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Medicare Reimbursement for Clinical Trial Services: Understanding Medicare Coverage in Establishing a Clinical Trial Budget

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Medicare Reimbursement for Clinical Trial Services: Understanding Medicare Coverage in Establishing a Clinical Trial Budget

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ABSTRACT: In designing and setting up a clinical trial, investigators and private sponsors must take into account what costs will or will not be covered by third-party insurers and government payment programs like Medicare and Medicaid. Failure to "cost out" the clinical trials accurately can yield one of two results: either third-party payors are billed improperly, or even illegally, for experimental care, or significant research-related care is not billed, with either the investigating institution, or the research subjects themselves, shouldering the cost. Unfortunately, because Medicare has established different coverage principles to be applied depending on the type of trial being conducted, costing out the trial is not an easy task. This Article looks at the various Medicare coverage principles as they apply to clinical trials, including the 2000 National Coverage Decision and the recent expansion in coverage for Class A Investigational Devices created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The Article then examines how the Medicare secondary payor rule, which states that providers may not bill Medicare for items or services when another party has primary responsibility for those services, relates to clinical trails in light of recent commentary. The Article concludes with the presentation of a general framework that investigators can use to establish a clinical trial budgeting and billing system.

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Clinical trials—unless they are direct comparisons of two different standard-of-care therapies—most often involve procedures, services, drugs, or devices that differ from routine treatment. The question of how these nonroutine, often experimental, research-related items and services are paid for appears to have gone long unaddressed and unanswered in many medical centers. The issue, however, is important in assuring lawful billing and collections, in informing research subjects of costs they will bear for participating in a clinical trial, and in making it possible for providers to secure appropriate funding from research sponsors. In these ways, rules relating to insurance coverage for research-related services actually determine the allocation of the social costs of performing human subjects research and achieving clinical advances.

Ideally, the private research sponsor of a clinical trial, which is the entity primarily benefiting from commercially sponsored research, or a government agency's research grant would cover the cost of any items or services needed for a protocol that exceed those required for routine treatment. In fact, most third-party insurers and government payment programs, like Medicare and Medicaid, tend to exclude "experimental" treatment from coverage and will reimburse only for established care that already has been proven efficacious. Yet investigators and their research institutions do not know what costs they should ask grantors and sponsors to cover unless they first determine what items and procedures will be covered by third-party payors. In the worst of all possible cases, investigators and medical centers fail to "cost out" trials accurately before agreeing to undertake them, and the result is that one of two things occurs: either third-party payors are billed incorrectly and even illegally for experimental care that has not been identified as such in billings, or significant research-related care is not billed, with either the investigators and their institutions, or research subjects themselves, shouldering the costs. Alarmingly, research regulations deem informed consent to be absent when research subjects are not told what costs they will incur when enrolling in a trial; thus, insufficient costing out can constitute a violation of research standards.[1]

Medical insurance policies, managed care plans, and government reimbursement programs vary in the extent to which they cover these research-related items and services. Several states have adopted specific statutes requiring private insurers to

[1] 45 C.F.R. § 46.116(b)(3) (2005).

cover research-related items and services for certain categories of insured patients enrolling in clinical trials.[2] In some states, the beneficiaries of these requirements are limited to certain categories of patients, such as oncology patients.[3] Yet despite these rules governing private insurers, the focus in establishing a clinical trial budget should be on Medicare. Medicare is the largest single payor for medical services in the United States, accounting for almost twenty percent of all personal healthcare expenditures and over thirty percent of all hospital expenditures.[4] Furthermore, Medicare rules governing reimbursement tend to be the most detailed and tend to be followed by private insurers. When one adds to Medicare's financial predominance the criminal and civil penalties that attach to any incorrect or abusive billing of Medicare, then the compelling leadership role of Medicare among third-party payors becomes clear: Medicare must be obeyed, because its rules are the most detailed, and its penalties are the harshest. In these ways, Medicare has a disproportionate impact on all reimbursement practices, including in the area of research-related medical items and services.

Without a proper understanding of the rules governing Medicare payments for clinical trial services, providers risk violating

[2] *See, e.g.*, CAL. HEALTH & SAFETY CODE § 1370.6 (West 2005) (requiring coverage of routine care costs related to most cancer clinical trials); CONN. GEN. STAT. §§ 38a-504a to -504g (2005) (mandating coverage of routine patient care costs associated with most cancer clinical trials); GA. CODE ANN. § 33-24-59.1 (2005) (prohibiting exclusions of coverage of certain routine patient care costs for dependant children of insureds enrolled in approved clinical trial programs for treatment of children's cancer); MASS. GEN. LAWS ch. 175, § 110L (2005) (requiring coverage of certain patient care services provided as part of "qualified" clinical trials intended to treat patients with cancer); NEV. REV. STAT. § 689A.04033 (2004) (mandating coverage of medical treatments received by policyholders or subscribers as part of an approved clinical trial or study for the treatment of cancer or chronic fatigue syndrome).

> The following states have passed legislation requiring some degree of medical coverage for those who participate in certain clinical trials: Arizona, California, Connecticut, Delaware, Georgia, Illinois, Louisiana, Maryland, Maine, Massachusetts, Missouri, New Hampshire, Nevada, New Mexico, North Carolina, Rhode Island, Vermont, Virginia, and West Virginia.

ERIN D. WILLIAMS, CONG. RESEARCH SERV., LIBRARY OF CONGRESS, CRS REPORT FOR CONGRESS— FEDERAL PROTECTION FOR HUMAN RESEARCH SUBJECTS: AN ANALYSIS OF THE COMMON RULE AND ITS INTERACTIONS WITH FDA REGULATIONS AND THE HIPAA PRIVACY RULE 56 n.132 (2005), *available at* www.fas.org/sgp/crs/misc/RL32909.pdf (last visited Sept. 16, 2005).

[3] *See supra* note 2.

[4] NAT'L HEALTH STATISTICS GROUP, CTRS. FOR MEDICARE & MEDICAID SERVS. (CMS), NATIONAL HEALTH EXPENDITURES TABLES, TABLE 9: PERSONAL HEALTH CARE EXPENDITURES, BY TYPE OF EXPENDITURE AND SOURCE OF FUNDS: CALENDAR YEARS 1996-2003 (2005), *at* www.cms.hhs.gov/statistics/nhe/historical/t9.asp (last visited Sept. 20, 2005).

