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www.AHIA.org Journal of the Association of Healthcare Internal Auditors Vol. 41, Number 5, 2022

Clinical Research Revenue Cycle

Understand regulations and risks to verify billing compliance

page 6

Staff Should Know to Report Suspected Diversion

Ensure education for recognizing/ reporting suspicious behaviors

page 13

What Does an Employee Fraudster Look Like?

Determine red flags and follow up cautiously

page 17

Hospice Audits

Assess the revenue cycle

page 24

FEATURE

Clinical Research Revenue Cycle

Understand regulations and risks to verify billing compliance

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Clinical research brings exciting opportunities for patients and healthcare institutions to gain insights and answers about the safety and effectiveness of drugs and other therapies. But clinical research also brings a host of regulatory risks, including billing compliance. Effective auditing requires understanding the background and basics of clinical research billing, the internal controls in the research revenue cycle, the most significant billing risks, and simple approaches for auditing to enhance compliance.

Clinical trials are complex and regulated, require the recruitment and retention of patients, and involve specialized roles and responsibilities.

Participants

Clinical trial sponsor – The clinical trial sponsor is often a pharmaceutical company, medical device manufacturer or government agency such as the National Institutes of Health (NIH), and may also be a principal investigator. The sponsor designs the study to address key research or medical questions. The clinical trial sponsor, Medicare, the healthcare provider institution, and other payers pay for the costs associated with the treatment under study.

Principal investigator – The principal investigator (PI), usually a physician, runs the clinical trial. The other clinical researchers can include doctors, scientists, nurses, and other research staff. The PI is responsible for overseeing and carrying out the clinical trial protocol.

Research subjects – The research subjects are patients who receive the clinical trial treatments and any routine medically necessary care.

Healthcare providers – Healthcare providers deliver both clinical trial treatments and any routine medically necessary care. They bill the sponsors, Medicare and other payers for the costs they incur in providing the clinical trial treatments and routine care.

Payers – Payers, including Medicare, typically reimburse for routine patient costs as defined by the Centers for Medicare and Medicaid services (CMS), such as doctor visits, hospital stays or tests that are the costs of medical care that patients would have received if they were not in the clinical trial.

Regulatory background

Prior to 2000, Medicare and private payers did not reimburse research-related items and services that occurred in clinical trials. In the early 2000s, CMS released the National Coverage Determination (NCD) – Routine Costs in Clinical Trials (NCD 310.1), also known as the Clinical Trial Policy (CTP).

The CTP provided new guidance on Medicare coverage of services performed within the confines of a clinical trial. Medicare allows reimbursement of specified routine costs in qualifying clinical trials, including reasonable and necessary items and services used to diagnose and treat complications arising from participation in all qualifying clinical trials.

In order for the services to be potentially billable to Medicare, NCD 310.1 requires that a clinical trial must be a qualifying clinical trial (QCT). If the study is determined to be a QCT, Medicare will pay for certain routine costs if no other Medicare rules limit coverage and no payment will be received from another funding source for that item or service.

Medicare is the largest payer of healthcare services and has the most sophisticated rules for clinical trial billing. Many

Research subjects receive clinical trial treatments and any routine medically necessary care.

Medicare has the most sophisticated rules for clinical trial billing.

third-party payers have adopted billing guidance based on Medicare's regulations.

Coverage analysis

To comply with NCD 310.1 and other federal and state regulations surrounding clinical research billing, healthcare institutions have established processes to ensure appropriate billing. One industry standard tool in these processes includes a coverage analysis (CA). A CA is a systematic review of research-related documents to determine the Medicare billing status of both the study and the items and services provided to the research subjects as required by the study.

The primary study documents that are utilized for the CA include the Study Protocol, Informed Consent Form (ICF), Clinical Trial Agreement (CTA) and any other relevant funding documents.

