



MEDICAL RESEARCH LAW & POLICY



REPORT

Reproduced with permission from Medical Research Law & Policy Report, Vol. 6, No. 23, 12/05/2007. Copyright © 2007 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

CMS Punts on the Medicare Clinical Trial Coverage Policy: What Do We Do Now?

By TIMOTHY P. BLANCHARD,
JENNIFER S. GEETTER,
BERNADETTE M. BROCCOLO, AND
JAMES W. KIM

The authors are members of the Health Department in the law firm of McDermott Will & Emery LLP.

Timothy P. Blanchard is a partner in the law firm's Los Angeles office.

Jennifer S. Geetter is a partner in the firm's Washington office and is the co-chair of the Health Life Sciences Affinity Group and a member of the Life Sciences Steering Committee.

Bernadette M. Broccolo is a partner in the firm's Chicago office and the chair of the Life Sciences Steering Committee of the firm's Health Law Department.

James W. Kim is an associate in the firm's Chicago office.

I. Introduction¹

Health care providers, researchers, and sponsors of clinical research need to understand the circumstances in which Medicare payment is available for services² provided to Medicare patients in the context of clinical research. This is essential both to decide whether a particular clinical trial is economically viable and to avoid inadvertent submission of improper claims for Medicare reimbursement that carry substantial overpayment and false claims liability risk. Unfortunately, recent formal and informal guidance from the Centers for Medicare & Medicaid Services of the U.S.

¹ This article is published in the interest of promoting further dialogue on this issue. It should not be considered as, or a substitute for, legal advice and is not intended to, nor does it create, an attorney-client relationship. The reader should not take (or refrain from taking) any action based on the information in this article without first obtaining professional counsel.

² This article focuses on Medicare reimbursement for services furnished in clinical trials, not costs associated with subject injuries. For a more detailed discussion of subject-injury reimbursement, see Ziegler et al., "When does a Sponsor's 'Promise to Pay' in the Clinical Trial Setting Trigger Medicare Secondary Payer Liability?" 6 *BNA Medical Res. Law & Pol. Rep't* 555 (Oct. 17, 2007).

Department of Health and Human Services (“CMS”) has cast considerable doubt and confusion on clinical trial reimbursement parameters and has the entire clinical research community asking: “What do we do now?”

A cornerstone of Medicare’s clinical trial coverage policy for the last seven years has been the National Coverage Determination regarding routine costs in clinical trials, commonly referred to as the “Clinical Trials NCD.”³ While providing helpful guidance on certain factors in the coverage equation, several overarching unanswered questions have arisen in the course of the Clinical Trials NCD’s implementation, such as: (1) which trials are within the scope of coverage under the Clinical Trials NCD and which ones are not; (2) for what trials outside the ambit of the Clinical Trials NCD will Medicare provide reimbursement; and (3) will Medicare exclude from coverage the costs of routine services provided to a subject in a clinical trial if the subject would have needed such services even if he or she were not a participant in a clinical trial; and (4) what is the effect of payments from a research sponsor for services provided under a clinical trial protocol? Therefore, providers, researchers, and sponsors frequently have struggled to understand and interpret the Clinical Trials NCD and have sought clarifications or revision of the policy from CMS.

In July 2006, CMS responded with an ambitious proposal to thoroughly reconsider the Clinical Trials NCD.⁴ The clinical research community was optimistic that this proposal would result in much-needed revision and clarification of the parameters of CMS policy on Medicare coverage of routine costs incurred in connection with clinical trials. In October 2007, however, CMS dashed these high hopes with the announcement of its decision to put off further policymaking based on these reconsiderations, at least for now, and to maintain the Clinical Trials NCD essentially as it was.⁵ This decision to maintain the *status quo* disappointed the clinical trial community. It also perpetuated the state of doubt and confusion about the economic and compliance implications of such key considerations as whether to engage in worthwhile research that is largely dependent upon having Medicare beneficiaries as subjects, whether to include Medicare beneficiaries in other worthwhile studies, whether to encourage a Medicare patient to participate in a trial for a leading-edge study that will provide access to an experimental procedure in the absence of any proven alternatives, and whether to provide certain clinical services in the course of a trial. An

³ Medicare Coverage ~ Clinical Trials: Final National Coverage Decision (Sept. 19, 2000) (hereafter “Clinical Trials NCD”), available at <http://www.cms.hhs.gov/ClinicalTrialPolicies/Downloads/programmemorandum.pdf>. The Clinical Trials NCD also is found in the CMS Manual System, in CMS Pub. 100-03, National Coverage Determinations Manual, § 310.1 (“Routine Costs in Clinical Trials”), and in CMS Pub. 100-04, Medicare Claims Processing Manual, Transmittal 487 (March 4, 2005), “Medicare Qualifying Clinical Trials.” These and other related documents are available on the CMS Web site at <http://www.cms.hhs.gov/ClinicalTrialPolicies/>.

⁴ NCA Tracking Sheet for Clinical Trial Policy (CAG-00071R), <http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=186>.

⁵ Centers for Medicare & Medicaid Services, Decision Memo for Clinical Trial Policy (Oct. 17, 2007), at <http://www3.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=210>.

unfortunate outcome of this decision by CMS, and one that would run counter to CMS’s own articulated goals,⁶ is the perpetuation of an actual or perceived disincentive for the inclusion of subjects from the Medicare population in clinical trials and the exclusion of Medicare’s beneficiaries from access to beneficial studies for fear of the consequences of “guessing wrong” about Medicare coverage and billing requirements.

This article will provide an overview of the evolution of the law, regulations, and policy pronouncements that have created this state of affairs that can be instructive for an effort to explore the critical but unresolved contracting and billing issues arising from it and provide practical suggestions for managing the economic and compliance challenges those issues present.

II. Historical Overview and Perspective

A review of the trajectory of the Clinical Trials NCD’s regulatory history and the informal guidance statements of CMS concerning it since its issuance in September 2000 is essential in order to identify and understand the points of ambiguity and confusion that have arisen concerning Medicare coverage for clinical trials.

In 2000, the Institute of Medicine reviewed Medicare payment for items and services in connection with clinical trials and concluded that the Medicare program “should reimburse routine care for patients in clinical trials in the same way it reimburses routine care for patients not in clinical trials.”⁷ The IOM did not conclude that the Medicare statute or regulations required amendment to accomplish this result, but simply stated that payment should not be denied by Medicare contractors for routine care just because it was furnished under a clinical trial protocol.

On June 7, 2000, President Clinton issued an Executive Memorandum directing the Medicare program to “begin to explicitly reimburse providers for the cost of routine patient care associated with participation in clinical trials, and to take additional action to promote the participation of Medicare beneficiaries in clinical trials for all diseases.”⁸ The Executive Memorandum

⁶ Those goals, as stated in the July 2007 proposal to reconsider the Clinical Trials NCD were to: allow Medicare beneficiaries to participate in research studies; encourage the conduct of research studies that add to the knowledge base about the efficient, appropriate, effective, and cost-effective use of products and technologies in the Medicare population; and allow Medicare beneficiaries to receive care that may have a health benefit, but for which evidence for the effectiveness of the treatment or service is insufficient to allow for full, unrestricted coverage. NCA Tracking Sheet for Clinical Trial Policy (CAG-00071R).

