BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

April 2, 2007

Ms. Laurieann Duarte
General Services Administration
Regulatory Secretariat (VIR)
1800 F Street, NW
Room 4035
Washington, D.C. 20405

Re: Amendment 2007-01, GSAR Case 2006-G522; GSA Interim Rule Regarding Federal Supply Schedule Contracts-Recovery Purchasing by State and Local Governments Through Federal Supply Schedules

Dear Ms. Duarte:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the General Services Administration's (GSA) interim rule regarding recovery purchasing by state and local governments through Federal Supply Schedules (the "Interim Rule").[1] BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products. BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. It is in this spirit that we offer the following comments to the Interim Rule on recovery purchasing.

A. As Currently Implemented, the Recovery Purchasing Program Is Not Truly Voluntary for FSS Contractors Under Schedule 65, Part I, Section B.

Under the John Warner National Defense Authorization Act for Fiscal Year 2007, which provides the authority for the recovery purchasing program Interim Rule, the Secretary of Homeland Security (DHS) is authorized to determine which goods and services may be purchased off of FSS contracts for the facilitation of disaster recovery.[2] The program applies for emergency purchasing, but also provides for advance purchasing in anticipation of emergency situations that may arise in the future.[3] In addition, the statute explicitly states that "participation by a firm that sells to the Federal Government through the supply schedule shall be voluntary with respect to a sale to the State or local government through such supply schedule."[4] Establishing this as a voluntary program was a reasonable approach, given the significant number of existing Federal and other types of contracts for emergencies and disaster recovery

---

[1] 72 FR 4649 (Feb. 1, 2007).
[2] Pub. L. 109-364 § 833(a). DHS made this determination for all supplies and services offered on FSS contracts. *See* Frequently Asked Questions about Disaster Recovery Purchasing, http://www.gsa.gov/Portal/gsa/ep/contentView.do?faq=yes&pageTypeId=8199&contentId=22410&contentType=GSA_OVERVIEW.
[3] 72 FR at 4651.
[4] 40 USC § 502(d)(3); P.L. 109-364 § 833.

that state and local governments can access – many of which are for pharmaceuticals, biologics, and medical supplies.

The Interim Rule provides an FSS contract clause, which will be required to be included in future, FSS contract solicitations, that permits the contractor to reject orders as follows:

> The Contractor is encouraged, but not obligated, to accept orders from such entities. The Contractor may, within 5 days of receipt of the order, decline to accept any order, for any reason. The Contractor shall fulfill orders placed by such entities, which are not declined within the 5-day period.[5]

As discussed below, given the unique contracting issues surrounding the sale of biologics and other products on Federal Supply Schedule 65, Part I, Section B, application of this clause would create a program that is by no means voluntary.

1. Five Days Is Not Sufficient Time to Reject An Order.

To be truly voluntary, the program must provide sufficient time for a contractor to reject an order. Given the nature of the market, a five-day period, as is contemplated by the Interim Rule, does not provide sufficient rejection time. For the most part, BIO's members sell their products to commercial and government customers through third party distributors.[6] Accordingly, the companies do not have visibility into who is purchasing their products at the time of the sales transaction. Rather, they only learn of the order when they receive a chargeback claim from the distributor, which can occur days, weeks, or even months after an order has been filled. The chargeback compensates the distributor for the difference between the price it paid for the product and the contract price (a price negotiated between the manufacturer and the end-customer) on which the distributor based its price to the customer.

At present, where a customer is authorized to access the FSS contract directly, often it will simply contact the distributor and reference the FSS contract number, and the distributor will extend the FSS contract price to the customer. The Interim Rule, as currently written, would permit state and local entities to follow this same pattern and place orders without giving the contractors an opportunity to reject. Thus, as a practical matter, the program would be mandatory, and inconsistent with the statutory grant of authority for a voluntary program. It is therefore necessary, in our view, for the final rule to provide that the ordering activity contact the manufacturer ***directly***. If a manufacturer then chooses to fill the order, it can certainly notify a third-party distributor and request that the product be shipped – and even invoiced – through that third party.

---

[5] 72 FR at 4655 (Feb. 1, 2007); GSAR 552.238-80(a)(5).

[6] While the FSS contract requires that the manufacturer sell direct, in practice, FSS eligible ordering activities often purchase pharmaceuticals and biologics through wholesalers.

