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"Business Administration for Clinical Trials: Managing Research, Strategy, Finance, Regulation and Quality"

R. Jennifer Cavalieri and Mark E. Rupp, 2015, 273 pages, Sigma Theta Tau International, $44.95

Review by Norman M. Goldfarb

"Business Administration for Clinical Trials: Managing Research, Strategy, Finance, Regulation and Quality" is a comprehensive introduction to the business side of clinical research. The section on Medicare coverage analysis illustrates the accessibility of the content:

> Institutions may require an independent review or an MCA to be conducted by the institution's billing specialists. For initial study approval, the investigator can expect their IRB to require a description of who is paying for the trial's testing and procedures. The IRB or the investigator's institution may have a clinical trial billing policy, and the investigator may need to demonstrate their compliance by completing related documentation.
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> If the protocol is amended during the course of the study, the investigator will need to re-review the impact of the protocol on medical billing compliance. Routine IRB reviews are likely to include a review of the billing compliance and a report of any unanticipated issues that might have occurred.
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> The cost of conducting the MCA, typically anywhere from $500 to $2,000, is a justifiable expense that can be negotiated as part of the start-up costs in a study budget for the sponsor to cover. The sponsor may have done this already, but because there are often regional variations, the investigator should protect their interests by automatically performing their own MCA.
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> One way to look at sorting out research billing charges is to sort them into three categories. Once the category is understood, the approaches become easier to understand. One category of charges is where sponsors pay for all study-related clinical trial charges with no charges going to the subject or their insurance provider. The billing practices in such cases may seem obvious, but in these cases it is very important to make sure that all of the study-related charges have been identified. One example of a potentially overlooked trial charge is any duplication of testing for eligibility. In this example, a research test is performed locally as well as by the sponsor's central lab. If the study requires that all patients of childbearing potential have a negative pregnancy test before enrolling and a blood sample for testing is collected and sent to the central lab, those results will not be known for at least 24 hours. The investigator cannot proceed with study-related activities, such as administering a study drug, until the result of the pregnancy test is reported. The investigator may be able to perform the same pregnancy test using the local laboratory and have a result within an hour and then proceed with study activities based on that result. However, the sponsor needs to approve this testing method and the local laboratory; this must be described in the IRB application as part of the methods, and the investigator must budget for the charge from the local lab.
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> Generally, a coverage analysis of this type is often an expedited process and will serve as an independent confirmation of billing compliance for the investigator, IRB and institution.

A second category is one in which the protocol activities are considered standard of care and the tests and procedures would be performed on the research subject whether or not they were involved in the research project. In this case, the coverage analysis will list the protocol activities, formally look up the guidelines, and document the location of the guideline. You may ask, "Why go through the motions if it's 'standard of care?'" Just because the investigator and the investigator's colleagues routinely do certain tests does not mean that they truly are standard care; these tests must be backed up by documentation, either from the patient's insurance company or Medicare rules and regulations.

Finally, many clinical trials fall into the category of being a mix of study-related clinical charges and standard-of-care charges. The coverage analysis will make sure that the protocol tests and procedures are completely identified and properly categorized. For example, administration of a study drug may require a combination of study-related and standard-of-care charges; the sponsor may provide the investigational drug, and the charges for infusion supplies and related costs may be standard care.

Other things to keep in mind include the need to treat all subjects' charges in an identical manner. You cannot bill research charges to only those subjects who have medical insurance and have the grant cover those who do not have insurance. Also, the sponsor may not ask the investigator to bill the subject's insurance first and then submit any remaining amount to them — in other words, making them the payer of last resort. Medicare and many other insurance providers will not allow this.

There is a significant cost to noncompliance. Clinical trial billing is an end-to-end process within a clinical trial. The MCA at the start-up of a study, and the monitoring and assignment of charges as the study activities are happening, conclude with the flow of research charges into the grant account. Investigators and institutions must create, educate, monitor and support the processes involved in clinical trial billing.

Some institutions use a checklist for each research study that requires review and signed approval from all of the clinical areas involved in the research. For example, a clinical drug trial for patients in intensive care that uses an investigational drug and requires an echocardiogram will need support from the nurse manager in ICU, the investigational pharmacist, and the cardiologists. Depending on the clinical trial volumes, the study may affect clinical business operations in each of these areas.

Incorrect assignment of research charges to the patient or their insurance provider can be a protocol violation because this violates what the subject was promised at the time of consent for participation and could also be insurance fraud. Research has been halted and large fines imposed for noncompliance. This noncompliance can be unintentional, for example, the use of inconsistent language in the contract and the consent form and where the charges actually ended up. It's a problem if the contract said the research was paying for a blood test, the consent form indicated the blood test was not paid for by the research, and finally the blood test was assigned to the patient's medical insurance.

This also results in patient/subject dissatisfaction which could (1) affect Hospital Care Assistance Program (HCAP) scores and thus Medicare payments to hospitals, and (2) result in a subject (and their family, friends, etc.) not willing to consider participating in clinical trials in the future.

Double dipping can be intentional or unintentional. Double dipping occurs when the sponsor pays the investigator for the cost of the blood test and the blood test also

gets submitted to subject's medical insurance. Intentional or not, it's wrong; it all matters, and the investigator will be held responsible.

The book consists of six chapters:

- The Business of Research
- Managing Administrative Information
- Managing Workplace Responsibilities
- Fostering Professional Relationships and a Productive Workplace Environment
- Managing Financial Performance
- Putting Regulations into Everyday Practice

The book is available in bookstores.

Reviewer

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