Medicare billing rules, sacrificing reimbursement, or both.[5] Medicare only provides coverage for those services that are reasonable and necessary for the diagnosis or treatment of an injury or illness.[6] Although this is true for all services, the rule presents unique questions in the context of clinical trials, where many treatments are experimental in nature or are conducted solely to satisfy clinical trial protocols. To help providers determine whether services are covered, Medicare has provided a great deal of guidance on coverage for clinical trial services. Unfortunately, much of this guidance has accreted over the years in response to particular issues or pressing political and legal concerns, and, as a result, Medicare has established not a single set of principles to apply to all clinical trials, but instead different coverage principles that are to be applied depending on the type of trial being conducted. Providers must therefore understand how to classify their trials under the Medicare typologies in order to determine which coverage principles will apply.

As an additional complication, Medicare may only be billed when another party does not have primary responsibility for payment.[7] Thus, when a trial sponsor or grantor funding a trial has agreed to pay for a particular service, the provider may not then choose to bill Medicare either instead of, or in addition to, the sponsor. This tenet is known as the Medicare "secondary-payor rule"—that is, Medicare is always a secondary, and never a primary, payor for healthcare services.[8]

This Article first examines the Medicare coverage principles for clinical trials, with an emphasis on recent regulatory changes and clarifications that have somewhat eased the process of obtaining coverage for aspects of clinical trial care. After examining the general coverage principles, the Article considers the Medicare secondary-payor rule and recent CMS actions that heighten the need for great care in drafting private reimbursement agreements with respect to clinical trials. Finally, after illustrating the basic reimbursement principles, the Article provides general guidance on how to establish a clinical trial

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[5] The terms "services," "items," "treatments," "procedures," and "therapies" are used interchangeably throughout this Article and are intended to encompass all items and services provided to patients.

[6] *See* 42 U.S.C. § 1395y(a)(1) (2005).

[7] *See id.* § 1395y(b).

[8] Medicare Coordination of Benefits, CMS, Medicare Secondary Payer and You (2004) [hereinafter Medicare COB], *at* www.cms.hhs.gov/medicare/cob/msp/msp_detail.asp (last visited Sept. 26, 2005). *See also* Margaret Manning, Am. Health Lawyer's Assoc., Health Law Practice Guide § 22:4 (2005).

budget and billing practice that is compliant with law and also secures appropriate and lawful provider reimbursement.

I. Medicare Coverage

Medicare has three different sets of coverage principles that may apply to a clinical trial, depending on whether the trial is: a "qualifying clinical trial," as defined below; a trial for one of two types of investigational devices; or a trial that is neither a device trial nor a "qualifying trial." Before examining the trial-specific rules, it is important to have an appreciation for certain general Medicare principles applicable to all clinical trials.

A. General Principles

Since its inception, Medicare has excluded from coverage all services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury.[9] Certain other categories of services have been excluded from Medicare coverage as well, either statutorily or through national noncoverage decisions.[10] Examples of these noncovered services include experimental therapies, elective cosmetic surgery, and hearing aids.[11] To the extent a clinical trial involves therapies that fall into a category of noncovered services, the provider will not be able to obtain reimbursement from Medicare for the excluded therapy itself. In many cases, it is relatively easy to determine that Medicare reimbursement is unavailable, as when a provider performs procedures that are clearly experimental or tests that are used for solely scientific, data-gathering purposes, and that would not be provided to patients with similar medical needs outside of a clinical trial.[12] On the other hand, when it is unclear whether a particular therapy should be deemed reasonable and necessary, providers may need to ask the local Medicare carrier or intermediary whether Medicare coverage will be permitted,

[9] 42 U.S.C. § 1395y(a)(1); CMS, HHS, Medicare Carriers Manual, pt. 3, ch. 2, § 2300 (2004), *at* www.cms.hhs.gov/manuals/14_car/3b2300.asp (last visited Sept. 20, 2005).

[10] *See* CMS, HHS, Medicare Nat'l Coverage Determinations Manual, ch. 1, pt. 4, § 310.1 (2005) [hereinafter CMS Determinations Manual], *available at* www.cms.hhs.gov/manuals/103_cov_determ/ncd103c1_Part4.pdf (last visited Sept. 15, 2005) (defining items and services generally available to Medicare beneficiaries as those items and services for which "there exists a benefit category, [they are] not statutorily excluded, and there is not a national noncoverage decision.").

[11] 42 C.F.R. § 411.15 (2005).

[12] Tests being used only for scientific purposes could include, e.g., a blood test or CT scan that is used only for data collection purposes, and would not have been provided to a beneficiary not enrolled in the clinical trial.

or look to the trial-specific principles discussed below for more guidance.[13] Virtually all clinical trials will involve at least some excluded therapies, either because a service is experimental or because it is being conducted for scientific, data-gathering purposes only. Nonetheless, once a provider determines that a clinical trial involves excluded therapies, the provider must then ascertain whether other, non-excluded services provided to the same beneficiaries are still covered by Medicare, or whether they too are no longer covered because of their relation to the excluded therapy.

This issue of whether a health service is "related to" a medical service for which coverage is excluded is critical because, historically, Medicare has not covered any services that are "related to" noncovered therapies.[14] This is often referred to as the "noncovered services rule." If a clinical trial has elements that are not covered because they are experimental, then any other services provided that are related to the excluded therapy are deemed noncovered as well.[15] Subsequent to September 2000, however, there has been an expansion in the coverage of services "related to" a noncovered therapy in some—but by no means all—types of clinical trials.[16] To determine whether services "related to" a noncovered therapy in a clinical trial may be covered by Medicare, one must therefore know whether the trial qualifies under the September 2000 guidance or whether it falls under the traditional Medicare principles.[17]

In addition to the "noncovered services rule," another traditional Medicare principle that tends to yield the same coverage result is a cost reporting rule, under the pre-DRG Medicare system, by which all "reasonable costs" were reimbursed to hospitals for their treatment of Medicare patients. Under the research costs rule, "[when] research is conducted in conjunc-

[13] See *infra* Section III for a discussion of the importance that the provider determine whether the Medicare carrier and/or intermediary will cover the item or service prior to entering into a clinical trial agreement with the trial sponsor.

