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BY ELECTRONIC DELIVERY

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Director
Medicare Drug & Health Plan Contract Administration Group
Centers for Medicare & Medicaid Services
Mail Stop C2-12-16
7500 Security Boulevard
Baltimore, MD 21244

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

Dear Ms. Moon:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments to the Centers for Medicare & Medicaid Services (CMS) on the draft update to Chapter 4 of the Medicare Managed Care Manual.[1] BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

BIO urges CMS to not implement the proposed change to section 10.2 to allow Medicare Advantage (MA) plans to restrict access for each covered Part B drug or durable medical equipment (DME) item to certain manufacturers' drugs and/or items because this change is inconsistent with the statute, regulations, and other manual provisions and would deny beneficiaries access to medically necessary drugs and biologicals. As explained below and in the attached comment form, the proposed changes are not merely a "clarification," as they are described in the memorandum announcing this update,[2] but are a clear contradiction of the statutory and regulatory

[1] 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/.
[2] Id.

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requirements that MA plans cover all Medicare-covered services, except hospice services.[3] Moreover, the proposed change misapplies MA plans' authority to restrict access to certain providers to allow plans to restrict access to certain items and services, ignoring the statutory and regulatory definition of "provider." Finally, the proposed change fails to recognize that multiple biologicals can share a generic description and a billing and payment code yet not be pharmaceutically or therapeutically equivalent. Allowing access to only certain manufacturers' products could prevent beneficiaries from receiving the most appropriate treatment for their conditions and could expose beneficiaries to greater risk of complications due to inappropriate changes in the course of treatment.

I. The proposed change is inconsistent with the statutory and regulatory requirements and manual provisions for MA plans requiring coverage of all Part B drugs and DME items covered by Original Medicare.

The current text of section 10.2 states, in relevant part:

MA plans are not required to provide MA enrollees the same access to providers as is provided under Original Medicare. (Refer to accessibility rules for MA plans in section 100 of this chapter.)[4]

The draft update to section 10.2 makes numerous edits to section 10.2, including revising the statement quoted above to read:

Access: MA plans are not required to provide MA enrollees the identical access to providers as is provided under Original Medicare (refer to accessibility rules for MA plans in section 110 of this chapter).

<u>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.</u>[5]

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[3] Social Security Act (SSA) § 1852(a)(1); 42 C.F.R. § 422.100.
[4] Medicare Managed Care Manual, ch. 4, § 10.2 (Rev. 94, eff. 01-01-11).
[5] Medicare Managed Care Manual, ch. 4, § 10.2 (proposed change) (emphasis added).

The proposed change correctly acknowledges that "MA plans must pay for all Part B drug or DME items covered under original Medicare," yet would allow MA plans to "restrict access – for each covered Part B drug or DME item – to certain manufacturers' drugs and/or DME items." The proposed change plainly contradicts the statute and regulations. The Medicare statute requires MA 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."[6] The related regulation requires 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."[7] The statute and regulations make no exceptions to these coverage requirements for drugs, biologicals, and DME items from certain manufacturers.

In addition, each MA plan must comply with CMS's national coverage determinations and the local coverage determinations (LCDs) of local Medicare contractors within the plan's jurisdiction.[8] When there is more than one LCD in effect in the plan's jurisdiction, the plan may elect to apply uniformly the LCD that is "most beneficial" to enrollees.[9] Thus, MA plans are not permitted to establish coverage requirements that are narrower than the "most beneficial" LCD in effect in each plan's jurisdiction. Unless an NCD or the most beneficial LCD in a jurisdiction denies coverage for a particular manufacturer's drug, biological, or DME item, an MA plan is not permitted to restrict access to those items.

Existing manual provisions that CMS does not propose to modify correctly recognize that MA plans may not restrict access to specific manufacturers' products. Section 10.3 of the manual states, "If the item or service is covered by Original Medicare under Part A or Part B, including Part B prescription drugs, then it must be offered and identified in plan bids as a basic benefit."[10] This provision makes no exception for certain manufacturers' drugs. Section 50.1 states,

> No dollar limits can be placed on the provision of Part B drugs covered under Original Medicare unless either the Medicare statute imposes the limit on Original

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[6] SSA § 1852(a)(1)(A) and (B); see also 42 C.F.R. § 422.100.
[7] 42 C.F.R. § 422.101(a).
[8] Id. at § 422.101(b).
[9] SSA § 1852(a)(2)(C); 42 C.F.R. § 422.101(b)(3).
[10] Medicare Managed Care Manual, ch. 4, § 10.3.

