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THE GOVERNMENT CONTRACTS UPDATE

COURT RULES HHS HAS NO AUTHORITY TO PROMULGATE 340B ORPHAN DRUG REGULATION (MEMORANDUM OPINION IN *PHRMA V. U.S. DEP'T OF HEALTH AND HUMAN SERVS., ET AL.*)

On May 23, 2014, the U.S. District Court for the District of Columbia permanently enjoined the Secretary of Health and Human Services ("HHS") from implementing regulations that required pharmaceutical manufacturers to offer orphan drugs[1] to covered hospitals at reduced prices if the drugs were to be used to treat non-orphan conditions. Section 340B of the Public Health Service Act, as amended by the Patient Protection and Affordable Care Act, provides covered hospitals with access to discounted pharmaceuticals. However, the Health Care and Education Reconciliation Act of 2010 and the Medicare and Medicaid Extenders Act of 2010 amended section 340B to exclude the majority of covered hospitals from accessing orphan drugs at discounted prices, providing, with respect to such hospitals, that the discounts available under section 340B do not apply to drugs "designated . . . for a rare disease or condition."

HHS issued a final rule in 2013 to "clarify" how the agency would implement the orphan drug exclusion. The final rule interpreted the exclusion to apply only if a hospital covered by the exclusion used an orphan drug to treat the rare disease or condition for which the drug received its orphan designation. Otherwise, the hospital could purchase the orphan drug at 340B prices. PhRMA challenged HHS' statutory rulemaking authority to promulgate the rule and separately argued that the plain language of section 340B, as amended, prevents the majority of covered hospitals from purchasing orphan drugs at 340B prices regardless of how the drugs are used.

U.S. District Judge Rudolph Contreras granted PhRMA's motion to permanently enjoin HHS from implementing the final rule. In doing so, Judge Contreras noted that the agency's issuance of a rule to clarify the implementation of the orphan drug exclusion was "the most reasonable way of administering the statute." However, applying a *Chevron* analysis to multiple statutory grants of rulemaking authority to HHS, he determined that "Congress has not given HHS the broad rulemaking authority to do so." As a result, he held that the Court "'must give effect to the unambiguously expressed intent of Congress,' and vacate the final rule under Chevron step one."

It is unclear whether HHS will continue to take the position that the majority of covered hospitals may take advantage of 340B prices for an orphan drug as long as the drug is not used to treat the rare disease or condition for which the drug received its orphan designation. Judge Contreras specifically left open the possibility that HHS could issue an interpretive rule or other form of guidance regarding the scope of the orphan drug exclusion. Because the decision concludes that HHS lacks general rulemaking authority to implement section 340B, however, the decision also could have implications for HHS' so-called 340B "mega-reg," which was set to be published for notice and comment as early

[1] Orphan drugs are drugs that treat rare diseases or conditions. They are so-named because efforts to research, invest in, and produce them might be abandoned if not for the incentives Congress provides pharmaceutical manufacturers. While orphan drugs can only be designated as such to treat rare diseases or conditions, they also are often used to treat non-rare diseases or conditions.

as this month. That regulation is expected to cover the definition of an eligible patient, contract pharmacy arrangements, hospital eligibility criteria, and eligibility of off-site facilities.

HOUSE APPROVES 2015 NDAA AMENDMENT TO REPAY CONTRACTORS FOR AFGHAN TAXES

In recent years, there has been considerable uncertainty regarding whether government contractors operating in Afghanistan are required to pay income or business taxes to the local authorities when performing pursuant to federal procurement contracts. The U.S. Government has taken the position that U.S.-funded reconstruction efforts in Afghanistan should not be subject to local taxation, leading many U.S. agencies to enter into bilateral tax-exemption agreements with the Afghan Ministry of Finance ("MOF"). Despite these agreements, the MOF has issued tax assessments and imposed penalties on many U.S. contractors and grantees. At the same time, the U.S. Government has refused to treat those tax payments as allowable costs.