[14] CMS, HHS, MEDICARE BENEFIT POLICY MANUAL, ch. 16, § 180 [hereinafter CMS POLICY MANUAL], *available at* www.cms.hhs.gov/manuals/102_policy/bp102index.asp (last visited Sept. 18, 2005); 65 Fed. Reg. 60442 (October 11, 2000).

[15] *See id*.

[16] *See generally* Program Memorandum from CMS, HHS, Medicare Coverage—Clinical Trials: Final National Coverage Decision [hereinafter Program Memorandum, Final National Coverage], *at* www.cms.hhs.gov/coverage/8d2.asp (last visited Sept. 26, 2005), discussed in greater detail in Section I.C., *infra*, notes 51-70 and accompanying text.

[17] See *infra* Section I.C, text accompanying notes 51-70, for a detailed discussion of the September 2000 guidance.

tion with or as a part of the care of patients, the costs of usual patient care are reimbursable to the extent such costs are not met by research funds."[18] Most hospitals are no longer subject to the "reasonable costs" payment methodology, but they are still required to file cost reports, and those reports must comply with Medicare rules.[19] Although these reports generally do not dictate payment amounts, they still embody a Medicare principle and approach to how research-related costs should be recorded and paid. Namely, that it is appropriate for providers to seek and gain reimbursement only for those costs that represent the "usual patient care" provided to patients who are also research subjects.[20] This means, essentially, that any increment in cost of patient care over and above the "usual" costs would not be reimbursable by Medicare. It is from this research cost principle that a common view has emerged that Medicare will not cover, and therefore should not be billed for, the "increment" in costs and services required by a trial that exceeds the cost of standard therapy.

Once the general principles are understood, providers can start to establish systems for determining whether individual services are covered by Medicare. In assessing whether services provided to enrollees in a clinical trial are covered, providers should divide the services into four categories: (i) the noncovered therapies themselves; (ii) services related to the noncovered therapies; (iii) services for conditions or complications that arise as a result of the noncovered therapies; and (iv) services medically necessary but unrelated to the noncovered therapies.[21] Services that are unrelated to a noncovered therapy but

[18] CMS, HHS, MEDICARE PROVIDER REIMBURSEMENT MANUAL, ch. 5, § 504.1 [hereinafter CMS PROVIDER REIMBURSEMENT MANUAL], *available at* www.meduohio.edu/research/medicare_research_costs.pdf (last visited Sept. 20, 2005).

[19] A few providers, such as oncology and pediatric hospitals, continue to be reimbursed under a "reasonable costs" methodology, but the relation of their actual reimbursements to their cost reports is increasingly attenuated. *See* Nina J. Crimm, *Evolutionary Forces: Changes in For-Profit and Not-For-Profit Health Care Delivery Structures; A Regeneration of Tax Exemption Standards*, 31 BOSTON COLLEGE L. REV. 1, 16-21 (1995) (describing the change from "reasonable costs" to the DRG-based system and the reasons oncology and pediatric hospitals were exempt).

[20] This reimbursement is subject, as always, to the secondary payor rules that are discussed below in Section II.

[21] *See* CMS POLICY MANUAL, *supra* note 14, at ch. 16, § 180. In providing guidance for determining whether a treatment is related to a noncovered service, the manual provides the following examples:

> A beneficiary was hospitalized for a noncovered service and broke a leg while in the hospital. Services related to care of the broken leg during this stay is a clear example of "not related to" services and are covered

that are necessary for treatment of a condition and thus within the standard of care, are covered by Medicare for all types of clinical trials.[22] So too are treatments for conditions and complications that arise as a result of an excluded therapy, as long as they are reasonable and necessary in all other respects and would not have been incorporated into a global fee had the underlying therapy been covered.[23] On the other hand, coverage of the noncovered therapies themselves and coverage of services related to the noncovered therapy will depend on the type of trial being conducted. It is for this reason that the trial-specific rules must be understood.

B. Trials for Investigational Devices

Medicare presently provides specific guidance on the coverage of medical devices investigated in clinical trials. These devices have typically not yet been approved by the Food and Drug Administration (FDA) for marketing, on the grounds that the safety and effectiveness of the devices have not been proven.[24] If a manufacturer wishes to study a medical device in a clinical trial, and the medical device has not been approved by the FDA for the applicable use, the manufacturer must generally obtain an "investigational device exemption" (IDE) from the FDA prior to using the device in a clinical trail.[25] The IDE specifically

under Medicare. A beneficiary was admitted to the hospital for covered services, but during the course of hospitalization became a candidate for a noncovered transplant or implant and actually received the transplant or implant during that hospital stay. When the original admission was entirely unrelated to the diagnosis that led to a recommendation for a noncovered transplant or implant, the services related to the admitting condition would be covered. A beneficiary was admitted to the hospital for covered services related to a condition which ultimately led to identification of a need for transplant and receipt of a transplant during the same hospital stay. If, on the basis of the nature of the services and a comparison of the date they are received with the date on which the beneficiary is identified as a transplant candidate, the services could reasonably be attributed to preparation for the noncovered transplant, the services would be 'related to' noncovered services and would also be noncovered.

Id.

[22] *Id*.

[23] *Id*. ("[S]ubsequent services that could be expected to have been incorporated into a global fee are considered to have been paid in the global fee, and may not be paid again.").

[24] *See* CMS Policy Manual, *supra* note 14, at ch. 14, §§ 10-20.

