March 4, 2016

BY ELECTRONIC SUBMISSION

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Joint Stakeholder Letter Concerning CMS-2345-FC; Medicaid Final Rule on Covered Outpatient Drugs

Dear Mr. Slavitt:

This letter provides a joint statement on the above-referenced final rule[1] from the following trade and professional associations: Academy of Managed Care Pharmacy (AMCP), American Pharmacists Association (APhA), Biotechnology Innovation Organization (BIO), Generic Pharmaceutical Association (GPhA), Healthcare Distribution Management Association (HDMA), National Alliance of State Pharmacy Associations (NASPA), National Association of Chain Drug Stores (NACDS), National Community Pharmacists Association (NCPA), and Pharmaceutical Research and Manufacturers of America (PhRMA). Our organizations collectively represent stakeholders across the pharmaceutical distribution chain, including pharmacists, pharmacies, managed care organizations, and healthcare distributors, that will be affected by the average manufacturer price (AMP) provisions in CMS's final rule. The purpose of this Joint Stakeholder Letter is to provide a unified request that CMS extend the effective date of the final rule through October 1, 2016. While we greatly appreciate the increased clarity on Medicaid AMP calculations, we have waited years for these new rules and ask the agency to consider giving us a few extra months to ensure we can successfully implement CMS' final rule.

The Final Rule is the most voluminous Medicaid rebate regulation ever published, including 78 provisions with numerous inter-related sub-provisions, all of which present operational challenges of varying magnitudes. Due to the sheer number of topics addressed—many with complex operational implications—stakeholders from across the supply chain are facing a multitude of challenges in their efforts to implement and comply with the Final Rule. Rushing this process could increase of the risk of errors, which could create legal risk for manufacturers that must certify to compliance with the new rules as of April 1st and impose increased burden on downstream entities that rely on these AMP calculations. Not allowing manufacturers time to "get it right" may result in inaccurate AMP-based federal upper limits (FULs), and impose a significant workload on states due to the increase in rebate restatements that may need to be submitted and reprocessed.

[1] 81 Fed. Reg. 5170 (Feb. 1, 2015).

To avoid these results, we strongly urge CMS to extend the effective date of the final rule to October 1, 2016, consistent with the agency's authority under the Administrative Procedure Act and as the agency has done with prior rules.

Our organizations feel strongly that CMS should extend the final rule's effective date in a timely manner given the short window of opportunity before April 1, 2016. Please feel free to contact any of the undersigned organizations if you have any questions or would like any additional information. We thank you for your attention to this important matter.

Sincerely,

Academy of Managed Care Pharmacy (AMCP)

American Pharmacists Association (APhA)

Biotechnology Innovation Organization (BIO)

Generic Pharmaceutical Association (GPhA)

Healthcare Distribution Management Association (HDMA)

National Alliance of State Pharmacy Associations (NASPA)

National Association of Chain Drug Stores (NACDS)

National Community Pharmacists Association (NCPA)

Pharmaceutical Research and Manufacturers of America (PhRMA)

cc: Tim Gronniger
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