The U.S. House of Representatives' version of the FY 2015 National Defense Authorization Act ("2015 NDAA") (H.R. 4435) seeks to address this issue. The House passed H.R. 4435 on May 22, 2014. It includes a provision that would require the Department of Defense ("DOD") to create a plan with the Government of Afghanistan to repay taxes assessed on U.S. government grantees, contractors, and subcontractors working in Afghanistan. If DOD does not submit such a plan by March 1, 2015, DOD would be required to use foreign aid funds withheld from Afghanistan to reimburse directly any grantee, contractor, or subcontractor for verified claims. The 2015 NDAA mandates that DOD withhold foreign aid funds from Afghanistan that are equal to 150 percent of all taxes assessed during FY 2014 by the Government of Afghanistan on "all Department of Defense assistance." Since passing the House, H.R. 4435 has gone through a proposed markup by the Senate Armed Services Committee, but the full Senate has not yet considered the measure.

STATE AND COMMERCE DEPARTMENTS PUBLISH INTERIM FINAL RULES IMPLEMENTING SATELLITE EXPORT CONTROL REFORM

On May 13, 2014, the U.S. State Department's Directorate of Defense Trade Controls ("DDTC") and the U.S. Commerce Department's Bureau of Industry and Security ("BIS") published interim final rules (79 Fed. Reg. 27180 and 79 Fed. Reg. 27418, respectively) transferring certain commercial communications and remote sensing satellites and related items from the jurisdiction of the International Traffic in Arms Regulations ("ITAR"), to the jurisdiction of the Export Administration Regulations ("EAR"). The interim final rules were issued as part of the Obama Administration's broader export control reform initiative and are designed to enhance the competitiveness of U.S. industry in the global commercial satellite marketplace while maintaining tight controls over sensitive satellites and related items vital to U.S. national security interests. Most of the transfers will take effect on November 10, 2014, but changes to controls on certain microelectronic circuits will become effective on June 27, 2014. For more information on these proposed rules, see the E-Alert published by Covington's International Trade group.

SBA PROPOSES INCREASING EMPLOYEE-BASED SIZE STANDARDS

As part of its ongoing comprehensive size standards review, the U.S. Small Business Administration ("SBA") has reviewed all 71 industries in North American Industry Classification System ("NAICS") Sector 42, Wholesale Trade, as well as the two industries in NAICS Sector 44–45, Retail Trade, that have employee-based size standards. On May 19, 2014, the SBA issued a proposed rule (79 Fed. Reg. 28631) to increase the employee-based size standards for 46 industries in NAICS Sector 42 and one industry in NAICS Sector 44–45. Since 1986, the size standard for SBA's financial assistance for all industries in the Wholesale Trade sector has been 100 employees. Under the

newly proposed scheme, size standards would vary between 50 and 250 employees, depending on the industry.

The 100-employee size standard typically has not applied to federal procurement programs. Rather, for federal procurements, under the SBA's nonmanufacturer rule, a firm that does not manufacture or produce goods qualifies as small if it is at or below 500 employees and supplies the end item of a small domestic manufacturer. The proposed rule does not modify this nonmanufacturer rule. As a result, if adopted, the rule would primarily affect eligibility for SBA's financial assistance programs; it would not significantly impact eligibility for federal procurements. Comments on the proposed rule are due on or before July 18, 2014.

CASE DIGEST

Contracting Officer's Notification That a Decision Would Be Issued in "At Least 60 Days" Constitutes a Deemed Denial of Claim (*Suh'dutsing Technologies, LLC,* ASBCA No. 58760 (April 28, 2014))

In 2010, the Defense Information Systems Agency ("DISA") awarded an indefinite-delivery/indefinite-quantity commercial services contract for the upgrade of computing services to Suh'dutsing Technologies, LLC ("Suh'dutsing"). After DISA reevaluated its acquisition strategy "based on several turn[s] of events" in 2011, Suh'dutsing submitted a certified claim for over $4 million to the contracting officer. The claim consisted entirely of a pass-through claim of its subcontractor which, in turn, incorporated the claim of a second-tier subcontractor.