[25] *See id*. It should be noted that when a medical device does not involve significant risk, an IDE from the FDA may not be required; in those cases only Institutional Review Board approval for the clinical trial will be necessary. *Id*. § 60.

permits shipment of the device for the purpose of conducting a clinical trial.[26]

Before examining the coverage principles as they exist today, however, it is important to understand the ambiguity and litigation that has previously surrounded trials of investigational devices.[27] Prior to 1995, there was little specific guidance regarding the Medicare coverage or noncoverage of investigational devices; providers were charged with applying the "traditional rules" to investigational devices in order to ascertain whether billing Medicare was appropriate.[28] Medicare consistently took the position that the noncoverage of all investigational devices was a longstanding, and unambiguous, policy.[29] The fact that the trial was taking place pursuant to an IDE was, according to Medicare, an indication that the device was experimental, and therefore not covered.[30] Based on the principles discussed above, this meant that those services "related to" the investigational device also would not have been covered.

Nonetheless, many providers billed Medicare for items and services related to the implantation of investigational devices, and Medicare made a large number of "erroneous payments" for these claims.[31] After becoming aware that providers were billing for services related to investigational devices, Medicare informed providers that these payments constituted overpayments and were subject to recovery.[32] What followed were numerous claims filed against more than one hundred hospitals throughout the United States seeking to recover Medicare payments that were made "for surgical procedures utilizing medical devices which had not been approved by the [FDA]."[33]

[26] 42 C.F.R. § 405.201(b) (2005).

[27] *See Testimony on Medicare Coverage of Investigational Medical Devices*: *Before the Permanent Subcomm. on Investigations of the S. Comm. on Gov't Affairs*, 104th Cong. (1996) [hereinafter *Testimony on Medicare Coverage*], *available at* www.hhs.gov/asl/testify/t960214a.html (last visited Sept. 20, 2005) (statement of Thomas Ault, Director, Bureau of Policy Development, Health Care Financing Administration).

[28] *See id*.

[29] *Id*.

[30] *Id*.

[31] *Id*.

[32] *Id*.

[33] Press Release, U.S. Dep't of Justice (DOJ), Pennsylvania Hospital to Pay United States $3.2 Million to Settle Medicare Billing Allegations (Aug. 23, 2000), *available at* www.usdoj.gov/opa/pr/2000/August/497civ.htm (last visited Sept. 20, 2005); *see also* Press Release, DOJ, Justice Department Intervenes in Medicare Case Against Two Cleveland Hospitals (July 1, 2003) [hereinafter Press Release, Two Cleveland Hospitals], *available at* www.usdoj.gov/opa/pr/2003/July/03_

To date, the government has entered into settlements with at least thirty-four of these hospitals, recovering more than forty-five million dollars.[34]

Spurred in part by these claims, providers sought greater clarity and greater coverage for trials of investigational device; in response to these requests, new rules were published in 1995 for the coverage of investigational devices and related services.[35] These rules were intended to be "less burdensome and more customer-focused . . . [and] to provide Medicare beneficiaries with greater access to advances in medical technology and encourage clinical researchers to conduct high quality studies of newer technologies."[36] The 1995 rules, however, did not expand coverage equally for all types of investigational device trials. When the FDA grants an IDE, it will place the investigational device into one of two categories.[37] To this day, the two categories, Category A and Category B, each possess their own set of rules with respect to Medicare coverage.

Category B encompasses devices for which "underlying questions of safety and effectiveness [concerning] that device type have been resolved," or for devices that are of a type known to be "safe and effective because, for example, other manufacturers have obtained FDA approval for [the] device type."[38] Because Category B devices may therefore be considered reasonable and necessary, the local Medicare contractor has discretion to decide whether the device itself will be covered, unless there is already a national Medicare coverage policy.[39] For the local Medicare contractor to allow coverage, the following requirements must generally be met: (i) the investigational device must be used within the context of an FDA-approved clinical trial; (ii) the investigational device must be used according to

civ_395.htm (last visited Sept. 20, 2005); Press Release, DOJ, Texas, Washington, Oregon & Florida Hospitals to Pay U.S. $4.9 Million in Cardiac Devices Litigation (Feb. 21, 2003), *available at* www.usdoj.gov/opa/pr/2003/February/03_civ_103.htm (last visited Sept. 20, 2005); Press Release, DOJ, U.S. Settles with Seven Hospitals; Files Complaints Against Four in Cardiac Devices Litigation (Oct. 17, 2002), *available at* www.usdoj.gov/opa/pr/2002/October/02_civ_600.htm (last visited Sept. 20, 2005).

[34] Press Release, Two Cleveland Hospitals, *supra* note 34.

[35] Medicare Program; Criteria and Procedures for Extending Coverage to Certain Devices and Related Services, 60 Fed. Reg. 48,417 (Sept. 19, 1995) (to be codified at 42 C.F.R. pts. 405, 411).

[36] *Id*. at 48,418.

[37] 42 C.F.R. § 405.201(b) (2005).

[38] *Id*.; *see also* CMS Policy Manual, *supra* note 14, at ch. 14, § 20.2; 42 C.F.R. § 405.203.

[39] CMS Policy Manual, *supra* note 14, at ch. 14, §§ 30, 50.

the trial's approved patient protocols; (iii) the investigational device must be medically necessary for the patient for which coverage is being sought; (iv) the investigational device must be medically appropriate in amount, duration, and frequency of use or application; (v) the investigational device must be furnished in a setting appropriate to the patient's medical needs and conditions; and (vi) the investigational device must meet national or local Medicare policy guidelines for similar FDA approved devices.[40] The manner in which the local Medicare contractor decides whether Medicare coverage is permissible is no different than under the general principles discussed above; the contractor must still determine whether the "reasonable and necessary" rule has been met.[41] The difference for providers and the contractor is that Medicare has provided additional guidance to help the contractors in making decisions about the reasonableness and necessity of investigational devices.

If the local Medicare contractor decides that it will cover the Category B device, then all services related to the Category B device are also covered.[42] These "related to" services include: (i) all services furnished in preparation for the use of a device; (ii) all services furnished contemporaneously with the device and necessary to use the device; and (iii) those services furnished as necessary after-care that are incident to recovery from the use of the device.[43] If the contractor determines that coverage is not appropriate, then both the device and all services related to the device are excluded.[44] It is helpful to remember that this is not a new rule, but merely the application of the general principle set forth above; namely, that for clinical trials not covered by the NCD, no coverage of related services is permitted if the underlying treatment is excluded.

