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August 17, 2007

BY ELECTRONIC DELIVERY

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**Proposed Decision Memorandum for Second Reconsideration of the
Clinical Trial Policy, Renamed the Clinical Research Policy (CAG-
00071R2)**

Dear Dr. Phurrough:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed national coverage decision memorandum entitled, "Proposed Decision Memorandum for Second Reconsideration of the Clinical Trial Policy, Renamed the Clinical Research Policy"¹ (Proposed CRP). ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's 650 member institutions and organizations treat 45 percent of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 60 percent of all U.S. cancer patients.

ACCC is committed to ensuring that cancer patients have access to the entire continuum of quality cancer care, including access to the most appropriate cancer therapies, both through participation in and outside of clinical trials. Indeed, our members depend on valid clinical

¹ Proposed Decision Memorandum for Second Reconsideration of the Clinical Trial Policy, Renamed the Clinical Research Policy (CAG-00071R2), July 19, 2007, <http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=210>.

data to provide the best quality care to their patients. ACCC supports CMS' efforts to clarify its clinical trial policy by issuing a second reconsideration of its Clinical Research Policy (CRP). CMS' current clinical trial policy, as first issued in 2000,² has dramatically increased Medicare beneficiary access to care in clinical trials, and we encourage CMS to build on this strong foundation.

We urge the agency to revise the Medicare clinical research policy in a manner that improves Medicare beneficiary access to clinical trials and recognizes the challenges faced by medical personnel carrying out these trials. ACCC strongly supports CMS' underlying goal of encouraging 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, thus improving the quality of care that Medicare beneficiaries receive. Indeed, our members depend on valid clinical data to provide the best quality care to their patients. We believe that continued research must be a priority for all stakeholders involved in cancer care, including CMS, and we support clinical trials that will help us use therapies most effectively.

We look forward to working with the agency to establish policies that will improve beneficiary access to clinical trials. We have reviewed this proposal carefully and believe that the National Coverage Determination (NCD) process is not the appropriate mechanism to establish a new policy regarding access to clinical trials; rather, we ask CMS to withdraw the Proposed CRP and issue a notice of proposed rulemaking ("NPRM") on these complex issues instead. Should CMS decide instead to proceed with this reconsideration in the form of an NCD, we have provided detailed comments on the Proposed CRP, with the goal of facilitating Medicare beneficiary access to cancer studies, as well as promoting provider participation in clinical research.

ACCC is concerned that the Proposed CRP would undermine CMS' goal of increasing Medicare beneficiary access to clinical research studies by withdrawing coverage for reasonable and necessary items and services unless provided in the context of a qualifying clinical research study. We do not believe this approach is consistent with the statute, and we urge CMS to issue an NPRM to explain its legal rationale. We appreciate CMS' proposal to establish a self-certification process, although we recommend that CMS maintain the deeming process for certain clinical research studies sponsored or reviewed by the National Cancer Institute (NCI) and other federal agencies. We also recommend that CMS revise the Proposed CRP to provide detailed guidance to those sponsors who would need to undergo the self-certification process. In addition, we urge CMS not to apply new coverage and coding requirements to items and services covered as "usual patient care." We also

² National Coverage Determinations Manual § 310.1.

ask that CMS delay the effective date, should it decide to issue a final NCD. Finally, we ask that CMS clarify that Medicare, and not the clinical trial sponsor, is the appropriate payer for covered routine medical costs, including complications related to the trial. Our comments on each of these issues are detailed below.

I. CMS Should Engage in Notice and Comment Rulemaking to Promulgate a Comprehensive Medicare Clinical Research Policy

ACCC urges CMS to withdraw the Proposed CRP and instead engage in notice and comment rulemaking to address the range of issues encompassed in the Proposed CRP and related to the administration of a Medicare clinical research policy. The scope of the Proposed CRP goes beyond the authority CMS has under the Social Security Act to issue an NCD. Instead, CMS should issue an NPRM to address comprehensively the wide range of issues that are necessarily part of a Medicare clinical research policy.

Indeed, CMS already has suggested that it plans to issue an NPRM in October of this year that will affect coverage and payment for services provided during a clinical research study. This suggests that a proposed rule is the more appropriate mechanism by which to issue a comprehensive Medicare clinical research policy. Furthermore, this pending NPRM also renders the comment period on the Proposed CRP somewhat meaningless. An NCD must comply with the relevant statutory and regulatory provisions. Thus, finalizing the Proposed CRP before revising the underlying regulations makes it extremely difficult, if not impossible, to provide meaningful comment on the Proposed CRP. At a minimum, any NCD regarding a Medicare clinical research policy should be proposed and reviewed after the underlying regulations are finalized.

