THE COALITION
for Government Procurement

January 22, 2018

Department of Defense
Office of the Deputy Chief Management Officer
Directorate of Oversight and Compliance
4800 Mark Center Drive
Alexandria, VA 22350

Subject: ***Revised Comments***—DHA Subgroup to the DoD Regulatory Reform Task Force, Review of the Existing TRICARE Regulation (DOD-2017-HA-0060)

DHA Subgroup,

The Coalition for Government Procurement ("the Coalition") appreciates the opportunity to provide comments to the Regulatory Reform Task Force's DHA Subgroup regarding opportunities to "repeal, replace, or modify" sections of the TRICARE regulation at 32 CFR part 199. These revised comments are timely submitted by the January 22, 2018 due date and supersede the previous submission.

The Coalition for Government Procurement (The Coalition) is a non-profit association of firms selling commercial services and products to the Federal Government. Our members collectively account for more than $145 billion dollars of the sales generated through government contracts including the GSA Multiple Award Schedules (MAS) program, VA Federal Supply Schedule (FSS), the Government-wide Acquisition Contracts (GWAC), and agency-specific multiple award contracts (MAC). Coalition members include small, medium, and large business concerns that provide more than $12 billion worth of pharmaceuticals and medical/surgical products to support healthcare needs of our nation's warfighters and veterans. The Coalition is proud to have worked with Government officials for more than 38 years towards the mutual goals of common sense acquisition.

The Department of Defense (DoD) Tricare Retail Refund Program (TRRP) program requirements, as outlined in the June 2017 Tricare Retail Refund Program Manufacturer Policy and Procedures Guide, generates unnecessary burdens on industry. The Coalition requests that the DHA Subgroup consider for repeal, replacement, or modification the following specific areas of the Tricare regulations.

Disputes, Interest, Payment and Admin Fees

As a preliminary matter, the regulation and June 2017 Tricare Retail Refund Program Manufacturer Policy and Procedures Guide implementing 10 U.S.C. §1074g(f) do not apply to items that are not covered drugs, such as diabetes test strips. Although DHA negotiates BPAs and rebates for items that are not subject to the regulation, they are governed solely by the terms of the contracts and are not subject to demand letters premised on DHA's refund rights under the regulation. The regulation should make it clear that its provisions and the automatic imposition of interest, penalties, and administrative charges (IPA) on a debt established by regulation do not apply to voluntarily negotiated rebates on non-covered drugs.

In addition, the dispute resolution process is unnecessarily complicated for disputing rebates owed on non-covered drugs under a voluntary agreement, and applying procedures intended to implement an inapplicable regulation lead to confusion and frustration. A simpler process for resolving these disputes should be available.

According to the June 2017 Tricare Retail Refund Program Manufacturer Policy and Procedures Guide, "DHA makes every effort to resolve all disputes within sixty (60) days. DHA will consider requests from manufacturers to waive a portion of IPA in cases where disputes were not resolved within sixty (60) days." Historically, DHA has been unable to address some of the open dispute balances within the 60-day period. This has caused the manufacturer to accrue unnecessary IPA. Additionally, the process of taking exception to the invoiced IPA has created an administrative burden on the manufacturer. To be fair, if delay in dispute resolution is the fault of DHA, and DHA ultimately resolves the dispute in its own favor, it should automatically waive IPA during the period of the delay. Addressing the issue in a timely manner would lessen the administrative efforts put forth in reconciling accrued interest, penalties and admin fees associated with these disputes. Industry expects that DHA will abide by the 60-day timeline associated with dispute resolution, which will mitigate recurring disputes quarter after quarter.

Additionally, DHA does not provide an explanation related to rejected claim level disputes. This places the burden on manufacturers to provide additional supporting documentation for appeals when the reasoning for the rejection is unknown.

The TRRP dispute process does not allow for a manufacturer to question a refund claim prior to payment, and timely resolve the issues through a healthy discussion with the DHA. Failure to have the ability to communicate with DHA in a timely manner can lead to discrepancies in payment which could cause manufacturers to owe interest, administrative fees and penalties. As the regulation is intended to treat refunds on prescriptions as if they were procurements, the disputes process implementing the regulation should provide a comparable level of fairness to that in the contract disputes process.

Recommendations:

1. Extend the timeline for resubmission of appeals from thirty days to sixty days, contingent that DHA provides manufacturers with a detailed explanation for the initial rejection.
2. Given the administrative burdens associated with the TRRP dispute resolution process described above, we recommend that it be modified to mirror that of the Medicaid Drug Rebate Program in which disputes can be resolved prior to quarterly refund payment processing.
3. If disputes are not resolved in 60 days and the delay is not within the manufacturer's control, automatically waive IPA for the period of the delay.
4. Revise the regulation and guidance to clarify that negotiated rebates due on items that are not covered by 10 U.S.C. §1074f(g) and the regulation are excluded from its scope to avoid confusion and erroneous application of rights established by regulation, and provide an alternate dispute resolution for these items.