⁷ Committee on Routine Patient Care Costs in Clinical Trials for Medicare Beneficiaries, Institute of Medicine, “Extending Medicare Reimbursement in Clinical Trials,” at 7 (Henry J. Aaron and Hellen Gelband, eds., 2000).

⁸ Press Release, Office of the Press Secretary, “President Clinton Takes New Action to Encourage Participation in Clinical Trials,” at 1 (June 7, 2000), at <http://www.hhs.gov/news/press/2000pres/20000607.html>. According to the Executive Memorandum:

One factor contributing to seniors’ low participation rate in clinical trials is the Medicare program’s failure to guarantee Medicare payment for the care associated with participation. This uncertainty regarding reimbursement often deters patients from participating in these trials, and deters physicians and other clinicians from recruiting pa-

did not suggest that statutory or regulatory change was required in order that the Medicare program cover these services.

CMS (then known as the Health Care Financing Administration) issued the Clinical Trials NCD in September 2000 in response to this executive directive.⁹ The Clinical Trials NCD provided that the Medicare program would pay “the ‘routine costs’ of services provided during the course of ‘qualifying clinical trials,’ as well as ‘reasonable and necessary items and services used to diagnose and treat complications’ arising from participation in all clinical trials.”¹⁰ Under the Clinical Trials NCD, qualifying trials were to include trials the Clinical Trials NCD defines as “deemed” qualifying trials and other studies, referred to herein as “non-deemed qualifying trials.”¹¹ According to the Clinical Trials NCD, “deemed” qualifying trials include only trials that are: (1) either funded by various specified government agencies, such as the Agency for Healthcare Research and Quality (“AHRQ”), the National Institutes of Health (“NIH”), and the Centers for Disease Control and Prevention (“CDC”), or supported by a center or cooperative groups funded by those agencies; and (2) trials conducted under an investigational new drug application (“IND”)¹² or under an exemption from having an IND.¹³ “Non-deemed” studies were to be recognized based on meeting certain “self-certification” standards to be considered qualifying trials.

The Clinical Trials NCD suggested a series of standards, known as “desirable characteristics,” in addition to three “requirements,” as a basis for self-certification. While two of the three requirements are not particularly problematic,¹⁴ the Clinical Trials NCD requires clinical trials that receive Medicare coverage for routine costs to “have therapeutic intent” and not “be designed exclusively to test toxicity or disease pathophysiology.”¹⁵ Whether therapeutic intent must be the primary purpose or simply one purpose of the clinical trial remains unanswered. This issue is of critical importance with regard to Phase I drug trials since those trials are “designed to determine the metabolic and pharmacologic

tients, contributing to low participation rates and slowing the development of new medical treatments and diagnostic tests that could benefit the entire Medicare population.

White House Office of the Press Secretary, “Presidential Memo on Participation of Medicare Beneficiaries” (June 7, 2000), at <http://www.clintonpresidentialcenter.org/legacy/060700-presidential-memo-on-participation-of-medicare-beneficiaries.htm>.

⁹ Medicare Coverage ~ Clinical Trials: Final National Coverage Decision (Sept. 19, 2000) (hereafter “Clinical Trials NCD”), at <http://www.cms.hhs.gov/ClinicalTrialPolicies/Downloads/finalnationalcoverage.pdf>.

¹⁰ *Id.* at 1.

¹¹ By its terms, the Clinical Trials NCD did not affect coverage for items and services specifically covered under the investigational device regulations; 42 C.F.R. §§ 405.201-405.215, 411.15, and 411.406, nor could it. See Clinical Trials NCD at 3. An NCD cannot trump regulations promulgated by notice and comment rulemaking.

¹² See, e.g., 21 C.F.R. § 312.2.

¹³ 21 C.F.R. § 312.2(b)(1).

¹⁴ These two requirements mandate that the item or service must fall within a Medicare benefit category and is not statutorily excluded from coverage; and the trial must enroll patients with diagnosed disease, and may only enroll healthy patients as a control group in the case of diagnostic interventions.

¹⁵ Clinical Trials NCD at 1.

actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.”¹⁶ Phase I drug studies are conducted, therefore, for the primary purpose of evaluating safety and effectiveness. If CMS were to require that therapeutic intent be a primary purpose for coverage under the Clinical Trials NCD, this might exclude all Phase I drug studies from Medicare coverage under the Clinical Trials NCD. In addition, CMS has stated that “it is the responsibility of the local contractor to determine whether or not a trial has therapeutic intent,”¹⁷ which leaves open the possibility of inconsistent categorization of clinical trial coverage for widespread multi-site trials that are subject to multiple local contractors.

The Clinical Trials NCD charged the AHRQ with the task of officially establishing “self-certification” standards to be used.¹⁸ Notably, however, AHRQ did not accomplish that task and the category of “non-deemed” qualifying trials never has been implemented. When issued in 2000, the Clinical Trials NCD included a self-certification process (albeit to be developed) to enable the research community to demonstrate that additional clinical trials should be eligible to qualify for coverage under the Clinical Trials NCD. This self-certification process was consistent with the stated goals of the Clinical Trials NCD, which included *expansion* of Medicare coverage. Failure to implement a self-certification process or some other procedure for qualifying trials precludes recognition of clinical trials other than deemed qualified trials under the Clinical Trials NCD. While CMS proposed to implement a different self-certification approach in the Proposed Decision Memorandum for the Second Reconsideration, the decision not to implement that proposal left the unimplemented self-certification provisions of the original Clinical Trials NCD in place. Thus, although CMS appears to recognize the need for some means to allow qualification of non-deemed trials, its failure to implement such a mechanism leaves coverage of services furnished under many unquestionably meritorious and well-designed studies in the shadow of CMS’s informal position that even routine services related to these trials may not be covered. Thus, unfortunately, the scope of expanded coverage contemplated originally by the Clinical Trials NCD has not been realized.

On July 10, 2006, CMS announced its plan to undertake a National Coverage Analysis of the Clinical Trials NCD and began a yearlong effort that included convening a Medicare Evidence Development & Coverage Advisory Committee to obtain public input and provide recommendations to CMS, asking the AHRQ to provide recommended changes, and receiving public comments on the proposed decision. At that time, CMS also noted that rulemaking might be required to accomplish the goals it set forth in its proposed revised clinical trial policy.¹⁹ CMS articulated three overarching goals for

¹⁶ Food and Drug Administration, CDER Handbook, at <http://www.fda.gov/cder/handbook/>.

¹⁷ AHHA Audioconference on Legal Issues in Medicare Reimbursement of Clinical Trial Services: Questions and Answers (Feb. 22, 2006) (on file with author).

