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.

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

VA medical staff is to provide scientific information about the company's products to assist them make informed decisions.

Although the Proposed Rule states that the VA does not intend to treat non-compliant communication with its medical personnel as a violation of its security regulation, such activity could easily be sanctioned under section 1.218(a)(8), because, pursuant to the Proposed Rule, it would be covered by the regulation and would not qualify for an exception, thereby creating the desired chilling effect on the representative's speech. We believe that the Proposed Rule goes too far in restricting the flow of information about particular drugs and biological products from company representatives during on-site visits. It is very troubling that the Proposed Rule would subject individuals and companies to sanctions and revoke their authorized access to VA property for impermissible conduct based solely on whether the clinical information provided relates to a product or use favored by VA policy. In sum, we urge the VA to distinguish between solicitation of sales and provision of information about a product and allow uncensored visits by representatives who abide by VA time, place and manner conditions on meetings with the public.

3. The Proposed Rule's Content-Based Restrictions on Speech Constitute Censorship that Impedes VA Practitioners' Access to Information and Patient Care

The CGP vigorously opposes the Proposed Rule's categorical permission (or denial of permission) for drug company representatives to visit VA medical personnel based solely on their substantive discussions. The Proposed Rule would permit representatives to visit medical staff within the rule's time, place and manner restriction to discuss those few drugs and biological products selected for the VA National Formulary or uses of non-formulary drugs included in the VA Pharmacy's Criteria -for-Use guidelines, but would ban discussions of most other products and uses under the same time, place and manner conditions unless approval was granted in advance by the regional Pharmacy Executive and local Chief of Pharmacy. Thus, the regulation's restrictions depend on whether the topic of discussion is favored or disfavored by VA policy implemented by VA pharmacy management.

First, we do not believe such censorship of speech is permissible under the standards for reviewing limitations on expressive activity imposed by the government when it is acting as a proprietor. *International Society for Krishna Consciousness, Inc. v. Lee*, 505 U.S. 672 (1992). In those situations, restrictions by the VA on commercial speech will satisfy the Constitution if they are reasonable, but only if the regulation is not an effort to suppress the speaker's activity because the government disagrees with or does not like the content of the speech. In short, to be reasonable, a regulation restricting speech must be content-neutral. *See, e.g., Christ's Bride Ministries, Inc. v. Pa. Transp. Auth.*, 148 F.3d 242, 256-257 (3rd Cir. 1998). Where, as here, the restriction on speech depends entirely on the VA's approval of its content, the restriction must

directly and materially advance a substantial government interest in a manner no more restrictive of speech than necessary. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York,* 447 U.S. 557, 564 (1980).

In the Proposed Rule, the VA is acting as a censor of the substantive discussions between its medical personnel and drug company representatives, including clinical liaisons. Although not its stated purpose, the apparent intent of the Proposed Rule is to discourage the flow of information about certain drugs disfavored by VA pharmacy management, and to impede the ability of representatives to provide information about these drugs, because the VA does not want its medical personnel to obtain this information directly from company representatives. The VA, however, has not explained how its content-based distinctions between permissible and impermissible communications are related to the goals enunciated in the rule. It does not conclude that there is anything unlawful or misleading about the restricted information or that provision of the information during visits would be any more disruptive or intrusive on patient privacy than other discussions. Accordingly, the Proposed Rule provisions that would deny visits and ban company representatives based solely on whether the content of their speech reflects VA drug preferences are per se unreasonable.

