The Coalition for Government Procurement

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Director, Regulations Management (02REG)
Department of Veterans Affairs
810 Vermont Ave., N.W.
Room 1068
Washington, D.C. 20420

Attn: Louis E. Cobuzzi, PBM Services (119)

Re: RIN 2900-AN42-Drug and Drug-Related Supply Promotion by Pharmaceutical Sales

Dear Mr. Cobuzzi:

The Coalition for Government Procurement ("CGP") appreciates the opportunity to submit these comments on the Department of Veterans Affairs ("VA") Proposed Rule on Drug and Drug-Related Supply Promotion by Pharmaceutical Sales (Docket No. RIN 2900-AN42), published in the Federal Register on May 11, 2010 ("Proposed Rule").

The CGP is a multi-industry association representing over 300 member companies that sell commercial products and services to the Federal government, including pharmaceutical manufacturers subject to the Proposed Rule. The Proposed Rule would regulate the conduct of our pharmaceutical company members' representatives on VA property. In particular, it would regulate the content of discussions between company representatives and VA medical professionals regarding the use of products that the companies have on contract with the VA, and materials furnished by the companies that address treatment of diseases and conditions.

The Proposed Rule states that its purposes are: 1) to reduce or eliminate any potential for disruption in the patient care environment, 2) to manage activities and promotions at VA facilities, and 3) to provide pharmaceutical sales representatives with a consistent standard of permissible business at VA facilities. In particular, the Proposed Rule states that it is intended to address patient privacy and appearances of favoritism or endorsement of particular vendors or products. The Proposed Rule also purports to facilitate mutually beneficial relationships between VA and pharmaceutical sales representatives.

While the CGP supports these objectives, we are concerned that certain provisions of the rule do not serve the enunciated purposes, and arbitrarily and unreasonably restrict the free flow of scientific and clinical information between drug manufacturers and VA medical professionals, to the detriment of our nation's veterans.

1. The Rule Is Overly Restrictive and Unrelated to the Stated Objectives

a. Communications During Visits with Medical Personnel

As a general matter, the CGP understands and appreciates the need of VA facilities to limit the time, place, and manner for conducting business with the VA, and believes that the existing regulations that pertain to all contractors adequately address the potential for disruption of activities from contractor representatives calling on their VA customers. The Proposed Rule, however, is more than a "time, place or manner" rule, and the restrictions on permissible business are not limited to those that would cause disruption, mislead the public, or violate patient privacy. Section 1.220(b) prohibits a company representative from "promoting" a drug or drug-related supply if the VA has not included the drug on its National Formulary and has not authorized the particular use of the drug under discussion, including new indications for existing drugs. As discussed below, the term "promote" is not defined in the Proposed Rule, which makes compliance difficult. Implicit in the structure of the Proposed Rule is the notion that conduct not permitted under the rule constitutes "solicitation" or vending. Yet the Proposed Rule appears to include any communications concerning the medical use of a particular product by any individual employed by the manufacturer of the product, including drug safety discussions, peer-to-peer scientific exchanges, and unsolicited requests for information. Accordingly, information on the use of non-formulary drugs without a VA approved Criteria-for-Use cannot be provided to VA medical practitioners unless approved by the regional Pharmacy Executive and the Chief of Pharmacy for the facility. Even "promotion" of a new drug that has yet to be reviewed for the VA Formulary is prohibited unless approved by the regional Formulary Leader. In short, permission to speak to VA doctors on VA premises is based on the content of the discussion and is under the control of non-medical personnel.

The CGP is concerned with the breadth of the Proposed Rule, its failure to differentiate between scientific exchanges and information intended to elicit sales, and the lack of explanation as to how control and censorship of clinical information communicated to medical personnel furthers the VA's stated goal of preventing disruption. Once a pharmaceutical company representative agrees to abide by rules intended to minimize disruption, such as scheduling an appointment, remaining in designated areas, and respecting do-not-call requests, discussion of non-promotable drugs or therapeutic uses of drugs at scheduled meetings is no more disruptive than discussion of drugs allowed by the VA.

Likewise, the CGP believes that the Proposed Rule's restrictions on the substance of communications between representatives and medical personnel have no connection to the goal of protecting patient privacy. We appreciate the need of VA facilities to protect the privacy of their patients, and we support those aspects of the rule that legitimately further those goals. However, a much narrower supplemental regulation targeting patient privacy would suffice to address concerns not addressed in the existing regulation. Again, once a sales representative agrees to abide by privacy restrictions, such as not participating in meetings at which individual patient information is discussed, there is no need to regulate the content of discussions concerning therapeutic indications of a drug. Moreover, the proposed limitations on discussions of medical treatments do not foster an appearance of impartiality. To the contrary, because VA formulary decisions are not made in the sunshine, the effect of the Proposed Rule is to keep practitioners uninformed about particular therapeutic uses of products that VA pharmacists want to discourage, thereby exacerbating perception problems arising from the closed-door formulary process. In short, the Proposed Rule does not articulate a rationale for a regulation that would condition all pharmaceutical representatives' meetings with VA medical personnel on the substance of their meetings.

As noted, the CGP is concerned with the Proposed Rule's failure to distinguish between sales and clinical information. For the same reason, the CGP believes that the Proposed Rule is overly broad in its definition of sales representative. "Clinical liaisons" are included in the definition of sales representative; these individuals, however, who are also referred to as medical liaisons and similar designations, are not employed by manufacturers to elicit sales orders and are not compensated on the basis of sales. Rather, they are medical professionals whose job is to educate other medical professionals on the most current clinical information available in the medical community pertinent to the use of the company's products or their relevant drug classes. Regardless of whether an exchange is proactive concerning on-label indications or is a response to an unsolicited request for information on off-label use, these individuals are an important source of scientific information. We recommend that the final rule exclude meetings with clinical liaisons. At a minimum, rules controlling the flow of information on drug therapies to VA medical personnel should be the responsibility of the facility's medical departments not its pharmacy managers.

Likewise, the CGP objects to the inclusion of residents in section 1.220(f)(5), which prohibits sales representatives from "marketing to …health profession students (including residents)" except if approved by and conducted in the presence of the student's clinical staff member. We appreciate the desire to insulate students who are not permitted to exercise clinical judgment from marketing activities. Residents, however, are not students but licensed physicians who are capable of making clinical decisions and are members of the clinical staff. We urge the VA to remove the parenthetical "(including residents)" from this paragraph.