July 1, 2019

Office of the Chief Management Officer
Directorate for Oversight and Compliance
Department of Defense
4800 Mark Center Drive, Suite 08D09
Alexandria, VA 22350-1700

Attn: Michael J. Zleit (Mailbox 24)

Subject: Department of Defense Civil Monetary Penalties and Assessments Under Military Health Care Fraud and Abuse Prevention Program, Proposed Rule (RIN 0720-AB74)

Dear Mr. Zleit:

The Coalition for Government Procurement ("the Coalition") appreciates the opportunity to provide comments in response to the notice of proposed rulemaking of the Department of Defense ("DoD"), published on May 1, 2019 (84 Fed. Reg. 18437) ("Proposed Rule"). The rule proposes to allow the Secretary of Defense, under the authority of the Social Security Act, to impose civil monetary penalties against providers and suppliers who commit fraud and abuse in the TRICARE program.

The Coalition is a non-profit association of firms selling commercial services and products to the Federal Government. Our members include small, medium, and large business concerns representing many different industries, including manufacturers, distributors of medical devices and supplies and brand and generic pharmaceuticals. Collectively, members account for a significant percentage of commercial items purchased annually by the Federal Government. The Coalition is proud to have worked with government officials for 40 years towards the mutual goal of common-sense acquisition.

The Proposed Rule applies to:

- manufacturers of medical or other items who sell their products to DoD military treatment facilities under government contracts;
- commercial customers reimbursed by TRICARE health plans under contract with DoD to provide health care to TRICARE beneficiaries; and
- retail pharmacies reimbursed by DoD for prescriptions they dispense to TRICARE beneficiaries.

Coalition members who sell medical supplies, and, in particular, manufacturers of pharmaceutical and biological products who have entered into refund agreements with DoD under the TRICARE Retail Refund Program, have an interest in the Proposed Rule.

Background

On May 1, 2019, DoD published a Proposed Rule that would (through a new Part 200 to the TRICARE regulations) implement the statutory authority currently exercised by the Secretary of Health and Human Services ("HHS") to impose civil monetary penalties against individuals or entities who submit false, fraudulent, or otherwise improper claims for payment under federal health care programs. The Proposed Rule would establish specific acts that would be subject to a civil monetary penalty. It also would provide administrative procedures within DoD for the investigation, assessment, and imposition of a civil monetary penalty and a determination of TRICARE-related health care fraud, which could subject a provider of supplies to exclusion from TRICARE pursuant to 32 CFR. 199.9(f)(1)(ii).

The TRICARE program is administered by the Defense Health Agency ("DHA"). Under the program, DoD beneficiaries receive health care services. Unlike Medicare and Medicaid, however, TRICARE provides health care directly through military treatment facilities and a mail order pharmacy. These entities procure medical supplies under government contracts entered into by the Defense Logistics Agency, as well as through health plans under contract with DoD and their network providers. It does not pay providers in the private sector directly on a fee-for-service basis. In addition, TRICARE pays for prescriptions dispensed by retail pharmacies to TRICARE beneficiaries through a pharmacy benefit manager under contract with DoD. It receives refunds on prescriptions from manufacturers who agree to provide them in exchange for TRICARE payment for their products.

Section 1128A(m) of the Social Security Act authorizes an agency that pays health care claims under a federal health care program to impose civil monetary penalties on individuals and entities who submit false, fraudulent, or otherwise improper claims for payment. Where a need has arisen for the imposition of a civil monetary penalty for specific conduct under a federal health care program, Congress has provided specific authority to do so. For example, Congress authorized the Health Resources and Services Administration within HHS to establish standards and procedures to impose a civil monetary penalty for knowingly and intentionally failing to charge the statutory ceiling price on certain covered transactions (section 7102 of the Affordable Care Act amending 42 U.S.C. §256b(d)(1)). More recently, Congress authorized application of a civil monetary penalty for misclassification of drugs under the Medicaid Drug Rebate Program (section 6(a) of the Medicaid Services Investment and Accountability Act, amending 42 U.S.C. 1396r-8(b)(3), Pub. L. No. 116-16 (April 18, 2019)).

