

Diane E. Bieri
Senior Vice President
General Counsel



December 18, 2007

BY E-MAIL AND FIRST CLASS MAIL

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Suite 314G
Washington, DC 20201

Re: National Association of Chain Drug Stores and National Community Pharmacists Association v. United States Department of Health and Human Services et al., Civil Action No. 1:07-cv-02017 (RCL) (D.D.C., complaint filed November 7, 2007)

Dear Acting Administrator Weems:

I am writing on behalf of the Pharmaceutical Research and Manufacturers Association of America (PhRMA) in regard to the above-referenced litigation. As you know, the plaintiffs in this litigation have sought preliminary and permanent injunctions against implementation of the final rule referred to in their complaint as "the AMP rule," which the Centers for Medicare and Medicaid Services (CMS) published in the July 17, 2007 Federal Register.¹ The rule has an effective date of October 1, 2007. In a hearing on December 14, 2007, the court announced from the bench its intention to grant the plaintiffs' motion for a preliminary injunction. The court is expected to issue a preliminary injunction order on December 19, 2007.

The final rule addresses the calculation and reporting by pharmaceutical manufacturers of Average Manufacturer Price (AMP) and Best Price (as well as addressing certain additional reporting requirements and the Federal Upper Limits for certain drugs). Pharmaceutical manufacturers have made, and continue to make, large investments in adjusting, testing and refining their data collection and reporting systems and policies so that they can calculate and report AMP and Best Price values that are

¹ Centers for Medicare and Medicaid Services, Medicaid Program; Prescription Drugs; Final Rule, 72 Fed. Reg. 39142 (July 17, 2007).

compliant with the final rule. This process has been a lengthy one. Manufacturers have now made one submission of pricing information under the final rule (the monthly AMP submission for October 2007, which was due November 30, 2007). The next submission will be due on December 30, 2007, at which time a preliminary injunction barring implementation of some or all parts of the final rule is now expected to be in place.

Given the uncertain scope of the preliminary injunction and the possibility that all or parts of the AMP rule could be permanently enjoined, companies face difficult decisions regarding how to report their calculations in the interim. It would be disruptive for manufacturers to revise their systems, at least immediately, so as to calculate AMP and Best Price in accordance with the pre-rule guidance, even assuming that were possible by the reporting deadlines. Consequently, manufacturers will need flexibility in making the next monthly AMP submission, and in making the remaining AMP and Best Price reports that will be submitted for the duration of the litigation. CMS should recognize this need for manufacturer flexibility and the need for manufacturer reliance on reasonable assumptions in calculating AMP and Best Price that might be consistent with the final rule or the pre-rule guidance. Furthermore, CMS should acknowledge that following the final resolution of the above referenced litigation, manufacturers, if able, will be allowed to make reasonable assumptions and appropriately restate their AMP and Best Price (beginning with the final quarter of 2007) to come into compliance with whatever legal requirements stand at that time.

The final rule also requires that manufacturers submit a certification to CMS, executed by a manufacturer representative meeting specified criteria, with their AMP and Best Price submissions. 42 C.F.R. § 447.510(e). As currently written, that certification provides that:

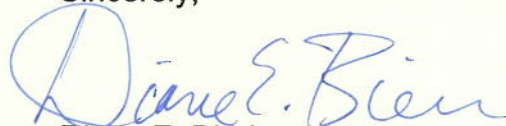
I hereby certify, to the best of my knowledge, the data being sent to CMS with this submission is complete and accurate at the time of this submission, and was prepared in accordance with the manufacturer's good faith, reasonable efforts based on existing guidance from CMS and the manufacturer's reasonable assumptions regarding the provisions of section 1927 of the Social Security Act, the National Medicaid Drug Rebate Agreement, and applicable federal regulations. I understand that the information contained in this submission may be used for Medicaid rebate and payment purposes and that civil monetary penalties and/or termination from the Medicaid Rebate Program may be enforced if the information provided is found to be misrepresented. I further certify that I am

authorized to submit this information in accordance with 42
C.F.R. § 447.510(e).

Because of the uncertainty associated with the final rule, CMS should remove the certification requirement from the DDR at least during the period in which a preliminary injunction affecting implementation of the final rule is in effect. The suspension of the certification requirement may need to be extended further if the Court were to grant a permanent injunction of all or parts of the AMP rule.

We appreciate your attention to these important issues, and we would be happy to provide any further information that you may need. Please be advised that PhRMA's member companies will proceed in making reasonable assumptions for the reasons set out above unless we hear otherwise from you by Friday, December 21st. Please contact Ann Kaplan or me at 202-835-3400 with any questions or concerns that you may have.

Sincerely,



Diane E. Bieri

cc: James Stansel, Esq., HHS Office of General Counsel
Wendy M. Ertmer, Esq., Department of Justice
Christopher W. Mahoney, Esq., Counsel to National Association of Chain
Drug Stores and National Community Pharmacists Association
Don L. Bell, II, Esq., National Association of Chain Drug Stores
John M. Rector, Esq., National Community Pharmacists Association