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July 12, 2010

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.

Additionally, the CGP is concerned that the scope of the Proposed Rule is overly broad because section 1.220(a) would include test strips and testing devices within the meaning of drug-related supplies. These diagnostic products are different from supplies sold together with drugs, such as drug delivery systems, are classified as devices, and are regulated under a totally different regime. The Proposed Rule defines drug-related supplies as supplies related to the use of drugs, but the term “related” is very vague, leaving it open to differing interpretations as to what medical supplies or even devices may be subject to the rule. Further, the Proposed Rule fails to articulate why testing devices are included in a rule aimed at promotion of particular pharmaceuticals and the conduct of pharmaceutical sales representatives. Information on the clinical use of testing devices can be critical in assuring proper outcomes. Yet the Proposed Rule provides no justification for curtailing promotion of testing devices or communications concerning their use, or for authorizing VA pharmacists to control access to information on these products by medical personnel who use them. We recommend that the final rule clarify that the term drug-related supplies means supplies sold in conjunction with a drug and used in its administration, not diagnostic tools, and that it exclude visits from industry representatives concerning test strips and testing devices.

b. Medical Education Material

The Proposed Rule would also unnecessarily restrict the availability of medical education literature provided by pharmaceutical companies. Again, the difference between sales promotion and education in section 1.220(d) is unclear and difficult to apply. For example, would brochures that provide instructions on how to use drugs or how to inject them, which are intended to assist pharmacists, nurses, and other practitioners provide patient education and counseling be considered promotional and therefore excluded from patient care areas? The Proposed Rule also fails to distinguish between sales and promotional material that would be left with medical staff and material presented by clinical liaisons that would be discussed but not furnished. Presentation of this material should be permitted without the need for prior approval as part of peer-to-peer scientific exchanges. Similarly, section 1.220(d)(6) would ban material on new drugs or new indications for drugs on the National Formulary that have yet to be reviewed by the VA unless clearly identified as such. In this regard, VA medical personnel may request a published medical journal article on a new drug or new indication, but the copyrighted material cannot be altered to identify the current VA review status of the drug. We do not believe facilitating VA staff access to journal articles that increase the reader’s knowledge thwarts any of the Proposed Rule’s goals. Please clarify that provision of such journal articles are exempt from the scope of the Proposed Rule, whether furnished in person or by mail, or advise how the material can be provided consistent with the marking requirement, *i.e.*, would a transmittal note from the representative stating the formulary status of a new drug or indication discussed in the article suffice?

Finally, in our view, leaving educational brochures in patient waiting areas does not disrupt treatment, interfere with waiting patients, or compromise their privacy. While we understand the VA's concern that brochures promoting a company's product could suggest endorsement or favoritism by the VA, the Proposed Rule goes much farther by restricting material that discusses diseases or conditions and their treatment without promoting a particular product. These types of brochures, which are produced in accordance with FDA guidelines and are available in patient settings outside the VA, benefit patients by providing important information on symptoms and treatments of which they may be unaware. Although section 1.220(d) of the Proposed Rule recognizes that legal requirements may make it impossible to omit the name of the company that produced the literature, the Proposed Rule gives total discretion to the local facility to approve or reject brochures based on the size or location of the company's name or logo. As a practical matter, the company would have to print special copies of its brochures, depending on the whim of the VA facility, or forego providing medical education literature to patients. The CGP fails to see how prohibiting medical education literature that meets FDA guidelines protects patients from misleading information, suggests the VA is endorsing a product, or otherwise furthers any legitimate goal of the Proposed Rule. To the contrary, we believe that the lack of standards for rejecting FDA-compliant literature creates the potential for arbitrary or biased decisions. We recommend that this provision be deleted, that literature meeting FDA guidelines be presumptively permissible, and that national standards be established for rejecting brochures that otherwise meet FDA guidelines.

2. Providing VA Medical Personnel with Information About a Pharmaceutical or Biological Product Is Not "Solicitation" of Money

As noted above, a major problem with the Proposed Rule is the failure to define the activity referred to as "promotion." The preamble to the rule suggests that any discussion of a particular drug by a representative of the drug's manufacturer constitutes promotion, as the Proposed Rule would include a clinical liaison within the term "sales representative" and would allow VA medical personnel to become "educated through the promotion of [new] drugs" under certain circumstances. This failure to recognize the distinction between selling and providing information permeates the Proposed Rule's restrictions on the substance of discussions with medical personnel and medical education materials, and is key to its rationale, as the Proposed Rule equates "solicitation" with any discussion of a product that can be ordered by the VA. The Proposed Rule is predicated entirely on the faulty premise that certain activity (*i.e.*, exchanges between company representatives and medical staff about products available on contract and certain clinical uses of those products) would, without VA permission, constitute prohibited "solicitation" under 28 U.S.C. 1.218(a)(8).

We agree that soliciting money from individuals - whether for commercial or charitable purposes - can be disruptive of business, and a

content-neutral prohibition against solicitation on government property is clearly reasonable. However, the activity that the Proposed Rule would regulate (and disallow) is not “solicitation,” and is not covered by the existing security regulation’s prohibition against solicitation. As the Supreme Court recognized in *United States v. Kokinda*, 497 U.S. 720, 733-735 (1990), soliciting funds is an inherently different activity than disseminating promotional information. Solicitation involves a request for funds and requires a response, whereas promotion does not. The distinction between sales and physician detailing was specifically addressed in a recent decision of the U.S. Court of Appeals for the Second Circuit. See *In re Novartis Wage and Hour Litigation*, C.A. 09-0437-cv (2nd Cir., July 6, 2010). In that case, the court determined that pharmaceutical representatives are not engaged in sales activities when they promote a product to a physician, because they cannot transfer ownership of drugs in exchange for anything of value, cannot take orders for its purchases, and cannot even obtain a binding commitment from the physician to prescribe the drug. (slip op. at 26).

Visits with VA medical personnel to which this rule applies do not involve the terms of a sale, as the VA has contracted for the sale of drugs covered by the Proposed Rule. Nor do they involve asking individuals for money or even asking them to place orders, as medical personnel are not responsible for buying drugs on behalf of the VA. Nor can representatives obtain binding commitments from VA physicians to prescribe or use drugs as all physicians are ethically bound to make those decisions on the basis of individual patient needs. Rather, these visits provide an opportunity for practitioners to ask questions about drugs and biological products available to the VA pursuant to established contract terms, and involve discussions of approved uses of contract items, dosing, protocols, and other important clinical information, including warnings and side effects, in accordance with FDA rules and guidelines. The activity informs the practitioner’s medical judgment but need not trigger a response. Although it is possible that providing information and answering questions about an approved new use of a non-formulary drug (not included in the VA’s Criteria-for-Use) might lead a VA practitioner, in the exercise of his or her medical judgment, to later prescribe the drug, that does not make the communication with that individual “solicitation,” or selling, so that the person who provided the information would violate the non-solicitation rule.

Moreover, even if detailing products to doctors by company representatives could be considered soliciting sales, the Proposed Rule goes much farther than regulating the conduct of sales representatives. It reaches expressive speech of medical liaisons who are responsible for providing clinical information to medical professionals, including results of clinical trials and scientific studies. These individuals, who are not compensated for sales volume, communicate research and clinical data, comparative studies, and other educational information useful to practitioners in the treatment of their patients and exercise of their medical judgment. For that reason, both FDA and PhRMA guidelines distinguish the conduct of clinical or medical liaisons from that of sales representatives. In sum, the sole reason for these individuals to meet with