Plasma Protein Therapeutics Association

March 9, 2012

Reference No. FASC12019

Mary K. Wakefield, Ph.D, RN
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Commander Krista Pedley
Director, Office of Pharmacy Affairs
Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane,
Parklawn Building, Mail Stop 10C-03
Rockville, MD 20857

Dear Administrator Wakefield and Commander Pedley:

The Plasma Protein Therapeutics Association (PPTA or the Association) would like to express serious concerns about two policy documents (Non-Discrimination Policy, Release No. 2011-01 and Penny Pricing Policy, Release No. 2011-02) issued by the Health Resources and Services Administration (HRSA) on November 21, 2011. HRSA described these issuances as clarifications of policy regarding the 340B Drug Pricing Program (340B program). PPTA believes that these documents represent more than simple policy clarifications.[1] They are instead substantive rules that change existing regulations. As such, the documents suffer from procedural defects because HRSA failed to engage in notice and comment rulemaking before promulgating them. The policies also have significant substantive flaws. For either or both reasons, HRSA should rescind the policies. If HRSA were to move forward without notice and comment rulemaking, the agency would be acting beyond its authority.

PPTA represents human plasma collection centers and the manufacturers of lifesaving therapies, including albumin, alpha1-proteinase inhibitor, antithrombin III, blood clotting factors, C1 esterase inhibitor, fibrin sealant, immune globulin, hyperimmune immune globulin, and protein C concentrate, from this human plasma. Several of our members also use recombinant DNA technology to produce blood

[1] It is significant to note that unlike Release Nos. 2011-01 and 2011-02, PPTA believes that Release No. 2011-03, regarding Audits, is an appropriate guidance document that summarizes and consolidates existing guidance and rules regarding audits for covered entities and manufacturers.

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clotting factors. Collectively, these therapies—both plasma-derived and recombinant—are known as "plasma protein therapies." Many plasma protein therapies are approved for marketing in the United States (U.S.) by the Food and Drug Administration (FDA) solely for the treatment of rare diseases, disorders and conditions[2]. The manufacturer membership of PPTA in the U.S. currently includes Baxter, Biotest, Cangene, CSL Behring, Kedrion and Grifols.

I. Procedural Violations

The Association is troubled by two recent 340B program notices released by HRSA because the agency issued them without complying with the notice and comment procedures of the Administrative Procedure Act (APA).[3] The issuances contain important and significant policy changes that go beyond mere technical clarification. For example, the non-discrimination policy establishes a new requirement that a manufacturer obtain HRSA pre-approval of the manufacturer's plan for allocating drugs when demand outpaces supply. HRSA states that it "has policy in place to ensure that manufacturers have the ability to develop alternate allocation procedures during situations when the available supply of a covered drug is not adequate to meet market demands*." See Release No. 2011-1* at 1. Upon review of the statute, PPTA questions whether such a policy exists. The 1994 guidelines the agency cites in support of this statement do not address the allocation of drugs in short supply. Moreover, the guidelines did not require **pre-approval** of a manufacturer's allocation plan by HRSA. The statute extends to HRSA the authority to issue non-binding guidance regarding the allocation of products to covered entities under the 340B program. However, HRSA does not have statutory authority to require government pre-approval of a manufacturer's plans for allocating such products. HRSA nevertheless described the pre-approval requirement as a "restatement" of existing policy and entitled it "Clarification of Non-Discrimination Policy." The pre-approval requirement is not a mere restatement or clarification of existing policy; it is a new substantive requirement and one that, as is discussed in Section II below, lacks any statutory basis.

The APA requires an agency to engage in notice and comment rulemaking when establishing substantive rules either through new policies or changes to existing policies that themselves were substantive rules. *See, e.g., Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87 (1995). HRSA cannot avoid rulemaking by denominating its policies "restatements" or "clarifications." Substantive rules in the guise of policy clarifications remain substantive rules for which notice and comment rulemaking is required. That has not occurred here. In such circumstances, the courts have made clear that the failure to engage in required notice and comment invalidates the rule. *See, e.g., Paralyzed Veterans of America v. D.C. Arena*, 117 F.3d 579 (1997).

For both of the referenced policies issued last November, HRSA either substantially changed existing policy or established a new rule where none previously existed. For example, HRSA cites nothing to support the prior existence of the penny pricing policy

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[2] In the U.S., a "rare disease or condition" is generally defined as a disease or condition that affects fewer than 200,000 people.