2. Contractors Cannot Review Order Terms and Conditions within Five Days.

The Interim Rule also contemplates that when a state or local entity seeks to purchase a product listed on the FSS, a separate contract between the purchaser and manufacturer will be established. The Interim Rule further suggests that the new contract will incorporate certain FSS contract clauses, and, at the same time permits the ordering activity to include additional terms and conditions to implement state statutes and regulations.[7] Simply put, the five-day rejection period fails to allow for informed decision-making and negotiation of the "new contracts" that will result upon acceptance of an order from a state or local ordering activity.[8] Five days does not provide sufficient time to conduct a review of the new contract terms and conditions to determine what, if any, additional obligations would apply upon acceptance of the order. Moreover, it certainly does not allow time for negotiation of those terms.

Accordingly, even if a contractor were to be contacted directly by the ordering activity, it likely would be unable to conduct an analysis and respond within the five-day period. It is therefore in the best interest of all involved to extend the 5-day period to 10 days to allow for appropriate consideration of recovery purchasing orders. This approach certainly would make sense for advance purchases – i.e., purchases for stockpiling that are not made under emergency circumstances. And, in the event of an emergency, this approach would allow an ordering activity the flexibility to require a faster turn-around if that were to be necessary. Since the government already maintains supplies of drugs for disasters, and there are medical disaster response mechanisms currently in place, this program should be reserved for the longer recovery phase. Thus, a longer contract lead time should not be an impediment.

B. The Interim Rule Needs Stronger Protection Against Diversion.

Diversion is a serious concern for biologics and pharmaceutical manufacturers that sell products under FSS contracts and also participate in other government pricing programs. Not only is there the obvious risk that ineligible entities may access product at the reduced prices, but in cases where that happens, a manufacturer may have to consider whether to include those transactions in the calculation of future government price points. Accordingly, it is of critical importance to incorporate the most robust protections against diversion in any program that seeks to expand use of the FSS.

1. The Anti-Diversion Language in the Contract Clause Should Be Strengthened.

The contract clause included in the Interim Rule provides that "[t]he supplies or services purchased will be used for governmental purposes only and will not be resold for personal use."[9] This language prohibits only one form of diversion; we suggest that the contract clause echo the proposed language of GSAR 538.7102(c) and state as follows:

---

[7] *Id.*
[8] 72 FR at 4650.
[9] *Id*. at 4655, 552.238-80(a)(6).

> State and local governments that wish to use the Federal Supply Schedules to facilitate recovery from major disasters or attacks are responsible for ensuring that only authorized representatives of their governments place orders against these schedules and that procured products and services are used only for the purposes authorized by Section 833 of Public Law 109-364.[10]

Including this more robust language in the contract clause will help ensure that ordering activities are aware of their responsibility to prevent all types of diversion.

2. The List of Eligible Entities Requires Additional Specificity.

Another step that likely would reduce the potential for diversion under the recovery purchasing program would be to provide additional specificity with respect to the actual state and local entities that are considered eligible to purchase pharmaceuticals and biologicals under the program. As currently written, the Interim Rule defines general categories of eligible entities, (e.g., "…states of the United States, counties, municipalities, cities, towns…..school districts, colleges and other institutions of higher education…."). [11] In our view, the best way to ensure clarity with respect to eligibility is to establish a government database of eligible entities — similar to that employed by Health Resources and Services Agency (HRSA) for its Public Health Service (PHS) 340B Program[12] — that lists each authorized ordering activity and its responsible official. Ordering activities could be required to register and be accepted into the database prior to placing an order with an FSS contractor. The database would serve as a reliable resource for contractors and would, for the most part, eliminate the risk that an ineligible entity would be granted access into the program.

C. GSA Should Clarify Whether Sales Under this Program are "Federal Sales."

The Interim Rule as currently written also requires clarification as to the issue of whether sales to state and local governments for recovery purchasing are to be considered Federal sales. Throughout the Interim Rule, there are references to state and local government "use of" the FSS contracts, as well as the entities "placing orders against Federal Supply Schedule contracts."[13] In addition, FSS contractors are required to pay the Industrial Funding Fee (IFF) to GSA or to the VA (depending on which agency administers the contract) on sales to the state and local ordering activities.[14] Moreover, GSA imports language developed under the Cooperative Purchasing Program that exempts sales to state and local entities under the program from triggering FSS price reductions under the FSS Price Reductions Clause.[15]

---

[10] 72 FR at 4653.

