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February 16, 2012

VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5060-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Proposed Rule for Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests
Docket No. CMS-5060-P
76 Fed. Reg. 78742 (December 19, 2011)

The Consumer Healthcare Products Association (CHPA) takes this opportunity to share our comments on the agency's proposed rule for Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 76 Fed. Reg. 78742 (December 19, 2011). CHPA is the 131-year-old trade association representing U.S. manufacturers and distributors of over-the-counter (OTC) medicines and dietary supplements.

CHPA supports the agency's decision to limit the disclosure trigger definition of "covered drug, device, biological, or medical supply" to only those drugs and biologicals that require a prescription by law in order to be dispensed, thus excluding drugs and biologicals that are available to consumers over the counter. We would further urge CMS to change the proposed rule to exclude payments or transfers of value related to OTC drugs altogether, including for manufacturers who produce both covered products and OTC drugs.

In general, OTC products are not covered by government payer programs. In fact, the Medicare Part D drug program explicitly *excludes* OTC medicines from coverage. (See 42 CFR sec. 423.100, definitions, limiting coverage to drugs that may be dispensed *only* upon a prescription [with an exclusion for smoking cessation agents, some of which require a prescription, and others of which are available OTC].) As noted in the preamble of the proposed rule, physicians and teaching hospitals have less influence over patients' choice of OTC products. Indeed, by their very nature and definition, OTC medicines are self-selected by consumers. Manufacturers have two basic means by which to inform consumer self-selection decisions: labeling, which is strictly regulated

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by the Food and Drug Administration; and advertising or promotion, which must be truthful and non-misleading and is under the authority of the Federal Trade Commission. Payments or transfers of value provided to physicians or teaching hospitals for OTC medicines are typically minimal. Yet the resources required to implement data tracking, collection, and reporting systems for a consumer healthcare division or company which happens to have an affiliation with a sister division manufacturing covered products would be significant. For companies with highly diverse product portfolios encompassing OTC medicines; covered drugs, devices, biological, or medical supplies; and products well outside the drug, biologic, or device sphere, the system burden would create even greater complications, raising the potential to create unintended consequences for both CMS, in terms of the ability to classify and analyze information received on products stretching beyond the core purpose of the statute related to potential influence on physicians or teaching hospitals, and for manufacturers.

For OTC medicines, the same logic that applies to the proposed rule's exclusion of OTC medicines should apply regardless of whether or not the manufacturer solely produces OTC medicines, or if they produce both prescription (or other covered products) and OTC medicines. We therefore request a change in the proposed rule to exclude payments or transfers of value related to OTC medicines for manufacturers, including for manufacturers who produce both covered products and OTC medicines. This change would assure that an undue burden would not be placed on manufacturers of OTC products that is not currently required by law, would reduce unintended consequences, and would avoid an inefficient burden on OTC manufacturers yielding minimal if any value to CMS.

In the event CMS moves ahead with the approach under the proposed rule *without* this broader clarification for OTC medicines, we recommend additional time to gather stakeholder input on this or other unintended consequences for firms with diverse product portfolios.

Thank you for your consideration.

Respectfully submitted,

David C. Spangler
Senior Vice President, Policy, and
General Counsel & Secretary