Congress has not expressly authorized the extensive administrative process within DoD to apply civil monetary penalties to TRICARE contemplated in the Proposed Rule's new Part 200. As discussed below, this approach is of great concern in the context of the TRICARE Retail Refund Program, created by regulation, in which manufacturers do not supply DoD. Manufacturer obligations are specified to a large extent in DoD guidance, but neither the cognizant regulation nor the guidance addresses retroactive adjustments to pricing information reported to the Department of Veterans Affairs ("VA").

General Comments

The Coalition is concerned that the Proposed Rule, which appears to be unnecessary to protect DoD against fraud by manufacturers and distributors of drugs and medical devices, could harm beneficiaries' access to critical care. DoD currently has tools to pursue fraud when these products are procured or provided by its contractors. If, as indicated, the particular problem driving the Proposed Rule is compounded drugs, a simple, far less risky approach is available. DoD could tighten requirements for payment of these services and supplies.[1] Additionally, there is a concern that the Proposed Rule is unclear as to how DHA will apply the "knowingly and intentionally" standard, especially considering that it lacks the experience of HHS to investigate and make determinations of health care fraud leading to the exclusions of entities from the TRICARE program. Unwarranted exclusion of drugs, medical devices, and supplies from TRICARE does not only penalize manufacturers and distributors unjustly. It jeopardizes beneficiaries' access to critical care, forcing them to pay for drugs and supplies out-of-pocket to avoid putting their health at risk.

The preamble to the Proposed Rule states the Rule is intended to supplement civil fraud cases brought by the Department of Justice ("DoJ"). DoJ purportedly lacks sufficient resources to pursue some instances of fraud in the TRICARE program, in particular the large number of cases involving payment for compounded drugs. The Coalition urges DoD to consider an alternative to the Proposed Rule, one narrower in scope and aimed at the compounded drug problem. Additionally, given the similarity of the Proposed Rule standard and the civil False Claims Act ("FCA") standard governing DoJ civil health care fraud actions, along with the serious consequences from an administrative determination of health care fraud by DoD, the Coalition is concerned that potential for parallel cases, with inconsistent standards applicable to the same conduct, will arise. Although the preamble to the Proposed Rule indicates that DoD may coordinate with DoJ, there is no requirement for such coordination, and DoD may proceed with determining health care fraud without applying the standards that would govern TRICARE claims

[1] The Coalition assumes the Proposed Rule's reference to "compound drugs" means drugs compounded from multiple ingredients by compounding pharmacies and not drug products that combine multiple drug substances that the FDA has approved for marketing and sale under New Drug Applications or Abbreviated New Drug Applications.

if handled by DoJ. As noted, it is unclear how DHA would interpret knowing and intentional conduct in imposing a civil monetary penalty under the rule.

The Proposed Rule provides a process for adjudicating civil monetary penalty cases, but it does not state how it would approach and handle a TRICARE claim if neither DoJ nor a Defense Criminal Investigative Organization were involved. Of particular concern is that the Proposed Rule does not state whether it would follow an internal DoJ memorandum that prohibits using noncompliance with agency sub-regulatory guidance as a basis for proving knowing violations of law in civil enforcement proceedings.[2] Nor does it ensure DHA will follow federal jurisprudence applicable to FCA cases despite the nonexistence of any precedent at DHA – administrative law judges holding hearings would lack authority under proposed section 200.2004 only to refuse to follow federal statutes and regulations – or prevent the same claims from proceeding under these rules and the FCA. Indeed, DHA could make a determination of fraud, issue notice of its determination and proceed with its case, all while a *qui tam* action arising from the same facts is litigated, even after DoJ declined to intervene. At the very least, the Proposed Rule should require DHA to inquire of DoJ whether a *qui tam* complaint has been filed and stay its administrative proceeding pending resolution of the case. In sum, the proposal to create this new parallel program for imposing civil monetary penalties for health care fraud related to TRICARE payments risks creating inconsistent outcomes or, worse, duplicative penalties for the same set of facts.

