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Court Vacates HHS Rule on 340B Discounts on Drugs With 'Orphan' Uses

The Department of Health and Human Services lacked the authority for a rule that allows rural hospitals and free-standing cancer hospitals to purchase discounted ''orphan'' drugs when the drugs aren't used to treat a rare disease or condition, a federal district court held May 23, vacating the rule (*Pharm. Research & Mfrs. of Am. v. HHS*, D.D.C., No. 1:13-cv-01501-RC, 5/23/14).

The Pharmaceutical Research and Manufacturers of America challenged the HHS rule in 2013 (192 HCDR, 10/3/13), and the U.S. District Court for the District of Columbia vacated the rule (RIN 0906-AA94). The court said that, although the rule was the ''most reasonable way of administering the statute,'' the statutory authorities the HHS had ''strung together'' were specific grants of authority by Congress for other purposes that didn't authorize the HHS orphan drug rule.

The HHS had published its final rule July 23, 2013, interpreting the effect of the Health Care and Education Reconciliation Act (HCERA) on the Section 340B Drug Pricing Program, which imposes ceilings on prices drug manufacturers may charge for medications sold to such facilities as hospitals that serve indigent populations. Orphan drugs, which receive such a designation by the Food and Drug Administration, are developed to treat rare diseases and conditions and can also be used to treat non-rare diseases or conditions.

Safety Net Hospitals for Pharmaceutical Access, which provided an amicus brief in support of the HHS rule (248 HCDR, 12/27/13), said in a May 23 press statement that the court's ruling will significantly raise the cost of orphan drugs for rural and cancer hospitals and their patients, noting that some of the drugs at issue could cost patients $300,000 a year or more.

The hospital group, and an attorney, noted in separate statements that this ruling might have implications for the HHS's efforts to promulgate a broader ''mega-rule'' on the 340B program this summer. That proposed regulation (RIN 0906-AB04) is expected to cover the definition of an eligible patient, among other things; the White House Office of Management and Budget began its review of the proposed mega-rule in April (69 HCDR, 4/10/14).

PhRMA Challenged HHS Rule. The backdrop of the litigation includes three federal laws: the Orphan Drug Act, which provides incentives to drug manufacturers that make orphan drugs, such as a seven-year market exclusivity period rather than the two-year period for a regular drug; Section 340B of the Public Health Service Act (PHSA), which provides discounts on pharmaceutical medications to designated entities; and the HCERA (part of the 2010 health-care reform law), which made changes to the 340B program.

The HCERA specified that, ''For covered entities described in subparagraph (M), (N), or (O) of subsection (a)(4), the term 'covered outpatient drug' shall not include a drug designated by the Secretary under section 526 of the Federal Food, Drug and Cosmetic Act [FFDCA] for a rare disease or condition.''

In its final rule, the HHS interpreted HCERA to mean that the discounted 340B price isn't available to the facilities covered by the Section 340B program when purchasing orphan drugs for their intended use, but it is available for orphan drugs purchased for a non-orphan use, such as when Rituxan, which is manufactured by Genentech to treat non-Hodgkin B-cell lymphoma, is used to treat rheumatoid arthritis or multiple sclerosis.

PhRMA challenged the HHS's rule, alleging that it contravened the plain language of the statute and was therefore invalid. The association moved for summary judgment and injunctive relief.

No Support for Rulemaking. In an opinion authored by Judge Rudolph Contreras, the court noted that PhRMA had relied in its arguments largely on *Gonzales v. Oregon*, 546 U.S. 243 (2006), which involved a challenge to an interpretive rule issued in response to Oregon passing the ''Death with Dignity Act,'' which exempted from civil or criminal liability state-licensed physicians who prescribed a lethal dose of drugs upon request of a terminally ill patient. The attorney general issued the rule under the Controlled Substances Act. The Supreme Court found that the attorney general had exceeded his statutory rulemaking authority.

Contreras wrote that the D.C. Circuit had taken a similar position in *Amalgamated Transit Union v. Skinner*, 894 F.2d 1362, 1364 (D.C. Cir. 1990) and *Motion Picture Ass'n of America v. FCC*, 309 F.3d 796 (D.C. Cir. 2002).