Initially, the contracting officer believed that Suh'dutsing had only submitted a pass-through subcontractor claim without asserting its own claim. Because the subcontractor lacked privity with the government, the contracting officer denied the claim. The contracting officer subsequently acknowledged that she had in fact received Suh'dutsing's claim but, on three consecutive occasions, had informed Suh'dutsing that she did not anticipate issuing a final decision on the certified claim for 60 days or more.

After receiving the third such 60-day deferral, Suh'dutsing appealed DISA's deemed denial of its claim to the Armed Services Board of Contract Appeals ("ASBCA"). The government moved to dismiss the appeal for lack of jurisdiction on the ground that the appeal was premature and asserted that the contracting officer had established a reasonable date by which she would issue her decision.

The ASBCA disagreed, holding that 41 U.S.C. § 7103(f)(2)(B) provides that "within 60 days of receipt of a submitted certified claim over $100,000," the contracting officer shall "(A) issue a decision; or (B) notify the contractor of the time within which a decision will be issued." The ASBCA found that a statement by a contracting officer that it would be "at least another sixty days … before I am able to issue a decision" is "insufficiently definite to comply with" 41 U.S.C. § 7103(f)(2)(B).

PSBCA Finds Jurisdiction Where Same Operative Facts Would Be Analyzed Regardless of Whether a New Theory Is Introduced on Appeal (*Oswald Ferro*, PSBCA No. 6485 (May 14, 2014))

On May 14, 2014, the Postal Service Board of Contract Appeals ("PSBCA") denied an attempt by the Postal Service to dismiss a contractor claim, finding that a change in the theory of recovery, particularly where the same amount in controversy is sought, is permissible, so long as the same operative facts will be examined. The contractor, Mr. Ferro, provided mail transportation services in

New York City to the U.S. Postal Service from July 1, 2001, to September 27, 2010. In 2011, he submitted a certified claim to the contracting officer for a final decision relating to his supply of "two (2) vehicles and trailers in order to fulfill the contract." The contracting officer issued a final decision denying the claim on the grounds that Mr. Ferro had negotiated a new contract with the Postal Service "to run three tractors and three trailers through the end of [his] contract." Mr. Ferro filed a timely appeal of the contracting officer's final decision. The Postal Service moved to dismiss the appeal for lack of jurisdiction, contending that, because Mr. Ferro presented a two-truck claim to the contracting officer but a three-truck claim during his appeal, the PSBCA lacked jurisdiction. The PSBCA held that, because "[b]oth the claim and appeal involve[d] Mr. Ferro seeking additional contract compensation for his use of trucks servicing the contract," Mr. Ferro's claim "certainly provided the contracting officer with adequate notice of the basis for and amount of the claim," and "[t]he same operative facts would be analyzed whether Mr. Ferro's theory on appeal involves his use of two trucks or three." Thus, the PSBCA could exercise jurisdiction.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our government contracts practice group:

Alan Pemberton	+1.202.662.5642	apemberton@cov.com
Robert Nichols	+1.202.662.5328	rnichols@cov.com
Susan Cassidy	+1.202.662.5348	scassidy@cov.com
Jennifer Plitsch	+1.202.662.5611	jplitsch@cov.com
Steve Shaw	+1.202.662.5343	sshaw@cov.com
Brian Walsh	+1.202.662.5980	bwalsh@cov.com
Kathy Brown	+1.202.662.5993	kbrown@cov.com
Scott Freling	+1.202.662.5244	sfreling@cov.com
Jade Totman	+1.202.662.5556	jtotman@cov.com
Anuj Vohra	+1.202.662.5362	avohra@cov.com
Christine Minarich	+1.202.662.5106	cminarich@cov.com