BNA, INC.

MEDICAL RESEARCH LAW & POLICY

BNA Employee-Owned Since 1947

REPORT

IRB Members Should Know More About the Reimbursement Rules For Clinical Trial Services

By Ryan D. Meade

The primary responsibility of institutional review board (''IRB'') members is to review proposed research studies with the welfare of the human subject in mind.[1] Following closely is to ensure that the research has scientific merit and that there is integrity to the study.[2] But what are the IRB's responsibilities related to scrutinizing studies for implications related to reimbursement from non-sponsors for the study's health care services?

There is no clear answer on the specific obligations of the IRB getting involved in the third-party payer reimbursement rules for research study services. However, there are increasing efforts by the federal government to ensure that health care services reimbursement rules are followed during clinical trials and an IRB may find itself at the center of these billing controversies. Up to this point, IRB members likely thought other parts of the institution were watching over the compensation issues of a clinical trial.

Recently, two important research compliance matters have occurred that involve reimbursement for clinical trial services. The Office of Inspector General for the Department of Health and Human Services issued a ''Draft Compliance Program Guidance for PHS Grant Recipients'' that specifically requires providers who receive federal funds for medical research to establish compliance programs that address appropriate application of financial reimbursement rules.[3] Additionally, in December 2005, Rush University Medical Center settled a voluntary disclosure of Medicare overpayments for cancer clinical trial services, which appears to be the first settlement involving enforcement of Medicare's National Coverage Decision on Clinical Trials (the ''Clinical Trials NCD'').

Reimbursement rules for clinical trials can be complex and vary by payer. Many payers tend to follow Medicare's Clinical Trials NCD, which allows coverage for certain defined ''routine costs'' for services provided during ''qualifying clinical trials.'' Certainly for most providers in the United States, Medicare is the primary payer and they usually design their billing mechanisms with the Medicare rules in mind. The Clinical Trials NCD increasingly is the foundation for any complex structures devised to manage billing for clinical trial services.

The Clinical Trials NCD can be a confusing rule with a number of ambiguities, but at the heart of complying with the rule is the need to harmonize the financial dimension of a variety of study documents. Control over

[1] *See* 21 C.F.R. § 56.111 and 45 C.F.R. § 46.111, generally.

[2] *See* 21 C.F.R. § 56.111(a)(1)(i) and 45 C.F.R. § 46.111(a)(1)(i) requiring an IRB to judge risks to subjects in light of whether the study procedures are ''consistent with sound research design.''

Ryan D. Meade is a consultant with Meade-Roach Consulting LLP in Chicago. He also is an attorney with the law firm, Meade & Roach LLP. Meade represented Rush University Medical Center in its recent research billing settlement with the federal government. He is an assistant professor at Rush University and adjunct professor at Loyola University Chicago's School of Law, where he teaches Medicare Law. He can be reached at RMeade@MeadeRoach.com.

[3] 70 Fed. Reg. 71316 (Nov. 28, 2005).

these study documents has tended to be the purview of different departments within providers with no one area having coordination responsibilities. However, the one place within institutions doing medical research where all of the documents converge for review is the IRB used by the institution. The IRB may be reviewing and approving documents that have serious financial implications and not realize that the reimbursement issues have converged on it.

Medicare Rule Requires Harmonization of Study Documents

In order to comply with the Clinical Trials NCD, a study must be analyzed to determine whether it is a ''qualifying clinical trial,'' and the protocol's schedule of events must be scrutinized to determine which items and services meet the definition of ''routine costs.'' The institution must apply the normal array of Medicare rules for any of the study events that meet the definition of ''routine costs.''

Equally important in the mix of research billing compliance are the sponsorship contract and the study informed consent process. The Clinical Trials NCD does not allow billing Medicare for any services that are being reimbursed by the sponsor through the compensation arrangement (budget) in the sponsorship contract. Additionally, the financial discussion of the study's informed consent process is implicated because anything promised free in the informed consent document cannot be billed to Medicare or charged to the study enrollee.

The IRB certainly has no obligation to be expert in Medicare rules, but IRBs do have access to the protocol and the sponsorship contract, and must approve the study informed consent, including the financial disclosure language in the consent document. If the financial disclosure language of the informed consent is not in sync with how reimbursement rules play out with the protocol's schedule of events and what the sponsor is paying for, then this language may not only be inaccurate but also may be placing the providers who use the informed consent document in precarious financial situations.

IRBs May Be Overlooking the Financial Disclosure Language of Informed Consents

The financial disclosure language of the informed consent may be one of the most overlooked sections when an IRB is reviewing the proposed document. This is likely because IRB members assume that the discussion of the third-party payer implications in the document have been tooled to meet both the provider's financial goals for the study and the complex charge capture and billing apparatus that providers typically must operate within. That the financial disclosure language of the informed consent has been adequately scrutinized and crafted before being submitted to the IRB may or may not be true.

Anecdotal evidence suggests that sometimes investigators ''borrow'' the language from other studies. When the proposed informed consent reaches the IRB, the language still may be placeholder language ''suggested'' by the sponsor in its template informed consent but not intended to be a definitive statement of the patient's responsibilities.