¹⁸ Clinical Trials NCD at 3.

¹⁹ NCA Tracking Sheet for Clinical Trial Policy (CAG-00071R), at <http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=186>.

the policy to be developed: (1) to allow Medicare beneficiaries to participate in research studies; (2) to encourage the conduct of research studies that add to the knowledge base about the efficient, appropriate, and cost-effective use of products and technologies in the Medicare population; and (3) to allow Medicare beneficiaries to receive care that may have a health benefit, but for which evidence for the effectiveness of the treatment or service is insufficient to allow for full, unrestricted coverage.

It identified 10 specific issues that it intended to address in the reconsideration process. These issues, expressed in terms of tasks to be undertaken, include:

- (1) clarifying payment criteria for clinical costs in research studies other than clinical trials;
- (2) devising a strategy to ensure that Medicare-covered clinical studies are enrolled in the NIH clinical trials registry Web site;
- (3) developing criteria to assure that any Medicare-covered clinical research study includes a representative sample of Medicare beneficiaries, by demographic and clinical characteristics;
- (4) clarifying the definitions of “routine clinical care costs” and “investigational costs” in clinical research studies including clinical trials;
- (5) removing the self-certification process that was never implemented;
- (6) clarifying the scientific and technical roles of federal agencies in overseeing IND-exempt trials;
- (7) determining if coverage of routine clinical care costs is warranted for studies beyond those covered by the current policy;
- (8) clarifying how items/services that do not meet the requirements of Section 1862(a)(1)(A) but are of potential benefit can be covered in clinical research studies as an outcome of the National Coverage Determination process;
- (9) clarifying whether and under what conditions an item/service non-covered nationally may be covered in the context of clinical research to elucidate the impact of the item or service on health outcomes in Medicare beneficiaries; and
- (10) discussing Medicare policy for payment of humanitarian use device (HUD) costs.²⁰

On April 10, 2007, CMS issued a Proposed Decision Memorandum for the reconsideration, which reiterated these issues.²¹ CMS issued the final decision memorandum on July 9, 2007, which announced that pending further consideration, CMS was reissuing the original Clinical Trials NCD with only two changes: first, coverage was granted under the Clinical Trials NCD for an investigational item or service in a qualified clinical trial if the item or service would be covered by the Medicare program outside of the clinical trial setting; and second,

²⁰ *Id.*

²¹ Proposed Decision Memorandum for Medicare National Clinical Trial Policy dated April 10, 2007; Decision Memo for Clinical Trial Policy (CAG-00071R). For further discussion of this proposed decision memorandum, See Jennifer S. Geetter, “Two Steps Forward, One Step Back: A Review of Proposed Clinical Trial Policy,” *G2 Compliance Report*, June 2007, p. 5.

CMS incorporated a procedure for granting “coverage with evidence development” (“CED”) for certain items or services.²² The memorandum stated that comments CMS had received in response to the Proposed Decision Memorandum focused CMS on the long history of Medicare payment for services rendered in trials outside the terms of the Clinical Trials NCD, as well as on Medicare policy statements that were inconsistent with the Clinical Trials NCD.²³ CMS also expressed its intent to amend its coverage policies in the future to make them clear and consistent, and to allow public review and comment as part of that process.

On July 19, 2007, however, CMS opened a second reconsideration of the Clinical Trials NCD and issued a Proposed Decision Memorandum including 10 proposed revisions to the Clinical Trials NCD:

- (1) setting forth the scope of the policy by defining “clinical research” and renaming the overall Clinical Trials NCD to clearly include all clinical research;
- (2) replacing the requirements and other necessary characteristics for qualifying clinical trials under the clinical trial policy with scientific and technical standards for certified clinical research studies;
- (3) preserving CMS authority to permit CED when appropriate;
- (4) redefining coverage for qualifying clinical research studies or CED to avoid confusion with terms used in other contexts, using the term “usual patient care”;
- (5) defining “routine clinical services” that are included in usual patient care;
- (6) clarifying the extent to which “investigational clinical services” are included in usual patient care;
- (7) clarifying that coverage does not include “administrative services” required to carry out studies but not required to furnish usual patient care;
- (8) establishing a process that clinical research study sponsors/principal investigators must use to certify to CMS that their study meets the standards described in this policy;
- (9) enumerate types of clinical research studies that are excluded from this policy; and
- (10) clarify the relationship between coverage under this policy and local coverage determinations (“LCDs”).²⁴

²² CMS, *MEDICARE NATIONAL COVERAGE DETERMINATIONS MANUAL*, § 310.1 (July 9, 2007), at <http://www.cms.hhs.gov/transmittals/downloads/R74NCD.pdf>. CMS authorizes coverage through CED for “certain items and services for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a ‘reasonable and necessary’ determination through the NCD approval process.”

²³ NCA Tracking Sheet for Clinical Trial Policy (CAG-00071R2), <http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=210>; Decision Memo for Clinical Trial Policy (CAG-00071R), <https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=186>.

²⁴ Proposed Decision Memorandum for Second Reconsideration of the Clinical Trial Policy, Renamed the Clinical Re-

The July 2007 Proposed Decision Memorandum renewed hope that CMS's reconsideration of the Clinical Trials NCD would produce significant changes that would be responsive to the public comments it had received. Ultimately, however, CMS published a Final Decision Memorandum on Oct. 17, 2007, that effectively maintained the status quo, but explicitly did not "impos[e] any additional conditions of coverage."²⁵ None of the issues and inconsistencies discussed in the first reconsideration was addressed or resolved in the second reconsideration. CMS reportedly based its decision to delay implementing any changes in its coverage policy surrounding clinical research on comments that questioned its authority to establish standards and coverage limitations applicable to research studies, comments that suggested that CMS employ notice and comment rulemaking to develop such standards and limitations, and new legislation²⁶ establishing "significant requirements for clinical trials and additional authority for other agencies in the Department of Health and Human Services."

III. Medicare Clinical Trials Coverage Policy Under Scrutiny

A. Avenues for Coverage for Clinical Trial Services

Charting a course through the Clinical Trials NCD's ambiguities and unresolved issues should begin with a

search Policy (CAG -00071R2) (July 19, 2007), at <http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=210>.

²⁵ Centers for Medicare & Medicaid Services, Decision Memo for Clinical Trial Policy (Oct. 17, 2007), at <http://www3.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=210>.

²⁶ Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85 (Sept. 27, 2007). It is unclear how the provisions of the FDAAA, which primarily effectuate changes in FDA procedure, reasonably can be interpreted to affect coverage of services under the Medicare statute. If CMS plans to engage in a far-ranging overhaul of Medicare clinical research coverage policy, however, it may wish to delay action to allow it to incorporate appropriate references to the new FDA processes.

determination of whether the clinical trial in which Medicare beneficiaries are receiving items or services is either a "qualifying trial" under the Clinical Trials NCD or a trial covered by the investigational device regulations,²⁷ and, if so, whether the requirements for coverage under the Clinical Trials NCD or such regulations have been met. If the study is not one that is covered under either of those coverage grants, one then must explore whether a basis for coverage of the services provided in connection with a clinical trial exists under Medicare's general coverage provisions.