[40] *See id*. § 50.

[41] *Id*. § 30.

[42] When a provider is submitting claims for services provided as part of a clinical trial of a Category B investigational device, the claim should include the investigational device's IDE number and the "QA" procedure code modifier. The QA modifier must be used on all physician claims and, while there is no mandate to use it on hospital claims, a hospital may also try to include it as a matter of practice. *See* Program Memorandum from Health Care Fin. Admin., HHS, Transmittal AB-01-74, Claims Processing Instructions for Clinical Trials on Carotid Stenting with Category B Investigational Device Exemptions (IDEs) (May 3, 2001), *available at* www.cms.hhs.gov/manuals/pm_trans/AB0174.pdf (last visited Sept. 26, 2005)).

[43] *See* CMS Determinations Manual, *supra* note 10, § 310.1. It should be noted that it is not clear whether this definition of "related to" should be applied to trials that do not involve an investigational device and are covered by the general principles.

[44] *See* CMS Policy Manual, *supra* note 14, at ch. 14, § 50, ch. 16, § 180.

Category A includes all medical devices "for which [the] absolute risk of the device type has not been established (i.e., initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type is safe and effective)."[45] Because these devices cannot be deemed reasonable and necessary, they may not be covered by Medicare.[46] Based on the general principles discussed, it would be reasonable to assume that, because the Category A devices are not covered, neither are any services related to the Category A device, and, indeed, for all dates prior to January 1, 2005, this was the Medicare coverage rule.[47] However, as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress expanded the coverage of routine costs of certain clinical trails involving Category A devices.[48] Effective January 1, 2005, CMS was instructed to cover routine costs for Category A device trials if: (i) the trial meets certain criteria established by the Secretary, which are intended to ensure that the trial conforms to appropriate scientific and ethical standards; and (ii) in the case of trials initiated before January 1, 2010, the device involved in the trial is intended for use in the diagnosis, monitoring, or treatment of "an immediately life-threatening disease or condition."[49] For purposes of determining whether a disease or condition is "immediately life threatening," CMS has instructed Medicare contractors to use the following definition: "a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment."[50] Unfortunately, while these rules have the potential to expand coverage of routine services for Category A trials, the criteria for a Category A device trial's conformity to appropriate scientific and ethical standards have yet to be developed. At this point, in regard to Category A

[45] *Id*. at ch. 14, § 20.1.

[46] *See supra* notes 9-23 and accompanying text.

[47] *See* CMS, HHS, Medlearn Matters No. MM3548, MMA—Coverage of Routine Costs of Clinical Trials Involving Investigational Device Exemption (IDE) Category A Devices 1 (2004) [hereinafter CMS Medlearn Matters], *available at* www.cms.hhs.gov/medlearn/matters/mmarticles/2005/MM3548.pdf (last visited Sept. 26, 2005).

[48] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 731(b), 117 Stat. 2066, 2351 (2003).

[49] 42 U.S.C. § 1395y(m) (2005). When a provider is submitting claims for services provided as part of a clinical trial of a Category A investigational device, the claim should include the investigational device's IDE number, the "QV" procedure code modifier, and the ICD-9 Code V70.7. The QV modifier should be included on claims for both physician and hospital services. CMS encourages the use of the QV modifier wherever possible; however, there may be circumstances in which the hospital may not be able to "fit" the modifier on inpatient claims. *See* CMS Medlearn Matters, *supra* note 47, at 2.

[50] CMS Medlearn Matters, *supra* note 47, at 2.

trials, institutions and their investigators must therefore look to the local Medicare intermediaries for guidance on billing for specific trials and their associated services.

C. The National Coverage Decision and Qualifying Clinical Trials

On June 7, 2000, in the middle of the Presidential campaign, President Clinton issued an Executive Memorandum directing the Medicare program to revise its payment policy and expand reimbursement for the cost of routine patient care associated with participation in clinical trials.[51] In response to the memorandum, CMS, to a cascade of national publicity,[52] issued a final National Coverage Decision (NCD) in September 2000, clarifying the extent to which Medicare covers the routine healthcare costs of beneficiaries enrolled in clinical trials.[53] The NCD, which applies to items and services furnished on or after September 19, 2000, states that Medicare will cover the "routine costs" of "qualifying clinical trials."[54] Its scope is therefore dictated by the definitions of these two terms.

In order to be considered a qualifying trial under the NCD, a clinical trial must meet four distinct requirements. First, the trial must have as its subject or purpose the "evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids)."[55] Second, the trial must

[51] Program Memorandum from CMS, HHS, Medicare Coverage, Clinical Trials: Claims Processing Instructions for Carriers, DMERCS, Intermediaries and Regional Home Health Intermediaries for Claims Submitted for Medicare Beneficiaries Participating in Medicare Qualifying Clinical Trials [hereinafter Program Memorandum, Claims Processing for Carriers], *at* www.cms.hhs.gov/coverage/8d3.asp (last visited Sept. 26, 2005).

[52] *See, e.g.*, David Brown, *Medicare to Pay for Experimental Treatments; Clinton Aims to Bring More Seniors into Clinical Trials*, WASH. POST, June 8, 2000, at A9; John E. Niederhuber, *Coverage for Clinical Trials Would Make a Difference for Cancer Patients*, MILWAUKEE J. SENT., Nov. 26, 2000, at 5J; Robert Pear, *Clinton to Order Medicare to Pay New Costs*, N.Y. TIMES, June 7, 2000, at A24; Nina Rao, *Some Doubt the Value of New Policy*, DENV. POST, June 8, 2000, at A8; *Medicare to Pay Clinical Trial Costs*, CHI. TRIB., June 7, 2000, at N6; Op-Ed., *Cutting Edge Care; Medicare Coverage for Clinical Trials Will Help Many*, HOUS. CHRON., June 11, 2000, at 2; *Medicare to Cover Clinical Trial Care Clinton Orders Change Helping Seniors, Disabled Pay Their Bills*, MIAMI HERALD, June 8, 2000, at 3A.

[53] Program Memorandum, Final National Coverage, *supra* note 16.