The primary purpose of a CA is to determine:

- Whether the trial qualifies for Medicare coverage
- Which routine care costs providers may bill to Medicare or other insurers and, conversely, which costs must be paid by the clinical trial sponsor or healthcare provider institution
- Whether Medicare rules allow for coverage of the specific routine costs within the clinical trial
- The application of the cost language of associated study documents (e.g., ICF, CTA and other relevant funding documents) to the CA

The CA can also be used to judge the financial viability and status of the clinical trial, as a budgeting and billing tool, a method to assist with managing compliance risks associated with research services, and for auditing and monitoring.

Development of a CA

Meet Medicare qualifying criteria

For any items or services to be potentially billable to Medicare, a clinical trial must meet CMS's qualifying criteria, which requires a two-part test:

- Is the study deemed to have the necessary seven desirable characteristics?[1]
- Does the study have all three necessary requirements?

Part one of the test is determining if the study is deemed to meet the seven desirable characteristics. Deemed studies include studies that fall into one of the four following categories:

- Trials funded by NIH, Centers for Disease Control (CDC), Agency for Health Research and Quality (AHRQ), Centers for Medicare and Medicaid Service (CMS), Department of Defense (DOD) and Veterans Administration (VA)
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA
- Trials conducted under an investigational new drug application (IND) reviewed by the FDA
- Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1)

Part two of the qualifying test is to verify that the study also meets all three of the necessary requirements:

- Investigates an item or service that Medicare reimburses (falls into a Medicare benefit category)
- Enrolls patients with diagnosed disease
- Has therapeutic intent

Analyze items for proper billing

Once the determination is made that a study is a QCT, the individual items and services occurring in the clinical trial (i.e., those that are required by the study protocol) are analyzed for potential coverage. The item or service must be something that Medicare routinely covers for its beneficiaries. If the item or service would not be covered outside the trial, then it would not be covered within a clinical

[1] See page 2 at https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/Downloads/finalnationalcoverage.pdf

trial. NCD 310.1 provides this guidance and structure for determining what services will be covered or not covered during a clinical trial.

For a nondevice clinical trial, you will need to thoroughly understand NCD 310.1 for an accurate analysis of whether certain items or services are billable. When determining the qualifying status of a device clinical trial, reference the coverage rules from regulations (21 CFR 812) and the Medicare Benefit Policy Manual, Chapter 14. If a device study qualifies, the remaining logic from NCD 310.1 may be applied (i.e., routine costs, Medicare rules, application of funding documents).

CMS identifies three categories of routine costs that will be covered during a clinical trial:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care)
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, particularly for the diagnosis or treatment of complications

NCD 310.1 specifically addresses the following items as noncovered services:

- The investigational item itself unless it is otherwise covered outside of the trial
- Items and services provided solely for data collection, that are not used in direct clinical management
- Items and services provided free of charge by the sponsor

Consider other Medicare rules

The third step of completing a CA is to overlay the concept from NCD 310.1 of "all other Medicare rules apply" to all items and services. This step includes the review and application of coverage determinations issued by both CMS and the local Medicare Administrative Contractor as well as any applicable Medicare manuals.

Research revenue cycle

The research revenue cycle includes the workstreams and processes by which an institution bills the charges associated with clinical research to the correct payer with proper codes and/or modifiers. The CA is a process within the wider research revenue cycle. While on the surface the concept may sound straightforward, the research revenue cycle encompasses every step and process of the clinical trial from the feasibility analysis through accounts receivable. Each step must have controls in place to ensure compliant billing.

Feasibility study and study intake

Many of the workstreams or processes in the research revenue cycle are carried out prior to subject enrollment. The institution's administration and the PI should collaborate to determine if the clinical trial will be beneficial for the institution and community, and if the trial is in alignment with the strategy, goals and operational portfolio of the institution.

Once the institution has decided to proceed with the clinical trial, a review of the associated study documents should occur as part of the study intake process. In this step, the institution should determine if the trial will proceed through the research revenue cycle for processing services that could generate a charge.