Finally, the Coalition objects to the use of a statistical sampling study as the basis for proving the number and amount of claims subject to assessment of civil monetary penalties (proposed section 200.1580). Imposition of penalties based on an extrapolation of the number and amount of claims is antithetical to determinations of liability in fraud cases and the civil monetary penalty statute, which contemplates a penalty for an actual instance of a false or fraudulent claim. It is particularly unfair to use statistical sampling when the number and amount of claims is an aggregating factor. Fairness also requires an accurate count of the number of claims because of the large civil penalty amount per claim now available under the statute, as adjusted pursuant to the Federal Civil Penalties Inflation Adjustment Act, as amended, and the Bipartisan Budget Act of 2018. Moreover, statistical samplings here risk violating the fundamental burden on the government to demonstrate an actual violation prior to imposing a punishment in favor of punishing a citizen for a violation they may not have committed.

To ensure consistency, the Coalition urges DoD to require coordination with DoJ to prevent concurrent DHA and FCA cases (including *qui tam* cases) arising from the same facts and adopt DoJ standards and guidelines for investigating and determining fraud in civil monetary penalty cases in which DoJ is not participating. We also urge DoD to eliminate the proposed regulation at 200.1580 and use of statistical sampling to establish liability.

[2] The memorandum was issued by DoJ's then-U/S. Associate Attorney General Rachel Brand on January 25, 2018.

The Proposed Rule Should Not Apply Civil Monetary Penalties to Procurements of Covered Drugs under VA Contracts and Pricing of Covered Drugs Required by the TRICARE Retail Refund Program

The Proposed Rule would allow DHA to impose a civil monetary penalty against "any person" for prohibited conduct, which could encompass manufacturers of pharmaceutical and biological products that agree to charge DoD no more than a statutory price under a program administered by the VA. The Proposed Rule, however provides no clear explanation of how the specified acts would apply to this program or to the Tricare Retail Refund Program, through which manufacturers rebate a portion of prescription charges paid by DoD to retail pharmacies. Of particular concern is the fact that the prescription refund program is implemented primarily through agency guidance and adopts terminology and records reported to the VA. This guidance process does not address retroactive price changes to previously reported prices; nor does it have a formal process to timely resolve issues relating to these retroactive changes. Under these circumstances, the Proposed Rule would potentially place additional liability and burden on manufacturers of drugs and biological products subject to a program administered by the VA.

Proposed 200.200(b)(3) would allow DHA to impose a civil monetary penalty on a drug manufacturer that makes, or causes to be made, a false statement, omission, or misrepresentation of material fact in a contract to participate as a supplier under a Federal health care program. Likewise, proposed 200.200(b)(5) would allow imposition of a penalty for knowingly making, using, or causing the making or using of a false record or statement material to a false or fraudulent claim for payment. In the context of the TRICARE Retail Refund Program, these sections of the Proposed Rule overlap with the responsibility of VA to administer the Veterans Health Care Act ("VHCA") and would usurp the VA's authority if applied to pricing required by the VHCA. Pursuant to the VHCA, manufacturers of covered drugs must calculate and report to the VA a Non-Federal Average Manufacturer Price ("Non-FAMP") for each covered drug, and they must establish with the VA a Federal Ceiling Price for each covered drug applicable to procurements of covered drugs by DoD.[3] In addition, they must offer all of their covered drugs on the Federal Supply Schedule contract administered by the VA[4], under which DoD procures drugs for its military treatment facilities and mail order pharmacy.