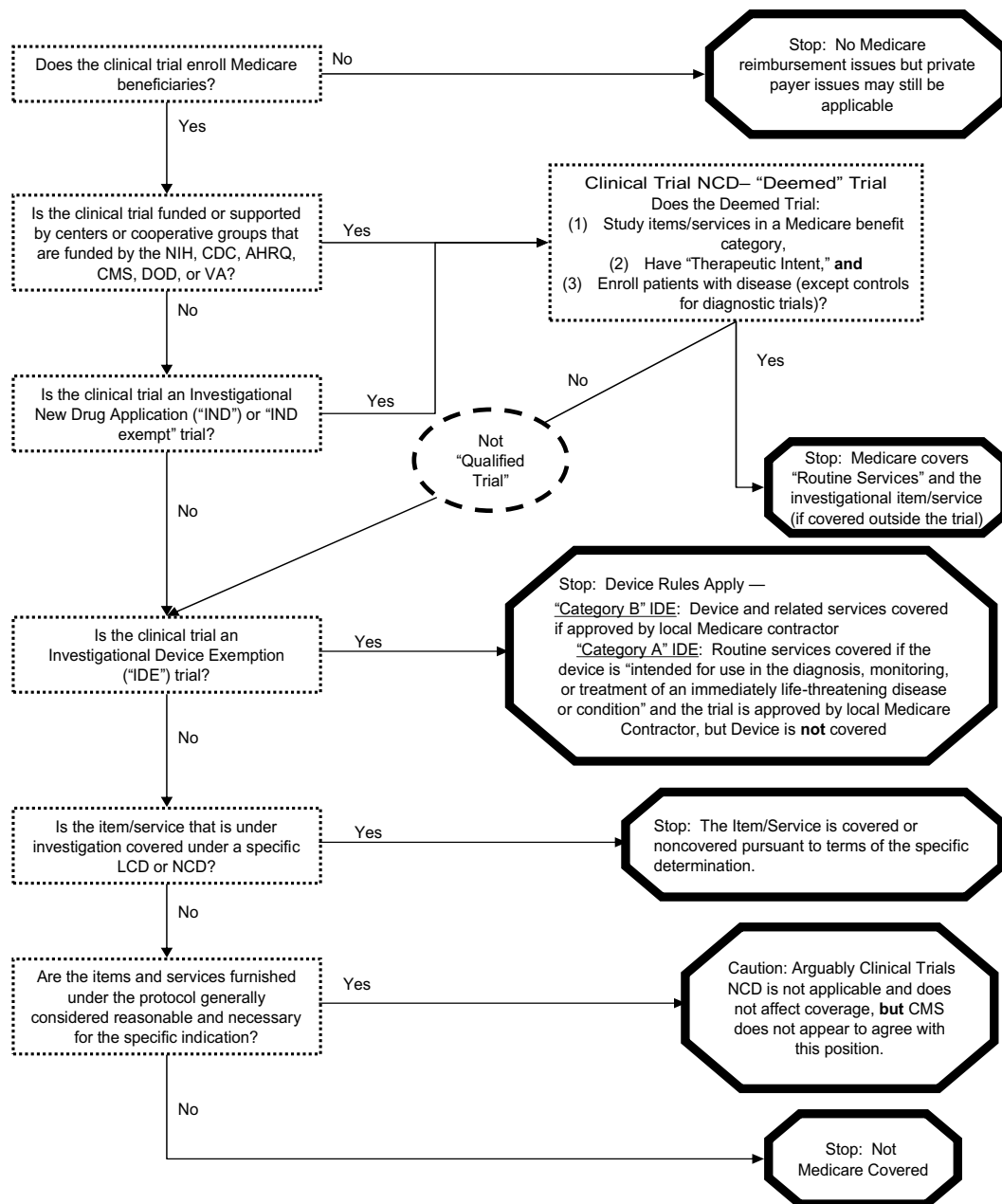
To establish eligibility for coverage under the Clinical Trials NCD, therefore, the first step is to demonstrate that a study is one of the two types of "deemed qualifying trials:" (1) trials that are funded by various specified government agencies, such as AHRQ, NIH, and CDC, or supported by a center or cooperative groups funded by those agencies; or (2) trials conducted under an IND²⁸ or under an exemption from having an IND.²⁹ Coverage under the Clinical Trials NCD is not the end of the road, however. Services furnished under a clinical trial also can be covered by Medicare under the investigational device rules, or pursuant to other NCDs or Local Coverage Determinations. Furthermore, as discussed below, there are good arguments that services that otherwise are considered reasonable and necessary for the diagnosis and treatment of patients remain covered and are not disqualified solely by failure to qualify under the Clinical Trials NCD or the device rules.

Exhibit A sets forth a flowchart that graphically illustrates the course of this analysis.

²⁷ Because the regulations governing coverage for services provided during a clinical trial involving an investigational new device were not affected by the NCD, we do not address them here.

²⁸ See, e.g., 21 C.F.R. § 312.2.

²⁹ 21 C.F.R. § 312.2(b)(1).



B. The Case for Coverage Beyond the Clinical Trials NCD

Perhaps no single question has bedeviled the research community more than the question of whether the Clinical Trials NCD is the exclusive route to coverage, or merely one pathway to coverage. Unofficial statements made by CMS officials suggest that CMS may take the position that Medicare will not cover research-related services *unless* they are provided in connection with research covered by the Clinical Trials

NCD or the investigational device regulations.³⁰ Such a position places in doubt even routine services a patient would need if he or she were not a subject/participant in a clinical trial.

Such a restrictive interpretation goes well beyond what is necessary to manage the reimbursement of

³⁰ Comments of Steve Phurrough, M.D., Director, Coverage Analysis Group, CMS, at the 2007 American Health Lawyers Association's Annual Institute on Medicare and Medicaid Payment Issues in Baltimore, Md., on March 22-23, 2007.

clinical-trial related costs and has a chilling effect on researchers, research sponsors, and provider research sites, frustrating the goal of affording Medicare beneficiaries access to emerging medical technologies and treatment modalities and the inclusion of beneficiaries as subjects in important medical research. Furthermore, such an interpretation is not supported by the plain text of the Clinical Trials NCD or its regulatory underpinnings. Rather, strong support exists for the position that a restrictive interpretation regarding the scope of Medicare coverage for the costs of health care services provided in connection with clinical trials is arguably unsupported by, and inconsistent with, the Medicare statute, and that the Clinical Trials NCD and investigational device exemption regulations are not the only avenues available for obtaining Medicare coverage of reasonable and necessary items and services furnished in connection with clinical research. Nothing in the Medicare statute or any properly promulgated regulation limits coverage of routine services under a clinical trial to services furnished in clinical trials qualified under the Clinical Trials NCD. Nothing in the Medicare statute addresses the effect of clinical research *per se* upon Medicare coverage.³¹