> Medicare coverage, it is specified in a national or applicable local coverage determination, or CMS imposes a dollar limit.

Restricting access to Part B drugs and biologicals made by certain manufacturers would effectively place a dollar limit of zero dollars on these drugs. This would be inconsistent with the requirements of section 50.1, the statute, and regulations. It simply is not possible to simultaneously provide access to <u>all</u> items and services, including drugs and DME, covered under Medicare Parts A and B and restrict access to drugs and DME made by certain manufacturers. For this reason, CMS must not implement the proposed change to the "Access" provision, underlined above, in section 10.2.

II. The proposed change mistakenly expands MA plans' authority to limit access to certain providers to also allow plans to limit access to items and services.

In addition to conflicting with the statutory, regulatory, and manual provisions requiring coverage of Part B drugs and biologicals, the proposed change mistakenly includes manufacturers of drugs and DME items in the definition of "provider." The statute defines "provider of services" as "a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of section 1814(g) and section 1835(e), a fund."[11] The MA regulations also define "provider" as:

> (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.

A manufacturer of drugs, biologicals, or DME would not be a "provider" under either of these definitions unless it also was engaged in the delivery of health care services. This is generally not the case, however, and MA plans cannot use their authority to limit access to certain providers to also restrict access to drugs, biologicals, or DME items from certain manufacturers.

[11] SSA § 1861(u).

III. Restricting access to drugs and biologicals from certain manufacturers would harm beneficiaries' care.

Additionally, BIO urges CMS to consider the profound impact that the proposed change to the "Access" provision in section 10.2 may have on patient care. The proposed change would deny beneficiaries access to medically necessary drugs and biologicals, and could prevent beneficiaries from receiving the most appropriate treatment for their condition. Restricting access to certain therapies may lead to suboptimal health outcomes or greater risk of complications for beneficiaries due to changes in the course of treatment. Beneficiaries should have access to all medically necessary therapies, as determined by both the patient and physician. To achieve the best possible outcomes, providers must have the flexibility to tailor the appropriate course of treatment for each patient based on individual patient medical condition and clinical circumstances. The proposed change does not maintain patient choice, nor does it preserve the patient-provider relationship.

The proposed change would be especially harmful to beneficiaries' access to biologicals because it fails to recognize that biologicals can share a generic description and a billing and payment code yet not be pharmaceutically or therapeutically equivalent or otherwise substitutes for each other. In particular, although biological products are not rated as equivalents by the Food and Drug Administration and are "single source" products for purposes of Medicare Part B reimbursement under the average sales price methodology, two or more of these products may be treated as "multiple source" if they were "within the same billing and payment code as of October 1, 2003."[12] Because these products may share a generic name and a Healthcare Common Procedure Coding System (HCPCS) code, MA plans may incorrectly conclude that the products are interchangeable. In reality, each biological has unique features that make it particularly suited to certain patients' conditions. Patients often cannot change biological therapies without risking complications. The proposed change to section 10.2 also seems to rely on this incorrect conclusion, and if implemented, would allow plans to deny beneficiaries access to the most appropriate therapies for their conditions.

[12] Id. at § 1847A(c)(6)(C) and (D).

IV. An informal announcement of a manual update is not an appropriate venue for proposing a significant change in policy.

Finally, not only does CMS lack authority to make the proposed change in policy, but an informal memorandum revising a manual is not the appropriate venue for a change of such magnitude. The informal memorandum, addressed to MA plans, announcing a draft manual update was not widely announced to all affected stakeholders, provides only two weeks for comments, and instructs the public to use a truncated format to submit comments. In addition, the memorandum does not describe CMS's rationale for the change, the expected impact on beneficiaries, or any of the important procedural measures that would need to be developed to implement this access-restricting policy (e.g. the standards that plans could use to make these determinations, CMS oversight of these determinations, appropriate advanced beneficiary notice). This informal memorandum announcing a draft manual chapter simply does not provide the opportunity for stakeholders to provide meaningful feedback on these and other important issues.

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In conclusion, we urge CMS to not implement the proposed change to the "Access" provision of section 10.2 because it conflicts with the statute, regulations, existing manual provisions, and appropriate use of drugs and biologicals. Instead, CMS should retain the current language of the manual because it is consistent with all of these requirements. BIO appreciates your attention to these comments. If we can be of any assistance as you consider these comments, please contact Laurel Todd at (202) 962-9220.

Respectfully submitted,

/s/

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cc:
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Enclosure