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Sent via e-mail: leslie.norwalk@cms.hhs.gov

Dear Ms. Norwalk:

I am writing to you on behalf of the membership of the Association of American Medical Colleges to express our community's grave concerns that the final clinical research policy (proposed CAG-0071R) issued by CMS will impose a barrier to Medicare beneficiaries' access to clinical trials and will put institutions that conduct the trials at risk of violating Medicare payment rules. In an e-mail from Dr. Steve Phurrough in response to an AAMC query, he stated that:

Routine care cost (routine clinical services in the proposed policy) only apply inside deemed trials both in the old and proposed revision. Regardless of the definition of routine costs, they do not apply outside of a deemed trial. Medicare's longstanding policy has been that costs of clinical services provided inside of trials are not reasonable and necessary under 1862(a)(1)(A). The 2000 policy found routine clinical costs to be R&N under 1862(a)(1)(E) only inside deemed trials. The LCD language in the current policy may have been confusing to some and we are clarifying that in this policy. Bottom line is that Medicare's longstanding policy, not changed by this revision, is that payment of service provided to Medicare beneficiaries in a clinical trial must meet the standards of the clinical trial policy.

Dr. Phurrough was correct when he stated that the "language in the current policy may have been confusing to some." In fact, a brief, informal survey of AAMC members revealed that a large number of respondents believe that current CMS policy allows for payment for standard of care services to beneficiaries enrolled in clinical trials even if those trials do not meet the criteria that would qualify them for Medicare payment for

routine costs. By “standard of care” services we mean services that fall under an existing Medicare benefit category and are reasonable and necessary for the patient’s condition. In other words, regardless of whether the beneficiary is enrolled in a clinical trial, and regardless of whether the clinical trial qualifies for Medicare coverage, an individual with the beneficiary’s condition is entitled by law to receive this care and have it paid for by Medicare.

A number of respondents to our survey provided thoughtful comments that are instructive in gaining a fuller understanding of the ramifications of this issue. For example:

Comment #1:

We have taken the position that if a standard of care service is being provided to a patient and that patient would be having the service regardless of their participation in a study, it is billable to third party payers.

If all third party payers take the stance that covered services are no longer covered services when provided within the context of a non-qualifying clinical trial, research will virtually come to a halt. Someone will have to pick-up the costs - NIH? Industry? Certainly the providers can't subsidize all this research. Will patients have to pay to be in studies?

Comment #2:

If the service is truly standard of care, and not being performed only for research purposes, then it meets the definition of medically necessary.

Comment #3:

The end result of this decision to not cover standard of care services for undeeded research efforts will in the least:

- 1) Severely limit Medicare beneficiary access to IND-exempt efforts, especially cancer patients, as physicians use drugs regimens to treat patients with off-label use rather than intending to market new uses of the product. To require clinics and hospitals the burden to provide these drugs at no charge to Medicare patients because they are using a research related drug regimen with an IND-exempt study is not a viable burden. Medicare patients will eventually be excluded from these life-saving efforts as providers will not be able to afford the studies and manufacturers typically do not fund these patient-care protocols.
- 2) Severely limit Medicare beneficiary access to industry-funded and provider self-funded research protocols that typically do not fund the full continuum of the patient encounter. The research may be related to a

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device or specific service that is part of the clinically indicated and otherwise covered patient care encounter. The non-research protocol services that would be covered under a Medicare benefit category and are medically necessary and reasonable would now be patient or provider responsibility. The proposed policy would require the industry or provider to fund all patient care surrounding the trial and as a result funding for research activities would be severely limited and Medicare patients would face access difficulties to research funded by these resources.

As always, we remain available to discuss this issue with you. Even at this late date, we would also be willing to set up a call so that you can talk directly to AAMC members about the implications of your proposed policy.

I appreciate your willingness to consider these comments, in addition to those that we and others submitted previously.

Sincerely,



Robert M. Dickler
Senior Vice President
Division of Health Care Affairs



David Korn, M.D.
Senior Vice President
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cc: Steve E. Phurrough, M.D.
Leslye Fitterman, Ph.D.
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