The review process will also ensure that study documents are gathered and stored in a central location and in a consistent manner. When the initial steps are omitted, the institution is put at risk for an avoidable strain due to lack of financial and/or organizational resources and capabilities to maintain a nonstandard process. The risk for improper billing is also minimized at study intake simply by identifying if the clinical trial will advance through the research revenue cycle, thereby necessitating a CA.

Coverage analysis

The CA is the tool used to ensure that the services occurring within a clinical trial are billed to the appropriate payer. The process to develop and implement the CA will vary from institution to institution depending on their clinical trial management system, billing department or other organizational characteristics. You should review the study documents to verify that the trial itself as well as the items and services (with accurate CPT or HCPCS codes) at the

Items or services that are typically provided absent a clinical trial will generally be covered by payers.

Coverage analysis ensures that the clinical trial services are billed to the appropriate payer.

correct timepoints are accurately analyzed according to NCD 310.1.

The CA is also a valuable instrument in the development of the internal study budget and the external budget and CTA negotiations. The CA must capture all study-related costs for the items and services as well as the costs related to personnel time and effort of the study team. The CA must also document that it is aligned with the budget and CTA. Study teams may review historical data such as previously negotiated budgets and CTAs to maintain consistency.

Document harmonization

When the CTA and the associated budget exhibit have been fully executed, and the ICF has been approved by the Institutional Review Board, the documents must be harmonized with the CA. This step ensures that the CA accurately reflects the items or services that may be billed to the patient or third-party payer and those that will be paid by the funding source or that have been promised free according to the ICF. Failing to complete this final step could result in improper billing and potentially False Claims Act violations and subject your institution to penalties and sanctions.

Subject registration and tracking

Once patient enrollment commences, subject registration and tracking is the critical next step in the research revenue cycle. Research subjects must be identified and flagged in the institution's billing system so that their claims can be reviewed, scrubbed (edits identified and corrected) and validated that they have been billed to the appropriate account based on the CA.

Costs that are to be paid to the institution by the sponsor should be invoiced, sometimes outside the patient accounting system, and payment rendered for the services. Accounts receivable management ensures that charge flows are monitored and completed in a timely manner.

Clinical research billing compliance risks

Multiple departments must be involved with clinical research billing to achieve compliance. The activities include:

- Pre-enrollment steps for ICF approval
- Study contracting/budgeting and coverage analysis
- Patient scheduling and check in
- Documentation, charge capture and claims review and billing

Each department must understand not only the workflows but also the risks involved in the process because of the many areas in the research revenue cycle where errors could occur.

Compliant clinical research billing is essential. Erroneous claims can result in overpayments. Overpayments that are not returned by the provider could result in False Claims Act penalties and/or civil monetary penalties. Overpayments that are the result of significant systemic problems could result in government imposed corrective actions, and possible loss of federal funding and participation in federal programs.

The complexities of the regulations and the billing process and the involvement of multiple departments make achieving compliance challenging. But other conditions can add to the challenges for appropriate billing.

Absence of training and understanding

A general lack of training and an insufficient understanding regarding clinical research billing risks often exists. Clinical research billing is a niche area of expertise, and expertise is not widespread at leadership or management levels to drive an understanding of risk and to develop appropriate internal controls. A lack of understanding about the risk is often coupled with a lack of understanding about research billing best practices and industry standards.

Additionally, the organization may lack the ability to recruit, identify or train for the expertise needed to perform certain elements in the research revenue cycle, particularly regarding the CA. Performing a CA requires a mix of regulatory, clinical, coding, and billing expertise that is very challenging to find or train for. Consequently, institutions struggle to have a best-practice CA process, which can lead to inappropriate billing.

Lack of appropriate documentation

Another challenge is a lack of appropriate documentation, including a lack of documented support for the CA, a lack of documentation regarding other decisions made regarding billing, or, more generally, a lack of document preservation and retention. When documentation is insufficient, or when documentation cannot be located, it becomes difficult to support billing decisions made in the past.

Documentation must be clear and address support relative to regulatory requirements. Study documents must be saved in a consistent location and format for future use, including for audits.