The VA is the sole agency responsible for administering the FSS contract and ensuring the accuracy of statutory and contract prices for covered drugs on behalf of DoD. Further, the VA Office of Inspector General ("OIG") has nearly 30 years of experience auditing complex contract pricing under the VHCA, again, on behalf of DoD, including instances of potential fraud. It is important not to have overlapping authority with the Proposed Rule to avoid inconsistent interpretation and application of the VHCA, not only where the Non-FAMP and Federal Ceiling

[3] 38 USC 8126(a)(2),(c)
[4] 38 USC 8126(a)(2)

Price set contract prices paid by DoD, but also where there is a rebate amount due on prescriptions dispensed by retail pharmacies to TRICARE beneficiaries and paid by DoD.

Proposed 200.200(b)(4) would allow imposition of a civil monetary penalty on any manufacturer that knows of an overpayment and does not report and return the overpayment in accordance with section 1128(d) of the Social Security Act. For overpayments on purchases under the FSS contract, the Federal Acquisition Regulation already prohibits retention of overpayments and requires their disclosure to the VA, the contracting agency. Because the Non-FAMP and FCP calculations are complicated, manufacturers of covered drugs routinely restate them, and the VA OIG provides contract support and validates reported restatements. The restated values can favor the manufacturer or the agency, depending on the nature of the discrepancy and the math. Not infrequently, restatements involve invoice amounts unintentionally overstated, and thus, necessitating refunds of the overpayment. When these routine contract administrative actions occur, the VA determines the amount due DoD for its procurements under contracts subject to the VHCA. Thus, the Proposed Rule raises serious concerns with overlapping authority and the application of the proposed overpayments provision to restated values under the VHCA, especially as the pricing information established with the VA impacts DoD's TRICARE Retail Refund Program.

The TRICARE regulation governing the retail refund program, 32 CFR 199.21(q), requires prescription rebate amounts invoiced by manufacturers to be treated as erroneous payments under 32 CFR 199.11, which must be refunded. DoD asserts entitlement to the refund amount using a per unit formula in the regulation and refund agreements, which is based on the Non-FAMP and Federal Ceiling Price administered by the VA pursuant to the VHCA, multiplied by the unit multiplied by the prescription units paid to pharmacies, all information that manufacturers do not have. The Proposed Rule defines "overpayment" to mean "any funds that a person receives or retains under TRICARE/CHAMPUS to which the person, after applicable reconciliation is not entitled under such program." Thus, subjecting amounts due DHS deemed "erroneous payments" by regulation and never paid the manufacturer by DoD to potential civil monetary penalties for non-reporting is unclear, as the amount of the refund is known to DoD and claimed as a debt. For that reason, the Coalition urges DoD to exclude refunds due under 199.21(q) from the Proposed Rule.

If the Non-FAMP or FCP is restated to capture information subsequently available or to otherwise correct errors or discrepancies in the calculation, as is a routine occurrence, the result could be a lower contract price than that previously charged. In the retail refund program, TRICARE never purchases drugs from a manufacturer, much less overpays it. Yet, the regulation does not address restatements to the VA, and the Proposed Rule is unclear about whether DoD would consider the difference between the payment to a pharmacy and a Non-FAMP or FCP restated after the refund is calculated and paid to be an "overpayment" retained by the manufacturer that it must report and return. If DoD does not exclude prescription refunds from the Civil Monetary Penalty rule for the

reasons stated, the Coalition is concerned that the Proposed Rule does not clarify when knowledge of an additional refund caused by a restated Non-FAMP or FCP would trigger the rule's overpayment provision. Because determination of an additional refund amount based on restated values requires an internal investigation, recalculation, reconciliation, validation by the VA, and establishment of the new values in the VA's database, the Coalition urges DoD to clarify that knowledge of an overpayment under TRICARE cannot begin until restated values are established by the VA.

We appreciate the opportunity to submit comments on the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation Notice. If there are any questions, please contact me at rwaldron@thecgp.org or (202) 331-0975.

Regards,

Roger Waldron
President