. One EHR provides a tool that adds a degree of automation to charge segregation, reducing the manual review needed by bucketing charges into research and non-research categories. This downstream streamlining requires end-user intervention upstream. Some CTMS systems can interface study-level billing designation information to an EHR, for example, with Epic as the EHR and OnCore as the CTMS.

Adding research identifiers to claims. Medicare, many Medicaid programs, and many private insurers require that routine clinical services provided as part of a research study are flagged on a claim and that those claims also show additional research identifiers, such as the study's National Clinical Trials (NCT) number. Some claims-generating systems can add clinical research identifiers to claims if the charge-generating system flags them upstream. This step can reduce the number of manual interventions, streamline the workflow, and reduce the risk of errors.

Assessing technology workflows

Before implementing any significant system change or implementation, assessing current workflows, barriers to compliance, and desired outcomes yields the best results. As a starting point, consider these questions:

- How will existing structures, workflows, and the willingness for change affect the desired transformation?
- Who will identify a patient as a research participant and flag their record?
- Who can determine if a visit is related to a study or has any research-related activity, even if the primary purpose is clinical?
- Will designated employees have the specialized knowledge needed to complete the tasks, and if not, how will they be trained?
- How much of an administrative burden will be added to designated employees, such as study coordinators, who have the most knowledge about a study, or schedulers, who are often participants' first point of contact?
- Can centralized resources play a role in carrying out additional upstream tasks?

New technology tools will only drive transformation when the workflows they support are well thought-out, trained, and reinforced. Solid infrastructure and consistent communication are also critical. With so many factors and stakeholders to consider, beginning with a similar set of questions can direct you to the right technology solutions for your clinical research teams.

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