In general, the Medicare program covers items and services if they fall within a covered benefit category and are determined to be “reasonable and necessary.” The Medicare statute delineates the health care items and services for which Medicare will provide reimbursement by specifying³² and defining³³ categories of covered services; and imposing a general rule excluding items that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”;³⁴ setting forth a list of specifically excluded items and services;³⁵ and delegating authority to make specific local and national coverage determinations to Medicare program administration and program contractors.³⁶

The Medicare statute does not specifically exclude items or services that are provided in connection with research or experimentation. The statute addresses items and services furnished in connection with “research” and “experimentation” in only two provisions,³⁷ both of which extend Medicare coverage to services that would not otherwise be covered under the statute’s general grant of coverage. “Experimental” therapies or services are not otherwise addressed in the statute or in regulations. To date, the only Medicare regulations promulgated on the topic of research or experimentation are those published in 1995 that exclude

“experimental” devices from coverage.³⁸ Further, CMS has not promulgated any regulation declaring all services furnished under clinical trial protocols as ineligible to be treated as “reasonable and necessary” or excluded from coverage as “experimental.”³⁹

Despite the absence of specific coverage exclusions in the Medicare statute or regulations, Medicare program contractors and representatives have sometimes taken the position that Medicare does not cover “experimental” services and thus does not generally cover services furnished in clinical trials or the routine services required in preparation for, monitoring of, or aftercare related to, experimental services.⁴⁰ The threat of coverage denials based on this restrictive interpretation and has a significant chilling effect on researchers and providers leading to the denial of access to potentially lifesaving therapies (available only through participation in clinical trials) to Medicare patients, resulting in under-representation of Medicare patient data in clinical trial results.⁴¹ This uncertainty and fear of Medicare coverage denials is also believed to have undermined participation in clinical trials by the Medicare population, which in turn has jeopardized the generalizability of research findings and hindered the development of effective and innovative treatments for life-

³⁸ These Medicare regulations exclude from coverage investigational devices (and services related to such devices) that are considered to be “experimental,” but extend coverage to investigational devices that are classified by the FDA as non-experimental (Category B) under specific circumstances set out in the regulations. See 42 C.F.R. § 411.15(o); 60 Fed. Reg. 48417 (Sept. 19, 1995), available by searching on the GPO Access Web site at <http://www.gpoaccess.gov/fr/index.html>. At the same time, the Medicare program added a regulation addressing coverage of health care technology, 42 C.F.R. Part 405, Subpart B, including payment for “services related to a noncovered device,” 42 C.F.R. § 405.207. That regulation provides:

(a) *When payment is not made.* Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not “reasonable” and “necessary” under section 1862(a)(1)(A) of the Act or because it is excluded from coverage for other reasons. These services include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related noncovered services.

(b) *When payment is made.* Medicare payment may be made for—(1) Covered services to treat a condition or complication that arises due to the use of a noncovered device or a noncovered device-related service; or (2) Routine care services related to experimental/investigational (Category A) devices as defined in § 405.201(b) and furnished in conjunction with an FDA-approved clinical trial.

³⁹ See 42 C.F.R. § 411.15(o), which excludes experimental or investigational devices, with the exception of certain IDE-related services, but does not define what services are to be considered “investigational” or “experimental” for Medicare coverage purposes in the first instance.

⁴⁰ See, e.g., National Institutes of Health, Questions and Answers About the Proposed Medicare Coverage for NIH-Supported Cancer Clinical Trials (Jan. 29, 1998), at <http://www.nih.gov/news/pr/jan98/nci-29c.htm>.

⁴¹ *Id.*; Hutchins et al., “Underrepresentation of Patients Aged 65 Years or Older in Cancer Treatment Trials,” 341 *NEJM* 2061, 2062 (Dec. 30, 1999).

³¹ See 42 U.S.C. §§ 1396y(a)(1)(D) and (E), which merely extend coverage to services that would not be considered reasonable and necessary under 42 U.S.C. § 1395y(a)(1)(A).

³² 42 U.S.C. §§ 1395d(a), 1395k, and 1395w-22.

³³ 42 U.S.C. § 1395x.

³⁴ 42 U.S.C. § 1395y(a)(1)(A).

³⁵ 42 U.S.C. §§ 1395y(a)(1)(B)-(N) and (b).

³⁶ 42 U.S.C. § 1395ff(f)(1)(B); see Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55634 (Sept. 26, 2003).

³⁷ 42 U.S.C. §§ 1320b-12, 1395ww(e)(6), and 1395y(a)(1)(D) and (E) (a noncovered item or service will be covered under these sections to the extent “reasonable and necessary to carry out the purposes” of the specified research or experimentation programs).

threatening conditions affecting this growing segment of the population.⁴² This uncertainty regarding the risk of forfeiting Medicare coverage of otherwise covered services also has led to denials of access to services in clinical trials for Medicare patients.⁴³ Ironically, this is precisely the hazard of underrepresentation and financial jeopardy that the Clinical Trials NCD was intended to remedy.

It also is important to recognize that according to CMS, the Clinical Trials NCD and the two subsequent reconsideration decision memos have been issued under the narrow authority of 42 U.S.C. § 1395y(a)(1)(E), which authorizes Medicare coverage of items and services that are “reasonable and necessary to carry out the purposes of [Section 1142 of the Social Security Act],”⁴⁴ and not as an interpretation of the Medicare statute’s general coverage for items and services that are “reasonable and necessary” for diagnosis and treatment of illness and injury.⁴⁵ Section 1142 directs the HHS secretary, through AHRQ, to “conduct and support research with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically” and to do so in a manner that appropriately reflects the priorities of the Medicare program.⁴⁶ By its own terms, therefore, the Clinical Trials NCD applies solely to “research conducted pursuant to section 1142,” and does not affect coverage for items and services that are otherwise considered reasonable and necessary under the general provisions of the Medicare statute. Although determining whether particular research is “supported by” AHRQ for purposes of Section 1142 may be difficult, it is important to remember that Section 1395y(a)(1)(E) is an additional grant of Medicare coverage, not a limitation on the statutory coverage for reasonable and necessary items and services.

CMS has stated that the Clinical Trials NCD was intended to *expand* coverage, not limit or remove coverage of otherwise covered items and services. Indeed, the Clinical Trials NCD plainly states that it “does not withdraw Medicare coverage for items and services that may be covered according to local medical review policies,” and that all other Medicare provisions continue to apply. Therefore, we believe that the better argument is that failure to satisfy the requirements for qualification under the Clinical Trials NCD does not disqualify from Medicare coverage those research-related routine services that otherwise qualify as covered services.

C. Uncertain Effect of Sponsor Funding

Once the research site has determined that the clinical trial is eligible for coverage under Medicare, there is a secondary question of *which specific* services will be covered. CMS’s decision not to make any further changes to the Clinical Trials NCD leaves unresolved several issues that relate to the ability to obtain reimbursement of costs even for deemed qualifying trials.