Siloed and decentralized departments

Siloed departments create another challenge because multiple departments need to contribute to compliant billing. Research operations, revenue cycle, compliance and legal departments need to have both an understanding of risk and controls, as well as have a forum for collaboration and communication.

Decentralized research operations and inconsistent processes across departments pose another challenge. Revenue cycle compliance is typically better if research operations and administration are centralized, with policies, procedures and other controls being centrally administered. In the absence of centralized research administration, consistent and clear policies and procedures should be in place, as well as open and intentional collaboration and communication between operations and administrative functions.

Lack of accountability

Lack of accountability can also be a significant barrier to achieving compliance. In organizational cultures where little accountability exists, administrative and research staff may feel less compelled to follow all policies and procedures when little oversight occurs and meaningful follow up or discipline is unlikely.

Insufficient auditing and monitoring

A lack of auditing and monitoring can contribute to poor compliance. Research operations staff should understand risk areas and conduct ongoing monitoring of high-risk activities, Concurrently, an independent and objective party, such as compliance, internal audit or an outside auditing partner, should conduct periodic risk-based auditing. Robust auditing and monitoring allow institutions to self-identify issues sooner and resolve them quickly, instead of an outside auditor identifying issues that may have accumulated into a more serious quantity and severity.

Ambivalence to key risks

The overarching and most significant billing risks in clinical research billing are rather straightforward:

- Double billing, such as billing a payer for items or services paid by the sponsor
- Billing for services promised free to the participant
- Billing for services that are for research purposes only (e.g., not used for clinical management, such as pure data collection)

Key controls

Operational controls for the research operations work-streams should be in place to prevent erroneous billing due to common revenue cycle risks.

A best practice research revenue cycle should include a robust CA process where compliance-savvy analysts review all protocol-required items and services against the requirements of NCD 310.1. They should document whether each item or service at each timepoint should be billed to the payer or sponsor.

The final approved ICF, the executed CTA and the associated budget exhibit should be reconciled to the CA before it is used for billing. Research participants need to be flagged so that their charges, based on the CA, are appropriately routed to either the payer or the sponsor.

Open lines of communication should exist between functions, clear and consistent policies and procedures should be in place, and ongoing education and training should be provided on the risks and application of the controls. Management should perform continuous monitoring of high-risk functions, and compliance or internal audit should perform intentional auditing to identify lapses in controls and potential aberrant billing.

Design and perform billing audits

Auditing clinical research billing may seem daunting to those who do not have expertise in this area. The first step for successful auditing is understanding the requirements of NCD 310.1, specific billing risk areas, and what internal controls should be in place.

Gain an understanding of operations and workflows in your research revenue cycle. Get to know the gatekeepers and assess whether key personnel understand and can clearly communicate both the risks and the overview of the research revenue cycle. Seek to map out the information flow and where the controls are in the processes. Determine the sufficiency of the controls in place.

Does a CA process exist, and is the CA in line with NCD 310.1? This area may require you to seek an outside

A lack of staff training and understanding poses clinical research billing risks.

Verify that sponsor-reimbursed items and services were not billed to a third-party payer or the participant.

perspective to evaluate correctness. The rest of the clinical research revenue cycle depends on the accuracy and appropriateness of the CA for compliant billing.

Is the final ICF applied to the final CA, documenting what services are promised free by the sponsor to the participant and cannot be billed to them or their insurance? Are the executed CTA and the associated budget exhibit applied to the final CA, documenting what items and services are to be paid by the sponsor, so that these are not billed to the participant or their insurance?

Does a clear and consistent way exist to flag research participants so their charges are appropriately captured? Are the charges routed, in alignment with the CA, to the appropriate payer, whether the sponsor, the healthcare provider institution or a third-party payer?

In addition to evaluating best practices in these specific areas, your audit should consider the presence, sufficiency and implementation of policies and procedures, and the provision of education and training. You should confirm that operational activities have checks in place and are monitoring the areas in the research revenue cycle that are most likely to affect billing compliance.