The Medicare statute sets forth a general coverage rule that Medicare may not pay for items and services “not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”³ The statute also establishes broad Medicare coverage categories. The NCD process is designed to establish coverage for a particular item of service within these broad coverage categories.⁴ As CMS has explained in its notice establishing the process for NCDs, “[f]or over 30 years, we have exercised these authorities to make a coverage determination regarding whether a specific item or service meets one of the broadly defined benefit categories and can be covered under the Medicare program”.⁵ An NCD is intended to address coverage of a particular item or service, and not establish new conditions for coverage of the broad range of items and services provided in the context of a clinical research study. CMS uses a evidence-

³ SSA § 1862(a)(1)(A).

⁴ SSA § 1862(l).

⁵ 68 Fed. Reg. 55634, 55635 (Sept. 26, 2003).

based process to develop an NCD, including “descriptive information, and scientific and clinical evidence,”⁶ and this process cannot be applied to the broad range of items and services provided in the course of a clinical research study.

CMS cites sections 1862(a)(1)(A) and 1862(a)(1)(E) of the Social Security Act as the authority for the Proposed CRP. However, neither of these provisions gives CMS the authority to alter basic Medicare coverage rules – through an NCD or otherwise – as CMS proposes in the Proposed CRP. Under § 1862(a)(1)(A), Medicare may not pay for items and services not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the treatment of a malformed body member. Once an item or service has been determined reasonable and necessary for a particular beneficiary, the item or service should be considered reasonable and necessary regardless of whether provided in the course of a clinical research study. The Proposed CRP, however, would withdraw coverage for items and services provided in the course of a non-qualifying clinical research study, even though these same items and services would be covered as reasonable and necessary outside of a clinical research study. This withdrawal of coverage would occur merely because a beneficiary is participating in a non-qualifying research study. Similarly situated beneficiaries not participating in a study would receive coverage for the exact same care. We believe that there is no basis in the statute for CMS’ proposed exclusion of these items and services from coverage for beneficiaries participating in clinical research studies.

Section 1862(a)(1)(E) permits Medicare payment for items and services that do not meet the reasonable and necessary threshold under § 1862(a)(1)(A) but that are provided pursuant to research administered by the Administrator for Health Care Policy and Research (AHCPR) under § 1142. Yet the Proposed CRP does not propose to apply to items and services provided in the research conducted under § 1142. Instead, the Proposed CRP would apply to all clinical research. Moreover, § 1142 permits coverage of items and services not otherwise covered by Medicare, and thus is an expansion of coverage. The Proposed CRP, in contrast, would withdraw coverage of reasonable and necessary items and services simply because they are provided in a clinical research study. Section 1862(a)(1)(E) does not provide the authority necessary for CMS to withdraw coverage of reasonable and necessary items and services. If CMS intends to take this step, it should issue an NPRM to explain its legal rationale for doing so.

Although ACCC strongly urges CMS to withdraw the Proposed CRP and issue an NPRM to address the Medicare clinical research policy, we have provided comments below on the Proposed CRP in the event that CMS decides to finalize the Proposed CRP in the form of an NCD.

⁶ *Id.*

II. CMS Should Maintain the Deeming Process

ACCC urges CMS to continue to deem certain trials, as set forth in the current NCD, rather than subject these trials to new coverage decisions. Requiring these research studies that already are well regulated to undergo a self-certification process is unnecessary and would create additional burdens for clinical research sponsors, providers, and CMS. Even though you noted at the August 7, 2007 Open Door Forum on this issue that CMS probably could review self-certifications for completeness in a day or two, we believe this is highly unlikely given the agency's limited staffing and that there currently are over 5,000 trials in oncology alone. Sponsor reluctance to self-certify, for reasons described in detail below, also will discourage beneficiary participation in research studies.

These studies operate under Food and Drug Administration (FDA) regulations or are sponsored by other federal agencies and undergo rigorous review. Findings generated from these types of studies have been critical to the development of innovative treatments, particularly in the area of oncology. Imposing additional and unnecessary administrative burdens on these highly regulated research studies simply will discourage sponsors from seeking Medicare coverage to the detriment of Medicare beneficiaries. We encourage CMS to reinstate the deeming process for these studies. This approach would be consistent with longstanding Medicare clinical research policy as well as with the recommendations of the Medicare Evidence Development and Coverage Advisory Committee (MedCAC). CMS' proposed self-certification process should be used only for studies that do not fall under one of the deemed categories.