The current Clinical Trials NCD raises as many questions as it does answers, and we address two illustrative questions below.

First, the Clinical Trials NCD states that routine costs of a clinical trial exclude “[i]tems and services customarily provided by the sponsors free of charge for any enrollee in the trial.”⁴⁷ The Clinical Trials NCD does not provide for any further description of what items and services would fall under this exclusion. This statement leaves open the scope of the coverage exclusion; sponsors are left without clear guidance on what items they may provide, and how this determination will be made. Moreover, this statement creates a disincentive for sponsors to provide free items and services—each provision for free items by a sponsor in a trial provides CMS with a potential rationale to exclude the item from coverage in subsequent trials. Sponsors are thus left to make decisions in contracting and billing situations based upon an incomplete picture of Medicare’s coverage methodology by balancing the desire to ensure that trial participants are not forced to pay out of pocket for services with a desire to efficiently manage clinical trial budgets.

Second, the Clinical Trials NCD has not resolved the ambiguous impact of Medicare Secondary Payer (MSP) rules on clinical trials. The MSP rules, in part, mandate that, under certain circumstances, Medicare may only be billed secondary to payment from other sources.⁴⁸ Thus, the ability of sponsors to guarantee payment for services only if first billed to and rejected by Medicare is put into jeopardy by potential application of the MSP rules to clinical trials. CMS has commented, at least in the limited realm of injuries resulting from clinical trial participation, in the form of a written response to an inquiry pertaining to the MSP rules issued in April 2004.⁴⁹ CMS stated within its response that MSP rules will apply when a “clinical trial sponsor’s agreement with trial participants that it will pay for medically necessary services related to injuries participants may receive as a result of participation in the trial.”⁵⁰ Thus, CMS has made clear that a sponsor may not act as a guarantor of payment for services secondary to Medicare in circumstances where an injury results due to participation in the clinical trial.

Nevertheless, this “clarification” by CMS raises several important questions relating to the MSP rules’ effect on clinical trials reimbursement by Medicare. Does this interpretation of MSP conform to the statutory language of the MSP rules and their interpretation by courts? An argument can be made that CMS’s application of the MSP rules to costs related to clinical trial injuries is inconsistent with the statutory framework of the MSP rules.⁵¹ Additionally, CMS has not stated how a cost is deemed related to a subject injury—is such an injury defined in a manner similar to an adverse event, or is some other formulation utilized? Until further

⁴² Institute of Medicine, *supra* n. 6.

⁴³ *Id.*

⁴⁴ See 42 U.S.C. §§ 1395y(a)(1)(E) and 1320b-12.

⁴⁵ 42 U.S.C. § 1395y(a)(1)(A); See, e.g., HCFA Coverage Issues Manual, Transmittal 126 (Sept. 19, 2000).

⁴⁶ See 42 U.S.C. § 1320b-12(a)(1).

⁴⁷ Clinical Trials NCD at 1.

⁴⁸ See 42 U.S.C. § 1395y(b)(2).

⁴⁹ Letter from Centers for Medicare & Medicaid Services, Office of Financial Management/Financial Services Group (April 13, 2004).

⁵⁰ *Id.*

⁵¹ For a more detailed discussion of this argument, see Ziegler et al., “When does a Sponsor’s ‘Promise to Pay’ in the Clinical Trial Setting Trigger Medicare Secondary Payer Liability?” 6 *BNA Medical Res. Law & Pol. Rep’t* 555 (Oct. 17, 2007).

clarification is forthcoming from CMS, parties to clinical trial research agreements are left guessing as to the terms of sponsor guarantees for payment. Finally, CMS has declined to address the impact of the MSP rules upon coverage of routine costs related to clinical trials. By declining to address this issue, CMS has left open the possibility that all costs of clinical trials, not only injury-related ones, are subject to the MSP rules. Should this be the case, sponsors could be left with primary rather than secondary responsibility for any costs where a guarantee of coverage was previously negotiated. Such a result would significantly change the economics of clinical trials for sponsors.

Together, these various gaps and ambiguities leave the clinical trial community in a lurch. Without clear guidance from CMS, parties to clinical trial agreements must individually assess their tolerance for risk of non-coverage for a potentially large portion of the costs of the trial.

IV. Practical Solutions

A. Coding Responses

Parties to clinical trial agreements must develop a plan for managing the financial and compliance risk associated with clinical trial billing decisions under the current state of uncertainty. The plan should address past, present, and future billing practices. Following are important considerations for such an undertaking:

1. Fundamental Rule for All Billing Practices

The fundamental requirement that services billed to Medicare must be reasonable and necessary unless specifically authorized under the statute and regulations applies in this context, as does the requirement that provider claim information must be accurate and compliant with applicable billing requirements. Thus, while it might *not* be necessary for a particular trial to be qualified under the Clinical Trials NCD in order to be covered, a provider must not represent when billing that services were furnished under a qualified trial unless the trial was in fact “qualified” and met the other criteria under the Clinical Trials NCD. Therefore, the QV modifier (or Condition Code 30), which represents that the service billed was “routine care in a Medicare qualifying clinical trial,” should not be used unless the trial so qualifies.

2. Past Billing Decisions

A research site must assess whether to take any action with regard to costs that have previously been incurred and billed to the Medicare program. Doing nothing carries the risk of false claims allegations, and potential resulting liability, such as potential trebling of damages and per-claim civil penalties under the False Claims Act.⁵² Of course, a potential defense against a

⁵² Furthermore, even if the services in question were determined to be non-covered, the institution may be eligible for limitation on liability, also known as waiver of liability, 42 U.S.C. § 1395pp(a)(2), for the resulting overpayment if, based on the state of the law at the time the services were provided (and indeed, technically, even today), the circumstances surrounding the implementation of the study, and the decisions to provide the services to particular patients/subjects, it neither knew nor should have known that the services in question would not be considered reasonable and necessary under Medicare rules. As discussed below, this position would be

false claims prosecution is that, in light of the ambiguity regarding the interpretation of the Clinical Trials NCD, a site cannot reasonably be held to have known that the services would not be considered reasonable and necessary.⁵³ Alternatively, notifying the Medicare program of the existence of a coverage question with regard to previously submitted bills would allow the site to protect its appeal rights while addressing the “failure to disclose” risk.⁵⁴ While false claims allegations could arise in the course of the government’s review of the disclosure, a voluntary disclosure can improve the tenor of discussions with the government. Making a voluntary refund for some or all of the payments received for services furnished under the protocol along with the notification may enhance the likelihood of a reasonable resolution. Nevertheless, the fiscal intermediary could choose to review the rationale and amount of the refund and refer the case to the HHS Office of Inspector General (“OIG”) for false claims investigation, particularly in light of the 2005 false claims settlement by Rush University Medical Center in connection with a clinical trial billing investigation.⁵⁵ Finally, reporting and refunding under the OIG’s “Voluntary Disclosure Program”⁵⁶ would satisfy any disclosure obligation regarding the matter and provide some arguments against whistleblower-initiated false claims action, but likely

based on an argument that the services in question were not subject to the requirements of the Medicare Clinical Trials NCD, Medicare National Coverage Determinations Manual, CMS Pub. 100-3, § 310.1, and the assumption that the treating physicians/investigators believed that the services provided under the study protocol were safe and effective in these selected cases, notwithstanding that they were provided in the context of a clinical trial protocol.