Perform specific testing

You can also perform specific testing. The most efficient and productive way to use your limited resources is to audit according to risk prioritization. Two of the most significant billing risks in clinical research billing are double billing and billing for items and services promised for free.

When examining clinical research billing enforcement actions over the last 20 years, these two items seem to be low hanging fruit from a government audit perspective. The items are easy to identify and are often under scrutiny, but, fortunately, they are also relatively simple to audit.

Any item or service that is paid by the sponsor according to the CTA and its associated budget exhibit should not be billed to the payer or participant. The CTA language should be written clearly so what the sponsor agrees to cover is obvious. Any item or service promised to the participant for free in the final ICF should not be billed to the payer or participant.

An ICF should be interpreted from no more than an eighth grade reading level, so a plain reading of the language should apply. However, sometimes interpreting ICF and CTA language can be difficult enough to justify seeking out a qualified opinion.

Simple approaches to auditing the two primary billing risks are recommended for auditors new to clinical research billing—a gap analysis to identify likely billing issues and detail testing.

Gap analysis

Identify process and control gaps that could allow incorrect billing related to double billing or billing services promised for free.

Determine if a process exists to analyze and segregate charges related to research studies before billing.

- Does a CA process analyze protocol-required items and services to determine if they are billable to the payer?
- Does the CA process include a harmonization step that incorporates the final approved ICF and executed CTA and its associated budget exhibit into the final CA?
- Is a process in place to flag research participants and charges at the time of scheduling and the visit?
- Are claims reviewed and charges segregated and sent to the appropriate payer at the time of billing?

If a CA process is in place, is the CA appropriately based on NCD 310.1? Determine the analysts' understanding of the regulatory risk and best practices, and the completeness of documentation. The step may require outside assistance, as the analysis can be quite technical. Since the CA is the basis for the billing decisions, the CA must comply with NCD 310.1 rules.

Detail testing

Use a simple approach to detail testing that is based on the highest risks—double billing, billing for services promised free and billing for services that are for research purposes only.

To test for double billing, identify a sample of CAs with their associated budget exhibits that have items and services that are paid by the sponsor. Audit a sample of claims for each CTA and budget to confirm these items and services were not billed to the third-party payer or the participant.

Anything promised to the participant for free should not be billed to the payer or participant.

References

- Basics About Clinical Trials (https://www.fda.gov/patients/clinical-trials-what-patients-need-know/basics-about-clinical-trials)
- Medicare Clinical Trial Policies (https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies)
- Medicare Coverage – Clinical Trials (https://www.cms.gov/medicare/coverage/clinicaltrialpolicies/downloads/finalnationalcoverage.pdf)
- National Coverage Determination – Routine Costs in Clinical Trials (https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=1&ncdver=2&chapter=all&sortBy=title&bc=18)

For promised-free testing, identify a sample of studies in which the ICF promises items and services for free. Audit a sample of claims for each study to confirm that these items and services were not billed to the third-party payer or the participant.

For services that are for research purposes only, identify a sample of clinical research studies that have potentially billable items and services. Determine the existence of a CA, and whether the CA appropriately analyzes billing according to NCD 310.1, and application of the final ICF and CTA.

Audit a sample of claims for each study to determine if what was billed to the participant and/or payer was appropriately billed according to the CA. Determine that services performed for research purposes, as designated by the CA, were not billed to the third-party payer or the participant.

Conclusion

Auditing clinical research billing can seem daunting without specific expertise, but you can perform an evaluation of internal controls and testing of the highest risk areas when armed with some basic information. Know the operational players and understand the workflows within the research revenue cycle.

Your assessment of controls, including policies and procedures, training, and monitoring and auditing, can provide important insights. Understand whether standards are in place and whether management understands the gravity of clinical research billing risks. In your audit process, include communication and collaboration with research operations and your compliance function. Perform assessments and testing where you have understanding. Consider outside expertise to partner on your auditing where you don't have understanding or when you identify potentially concerning findings. **NP**

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The fact that an opinion has been widely held is no evidence whatever that it is not utterly absurd. – Bertrand Russell