III. CMS Should Provide Greater Clarification on the Thirteen Proposed Standards

ACCC supports CMS' efforts to provide clinical research sponsors with a mechanism for self-certifying. This self-certification process is necessary to ensure that Medicare beneficiaries have access to the full range of research studies being conducted. It also will help physicians determine whether a study is covered, making it easier to advise Medicare beneficiaries about their treatment options. We are concerned, however, that the Proposed CRP does not provide adequate guidance to sponsors seeking to self-certify. The lack of adequate guidance on these standards would make it difficult for sponsors to self-certify, resulting in a lack of coverage for Medicare beneficiaries seeking to participate in the study. We urge CMS to provide greater detail, including examples, for each of the thirteen proposed

standards to enable sponsors to reasonably certify that their studies meet the CRP requirements.

At the outset, we encourage CMS to clarify who the “sponsor” of a clinical research study is for purposes of self-certification. CMS could rely on definitions used by FDA in the context of an IND trial or propose an alternative definition. This would help ensure that the appropriate party is completing the self-certification. We also urge CMS to provide guidance for sponsors on whether or how to address changes in study circumstances that may result in a study no longer meeting specific CRP standards. We also recommend that CMS provide a template for submission of the self-certification with accompanying instructions regarding length and clarify that a protocol does not need to be attached to the self-certification, as CMS stated in its August 7, 2007 Open Door Forum on the clinical research policy.

We also ask that CMS implement each of the thirteen standards in a manner that reflects the wide range of clinical research that may fall under the CRP. For example, CMS proposes that the “research study must explicitly discuss subpopulations.”⁷ Depending on how it is interpreted by CMS, this standard may be burdensome for small trials, and may be inappropriate for others. We encourage CMS to implement this standard in a manner that expands access to care and does not have the effect of curtailing access to promising therapies. We ask that CMS recognize that many patients, particular the elderly, are not eligible to participate in clinical research studies. For example, approximately 3 percent of adult cancer patients are enrolled in clinical research studies, and only a small fraction of those patients are over age 70. There are many factors influencing the low participation rates of seniors in cancer trials. Many Medicare beneficiaries are ineligible for clinical trials because of comorbidities and complications. Some studies, particularly those testing medical devices, contain only a small number of enrollees and may not be appropriate for most Medicare beneficiaries in early stages.

IV. CMS Should Clarify the Review Process for Self-Certification and Liability of Sponsors, Principle Investigators, and Providers

ACCC is concerned that the self-certification process, as proposed, is confusing and has the potential to expose sponsors, principle investigators (PIs), and providers to liability for payment for services provided in a study that is determined not to be covered under the CRP. We urge CMS to describe its review process for sponsor self-certifications clearly, as well as any liability for payment should a study be determined not to meet the CRP standards after the beneficiary

⁷ Proposed CRP § IV.C.

has been treated. In the Proposed CRP, CMS states that it will review self-certifications only for completeness, yet CMS also states that its Chief Medical Officer may determine that a study is not covered where he finds that the study does not meet the CRP criteria or that the study jeopardizes the health or safety of Medicare beneficiaries. It is not clear whether this review would occur after a study is underway or even completed, nor what the implications for coverage would be should the Chief Medical Officer decide that a study does not meet the CRP standards.

It is critical to clarify a process for CMS review in order to provide sponsors and other parties with a full understanding of the potential liability for participation in a Medicare-covered research study. Importantly, sponsors and PIs could be exposed to liability under the False Claims Act if CMS were to determine that the study did not comply with the CRP criteria. The threat of this liability will discourage sponsors and PIs from seeking to self-certify. Because the process for reviewing research studies is not clear, the uncertainty of this risk is significant enough to make sponsors and PIs reluctant to participate in Medicare-covered studies. The standards in the Proposed CRP are sufficiently broad and open to a range of interpretation that sponsors will have little certainty as to whether a study meets these requirements.

Similarly, providers who may be liable for the costs of providing care in the course of a study, should CMS retroactively determine that the study not meet the CRP criteria, are less likely to participate in self-certified studies. The ability of providers to continue to participate in research studies for oncology therapies is essential to the development of new, life-saving therapies for Medicare beneficiaries and others.