[54] *Id.*

[55] *See* CMS, HHS, COVERAGE ISSUES MANUAL, CLINICAL TRIALS § 30.1, [hereinafter CMS COVERAGE ISSUES MANUAL], *at* www.cms.hhs.gov/manuals/06_cim/ci30.asp (last visited Sept. 26, 2005).

have a "therapeutic intent," meaning that the trial can not be designed solely to test toxicity or disease pathophysiology.[56] Third, "trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers."[57] Each of these requirements is fairly straightforward, and providers can work to develop clinical trial protocols that will satisfy each condition. Unfortunately, the fourth and final requirement has caused significantly more confusion and has many aspects that still need to be resolved by regulators.

The fourth prerequisite is that the trial must either show that it has "desirable characteristics" or be deemed under the NCD as "automatically qualifying."[58] The NCD provides a list of the "desirable characteristics."[59] In order to prove that a trial possesses the desirable characteristics, however, the principal investigator is asked to certify to Medicare that the trial meets "qualifying criteria that . . . indicate a strong probability that a trial exhibits the [characteristics]."[60] The Agency for Healthcare Research and Quality (AHRQ), in conjunction with certain other government agencies, was charged in 2000 with developing the qualifying criteria.[61] The criteria were intended to be "easily verifiable, and where possible, dichotomous" in order

[56] *Id*.

[57] *Id*. It should also be noted that these trials may enroll healthy patients in order to have a proper control group. *Id*.

[58] Program Memorandum, Final National Coverage, *supra* note 16.

[59] *Id*. The desirable criteria include:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

Id.

[60] *Id*.

[61] *Id*. The other agencies include the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Office of Human Research Protection, and the research arms of the Department of Defense and the Department of Veterans Affairs. CMS Coverage Issues Manual, *supra* note 55.

to help providers and carriers quickly ascertain whether individual trials qualified for routine cost coverage.[62]

Unfortunately, while AHRQ has indicated that draft criteria have been developed and forwarded to CMS for review, the criteria have yet to be finalized. Because clinical trials lack the criteria necessary to show Medicare that they possess the desirable characteristics, only those trials that meet the first three requirements *and* are deemed as "automatically qualifying" can be considered qualifying trials at this time. These "deemed" trials include:

- Trials funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), AHRQ, CMS, Department of Defense (DOD), and Department of Veterans Affairs (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; and
- Drug trials that are exempt from having an IND.[63]

Having delineated which trials are covered by the NCD, it is important to consider what one gains by being a qualifying trial. As mentioned above, the NCD states that CMS will cover the "routine cost" of qualifying trials. A treatment must meet two tests to be considered a "routine cost" under the NCD. First, the treatment must be generally available to Medicare beneficiaries.[64] Second, while the treatment may be provided as part of either the experimental or control arm of a clinical trial, it may not fall into a category of services and items specifically excluded from routine costs.[65] These include:

> [t]he [noncovered] item and service itself; [i]tems or services provided solely to satisfy data collec-

[62] *Id.*

[63] Program Memorandum, Final National Coverage, *supra* note 16. Trials that are exempt from having an IND are only deemed qualifying while the qualifying criteria and certification process are being put in place. Once principle investigators are provided with a mechanism for showing that they do or do not possess the desirable characteristics, trials exempt from having an IND will no longer be deemed as qualifying, but will instead need to show that they possess the desirable characteristics through the developed mechanism. *Id.*

[64] *See* CMS DETERMINATIONS MANUAL, *supra* note 10, § 310.1 (noting that an item or service will be considered generally available so long as "there exists a [Medicare] benefit category, it is not statutorily excluded, and there is not a national noncoverage decision.").

[65] *See id.*

> tion and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan) . . . [;] items and services customarily provided by the research sponsors free of charge for any enrollee in the trial,[66]

and "items and services provided solely to determine trial eligibility."[67]

Although this definition provides a general framework for assessing which treatments must be excluded from routine costs, CMS has also provided specific categories of services that, in its judgment, meet the definition of routine costs, including:

- 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; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service—in particular, for the diagnosis or treatment of complications.[68]

The NCD therefore expands the level of coverage for medical services delivered to patients enrolled in qualifying trials, but not drastically. Services that are provided only to meet trial protocols, such as services provided to determine patient eligibility and monitoring solely for data collection, are still not covered.[69] The benefit of the NCD rests primarily in that unlike trials covered only by the general principles, qualifying trials receive coverage for: conventional care that is "related to" an excluded therapy; items necessary for the provision of an investigational item or service; and the monitoring of side effects and complications of an excluded therapy.[70] Thus, the

[66] *Id*.
[67] Program Memorandum, Claims Processing for Carriers, *supra* note 51.
[68] CMS Coverage Issues Manual, *supra* note 55.
[69] *Id*.
[70] When a provider is billing Medicare for "routine costs" of a qualifying clinical trial, all claims for services should be submitted with the "QV" procedure code modifier. CMS encourages the use of the QV modifier wherever possible; however, there may be circumstances where the hospital may not be able to "fit" the modifier on inpatient claims. Claims should also include the proper ICD-

NCD carves out and allows Medicare coverage for a range of services and items, even though they are "related to" the investigational item or service and even though they may represent an increment over and above the costs of "usual patient care" for those enrolled.

II. Coordination of Benefits and the Medicare Secondary Payor Rule

A provider will sometimes have more than one payment source available to cover the services it provides. For example, a patient may simultaneously be covered by Medicare, by a private third-party health insurer, and by workers' compensation insurance. Coordination of benefits refers to the determination of which of two or more payment sources will pay for a particular service, either as primary or secondary (or tertiary) payment source.[71] Such coordination is intended to preclude providers from receiving an aggregate of more than 100% of the total charges and to determine the relative obligations of the different potential payment sources.[72] Medicare has its own set of rules relating to coordination of benefits.[73] Although these rules apply to any situation in which payment is available from both Medicare and another source, this Article focuses on how Medicare's coordination of benefits rules specifically affect billing for clinical trials.