The court stated that the HHS had relied on five statutory authorizations of rulemaking authority:

- Section 215 of the PHSA, 42 U.S.C. § 216, as amended;
- Section 526 of the FFDCA, 21 U.S.C. § 360bb, as amended;
- Section 701(a) of the FFDCA, 21 U.S.C. § 371(a);
- Section 1927 of the Social Security Act, 42 U.S.C. § 1396r-8, as amended; and

■ Section 340B of the PHSA, 42 U.S.C. § 256b, as amended.

The court found that the first four provisions clearly didn't confer any rulemaking authority for orphan drugs:

■ 42 U.S.C. § 216 (b) grants the HHS secretary rulemaking authority for the administration and not the implementation of the PHSA;

■ 21 U.S.C. § 360bb and 21 U.S.C. § 371(a) grant the secretary the authority to implement procedures under the FFDCA and not the PHSA; and

■ 42 U.S.C. § 1396r-8 specifically pertains only to Medicaid payments.

Contreras wrote that the provisions within Section 340B of the PHSA upon which the HHS relied for its authority required more analysis.

Can't Go Beyond Clear Line. Within Section 340B, Contreras wrote, Congress specifically authorized rulemaking in the establishment of an administrative dispute resolution process, in the ''regulatory issuance'' of precisely defined standards of methodology for calculation of ceiling prices and in the imposition of monetary civil sanctions.

The HHS first relied on *National Petroleum Refiners Association v. FTC*, 482 F.2d 672, 681 (D.C. Cir. 1973) for the proposition that courts have recognized that use of rulemaking to make innovations in agency policy may actually be fairer to regulated parties than total reliance on case-by-case adjudication.

Contreras stated, ''Unfortunately for HHS, the Court's holding in *National Petroleum* turned on the fact that the FTC had a grant of broad rulemaking authority 'to carry out' the provisions of its adjudicatory power, as well as broad rulemaking authority in its governing statute, that are absent here. Here, Congress has given HHS rulemaking power specifically for purposes of administering a dispute resolution process 'for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by'' manufacturers of violations of the prohibition on duplicate discounts and/or resales.

The HHS didn't receive congressional authority to ''determine the particular matter at issue in the particular manner adopted,'' Contreras wrote, quoting *City of Arlington, Tex. v. F.C.C.*, 133 S. Ct. 1863, 1874 (2013), but instead ''gave HHS a specific delegation of rulemaking authority to establish an adjudication procedure to resolve disputes between covered entities and manufacturers. Though the Court finds the agency's proactive, prophylactic rule to be the most reasonable way of administering the statute, Congress has not given HHS the broad rulemaking authority to do so, and '[w]here Congress has established a clear line, the agency cannot go beyond it . . . .' [quoting *City of Arlington* at 1874]. As such, the Court must vacate the final rule, and grant the plaintiff's motions.''

The court then briefly considered the HHS's alternative request to uphold the rule as interpretive rather than legislative. Contreras wrote that the HHS argument appeared ''half-hearted'' and would require specific briefing for the court to consider it further.

What's Next for HHS? Alice Valder Curran of Hogan Lovells, Washington, said in a statement May 27 that the HHS will have to decide in the near term whether it will appeal this decision or pursue its alternative argument that the orphan drug regulation is an ''interpretive'' rather than a substantive rule. She added in an e-mail to Bloomberg BNA, ''At least one other option is to simply stand down and consider whether to seek legislation granting the rule-making authority that the court says it now lacks.''

Manufacturers now need to determine their approach to orphan drugs going forward, Curran said in her statement. Although the HHS is likely to issue some guidance on the topic, manufacturers should evaluate this issue on their own as well, she said.

Like the hospital group, Curran noted that this ruling has implications for the mega-rule on 340B under development. She said that if the HHS doesn't have authority to issue regulations to implement the 340B program as a general matter, as the decision implies, and the HCERA/Affordable Care Act's grant of rulemaking authority as to specific topics is limited to those topics alone, that then ''begs the question of whether HHS has authority to issue regulations on the topics expected to be included in the mega-rule,'' such as the definition of an eligible patient, the compliance requirements for contract pharmacy arrangements, hospital eligibility criteria and eligibility of hospital off-site facilities.

PhRMA is represented by Jeffrey L. Handwerker, of Arnold & Porter in Washington.

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