

February 24, 2011

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*BY ELECTRONIC DELIVERY*

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**Re: Draft Update to Chapter 4 of the Medicare Managed Care Manual**

Dear Ms. Moon:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) draft update to Chapter 4 of the Medicare Managed Care Manual.<sup>1</sup> 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. We are greatly concerned that the proposed update to the Medicare Managed Care Manual will allow Medicare Advantage (MA) plans to deny beneficiaries access to the drugs and biologicals needed to fight cancer. Among other changes,

<sup>1</sup>Memorandum from D.R. Moon to Medicare Advantage Organizations and MA Employer/Union-Sponsored Group Health Plans, Feb. 10, 2011, <http://www.cms.hhs.gov/HealthPlansGenInfo/>.

the proposed update would add the following language to the “Access” provision in section 10.2 of chapter 4 of this manual:

For example, while MA plans must pay for all Part B drug or DME items covered under Original Medicare, they may restrict access – for each covered Part B drug or DME item – to certain manufacturers’ drugs and/or DME items, provided these drugs and/or DME items are accessible to plan enrollees through all contracted network providers.

If implemented, this provision would allow MA plans to deny coverage of medically necessary cancer therapies based not on clinical data, but on other, possibly financial considerations, such as the availability of discounts from the manufacturer. This would be simply unacceptable not only morally, but also as a clinical and legal matter.

First, the proposed update seems to assume that the drugs and biologicals used to treat cancer and its complications are completely interchangeable, and that appropriate care can be provided without access to certain manufacturers’ therapies. To the contrary, cancer is an extremely complex disease with many variations among stages, organs, and complications. Treatments also vary by stage, organ, and complications and often consist of multiple-drug regimens. The standard of care constantly is evolving through continued research, as new drugs and new combinations of drugs are tested for different types of cancer. Patients and their physicians need access to a wide array of drugs and biologicals, from all manufacturers, in order to select the most appropriate therapy for the patient’s condition. For cancer patients, timely access to appropriate therapies can be the difference between life and death. Allowing MA plans to restrict access to certain manufacturers’ drugs would only hurt the quality of care provided to beneficiaries.

In addition, many cancer therapies have unique clinical characteristics, although they share generic names or billing codes. Biologicals, for example, may have the same generic name, but are not rated as therapeutic equivalents by Food and Drug Administration. These therapies also may share a Healthcare Common Procedure Coding System code, but one therapy often cannot be substituted for another without putting the patient at risk for complications. Quality cancer care requires access to all of these therapies to ensure that each patient can receive the drug or biological best suited for their condition and most compatible with other therapies in the patient’s regimen.

Second, the proposed update is inconsistent with the statute, regulations, and existing manual provisions regarding access to prescription drugs. Congress recognized the importance of protecting beneficiary access to cancer therapies when it defined “drugs and biologicals” that are covered by Medicare to include “any drugs

or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication.”<sup>2</sup> Congress extended this protection to beneficiaries in MA plans by requiring these plans to provide “those items and services (other than hospice care) for which benefits are available under parts A and B to individuals entitled to benefits under part A and enrolled under part B.”<sup>3</sup> Therefore, MA plans must cover all drugs and biologicals used in an anticancer chemotherapeutic regimen that are covered by Medicare Parts A or B.

Beneficiaries’ access to drugs and biologicals also is protected by the requirement that MA plans comply with CMS’s national coverage determinations (NCDs) and the local coverage determinations (LCDs) of local Medicare contractors within the plan’s jurisdiction.<sup>4</sup> If there is more than one LCD in effect in the plan’s jurisdiction and the plan elects to adopt a uniform coverage policy, the plan must apply uniformly the LCD that is “most beneficial” to enrollees.<sup>5</sup> While there are NCDs and LCDs that define coverage limits for cancer drugs based on clinical criteria, we are not aware of any NCDs or LCDs that restrict access to drugs or biologicals based on their manufacturers. Therefore, MA plans must not restrict access to specific manufacturers’ therapies when those drugs or biologicals are covered NCDs or LCDs.

CMS acknowledges these requirements in other sections of the Managed Care Manual. For example, section 10.3 of the manual requires MA plans to include in their basic benefits items and services, including Part B prescription drugs, that are covered by Original Medicare under Part A or Part B.<sup>6</sup> Section 50.1 also prohibits plans from placing dollar limits on the “provision of Part B drugs covered under Original Medicare unless either the Medicare statute imposes the limit on Original Medicare coverage, it is specified in a national or applicable local coverage determination, or CMS imposes a dollar limit.”<sup>7</sup> By restricting access to a certain manufacturer’s drugs, an MA plan would establish a dollar limit of zero for these drugs, and this would not be permitted by the statute, regulations, or manuals.

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<sup>2</sup>Social Security Act (SSA) § 1861(t)(2)(A).

<sup>3</sup>SSA § 1852(a)(1)(A) and (B); see also 42 C.F.R. § 422.100. CMS’s regulations also require plans to “provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the plan’s service area.” 42 C.F.R. § 422.101(a).

<sup>4</sup>Id. at § 422.101(b).

<sup>5</sup>SSA § 1852(a)(2)(C); 42 C.F.R. § 422.101(b)(3).

<sup>6</sup>Medicare Managed Care Manual, ch. 4, § 10.3.

<sup>7</sup>Id. at ch. 4, § 50.1.

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Finally, the proposed update appears to expand the definition of “providers” to include “manufacturers.” This revised definition is inconsistent with the statute and regulation’s definition of “provider.” Under the MA regulations, a “provider” is:

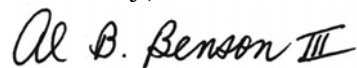
- (1) Any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State; and
- (2) Any entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation.

This definition clearly does not include manufacturers of drugs and biologicals, except in the rare case that the manufacturer also is “engaged in the delivery of health care services.” Therefore, although MA plans may restrict access to certain providers, they may not restrict access to drugs and biologicals made by certain manufacturers.

ACCC urges CMS to not implement the proposed update to section 10.2 because it would deny beneficiaries access to medically necessary drugs and biologicals and because it is inconsistent with the Medicare statute, regulations, and manual guidance. We recommend that CMS continue to use the current language of “Access” provision of section 10.2 because it does not restrict beneficiaries’ access to necessary drugs and biologicals and complies with the statute, regulations, and existing manual provisions.

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)

Attachment