

DECEMBER, 2009

Surprise Tricare Ruling Handed Down

By: Dave Rice, CIS Director of Federal Contracting

As many of you may have heard, the United States District Court for the District of Columbia recently ruled on the Tricare Retail Pharmacy Program (TRRx) issue in a decision that surprised many, including myself. Below is some basic background information on the issue as well as analysis of the ruling that was provided to us by Joy Sturm, Partner, [Hogan & Hartson LLP](#).

Background

On January 28, 2008, Congress enacted the National Defense Authorization Act for Fiscal Year 2008 ("NDAA-08"). Section 703 of NDAA-08 requires that pharmaceuticals paid for by the Department of Defense ("Department" or "DoD") under its TRICARE retail pharmacy program be subject to pricing standards known as Federal Ceiling Prices. The Department promulgated a final rule implementing section 703 on March 17, 2009. Under this rule, pharmaceutical manufacturers cannot receive more than the Federal Ceiling Prices for pharmaceuticals purchased by DoD for the retail pharmacy program, and must refund amounts in excess of the Federal Ceiling Prices for prescriptions filled on or after January 28, 2008. The Coalition for Common Sense in Government Procurement ("Coalition") challenged the Department's rule, asserted that the rule should be set aside because, inter alia, the Department erroneously interpreted NDAA-08 to require refunds by manufacturers to DoD and to require the statute's obligations to apply beginning on January 28, 2008.

Analysis of Ruling

In a surprising decision, on December 7 the U.S. District Court for the District of Columbia ruled that while the Department of Defense (DoD) did not follow proper procedures in issuing its Tricare Retail Pharmacy (TRRx) Final Rule (74 Fed. Reg. 11,279 (Mar. 17, 2009)) implementing Section 703 of the National Defense Authorization Act for FY 2008, the statute "requires that Federal Ceiling Prices apply to all retail pharmacy program prescriptions filled on or after January 28, 2008."

While the court found for the Coalition on its procedural challenge to the Final Rule, it sided with DoD on the substantive issue presented in the case. The court held that because Section 703 did not mandate a rebate program, DoD had been required to exercise its discretion in requiring rebates from manufacturers under its Final Rule. The court therefore concluded that DoD's statements throughout the Final Rule that such a program was required "by operation of law" by Section 703 rendered the Final Rule procedurally defective.

The court held that remand of the Final Rule was necessary so that the agency could exercise its discretion in implementing the statute. However, the court was clear that DoD could, in exercising its discretion, reissue a rule with the same substantive requirements. In view of this conclusion, the court decided not to vacate the TRRx Final Rule, thereby leaving the voluntary agreement program in place.

In addressing the substantive issue presented, the court agreed with DoD that the statute entitles DoD to FCP-based pricing as of January 28, 2008. The court rejected the Coalition's argument that the Final Rule was impermissibly retroactive, holding instead that "[i]t is the statute, not the rule, which made transactions on or after January 28, 2008, subject to Federal Ceiling Prices" The court did not analyze how a rebate could be applied absent a contractual agreement by the manufacturer.

Accordingly, pending DoD's consideration on remand, the Final Rule remains in place as do TRRx voluntary rebate agreements. DoD is required to report to the court by March 1, 2010 on its reconsideration of the Final Rule.

It is likely that DoD will now turn its attention to outstanding rebate amounts for quarters pre-dating the voluntary agreements.

Whether this decision will have any impact on Non-FAMP and AMP remains to be seen. The VA has not yet stated whether this decision will impact its earlier guidance to manufacturers to identify and exclude TRRx utilization from Non-FAMP as Federal sales.

If you have any questions regarding this new TRRx development or surrounding the program generally, please contact Joy Sturm at (301) 294-5995 or at jesturm@hhlaw.com.

For the 11/30/09 Memorandum Opinion please see the following link:

<http://www.fdalawblog.net/files/mem.-op.-the-coalition-for-common-sense-.-.v.-u.s.-08-cv-996-d.d.c.-nov.-30-209-2.pdf>