September 14, 2015

Shaun Donovan
Director
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

**Re: Medicaid Program; Covered Outpatient Drugs; Final Rule [CMS-2345-F]**

Dear Director Donovan:

On behalf of the Biotechnology Industry Organization (BIO), Generic Pharmaceutical Association (GPhA), Healthcare Distribution Management Association (HDMA), National Association of Chain Drug Stores (NACDS), and Pharmaceutical Research and Manufacturers of America (PhRMA), we are writing to reiterate our concerns about the above-referenced draft final rule, which we understand your office is reviewing, and to request an opportunity to meet with you to discuss the rule in person. Our organizations represent stakeholders across a broad spectrum of the pharmaceutical distribution chain, and our hope is that, through dialogue with your office, we can work together to resolve our concerns, which we expressed in timely submitted comments on the proposed rule.

We have certain concerns about the rule that we would like to discuss. Chief among them is the "build-up" approach to calculating Average Manufacturer Price (AMP). As we explained in a joint comment letter to the Centers for Medicare & Medicaid Services (CMS) dated April 2, 2012, CMS's proposal to abandon the longstanding "presumed inclusion" approach in favor of a build-up approach would have many undesirable consequences, including creating AMPs that are less rather than more reflective of prices in the marketplace, increasing volatility in AMPs, and imposing unnecessary and substantial burdens throughout the pharmaceutical distribution chain. A copy of our joint letter from 2012 is enclosed for your reference. As noted in that letter, each of our organizations also submitted individual comment letters reflecting additional concerns about the proposed rule. We would be happy to provide you with copies of those comment letters upon request.

We would welcome the opportunity to meet with you to explain these concerns and our comments in the hope that we can address them in a cooperative manner and reduce the likelihood of litigation. We will contact your office to inquire if there is a time that would work for such a meeting. Thank you for your consideration.

Sincerely,

Biotechnology Industry Organization

Generic Pharmaceutical Association

Healthcare Distribution Management Association

National Association of Chain Drug Stores

Pharmaceutical Research and Manufacturers of America

cc. Adaeze Akamigbo, Ph.D., M.P.P.
Associate Director for Health
The Office of Management and Budget

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services

John Coster
Director, Division of Pharmacy
Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services

Enclosure

April 2, 2012

***HAND DELIVERED***

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–2345–P
P.O. Box 8016
Baltimore, MD 21244–8016

**Re: Joint Stakeholder Letter concerning CMS-2345-P; Medicaid Proposed Rule on Covered Outpatient Drugs**

Dear Ms. Tavenner:

This letter provides a joint statement on the above-referenced proposed rule[1] from the following organizations: Biotechnology Industry Organization (BIO); Generic Pharmaceutical Association (GPhA); Healthcare Distribution Management Association (HDMA); National Association of Chain Drug Stores (NACDS); and Pharmaceutical Research and Manufacturers of America (PhRMA). We appreciate the opportunity to comment on the proposed rule, which if finalized could have a major impact on the calculation of Average Manufacturer Price (AMP), with repercussions throughout the pharmaceutical distribution chain. Our organizations collectively represent the stakeholders across the entire pharmaceutical distribution chain that will be affected by the AMP provisions in CMS' final rule. We are coming together to write this Joint Stakeholder Letter in order to provide a clear, unified voice on one of the key issues addressed in the proposed rule.

We urge CMS to maintain the traditional default rule on the treatment of sales to wholesalers in the AMP calculation. Under this rule, formerly codified at 42 C.F.R. §447.504(g)(1), AMPs include "[s]ales to wholesalers, except for those sales that can be identified with adequate documentation as being subsequently sold to any [excluded entity]."[2] CMS should not finalize its proposal to reverse the traditional default rule. All of the undersigned stakeholders agree that CMS should preserve the traditional default rule. We are each concerned that the CMS proposal (which would base AMPs on a smaller set of sales than under the traditional default rule), could: (1) cause greater volatility in the AMPs; (2) create AMPs that may be less rather than more representative of prices to retail community pharmacies; and (3) generate unnecessary burdens and unintended costs for companies involved in the distribution chain. We urge CMS to avoid these risks and maintain a long-standing principle that has worked well over many years.

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1 Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. 5318 (Feb. 2, 2012).

2 42 C.F.R. § 447.504(g)(1)(2010).

Each of our organizations has submitted individual comment letters on the proposed rule, and you will find further detail on this issue in our individual letters. Please feel free to contact any of the undersigned if you have any questions or would like additional information.

We thank CMS again for the opportunity to submit comments on the proposed rule, and we hope this letter will assist CMS in developing final regulations.

Sincerely,

Biotechnology Industry Organization

Generic Pharmaceutical Association

Healthcare Distribution Management Association

National Association of Chain Drug Stores

Pharmaceutical Research and Manufacturers of America