9-CM codes. For physician services, the ICD-9-CM code V70.7 (examination of a participant in a clinical trial) should be listed as the primary diagnosis on the claim for services rendered to healthy control group volunteers. *See* CMS, HHS, Transmittal No. 1770, Medicare Carriers Manual, pt. 3, §§ 4911, 4913 (Sept. 19, 2002), *available at* www.cms.hhs.gov/manuals/pm_trans/R1770B3.pdf (last visited Sept. 26, 2005). For hospital services, the ICD-9-CM code V70.7 should be listed as the secondary diagnosis for all services. *See* Program Memorandum from CMS, HHS, Transmittal No. AB-01-142, Revised Guidelines for Processing Claims for Clinical Trial Routine Care Services (Oct. 2, 2001), *available at* www.cms.hhs.gov/manuals/pm_trans/AB01142.pdf (last visited Sept. 26, 2005). There are also specific HCPCS codes for hospital outpatient services provided under clinical trial, including G0292 (administration of experimental drugs in a Medicare qualifying clinical trial), G0293 (noncovered surgical procedures using conscious sedation, regional, general or spinal anesthesia in a Medicare qualifying trial), and G0294 (noncovered surgical procedures using either no anesthesia or only local anesthesia in a Medicare qualifying trial). Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2003 Payment Rates; and Changes to Payment Suspension for Unfiled Cost Reports, 67 Fed. Reg. 66,718, 66,734 (Nov. 1, 2002) (to be codified at 42 C.F.R. pts. 405, 419).

[71] Charles J. Steele & Jacqueline M. Saue, Am. Health Lawyer's Assoc., Health Law Practice Guide § 14:5.

[72] *See id.*

[73] *See* Medicare COB, *supra* note 8.

Under the Medicare secondary-payor rule, providers may not bill Medicare for items or services when another party has primary responsibility for payment of those services.[74] In applying this rule to research, the Medicare Provider Reimbursement Manual states that "(w)here . . . research is conducted in conjunction with or as a part of the care of patients, the costs of usual patient care are reimbursable *to the extent such costs are not met by research funds*."[75] Thus, when a research sponsor has agreed to pay certain clinical trial costs, those costs are not properly billable to Medicare.

It is important to understand how this rule relates to the determination of whether Medicare covers a particular item or service. In order to bill Medicare for an item or service, providers must ascertain whether the item or service meets Medicare coverage principles[76] *and* whether any other party has primary responsibility for payment of the claim. If either of these tests is not met, then Medicare may not be billed for the item or service. Therefore, to the extent sponsors are willing to cover some of the costs of operating a clinical trial, providers should concentrate foremost on negotiating sponsor coverage for those services not covered by Medicare. This will help to ensure that the provider is able to bill either Medicare or the trial sponsor for all services provided to Medicare beneficiaries who enroll in the clinical trial.

Historically, some providers have felt that the simplest way to guarantee coverage for all clinical trial services has been to secure a provision in the clinical trial agreement that requires the sponsor to pay for all services related to participation in a clinical trial, "provided that these services are not otherwise covered by another payor." In addition to ensuring coverage for the providers, sponsors have tended to believe that this structure would restrict their payments to only those services that would not meet Medicare coverage principles. This structure also had the benefit of not requiring the sponsor and provider to determine at the outset of the trial which services were and which services were not covered by Medicare. Rather, the parties could merely state that the sponsor would cover services only when other coverage was not available, and the provider could

[74] *See* 42 U.S.C. 1395y(b)(5) (2005); MEDICARE COB, *supra* note 8 (noting that other third parties which may be primarily responsible for payments include employer group health plans, liability, auto, or workers' compensation insurance, or third-party tortfeasors).

[75] CMS PROVIDER REIMBURSEMENT MANUAL, *supra* note 18, § 504.1 (emphasis added).

[76] See *supra* notes 9-23 for a discussion of the Medicare coverage principles.

decide at the time of billing whether it believed the particular service was covered by Medicare, confident that if Medicare denied coverage, the sponsor would pick up the tab.[77]

Unfortunately for many providers and private research sponsors, CMS recently issued a letter interpreting how the Medicare secondary payor rule applies in the clinical trial context, and this new ruling severely limits the ability of sponsors and providers to utilize clinical trial agreements with the structure described above.[78] CMS issued its interpretation in response to an inquiry from the legal representative of a provider.[79] In the provider's inquiry, CMS had been asked whether

> Medicare would be the primary payer for services related to the complications arising from the implantation of investigational devices if the trial sponsor states in its consent documentation that it would "pay for medically necessary services related to injuries received as a result of participation in this trial, provided that these services are not otherwise covered by another party."[80]

In a letter response dated April 13, 2004, CMS indicated that the Medicare secondary payor rule renders Medicare payment secondary to benefits payable by a third party, even if the third party states that its coverage is secondary to Medicare, or otherwise limits its payments to Medicare beneficiaries.[81]

Thus, if a private research sponsor such as a pharmaceutical company or medical device manufacturer has indicated that it will cover "all services not otherwise covered by another payor," the provider must bill the sponsor, and not Medicare, for *all* services related to the trial, even if those services otherwise meet the Medicare coverage principles. In addition, presumably because this CMS letter provides an interpretation of a preexisting rule, and not the implementation of a new rule, the letter suggests that when a trial sponsor or a provider is aware that Medicare has improperly been billed under these circumstances, the sponsor or provider must reimburse Medicare for any pay-

[77] Or, in the case of a non-Medicare beneficiary, by a third-party insurer.
[78] Letter from Gerald Walters, Director, Financial Services Group, Office of Financial Management, CMS, to the law firm of Gardner, Carton, & Douglas (Apr. 13, 2004) (on file with the authors).
[79] *Id.*
[80] *Id.*
[81] *Id.*

ments that were improperly made.[82] It should also be noted that while the letter was written in response to a single inquiry, it was widely distributed to all CMS Regional Administrators, Associate Regional Administrators for Financial Management, and Regional Medicare Secondary Payer Coordinators, thus having a potentially very wide application and use throughout the many Medicare carriers and intermediaries.

III. Billing Compliance Guidelines

The rules set forth in the preceding sections supply providers with the tools necessary for determining when Medicare billing is permissible. However, understanding these rules is only the first step toward establishing a clinical trial budgeting and billing system that assures appropriate provider reimbursement. Although every clinical trial is different, this section provides a general framework that providers can use to establish a clinical trial budgeting and billing system.