During the Open Door Forum on August 7, 2007, CMS staff stated that a physician or other provider of services participating in a research study would be responsible only for verifying that a research study is on CMS' *Federal Register* list of Medicare-covered trials, as well as for including the clinical trial number and any other billing information on the claims form, but that providers would not be liable for payment for services should CMS later determine that a research study does not meet the CRP standards. We urge CMS to state this policy explicitly in a final Medicare clinical research policy, making clear that physicians and other providers will not be liable for claims if these requirements are met. A clear policy regarding review of self-certifications, liability, and the process for appealing any denials of coverage will have the effect of encouraging more providers to offer clinical trials as treatment options for their patients.

V. CMS Should Clarify the Scope of the CRP

CMS proposes to apply the Proposed CRP to “clinical research,” excluding data collection processes that are based upon previously collected data or data collected “in such a manner as to not influence current patient management or health outcomes.”⁸ During the Open Door Forum, you stated that “clinical research” subject to the policy included studies in which informed consent is required. ACCC is concerned that this standard is exceedingly broad and may include cancer registries or other types of studies that do not affect the health care decisions made by patients or their physicians. We request that CMS clarify this standard in a manner that does not include prospective data collection, such as registries, that may require informed consent. We also ask CMS to address the treatment of cancer control trials and trials addressing symptom management specifically and to provide examples where possible.

VI. CMS Should Minimize and Clarify the Billing Requirements

ACCC requests that CMS clarify the billing requirements that are likely to be implemented under the CRP in a manner that reduces the burdens these requirements place on sponsors, investigators, and clinical research sites. A number of procedural changes will be necessary to identify Medicare recipients who are participating in approved clinical research studies using a clinical trial number. The existing requirements for billing clinical trial services already are complicated. We are concerned that the Proposed CRP will add to this confusion as well as prove costly for clinical research sites. Facilities typically bill charges to Medicare using a HCFA 1500 or UB-92. Currently, there is not a place on either form to insert a clinical trial number. Medicare either would need to revise both the HCFA 1500 and the UB-92 in order to accept a clinical trial number or would need to indicate an existing field where the number should be inserted.

Facilities would need to make significant and costly changes to billing software in order to include clinical trial numbers as well as to label “usual patient care” that has been provided in the context of a clinical research study. This would require facilities to follow a different set of billing rules for research studies covered under the existing NCD than for studies covered under the new policy. A hospital also would need to develop a method for notifying all departments within the hospital that bill separately (such as radiology and pathology) which Medicare beneficiaries are participating in a clinical research study in order to have this number included on each department’s billing.

⁸ Proposed CRP § IV.D.

After reviewing the Proposed CRP, one of our hospital members concluded that it would need to search all of its Medicare charges each day to identify those patients who were on a clinical trial. The clinical trial number would be inserted into each charge rendered on a Medicare patient on an appropriate clinical trial. As an example of the volume of charges, this particular center rendered 13,458 charges on Medicare recipients in the month of May 2007 (there were 22 days in May that the center was open). This means that approximately 612 charges each day would need to be searched manually to identify any patients on clinical trials and the appropriate clinical trials number added to the claim before the claim was sent to billing.

This example highlights our concerns that the Proposed CRP would be extremely burdensome for health care facilities and would discourage providers from including Medicare beneficiaries in their research studies. We request that CMS work with stakeholders and contractors before implementing any new billing and coding requirements to ensure that any such requirements are implemented in the least burdensome manner possible.

VII. CMS Should Implement a Clear Transition Plan

ACCC appreciates CMS' proposal that ongoing clinical research studies will not be subject to the revised CRP. We believe that this exemption should apply not only to studies that already are underway and that have enrolled patients, but also to new sites in ongoing multi-site studies as well as studies that already have received approval from an institutional review board (IRB). With regard to multi-site studies, we believe that it would be unduly burdensome for these studies to have to apply two different sets of rules to different study sites. With regard to studies already approved by an IRB but that have not yet begun to enroll patients, these studies have been planned and approved under the existing NCD and should not be required to change course after IRB approval.

ACCC also requests that CMS delay the implementation date of a final NCD, should CMS decide to continue with the NCD as a means of finalizing a clinical research policy. Under the NCD provisions of the statute, CMS must issue a final decision within a specified timeframe, but CMS is not required to make that final decision effective immediately.⁹ In the past, CMS has delayed the implementation of an NCD in order to give providers and contractors the time necessary to implement new billing requirements. Indeed, CMS has stated that it expects to implement any necessary changes in payment or other systems within 180 days of the first day of the next full calendar quarter following the issuance of a decision

⁹ SSA § 1862(l).

memorandum.¹⁰ Clearly such a delay is warranted for a policy that affects coverage for a broad range of items and services, well beyond the scope of most NCDs.

