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April 19, 2007

Via Hand Delivery

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments on CMS-2238-P, Medicaid Rebate Program; Prescription Drugs (Proposed Rule)

Dear Sir or Madam:

On behalf of Talecris Biotherapeutics, Inc., we are pleased to provide these comments on the above-referenced rule proposed by the Centers for Medicare & Medicaid Services ("CMS"), which was published in the Federal Register on December 22, 2006.[1] We recognize that the comment period for this proposed rule has closed, but we urge CMS nonetheless to consider our comment on the narrow issue of sales directly to patients.

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1 CMS, Medicaid Program; Prescription Drugs; Proposed Rule, 71 Fed. Reg. 77,174 (Dec. 22, 2006).

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Average Manufacturer Price ("AMP")

CMS proposes to define AMP as "the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade."[2] CMS also proposes to define a wholesaler as "any entity (including a pharmacy, chain of pharmacies, or PBM) to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs,"[3] and retail pharmacy class of trade as "any independent pharmacy, chain pharmacy, mail order pharmacy, pharmacy benefit manager (PBM), or other outlet that purchases, or arranges for the purchase of, drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public."[4]

The proposed rule, however, goes on to include in AMP "[s]ales directly to patients."[5] In the preamble to the proposal, CMS describes these sales as "usually for specialty drugs through a direct distribution arrangement, where the manufacturer retains ownership of the drug and pays either an administrative or service fee to a third party for functions such as the storage, delivery and billing of the drug."[6] CMS notes that manufacturers have contended that drugs sold through a direct distribution channel should not be included in AMP because the statute and the Rebate Agreement do not address covered outpatient drugs that are not sold to wholesalers and/or not distributed to the retail pharmacy class of trade.[7] In response, CMS opines that in such situations "the distributor is acting as a wholesaler and these sales are to the retail pharmacy class of trade" and should therefore be included in AMP.[8] CMS invites comments on this issue.

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2 Id. at 77,196 (proposed 42 C.F.R. § 447.504(a)).

3 Id. (proposed 42 C.F.R. § 447.504(f)).

4 Id. (proposed 42 C.F.R. § 447.504(e)).

5 Id. at 77,197 (proposed 42 C.F.R. § 447.504(g)(7)).

6 Id. at 77,180.

7 Id.

8 Id. at 77,180-81.

The principal problem with CMS's position is that there is no support for expanding the notions of "wholesaler" and "retail pharmacy class of trade" to cover direct-to-patient sales by a manufacturer. A manufacturer may have a pharmacy license and sell drugs directly to patients, or it may contract with a third party pharmacy to dispense drugs directly to patients, with that specialty pharmacy merely providing the services that the manufacturer chooses to outsource. In either situation, the manufacturer does not sell the drug to anyone other than the patient to whom it is dispensed. The manufacturer retains ownership of the product until it is sold to the patients, and in no case does the manufacturer sell the product to the specialty pharmacy. If the manufacturer utilizes the services of a specialty pharmacy, the specialty pharmacy may also submit a claim to a third party payor or an invoice to a patient in the name of the manufacturer, but the specialty pharmacy would not keep any payment that is remitted to it by the patient or the third party payor. For the reasons set forth below, we disagree with CMS's proposal that the sales made under such arrangements should be included in AMP.

First, the entire concept of a "direct sale" hinges on the fact that there is no wholesaler. Under any rational construction of the definition of wholesaler, the patient is not a wholesaler. Moreover, although CMS takes the position that the specialty pharmacy acts like a wholesaler in this situation, the specialty pharmacy is not a wholesaler under the proposed definition because the manufacturer does not "sell[]" to the pharmacy or "arrange[] for the sale" to the pharmacy.[9] If CMS nonetheless takes the position that a specialty pharmacy in this situation is a wholesaler, there are no sales to include in AMP because the entity which CMS is characterizing as the wholesaler does not purchase the drug.

Second, even if the specialty pharmacy in a direct sales situation may be considered by CMS to be a wholesaler, that does not lead to the conclusion that there are any AMP-includable sales. The purchasers of the drug, i.e., patients, are not within the definition of the retail pharmacy class of trade, despite CMS's assertion to the contrary in the preamble to the proposed rule. Patients are members of the general public; they are not entities that "subsequently sell[] or provide[] the drugs to the general public."[10] CMS has provided no analysis regarding why it believes patients are within the retail pharmacy class of trade.

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9 Id. at 77,196 (proposed 42 C.F.R. § 447.504(f)).

10 Id. at 77,180-81, 77,196 (proposed 42 C.F.R. § 447.504(e)).

Indeed, in another section of the preamble, CMS seems to accept this logic, when it explains that "retail pharmacy class of trade means that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public. . . ."[11] That characterization cannot fairly be read to include patients.

A specialty pharmacy providing services under contract with a manufacturer may be considered within the retail pharmacy class of trade.[12] Again, there are no AMP-includable sales because there are no sales to the pharmacy and there is no other wholesaler involved in the transaction. CMS's apparent effort to recast direct sales to patients as sales to the entity that provides the manufacturer with pharmacy services flies in the face of reality because that entity does not purchase the drug from anyone or sell the drug to anyone. AMP is intended to reflect prices from a manufacturer to commercial retail entities (after chargebacks and price concessions are accounted for), not prices to patients.

Best Price

For similar reasons, we disagree with CMS's proposal that "[p]rices of sales directly to patients" should be included in best price.[13] CMS proposes to define best price as "the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure. . . ."[14] This proposed definition exceeds the statutory definition of best price, which is "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States. . . ."[15] The statutory definition identifies specific types of entities whose purchases are included in best price. Patients are not among the enumerated entities. It must be assumed that, if Congress intended best price to include prices to all entities, the statute would have been so drafted.

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11 Id. at 77,178.

12 Id. at 77,196 (proposed 42 C.F.R. § 447.504(e)).

13 Id. at 77,197 (proposed 42 C.F.R. § 447.505(c)(7)).

14 Id. (proposed 42 C.F.R. § 447.505(a)) (emphasis added).

15 42 U.S.C. § 1396r-8(c)(1)(C)(i).

The listing of certain entities shows that the definition was not intended to be all-encompassing. Rather, the statutory definition is intended to capture prices to commercial entities, and CMS's interpretation goes beyond, and is inconsistent with, the plain language of the statute.

* * *

Direct-to-patient programs are an efficient, cost-effective means to provide much-needed therapies. Federal policy should encourage such programs rather than discourage their development and use. However, requiring manufacturers to include such sales in AMP and best price may have the unintended effect of discouraging manufacturers from implementing such programs. Accordingly, for the above reasons, we urge CMS to revise its proposed rule so that direct sales to patients are excluded from AMP and best price. We appreciate the opportunity to comment on this proposed rule. If you have any questions about these comments, please do not hesitate to contact me at 202/737-7551.

Respectfully submitted,

Michelle L. Butler

MLB/dcp