The provider needs to take action well before the commencement of a clinical trial to ensure that costs associated with the trial will be paid by the sponsor, insurance and other third-party payors, or the patient. First, the provider should note all of the potential costs associated with the clinical trial, including the study drug or device, all services related to the study drug or device, and all administrative costs. The provider must then allocate these costs to their anticipated reimbursement source. If the sponsor agrees to cover all costs associated with the study, this process will be simple; the sponsor should be billed for all clinical trial costs, and no costs should be billed to insurers, including Medicare, or to the patient. If, on the other hand, the sponsor will cover only some of the costs associated with the trial, the provider must negotiate a clinical trial agreement that either identifies the specific services covered by the sponsor or that describes the general understanding of the parties with regard to coverage.

If the parties will be identifying each covered service in the clinical trial agreement, then the provider must ascertain the Medicare coverage or noncoverage of trial services before the trial begins. This process will involve first establishing whether the trial is covered by the NCD, whether it involves an investi-

[82] *Id.* CMS has stated, however, that it will work with sponsors and providers to resolve repayment obligations with "minimal inconvenience to participants and their health care providers."

gational device, or whether it is covered by the general Medicare principles discussed above. Once this determination has been made, a medically qualified person can use the appropriate coverage principles to determine whether each cost associated with the clinical trial is covered by Medicare, Medicaid, or commercial payors.[83] If the provider is having difficulty in determining whether services are covered by Medicare, the provider may wish to contact the local Medicare contractor for guidance, or contact a billing expert. Once the coverage or noncoverage of each service has been established, the provider should seek to refine the clinical trial agreement budget with the trial sponsor so that the sponsor's funds cover as many of the noncovered services as possible. If the sponsor covers some of the services that are covered by Medicare, Medicare of course may not also be billed for these services.

When a clinical trial agreement and its attached budget do not enumerate which services are covered by the sponsor, but instead state that the sponsor will give the provider a specific dollar amount to cover some of the costs of the trial, the provider should still conduct a detailed analysis of Medicare coverage before signing the clinical trial agreement and thus agreeing to specific private sponsor funding. The provider will be able to use this analysis to forecast the total cost of the clinical trial, and the extent to which these costs are covered by a combination of insurance and the sponsor's funding. The provider should then allocate the sponsor funding to specific services, starting first with those services not covered by Medicare or other insurers. Those services might include services specific to a clinical trial but obviously not covered by insurers, such as informed consent counseling of potential subjects, screening of potential subjects using protocol inclusion and exclusion criteria, and research data collection and analysis. The provider must keep in mind that if the grant amount exceeds the cost of those services not covered by Medicare or other insurers, then some of the grant will need to be allocated to services that are covered by the insurers. In these instances, and applying the coordination of benefits principles discussed in Section II, the provider will

[83] This Article does not discuss coverage determinations for non-Medicare payors. Each payor will have its own coverage principles, but many will apply a "reasonable and necessary" test similar to the Medicare principles. Further conversations with individual insurance companies are necessary to make precise coverage determinations. In some instances, insurance companies will have published policies regarding coverage of clinical trials. *See*, *e.g.*, AETNA, CLINICAL POLICY BULLETINS NO. 0466, CLINICAL TRIALS, COVERAGE OF ROUTINE PATIENT CARE COSTS (Nov. 23, 2004), *at* www.aetna.com/cpb/data/CPBA0466.html (last visited Sept. 20, 2005).

not be able to bill Medicare or other insurers for these services, because their costs have already been covered by the sponsor. If, on the other hand, the grant fails to cover the cost of some medical services not covered by Medicare or other insurers, then the provider will either need to bill the patient for those costs, telling the patient in the informed consent process that he or she must expect to bear such additional costs,[84] or the provider will need to be prepared not to accept any reimbursement for these services at all, and thus to absorb a financial loss. It is in part to avoid such direct financial losses that providers engaged in or hosting clinical trials need to forecast and negotiate all costs prior to signing a clinical trial agreement and agreeing to a sponsor budget.

A similar process should be used when research funding is provided by grants from federal agencies, such as NIH. In these instances, the federal agency is a research sponsor and the same coordination of benefit rules discussed above dictate that the provider may not bill Medicare for services covered by the research grant. Before submitting the grant application, the provider therefore needs to understand which services will not be covered by Medicare and other insurers in order to "fully load" costs in the proposed grant budget.

Once the clinical trial begins, all patients being enrolled should first sign informed consents and advance beneficiary notices that accurately inform the subject about his or her responsibility, if any, for any costs that may not be covered by the sponsor or third-party payors, including co-payments and deductibles.[85] The provider must also implement specific procedures for identifying costs associated with clinical patients and making

[84] See *supra* note 1 and accompanying text for the requirement discussed.

[85] As discussed in the text accompanying note 1, proper informed consent for clinical trials includes advising research subjects of any costs they might incur as a result of participation in the clinical trial. The advance beneficiary notice informs the research subject that, if Medicare denies payment for certain items or services, the subject agrees to personally accept responsibility for payment of those items or services. If the provider does not have the patient sign an advanced beneficiary notice, then the subject's allegation that he or she did not know that Medicare might deny payment is sufficient to limit the subject's liability for all such expenses under § 1879 of the Social Security Act. 42 U.S.C. § 1394pp(b) (2005); Program Memorandum Intermediaries from CMS, HHS, Transmittal No. A-03-025, Advance Beneficiary Notices (ABNs) for Services for Which Institutional Part B Claims Will Be Processed by Fiscal Intermediaries (July 17, 2000), *available at* www.cms.hhs.gov/manuals/pm_trans/A0043.pdf (last visited Sept. 20, 2005).

sure that they are billed to the appropriate payors and with the proper billing codes.[86] If the provider follows these steps, and understands the coverage rules discussed above, its third-party billing and clinical trial budgeting should fully comply with Medicare rules and will not leave the provider or research subjects unwittingly subsidizing the costs of a clinical trial.

[86] *See supra* notes 42, 49, and 70.