[11] 72 FR at 4650, 4654.

[12] HRSA maintains and posts the list of 340B-eligible entities at www.hrsa.gov/opa.

[13] 72 FR 4649.

[14] *Id*. at 4650.

[15] 72 FR at 4653 (providing that contracts for recovery purchasing will include Alternate I to GSAR 552.238-75, Price Reductions).

At the same time, however, the Interim Rule provides that "a new contract will be formed when the schedule contractor accepts an order from a State or local government," which may include state or locality-specific terms.[16] Additionally, it disavows any Federal liability that could be connected with the performance of contracts under the recovery purchasing program.[17]

Whether sales to state and local entities under this program[18] are considered Federal sales is critical to BIO members. In short, treatment of these sales as non-Federal could result in their inclusion in the calculation of pricing under various Federal pricing programs under which biologics are considered "covered drugs" or "covered outpatient drugs." These include the Medicaid Average Manufacturer Price (AMP) and Best Price,[19] the Average Sales Price (ASP) and the Non-Federal Average Manufacturer Price (Non-FAMP)[20], which is used to calculate the Federal Ceiling Price that caps the pricing charged to VA, DoD, PHS, and the Coast Guard on VA FSS contracts. It also could have implications in the context of the FSS Commercial Sales Practice Disclosure. Given the fact that these sales are excluded from application under the FSS Price Reductions Clause and that they are generating IFF, in our view it would be appropriate to treat them as Federal.

D. There Should Be A Time Limitation on Recovery Purchasing.

As currently drafted, the Interim Rule does not specify an end date after which state and local governments would no longer be permitted to access the FSS to facilitate recovery from a disaster or attack. Without a temporal limit on when entities can procure product for disaster recovery, the Interim Rule essentially provides for full, unbounded access to the FSS contracts, which clearly was not contemplated by its authorizing statute. Moreover, the absence of an end date for recovery purchasing places a significant administrative burden on contractors, who must continuously interact with thousands of state and local governments seeking to place orders. An even greater concern is that if the state and local governments can purchase for disaster recovery at any time, there is an increased likelihood that entities will divert product to non-disaster recovery uses. Accordingly, BIO respectfully suggests that the Interim Rule be revised to provide for a limitation on how long before or after a triggering event (i.e., disaster or attack) an entity may access the FSS contract for purposes of recovery purchasing under the program.

E. Contractors Should Not Be Required to Provide Utilization Data.

Finally, to the extent that GSA seeks data regarding recovery purchases[21], we respectfully submit that the ordering activities, and not the schedule contractors, should be responsible for reporting their purchases directly to the government. FSS contractors are already required to report quarterly information regarding FSS sales for purposes of computing the IFF. Requiring contractors to filter their transactional data to identify all transactions

---

[16] 72 FR at 4650.
[17] 72 FR at 4650.
[18] Moreover, sales to state and local government under this program at pricing below the FSS price should also be considered Federal sales.
[19] 42 USC § 1396r-8(k)(1); 42 USC § 1396r-8(c)(1)(C)(i).
[20] 38 USC § 8126(h)(5).
[21] 72 FR at 4651.

associated with this new state and local purchasing program would require considerable additional efforts – and, in some cases, the implementation of new systems to track the data. And, again, the burden would be an unnecessary one given that GSA could certainly acquire the data directly from the ordering activities. As an alternative, VA could be responsible for collecting utilization data as it receives this information with manufacturers' submission of IFF.

F. Conclusion

BIO greatly appreciates the opportunity to comment on the important issues raised by the Interim Rule, and we look forward to working with the government to ensure that state and local governments continue to have access to critical drug and biological therapies. We sincerely hope that GSA will give thoughtful consideration to our comments and will incorporate our suggestions into its final rule. Please feel free to contact Jayson Slotnik at (202) 312-9273 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Jayson Slotnik
Director, Medicare Reimbursement & Economic Policy
Biotechnology Industry Organization (BIO)

Cc: Carole O'Brien
Director, Federal Supply Schedule Service
Department of Veterans Affairs, National Acquisition Center

Melbourne A. Noel, Jr.
Senior Contracts Attorney
Office of General Counsel
Department of Veterans Affairs