



Safety Net Hospitals for Pharmaceutical Access



October 4, 2010

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238—P2, P.O. Box 8016
Baltimore, MD 21244-8016

**Re: CMS–2238–P2, Comment on Proposed Rule on AMP (Published in
75 Fed. Reg. 54073-54076 (September 3, 2010))**

To Whom It May Concern:

This letter sets forth comments by Safety Net Hospitals for Pharmaceutical Access (SNHPA) and Planned Parenthood Federation of America (PPFA) on a proposed rule published in the Federal Register on September 3, 2010, relating to the definition of the term “average manufacturer price” (AMP). SNHPA represents approximately 500 public and private non-profit disproportionate share hospitals (DSH hospitals) that participate in the 340B discount drug program as well as rural hospitals newly eligible for the 340B program under the Patient Protection and Affordable Care Act (PPACA). These safety net providers qualify for federal drug discounts under the 340B program due to the large volume of services they provide to Medicare, Medicaid and indigent patients, as well as to patients who reside in geographically remote areas of the country. PPFA is a national not-for-profit organization that provides support services to 87 separately incorporated affiliates that operate over 840 health centers nationwide. Each year, Planned Parenthood health centers provide basic health care services, including pelvic exams, breast and cervical cancer screenings, contraceptive services, HIV testing and education, and sexually transmitted infection testing and treatment to over three million patients, the vast majority of whom are at or below 200 percent of the Federal Poverty Level.

The 340B statute defines the discounted drug price available to 340B covered entities as the AMP of a drug reduced by the Medicaid drug rebate percentage. Therefore, how the Center for Medicare & Medicaid Services (CMS) defines AMP will directly affect the discounted drug price 340B covered entities receive. Accordingly, we urge CMS to ensure that 340B prices are calculated using the new AMP and that such calculations are shared and coordinated with the Health Resources and Services Administration (HRSA), the agency that administers the 340B program.

It is our understanding that CMS currently defines AMP based on a final rule published in the Federal Register on July 17, 2007, known as the “AMP final rule”. The AMP final rule codified the parts of section 1927 of the Social Security Act that reference AMP. The CMS proposed rule published on September 3, 2010, proposes to withdraw the AMP final rule and directs drug manufacturers to define AMP based on the definition included in section 1927 of the

Social Security Act, including changes made by section 2503 of PPACA, as amended by the Health Care and Education Reconciliation Act and the FAA Air Transportation Modernization and Safety Improvement Act.

As CMS implements this new definition of AMP, we urge CMS to ensure that the new definition is used to calculate 340B ceiling prices. The 340B statute requires the price discount to be calculated based on the AMP as defined by section 1927 of the Social Security Act.¹ The statute, as passed in 1992, included a provision intended to “freeze” in time the Social Security Act definition of AMP and preclude any future changes to the definition from affecting 340B price calculations.² Some federal regulators have felt compelled to ignore post-1992 changes to AMP for purposes of 340B price calculation because of this provision. However, because Congress repealed the relevant freezing provision as part of PPACA, the 340B statute no longer requires CMS and HRSA to apply the 1992 definition of AMP.³ The agencies should therefore use the new definition of AMP to calculate the 340B price ceiling.

It is of particular importance that 340B prices are calculated using the definition of AMP as amended by the FAA Air Transportation Modernization and Safety Improvement Act. This legislation created a separate AMP for outpatient drugs that are not ordinarily dispensed by retail pharmacies. Among the drugs subject to the new AMP are infusion drugs, inhalation drugs, implanted drugs, and injectable drugs. Calculating AMP by taking into account discounts and rebates provided to non-retail pharmacies for this category of drugs is important for 340B providers because the use of retail pricing alone would distort 340B price calculations. An AMP that is based only on discounts and rebates provided to retail pharmacies would not make sense for 340B entities, because outpatient drugs administered or dispensed in a 340B facility are only available to patients of the facility, not to the general public. Such drugs are by definition not drugs dispensed in a retail setting. We therefore urge CMS to ensure that the new AMP definition used to calculate 340B drugs incorporate the changes to the definition made by the FAA Air Transportation Modernization and Safety Improvement Act.

On a final note, we request that CMS coordinate with HRSA with respect to application of the new AMP definition to 340B price calculations. HRSA receives the AMP from CMS each quarter under the terms of an intra-agency agreement.⁴ How recent AMP changes should be extended to the 340B program is just one of many issues that we believe should be addressed jointly by CMS and HRSA as part of a proposed 340B working group. Our recommendation of a joint CMS/HRSA working group was recently endorsed in a report accompanying the Senate Appropriations Committee’s Fiscal Year 2011 Departments of Labor, Health and Human Services, Education and Related Agencies Appropriations Act. In particular, the committee asked the two agencies to form a working group “to ensure that all phases of the 340B drug discount program are administered without redundancy or contradiction by the two agencies of jurisdiction.” We suggest that CMS keep this request in mind as it implements the new AMP definition.

¹ 42. U.S.C. § 256b(b)

² 42. U.S.C. § 256b(c)

³ See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2501(f)(1)(B)

⁴ DEP’T OF HHS, OIG, REVIEW OF 340B PRICES, 3 (July 2006).

We would like to thank CMS for the opportunity to comment on the proposed changes to the definition of AMP. If you have any questions or need additional information, please do not hesitate to contact SNPHA at 202-872-6765 or william.vonoeshen@snhpa.org or PPFA at 202-973-4800.

Sincerely,



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cc: Dr. Mary Wakefield, R.N., PhD., Administrator, HRSA