Federal Rules Minimal on Specific Language

Federal rules governing IRBs that review federally funded medical research (and typically adopted as governing all medical research reviewed by the IRB) obligate the informed consent to explain the financial implications of the patient participating in the research study. But the regulatory obligation is brief, stating merely that the informed consent document shall state, ''any additional costs to the subject that may result from participation in the research.''[4]

The lack of specifics in the federal rule has its up sides and down sides. On the up side, it is not difficult to comply with from a technical perspective. On the down side, the specifics of the wording of the financial disclosure section of the informed consent do not get enough scrutiny because the federal rule is so broad and easy to comply with.

Providers Need to Live Up to the Financial Disclosure Language of the Informed Consent

The legal status of a research informed consent document is a matter that is not well settled in the law, but the trend is to treat a written research informed consent as a contract.[5] This means that whatever the provider promises in the informed consent, it must live up to. If the provider agrees to provide free services or free drugs during the course of the study, and the patient signs the document and begins receiving treatments, the provider needs to live up to the informed consent's commitments even if the language of the informed consent document does not accurately reflect the financial arrangement with the sponsor or the reimbursement available to the sponsor from third-parties. If a drug is promised to be provided free, then it should be provided to the patient without charge. If services or types of services are promised to be provided without charge to the patient or the patient's third-party payer, then the services should not be billed even if the billing rules would have allowed the service to be billed.

While living up to the financial disclosure commitments in the informed consent may not be pleasant for the provider, this is not only a matter of a legal commitment but a matter of integrity for the provider. If providers have not been scrutinizing the financial disclosure language of the informed consent and decide wholesale to ignore these commitments, this could be a public relations nightmare for research at the institution.

What this means, however, is that there is a need for better up-front scrutiny of the financial dimension of the informed consent. Institutions should more carefully craft the language before the draft document goes to the IRB for review and IRB members should press institutions as to how the financial disclosure language came about and whether there has been sufficient scrutiny of the implications of the language.

Interestingly, scrutiny of the financial disclosure section of the informed consent not only helps the institution but also has the study enrollee's best interest in mind. The informed consent process in a research context should be one of full disclosure of all material facts.

---

[4] 21 C.F.R. § 50.25(b)(3) and 45 C.F.R. § 46.116(b)(3).

[5] *See, e.g., Grimes v. Kennedy Krieger Institute Inc.,* 782 A.2d 807 (Md. 2001); *Dahl v. HEM Pharmaceuticals Corp.,* 7 F.3d 1399 (9th Cir. 1993).

  MRLR ISSN 1539-1035

Certainly the cost to the enrollee and financial barriers that the patient must cross to participate in the study are material facts.

Not only should IRBs pay attention to whether the financial disclosure language of the informed consent accurately describes the reality of the situation, but research administrators should pay careful attention to this proposed language to ensure that it accurately reflects how the billing process intends to charge for clinical trial services.

What IRBs Can Do to Help With Billing Compliance

There are several things that an IRB can do to help providers maintain clinical trial billing compliance or assist in the harmonization of the financial disclosure language of the informed consent with the other study documents and the reimbursement rules.

1. IRB members should be educated on the implications of the financial disclosure section of the study informed consent. This should involve education on how the informed consent fits into the other study documents for billing purposes. Many IRB members do not understand that there are serious compliance and financial implications to the financial disclosure language of the informed consents that they review. In-service training for the IRB should include an overview of the Medicare program and not only its clinical trial billing rules but also the basics of how Medicare works and interacts with research and how commercial insurers view reimbursement for clinical trial services.

2. IRB members should be educated on the OIG's proposed research compliance program guidance and how a research compliance program may affect the IRB. Though the OIG guidance is in draft form, there is little doubt that some version of the guidance will be issued in final form in the near future.

3. IRBs should find out whether the institution has a clinical trials billing compliance initiative underway and ensure that there is coordination between the IRB administrators and the persons in charge of the compliance initiative. IRBs should learn from the compliance initiative where the institution ''fits in'' during the billing review process and how that process relates to the investigator crafting the financial disclosure language of the informed consent. Does the drafting of the language come after a Medicare review of the study has been performed and the sponsorship contract signed or is the language crafted in the middle of the process? There is considerably less compliance risk if the language is crafted after the sponsorship contract is signed because the landscape of the potential financial burden to the patient is unknown until negotiations with the sponsor are concluded.

4. If an institution does not have a clinical trial billing compliance initiative underway, then the IRB should raise to the institution the compliance risks of not undertaking such an initiative. Without proper billing analysis of the study, the IRB may not be well-informed as to what it has been asked to review in the financial disclosure language of the informed consent.

5. IRBs should ask investigators whether the study has been reviewed for billing purposes and whether the financial disclosure language of the informed consent has been properly crafted with the billing review in mind. The IRB may want to see the work papers of the billing review to confirm that it has been performed.

6. IRBs should ask investigators the origins of the financial disclosure language of the informed consent. Was the language written by the sponsor? Was the language borrowed from another study? Was the language crafted with the help of billing professionals?

While IRB members need not become Medicare or billing experts, they should keep in mind that the informed consent that they review and approve has far-reaching financial implications for the patients and the providers.