Pay Level Discrepancies

DHA does not timely and proactively adjust pay price differences prior to payment adjudication by manufacturers. This continues to be a burden on manufacturers for any pay price differences. Manufacturers risk overpaying on utilization or underpaying on utilization, which could result in IPA fees. For example, if DHA submits an erroneous pay price, the manufacturer is requested by DHA dispute guidance to dispute the entire claim rather than pay what it believes the proper pay price to be. By disputing the entire claim, the Manufacturer is at risk of incurring penalties and interest on the entire claim, rather than just on the pay price variance.

Recommendations:

1. The Manufacturer and DHA attempt to resolve the pay price discrepancy prior to payment, rather than the Manufacturer disputing the entire claim.
2. Alternatively, the Coalition supports paying at the price believed to be correct, while supplying DHA necessary supporting documentation so that payments can be applied accurately.

340B Dispute Process

Federal regulation at 5 C.F.R. 199.21(q)(2)(iii)(E) provides that a prescription drug "dispensed by a pharmacy under section 340B of the Public Health Service Act" is not considered a covered drug under the TRRP and is not, therefore, subject to a TRICARE retail rebate. In previous communications, the DoD has committed to establishing two distinct processes for excluding 340B claims from utilization data based on whether the pharmacy exclusively dispensed 340B drugs or dispensed a mix of 340B and non-340B drugs:

> "With respect to pharmacies that dispense only prescriptions covered by the 340B program those pharmacies will be excluded from DoD's

> utilization data reported to manufacturers. Regarding other pharmacies that are eligible to participate in the 340B program but also fill other prescriptions, DoD will incorporate into the process appropriate procedures to identify and exclude 340B covered prescriptions." 74 Fed. Reg. 11279, 11288 (Mar. 17, 2009).

DHA, however, has never provided a mechanism to identify and exclude drugs acquired under the 340B program by retail pharmacies that dispense non-340B drugs. In short, DHA has unfairly imposed the burden of proving DHA has no right under the regulation to a refund on a prescription it paid for, even though the information is not transparent or readily accessible to manufacturers and could be obtained by DHA's TRICARE Pharmacy Benefit Manager as a condition of payment of the prescription claim. This information is known to the retail pharmacy as it must maintain a system that accumulates 340B prescription units in order to obtain replacement units from the covered entity.

Despite the regulation, and the commitment to exclusion process steps, subsequent DoD guidance has created significant and unreasonable burden on manufacturers when disputing any TRICARE/340B claims. The burden has become so significant, in fact, some manufacturers have ceased the practice of disputing TRICARE/340B Claims. The TRRP Manufacturer Policy and Procedures Guide requires that the manufacturer work with the Covered Entity to complete the 340B Dispute Verification Form (Appendix III) prior to submission of the dispute. This requirement is extremely burdensome to the manufacturer. It is not feasible that the Covered Entity will assist with this requirement in the imposed timeframe. Coalition members report that a very limited number of such disputes are accepted by DHA, which results in substantial financial liability due to the accrual of IPA fees. We recognize that identification of 340B claims is complex as there is no single universal identification requirement.

Recommendations:

1. DHA should strengthen its processes for identifying and eliminating TRICARE/340B claims from invoices. DHA should require its contractor PBM to obtain information from its TRICARE retail network pharmacies on the 340B units paid by TRICARE as a condition of payment, which would allow DHA to easily eliminate the utilization from its refund claims. For example, the new NDPDP "Manufacturer Rebate Utilization, Plan, Formulary, Market Basket, and Reconciliation Flat File Standard Implementation Guide Version 07 Release 02" now includes a 340B discount indicator.
2. Also, the HRSA OPA Medicaid exclusion file should be accepted by DHA as sufficient documentation for a 340B dispute. This OPA exclusion data file is commonly recognized and accepted in support by state Medicaid programs.

Transparency in Reviewing Tricare Regulations

The Coalition appreciates the DHA Subgroup for requesting comments from the public on opportunities to reduce unnecessary regulatory burdens associated with the Tricare regulations

at 32 CFR part 199. We ask that the DHA Subgroup and the TRRP continue outreach with industry as it addresses potential solutions to the concerns addressed herein related to disputes, IPA fees, pay level discrepancies and the 340B dispute process.

Recommendation:

1. TRRP establish an Operations Work Group to address issues and concerns of manufacturers.

The Coalition for Government Procurement would be pleased to assist TRRP in facilitating an Operations Work Group with industry.

Thank you for considering our comments concerning the DHA Subgroups review of the Tricare regulations. If there are any questions, please contact me at (202) 331-0975 or rwaldron@thecgp.org.

Sincerely,

Roger Waldron
President