⁵³ Furthermore, even if the services in question ultimately were determined to be non-covered, a party may be eligible for limitation on liability pursuant to 42 U.S.C. § 1395pp(a)(2) for the resulting overpayment if it neither knew nor should have known that the services in question would not be considered reasonable and necessary. A provider might reasonably argue that given the state of the CMS instructions regarding these issues and the ambiguity regarding the interpretation of the Clinical Trials NCD, it cannot reasonably be held to have known that the services would not be considered reasonable and necessary in this case.

⁵⁴ See 42 U.S.C. § 1320a-7b(a)(3) (providing criminal penalties against anyone who, having “knowledge” of an “event” affecting the initial or continued right to Medicare payment, conceals or fails to disclose such event with an intent fraudulently to secure payment either in a greater amount than is due or when no payment is authorized).

⁵⁵ See, e.g., News Release, Rush University Medical Center, “Rush Settlement with Government May Help Clarify Billing Requirements for Medicare Patients in Research Studies” (Dec. 9, 2005).

⁵⁶ According to the OIG:

The Provider Self-Disclosure Protocol is intended to facilitate the resolution of only matters that, in the provider’s reasonable assessment, are potentially violative of Federal criminal, civil or administrative laws. Matters exclusively involving overpayments or errors that do not suggest that violations of law have occurred should be brought directly to the attention of the entity (e.g., a contractor such as a carrier or an intermediary) that processes claims and issues payment on behalf of the Government agency responsible for the particular Federal health care program (e.g., HCFA for matters involving Medicare).

63 Fed. Reg. 58399, 58400 (Nov. 30, 1998).

would result in the negotiation of a settlement, potentially including additional damages, civil penalties, and Corporate Integrity Agreement obligations.

3. Budgeting as a Key to Future Billing Processes

Even if the Medicare coverage policy were clear, a well-established process is essential for managing clinical trial billing compliance risk. Such a process has two critical compliance moments: *first*, the budgeting and contract negotiation in which the services that the research site, investigators, and research team members will provide are identified and articulated; and *second*, the determination of whether charges should be billed to the patient's insurance, an outside sponsor, or an internal research fund.

Clinical trial billing compliance begins with the development of a budget. Budgets are best done with specificity. Generalized cost information, such as per subject fees without further documentation make it difficult, if not impossible, to unpack negotiated fee amounts in the course of a trial. As a result, generalized budgets make it difficult to identify those specific items and services that the research site and investigator have agreed to provide and undermines efforts to appropriately allocate charges for items and services to third-party payers, third-party funders, and internal accounts. Thus, this inability to accurately identify and bill for study costs can result in hidden financial losses for the hospital and billing errors.

Experience suggests that research sites often underestimate the full extent of actual costs by not undertaking a disciplined budgeting process. As a result, sites are unable to make the important up-front assessment of whether third-party funding sources will cover such costs and, if not, whether the extent of a potential loss on a study is justified by the important contributions the study findings will make to the advancement of medical science and the public health and scientific objectives.

Generally, a compliant and business-savvy budgeting process should include two steps. First, research sites and investigators should create a master list of *all* services to be provided, including: overhead and administrative services provided by the research site (e.g., services provided by the institutional review board ("IRB"), time spent by the pharmacy to perform research pharmacy set-up, tests run by the site's laboratory, radiology services), by research team members who are site personnel (e.g., clinical research coordinator time spent assisting with subject visits), by investigators who are engaged by the site (e.g., time spent enrolling subjects or conducting data analysis), and by vendors in the form of pass-through expenses (e.g., outsourced laboratory tests); as well as in-kind items (e.g., the investigational test article or other pieces of specialized equipment). Such a master list does not take into account the ultimate financial source for these items and services. Rather, it serves as a catalogue of what the research site will do during the course of the study. It also will create a crucial opportunity for physicians and the research site to reach a consensus on the relative contributions of the physicians and the institution as well as the corresponding allocation of research dollars. This helps to avoid under-budgeting that results in inappropriate billing and unsubstantiated shortfalls, unsubstantiated residual balances, and disputes over the allocation of substantiated residual funds.

The detailed budget then provides a sound basis for a clinical trial billing analysis and for the payment terms

of the research agreement. The purpose of this analysis is to identify the extent to which each of the categories of items and services, and the corresponding amounts, can be billed to a third-party payer such as Medicare, to an industry sponsor, or to federal grant funds. Some items and services clearly will not be billable to third-party payers, such as IRB services or time spent on data analysis.

B. Contracting Process and Strategies

Sponsors, investigators, and clinical trial sites in industry-sponsored trials should proceed with caution in negotiating clinical trial agreements. A careful review of clinical trial billing compliance considerations is essential, and the review must focus closely on the unresolved issues surrounding the Clinical Trials NCD. Clear and contemporaneous documentation of the rationale supporting the approach the parties take to coping with these issues will be essential in the management of associated compliance risk.

Addressing the Medicare coverage complexities requires more than just a general provision stating the parties' intent to comply with applicable billing and anti-kickback laws and regulations. This is particularly true with regard to the MSP risk. The contract must take into account the research site's analysis of whether it believes that the MSP rules apply to routine costs, the research site's assessment of its own compliance risk tolerance, and the research site's calculation of the price tag of services for which coverage is vulnerable.

The most conservative approach to addressing the MSP rules with regard to routine costs of reasonable and necessary care provided in the course of the trial would be to eliminate the Medicare payment risk to the site by requiring the sponsor to guarantee to pay all such costs, regardless of the site's ability to bill Medicare. Such an approach may be feasible for trials with relatively small dollar amounts at issue. A moderately conservative alternative would be to provide that the site will bill Medicare for the reasonable and necessary items and services provided in the course of the trial, and look to the sponsor to cover the cost of routine services denied by Medicare and to cover all costs associated with subject injuries. As a variation on this approach, the research site also could more closely review the services potentially billable to Medicare and consider the incidence, associated costs, and risk of denial in order to propose to the research sponsor that it cover some portion of these routine costs.

These latter two approaches are consistent with the guidance from CMS that injury-related costs are subject to the MSP rules and attempt to minimize payments by the sponsor for services and items that Medicare may cover. They are based on the position that sponsors of clinical trials are not self-insuring primary plans when they provide funding for routine services. Accordingly, these approaches may be more palatable to the sponsor when significant routine site costs are anticipated. Mixed signals from CMS regarding the applicability of the MSP rules to routine costs suggest that these approaches certainly are not without risk.