VIII. CMS Should Clarify that Medicare, and Not the Clinical Trial Sponsor, is the Primary Payer for Covered Medical Costs, Such as Complications Related to the Trial.

It is critical that CMS reaffirm that payment of routine costs in clinical trials are covered by Medicare. In the 2000 NCD, CMS states that routine costs in clinical trials include the “provision of an investigational item or service--in particular, for the diagnosis or treatment of complications.”¹¹ CMS regulations regarding medical devices also clearly sanction Medicare payment for complications arising in medical device clinical trials.¹² It is essential that CMS not create uncertainty about Medicare coverage of clinical trials because this ambiguity will discourage sponsors from including Medicare beneficiaries in them. We urge CMS to clarify in the CRP that Medicare covers routine costs as the primary payer even where the clinical trial sponsor offers in an informed consent document to make payment for uncovered expenses relating to illness or injury resulting from the trial.

Clinical trial sponsors clearly are not primary payers. This is consistent with the Medicare Secondary Payer (MSP) statute, providing that Medicare will not pay for any item or service “to the extent that payment has been made or can reasonably expect to be made” under a “primary plan.”¹³ The MSP statute defines a “primary plan” as a group health plan (including large group health plans), a worker’s compensation law or plan, an automobile or liability insurance policy or plan, or an entity with a risk-bearing self-insured plan.¹⁴ Any interpretation that a clinical trial sponsor is a “primary payer” under the MSP statute seems a far cry from what Congress intended in any of its MSP enactments. Nothing in the statute or the legislative history suggests that Congress intended to expand the reach of the MSP provisions to preclude Medicare payment for covered items or services when the sponsor of a clinical trial offers in an informed consent document and related clinical trial agreement to make payment for uncovered expenses relating to illness or injury resulting from the trial. Any interpretation to the contrary will have a chilling effect on the enrollment of Medicare beneficiaries into clinically appropriate trials.

¹⁰ 68 Fed. Reg. at 55640.

¹¹ National Coverage Determinations Manual § 310.1.

¹² 42 C.F.R. § 405.207(b).

¹³ Social Security Act § 1862(b)(2)(A).

¹⁴ Id.

More generally, we also urge CMS to be sensitive to patients' costs of participating in clinical trials. Trial sponsors currently underwrite most of patients' costs of participating in clinical trials. The drug or device under investigation, as well as many of the other drugs and services involved in the trials, are provided at no cost to the patient. If pharmaceutical manufacturers are dissuaded from donating their drugs, patients' costs of participating in trials could increase substantially. We strongly recommend that CMS ensure that its coverage proposals do not discourage industry support for clinical trials or increase beneficiaries' costs of care. CMS must clarify that its payment policies will be applied in a manner that weighs and minimizes any increased costs for beneficiaries.

V. Conclusion

ACCC greatly appreciates this opportunity to comment on the Proposed CRP. ACCC supports Medicare's current clinical trial NCD, and we look forward to working with the agency as it develops a revised clinical trial policy. The American clinical research system relies on the talent, financial resources, and collaboration of a wide variety of entities, including patients, physicians, researchers, the pharmaceutical and biological technology industries, and hospitals and other health care providers. Any effort to expand clinical research opportunities and clarify Medicare coverage of clinical trials and other research studies must be undertaken with a full understanding of these entities' contributions to the system and the complex relationships among them. In sum, we request that CMS consider the following measures as it continues to develop and finalize a revised Medicare clinical research policy:

- issue an NPRM rather than a final NCD;
- maintain the deeming process for certain clinical research studies and provide a self-certification process for studies not falling within one of the deemed categories;
- provide detailed guidance in a number of areas for those sponsors who would need to undergo the self-certification process;
- not apply new coverage and coding requirements to items and services covered as "usual patient care;"
- delay the effective date, should CMS decide to issue a final NCD; and
- clarify that Medicare, and not the clinical trial sponsor, is the appropriate payer for covered routine medical costs, including complications related to the trial.

Dr. Phurrough
August 18, 2007
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We would be pleased to answer any questions about these comments. Please contact Matt Farber at 301-984-9496 x221 if ACCC can be of any assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Edward L. Braud, MD". The signature is written in a cursive style and is positioned to the left of a vertical red line.

Edward L. Braud, MD
Chair
Government Affairs Committee
Association of Community Cancer Centers