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Disclosing the Routine Costs of Participating in a Clinical Study

By Tammy Cobaugh

Informed consent of a potential study participant must include information about the potential financial costs the participant will or might incur during the study:

> When appropriate, one or more of the following elements of information shall also be provided to each subject:… Any additional costs to the subject that may result from participation in the research. (CFR 50.25 (b))

In this regulation, "additional costs" means those costs that the participant would not incur in the absence of the study. For example, if a hypertension study requires a treadmill test that is not standard of care, the sponsor typically covers that cost. This article addresses routine costs, not those incurred if a participant is injured.

Aside from the law and ethics, unexpected charges might cause participants to lose interest in participating or to contest the charges.

Different study sponsors — and even studies — have different policies as to what costs they will cover. Some sponsors pay for all study tests and procedures. Others do not pay for standard-of-care items. Others charge participants for certain items, such as a medical device. In addition, different institutions have different policies.

It is not always possible for the site to know in advance what the participant's costs will be, for the following reasons:

- Standard of care varies by region, site and physician.
- A given participant may or may not be due for a particular test or procedure. If he or she just had a treadmill test, for example, another one for the study probably would not be standard of care. During the study, a participant might be given a test outside the study right before it was scheduled for the study.
- Medicare and Medicaid reimbursement policies can vary by region or state. State laws vary, especially in oncology. Private insurance coverage varies by insurer and plan and can be unclear without pre-authorization. Deductibles, copays and limits vary. Some people do not have insurance.

Informed Consent Language

The following statement in the informed consent form may, technically, meet the regulatory requirement, but lacks detail:

> You or your insurer will be responsible for the costs of services required by the research study that are routine to treat your condition. You will not be responsible for the costs of services that are required only because you are enrolled in the research study.

However, if the site can provide additional information that would be helpful to the participant, the informed consent form should include additional detail:

- Itemize items for which the participant or insurer will or will not be responsible. If responsibility is mixed, e.g., the study pays at Visit 1 but not Visit 2, make this clear.

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- Make it clear if the participant's responsibility depends on anything. For example, the participant might be responsible for items that are normally standard of care but not necessarily in this case.
- Remind the participant that insurance coverage is subject to deductibles, copays and limits, which might affect his or her costs.
- Make it clear if pre-authorization from a private insurer is required to ensure coverage, e.g., for oncology studies in some states. Clarify what, if any, assistance you will provide.
- If the clinical research study is enrolling patients with Medicare Advantage (MA) or a private Medicare managed care plan, state that the participant might incur costs in addition to what MA or Medicare pays. Provide the CMS education sheet, available at https://www.medicare.gov/Pubs/pdf/02226.pdf. (These rules may change in the near future.)

A selection of the following statements can be adapted to cover most situations:

- We will cover the costs of all tests and procedures performed during the study.
- You or your insurer will have no costs for participating in this study.
- You or your insurer will be responsible for the cost of care you would have received if you were not enrolled in this study. However, you will not be responsible for the following costs:
- The following tests and procedures are normally covered by Medicare, Medicaid and health insurance plans. We will assist you in determining whether they are covered for you. If not, you will be responsible for the cost of these items:
- The following tests and procedures are standard items that are NOT normally covered by Medicare, Medicaid or health insurance plans. You will be responsible for the cost of these items:
- This study is entirely within routine care, so you or your insurer will be billed in the usual way for all costs.

Participants often do not know what costs their insurance covers, so a sentence like this could be used:

> Because you are in a research study, your health insurance might not cover these costs. If so, you may incur unexpected expenses from being in this study. If you are uncertain as to which costs are covered by the study, please talk to the study doctor or a member of the study team, or call your insurer's medical reviewer.

Example

Who will pay for the costs of the study?

The study will pay for the following items at no cost to you or your insurer:

- Medical history and physical exam at Visits 1 and 4
- XYZ drug (or placebo) provided at Visit 1
- Vitamins provided at Visit 1
- Lab tests performed at each study visit
- Electrocardiograms performed at Visits 1 and 4
- Other study tests and procedures not listed below

You or your insurer will be responsible for the following costs:

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- Glucose blood tests needed for Visits 2, 4, 6 and 8, whether or not these tests occur outside of these visits
- The $329 cost of the glucose monitoring device and supplies that you will use in the study and can keep after the study
- Standard medical care for diabetes that would occur if you were not in this study

Because you are in a research study, your health insurance might not cover these costs. If so, you may incur unexpected expenses from being in this study. If you are uncertain as to which costs are covered by the study, please talk to the study doctor or a member of the study team, or call your insurer's medical reviewer.

IRB Review

Most IRBs are not familiar with billing rules for clinical study costs and may, therefore, prefer only a general disclosure. It is unreasonable to ask them to read through protocols to find items that may or may not be billable to the participant or become experts in coverage analysis. Therefore, the investigator should provide the information in a straightforward manner that the IRB can understand and rely on, referencing pertinent sections of the protocol and other data used to draft this section of the informed consent form.

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