Finally, notwithstanding CMS's informal comments, some institutions, based on reasonable arguments, may decide not to concede to the applicability of the MSP rules in these situations. Therefore, in certain circumstances, it may be reasonable to negotiate a research agreement that provides sponsor funding for the cost of

routine or subject injury-related costs that are denied by Medicare.

If the research study will include items and services that cannot be properly billed to insurance, the research site should create a designated research account against which non-billable items and services can be charged against the funds made available by the sponsor. Such an accounting mechanism provides the research site with critical, real-time information about the financial viability of individual studies and, over time, will allow the research site to analyze whether its budgeting process and financial projections are accurately capturing the flow of research dollars through the institution.

Following the execution of the contract with allocation of payment and billing responsibilities and risks, the compliance challenge shifts to proper allocation of charges appropriately to payers, funding sources, and research accounts and the maintenance of clear documentation of such allocation. This process starts with the up-front establishment of a system for consistently identifying patients who also are study subjects so that

any encounters with those individuals by the research site can be accurately sorted as billable or non-billable (or a combination of both). Research sites frequently find this initial step to be frustrating, but without it, successfully implementing the other essential billing process steps likely will be impossible unless this initial step is achieved.⁵⁷ After a study begins, compliant billing by a research site can be promoted through the following eight steps:

⁵⁷ Implementation of a system that carefully monitors billable and non-billable costs may help to prevent allegations of False Claims Act violations. See, e.g., Press Release, Department of Justice, "University of Alabama-Birmingham Will Pay U.S. \$3.39 Million to Resolve False Billing Allegations" (April 14, 2005) (detailing settlement of allegations of False Claims Act violations that included billing services to Medicare that already had been billed to the research sponsor); News Release, Department of Justice, "Arizona Heart Hospital Allegedly Billed Medicare for Non-Covered Procedures" (Nov. 5, 2007), at <http://www.prnewswire.com/> (describing settlement based on allegations of billing to Medicare procedures that were not covered).

Key Components of Billing Process

- 1. Identifying subjects:** Research sites often have difficulty identifying individuals seeking care at the site as subjects, often because the care requested is indistinguishable from what a patient might request. Research sites need to develop mechanisms to maximize the chances that an individual will be tagged as a subject, for example requiring the clinical research coordinator to notify a hospital registration department of each subject enrolled and to schedule anticipated visits for the subject. Sites may need to invest in registration upgrades that allow a subject's billing record to be flagged accordingly.
- 2. Review of charges:** Once the billing department receives an encounter for a Subject, it places a hold on the entire encounter to prevent immediate billing. The site is responsible for reviewing the encounter prior to any charges being processed to determine whether the charges are billable to insurance by reviewing the research protocol, the master list of services, and/or the final budget.
- 3. Processing billable versus non-billable charges:** The site segregates billable items from non-billable items. Billable charges are released for normal processing and non-billable items are charged to the designated research account associated with that study. To prevent so-called "double billing," non-billable charges that have been reimbursed by an insurer may not be charged to the subject or the subject's payer.
- 4. Reconciling charges:** Periodically, the principal investigator and other research personnel should work with the research support or contracting office to collate relevant documentation regarding the site's completion of research services triggering invoicing and payment.
- 5. Invoicing:** The research site personnel in charge of contracting and invoicing prepares an invoice for the research study using the applicable payment schedule (for example, quarterly, per case report form ("CRF"), as services are performed). After research site approval of the invoice, it is transmitted to the funder and documentation of the invoice is maintained by the research site.
- 6. Receipt of payment:** Upon receipt of payment, the research site should allocate payment to the applicable research account and track the payment in any centralized research management software used by the site.
- 7. Reconciling payments received:** At the conclusion of a study, the site should review the documentation and confirm that budget items were appropriately categorized as billable or non-billable. If items were incorrectly billed (or not billed), the research site should trigger its compliance mechanism for handling these issues.
- 8. Research study close-out:** The research site then should allocate the residual balance funds (if any) as appropriate per its policies and close out the study and its related documentation.

These steps are designed to work together to provide checks and double-checks for the research site to identify items and services and confirm whether they are billable to Medicare or a research account.

C. Reconciling Existing Agreements

Existing clinical trial agreements may not have drawn the types of lines discussed above as to categories and amounts of costs and the sources of payment for them. Improved processes going forward will apply to existing agreements only if the parties agree to amend them. If the parties are willing to consider amendments, they should first utilize the eight-step pro-

cess set forth above to properly classify the type of trial within the current framework of the Clinical Trials NCD and Medicare billing rules. A key issue to be addressed thereafter is whether, if the trial falls outside the coverage of the Clinical Trials NCD as currently interpreted and applied, a sponsor or investigator should guarantee payment for costs denied by Medicare. The associated compliance risks and resulting economics are considerations relevant to that issue. A well-reasoned and documented rationale for billing the Medicare program for items and services provided for trials CMS considers outside the scope of the Clinical

Trials NCD and the investigational device regulations is essential to managing whatever compliance risk is assumed and allocated under the agreement, particularly for costs incurred to treat trial-related injuries. The parties also should include provisions that anticipate the need for additional amendments following the issuance of additional CMS guidance in this area.

D. Advocacy

Sponsors, investigators, research sites, and seniors who are potentially affected by CMS's current policy position on the Clinical Trials NCD would be well-served by advocacy initiatives on this front. Even if formal rulemaking is not technically required, a rulemaking initiative that undertakes a comprehensive review and development of Medicare coverage of clinical trial costs may be a prudent and welcome approach to resolving the controversy surrounding the proper scope and interpretation of the Clinical Trials NCD. Unfortunately, however, significant Medicare rulemaking historically has taken years to complete, and health care service providers and manufacturers actively engaged in conducting important research involving the Medicare population would be forced for too long to continue to operate within the current environment of uncertainty and risk. Accordingly, while undertaking other interim steps such as billing process development and focused refinements of contracting approaches, all

interested parties should consider engaging in informal dialogue with CMS through open-door forums and individual correspondence. Together with public commentary during formal rulemaking, such informal efforts will encourage CMS to expeditiously reconsider the Clinical Trials NCD and adopt a workable clinical trial reimbursement policy that is consistent with the governing law.

V. Conclusion

CMS's decision to maintain the status quo has left a number of substantial unresolved issues relating to the coverage of costs associated with clinical trials. It is impossible to predict when and how CMS will resolve them. Until CMS publishes new rules and/or additional guidance, sponsors, investigators, and research sites would be well-served by carefully monitoring further developments and remaining cautious about entering into clinical trial agreements that do not conform with a carefully considered interpretation of the Clinical Trials NCD as it currently stands. They also should review and amend existing clinical trial agreements for financial and compliance implications of the current policy position, develop billing processes and contracting approaches that will improve compliance in a fiscally palatable and responsible way, and prepare thorough and timely documentation of the compliance rationale for the billing and contracting approaches they adopt.