[3] 5 U.S.C. § 553(b).

contained in Release No. 2011-02. Indeed, the issuance acknowledges that the policy results from a statutory change that did not even become effective until January 1, 2010.[4] Moreover, the statutory change did not relate to the 340B program but instead affected calculation of average manufacturer price under the Medicaid drug rebate program. Thus, the new penny pricing policy did not "simply explain[] something the statute already requires"; rather, the statute "neither requires nor specifically authorizes" it. *Cedars-Sinai Medical Center v. Shalala*, 939 F.Supp. 1457, 1465 (C.D.Cal. 1996). Consequently, even assuming that penny pricing under the 340B program were permissible, HRSA still is required to go through notice and comment rulemaking to establish penny pricing as a requirement.

The policy underlying notice and comment rulemaking – providing the public an opportunity to participate in the rulemaking process – is one that PPTA fully supports and believes is crucial to the 340B program. Further, PPTA believes that utilizing the notice and comment process in this complex area also would benefit HRSA. It is impossible to arrive at an appropriate and balanced policy on these issues without soliciting comment from the many stakeholders and others who have an interest and who could offer important perspectives.

II. Substantive Violations

Not only do Release Nos. 2011-01 and 2011-02 violate the procedural requirements of the APA, but they also substantively violate their underlying legislative mandate. Under 5 U.S.C. § 706(2)(C), a policy in excess of an agency's statutory authority is unlawful. In addition, under 5 U.S.C. § 706(2)(A), even where an agency possesses statutory authority to establish a policy in an area, the policy ultimately adopted must not be arbitrary and capricious or it is similarly unlawful. In the case of the non-discrimination and penny pricing policies, HRSA has both exceeded its statutory authority and adopted arbitrary and capricious policies. For example, the non-discrimination policy includes a requirement that a manufacturer offer each covered entity products for purchase at or below the 340B program price if the product is made available to any other purchaser at any price. This "must offer" requirement was enacted in section 7102(b)(1) of the Patient Protection and Affordable Care Act (ACA).[5] However, the ACA makes the must offer requirement contingent on amendment of the pharmaceutical pricing agreement between a manufacturer and HRSA. Thus, HRSA has exceeded its authority in attempting to impose the must offer requirement solely though Release No. 2011-01. Similarly, as explained above, there is simply no statutory basis for the non-discrimination policy's requirement for pre-approval of a manufacturer's allocation plan and therefore that requirement exceeds HRSA's authority. The penny pricing policy suffers from similar substantive defects. Moreover, even if the agency possessed the authority to establish such policies, which it does not, the policies adopted are arbitrary and capricious because they fail to consider important

[4] The issuance says that it is the result of the effects of "section 1927(c)(2)(D) of the Social Security Act that limits the unit rebate amount to 100% of the AMP, effective January 1, 2010 . . . ." Release No. 2011-02 at 1.
[5] Pub. L. No. 111-148, 124 Stat. 119, as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029.

aspects of the issues presented. *See* *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983).

PPTA and its members are committed to working with the agency to address the very complex and difficult issues presented under the 340B program. We are pleased with HRSA's guidance regarding manufacturer audits of 340B covered entities in Release No. 2011-03, which summarizes and consolidates existing guidance and rules regarding audits, but are deeply concerned about the procedures HRSA has used in promulgating Release Nos. 2011-01 and 2011-02. We are also deeply concerned about the policies contained in those releases. The 340B Drug Pricing Program serves an important role in the U.S. health care system by supporting increased access to prescription drugs and biologicals for uninsured, underinsured and low-income patients. However, it is well-documented[6] that the program has suffered from resource limitations and other oversight issues that have impeded fulfillment of its intended mission.[7] The issuance of policy "clarifications" that lack statutory authority, impose new substantive obligations and bypass the rulemaking process will only increase the program's operational issues. These problems will be exacerbated by the program's rapid expansion and the lack of a clear, and actively enforced, definition of a "patient."

PPTA appreciates your consideration of our concerns and welcomes an opportunity to discuss our member's concerns with you further. Please feel free to contact me or Kym H. Kilbourne, Director, Federal Affairs at kkilbourne@pptaglobal.org with any questions.

Sincerely,

Julie Birkofer

Julie Birkofer
Senior Vice President, North America

cc: Michelle Herzog, Deputy Director, Office of Pharmacy Affairs, HRSA
David Benor, Associate General Counsel, Department of Health and Human Services Office of the General Counsel
William Burgess, Department of Health and Human Services Office of the General Counsel
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[6] *See* Government Accountability Office report: DRUG PRICING Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, September 2011, available at (http://www.gao.gov/new.items/d11836.pdf)

[7] *See* Testimony of John Dickens (GAO) on "Oversight of Drug Pricing in Federal Programs" (Feb. 2007), *available at* http://www.gao.gov/new.items/d07481t.pdf; Office of the Inspector General Report, "Deficiencies in the Oversight of the 340B Drug Pricing Program" (October 2005), *available at* http://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf.