

December 16, 2010

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BY ELECTRONIC DELIVERY

Donald M. Berwick
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 314G
Washington, DC 20201

Margaret A. Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Room 2217
Silver Spring, MD 20993

Re: Parallel Review of Medical Products [FDA-2010-N-0308]

Dear Dr. Berwick and Dr. Hamburg:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the notice and request for comments from the Centers for Medicare and Medicaid Services (CMS) and Food and Drug Administration (FDA) regarding parallel review of medical products.¹ 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 more than 900 member institutions and organizations, when combined with our physician membership, treat 60 percent of all U.S. cancer patients.

ACCC is committed to ensuring that patients have access to the most appropriate treatments and diagnostic tools needed to prevent, diagnose, and treat cancer. Cancer is an extremely complex disease

¹75 Fed. Reg. 57045 (September 17, 2010).

with many variations among stages, organs, and complications, and the standard of care constantly is evolving through continued research. For cancer patients, timely access to a new therapy or diagnostic tool can be the difference between life and death, and we strongly encourage both agencies to continue to work to ensure that appropriate, innovative technologies are available to Medicare beneficiaries.

CMS and FDA propose to implement a parallel review process that would allow CMS to begin its national coverage determination (NCD) analysis for a new technology concurrent with the FDA's review of the technology for approval or clearance. As described in the notice, this process would involve CMS and FDA input at the early stages of designing the protocol for the trials that would lead to Medicare coverage and FDA approval, as well as opportunity for public input on the development of the NCD upon conclusion of the trial. The goal of the process would be to reduce the time between FDA approval and issuance of a Medicare NCD and to provide more timely access to these new technologies.

We appreciate the FDA and CMS's desire to "accelerate consumer access to new, particularly innovative, safe and effective medical products,"² but we believe that the proposed parallel review process is not needed to ensure timely access to many innovative cancer therapies. Within the statutory definition of drugs that must be covered by Medicare, Congress specifically included "any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication."³ A "medically accepted indication" includes indications approved by the FDA, as well as certain uses supported by one or more citations in certain authoritative compendia.⁴ Thus, there is no need for parallel review of a drug or biological used in an anticancer chemotherapeutic drug regimen because any such FDA-approved use is a "medically accepted indication" that must be covered by Medicare. Any off-label uses subsequently supported by the compendia also must be covered by Medicare. Although manufacturers may choose to pursue parallel review for these therapies, we urge CMS to recognize that these therapies should not be subject to additional coverage analysis and would not be appropriate candidates for parallel review.

With regard to other therapies and diagnostic technologies used in cancer care, such as imaging technologies and radiation therapy, we are concerned that parallel review could delay, rather than expedite, access to innovative care. In the notice, CMS acknowledges that it may seek evidence different from that required for FDA-approval, such as "community or home based use outside of clinical trial protocols, generalizability of the results to target populations that may have not

² Id. at 57046.

³ Social Security Act (SSA) § 1861(t)(2)(A).

⁴ SSA § 1861(t)(2)(B).

been studied, and the incremental clinical utility of these products compared to currently available technologies.”⁵ Designing pre-approval trials to collect this information could make the trials more complex and expensive to conduct, especially if CMS seeks to include patients from the Medicare population. Approximately 85% of Medicare beneficiaries are ineligible to participate in clinical trials due to comorbidities. Among the few patients who are eligible, some may choose not to participate in trials if they would be required to change providers or travel significant distances to receive care. Similarly, including additional settings of care or comparisons to additional treatment options, beyond those required for FDA approval, would significantly increase the costs and time associated with conducting these trials. Although we support the goal of increasing the evidence available for clinical decision-making, we are concerned that making the approval process more difficult ultimately will result in fewer treatment options, will delay beneficiaries’ access to improved care, and will discourage continued investment in research. Therefore, we recommend that any parallel review process be conducted in a manner that does not increase the costs and timeframe of bringing new technologies to patients and providers.

We also recommend that any parallel review process implemented by CMS and FDA be voluntary for the manufacturer involved and not replace the existing local coverage process through which most new technologies are covered. Our members are able to provide a continually improving standard of care to their patients because Medicare’s local contractors have the flexibility to cover new technologies as the clinical evidence evolves. In particular, local contractors are able to make evidence-based determinations regarding whether a treatment is reasonable and necessary for a specific patient. This process allows beneficiaries to receive appropriate innovative care while also allowing manufacturers to invest in additional research. If they are unable to obtain coverage at the local contractor level, manufacturers may choose to seek an NCD after they have built up a significant body of clinical literature on a broader patient population. Manufacturers should not be forced into parallel review because initiating the NCD process prematurely could result in a non-coverage decisions that hinder future research. We believe that parallel review and the NCD development process should be optional for manufacturers, and that local contractors must continue to be free to make their own determinations of whether to cover new technologies for particular patients.

Finally, if a parallel review process is implemented, we recommend that it also consider applications for new codes and reimbursement, regardless of whether the manufacturer also seeks an NCD. Timely access to new technologies often depends on the availability of appropriate coding that allows providers to bill for the

⁵ 75 Fed. Reg. at 57046.

item or service and receive appropriate reimbursement. Currently, CMS often does not review applications for new Healthcare Common Procedure Coding System (HCPCS) codes or special payment status to protect access to new technologies, such as pass-through status and new technology ambulatory payment classifications under the outpatient prospective payment system, until after the technology has received FDA approval or clearance. Even in the cases in which CMS will accept an application prior to FDA approval of the technology, such as applications for HCPCS codes and pass-through status for drugs and biologicals, CMS may not approve the application until several months after the product receives FDA approval. As a result, providers may have difficulty obtaining appropriate payment for new technologies upon introduction to the market. Delays in reviewing and approving these applications also may prevent a technology from receiving the benefit of payment provisions intended to protect access to new technologies for the full eligibility period. Consistent with CMS's stated desire to accelerate access to new technologies, we recommend that CMS offer parallel review of technologies for coding and reimbursement purposes separate from any review for coverage purposes.

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ACCC appreciates the opportunity to submit these comments. We would be pleased to answer any questions. Please contact Matt Farber at 301-984-9496, ext. 221 if ACCC can be of any assistance.

Sincerely,



Al B. Benson III, MD, FACP

President

Association of Community Cancer Centers (ACCC)