Second, assuming the unstated reason for suppressing speech is to discourage familiarity with more expensive drugs, it does not justify the rule, as there are means for discouraging use of costlier drugs other than censoring scientific information and impeding VA medical practitioners from becoming more knowledgeable about developments in clinical care of our nation's veterans. In order for the VA to maintain high standards of patient care, patients should have access to medical personnel with knowledge of the same current scientific information and developments in drug therapies that practitioners have outside the VA system. Placing complete control over medical staff access to information on new indications for drugs and other scientific information in the hands of pharmacy management, whose knowledge of clinical studies may not be current and whose interests are in cost containment, prevents medical departments from deciding what information would be useful and should be available in their practice of medicine. Moreover, the VA's Criteria-for-Use is generally outdated and inconsistent with current practices in many health care systems. If a VA practitioner is interested in exploring whether a newly approved indication of a non-formulary drug could provide a better outcome for a patient, the Proposed Rule would bar a representative of the drug's manufacturer from discussing it because it is inconsistent with the old Criteria-for-Use. It is difficult to understand how the VA can consider suppression of communications on new therapeutic uses for existing drugs to be in the "interest" of its practitioners and patients, as it states in the preamble to the rule. Further, as a practical matter, where the subject of a non-formulary drug or a new drug is spontaneous or raised at a meeting by the VA practitioner, it would be impossible to get the approvals necessary to discuss it, so the practitioner will be denied access to the information sought.

Clearly, the Proposed Rule suggests a paternalistic view of its professional medical staff – that they cannot be trusted to make sound prescribing decisions if exposed to information provided by company representatives. This unfortunate view denies patients the benefit of their doctors' most informed judgment on what is the right approach for their individual situation. It also conflicts with the widespread belief among health care professionals that more information, not less, is key to making patient care decisions. In fact, central to health care reform is the concept of comparing cost and effectiveness using multiple benchmarks. It makes no sense to eliminate an important source of information from the totality of information factored into a practitioner's judgment. We recommend the Proposed Rule allow medical departments and practitioners, not pharmacy management, to approve on-site visits and to determine what is in their interest to discuss with company representatives during such visits. At a minimum, no approval should be necessary for representatives to respond to questions raised by VA personnel.

4. The Proposed Rule Conflicts with FDA Rules Governing Drug Promotion

The Proposed Rule is unworkable because it can conflict with FDA regulations governing the marketing and promotion of products. Company representatives are bound to adhere to FDA disclosure requirements, and those rules apply to the VA. For example, if an approved on-label indication requires disclosure of safety information, that information must be provided regardless of whether the indication is being promoted by the representative. However, under the Proposed Rule, if a sales representative, in discussing an indication of a drug permitted by the rule also provided information required on the drug's label in connection with an indication that is not included in the VA's Criteria-for-Use (as would be required under FDA rules), the representative would violate the VA rule. As the FDA is vested with responsibility to regulate drug safety and the information that must be provided by drug company representatives in promotional activities, the Proposed Rule should not create conflicts with FDA requirements.

5. The Proposed Rule Does Not Create a Uniform National Standard of Conduct because It Lacks Meaningful Criteria and Leaves the Regulation of Conduct at the Local Level

a. Medical Education

The CGP does not object to the portion of the Proposed Rule that bars public distribution on VA property of literature promoting or advertising a company's brand name products, as the VA's concern with the public's perception regarding endorsement and bias seems reasonable, and the ban seems to be consistent with general rules prohibiting dissemination of promotional brochures by other industries. In this regard, we believe there is a big distinction between material provided to medical professionals and literature

aimed at the public. However, as previously discussed in these comments, we believe the Proposed Rule would benefit from definitions that clarify what is meant by product promotion, in order to avoid confusion and assist patients with their treatments. For example, a facility might prohibit a drug manufacturer from sponsoring a program concerning a drug therapy or regime solely because the sponsor is a manufacturer of a pharmaceutical or biological product within the therapeutic class being discussed.

The CGP is also concerned that the Proposed Rule will not achieve uniformity in permissible activity of pharmaceutical representatives at VA facilities. In particular, approval of medical education programs, and distribution in patient areas of patient education brochures that do not advertise or promote named products, are subject to the whim of the local facility. Section 1.220(d) provides that all educational programs must be approved by the local facility, usually the Chief of Pharmacy, and that patient education materials are subject to exclusion if the Pharmacy Benefit Manager thinks the name or logo of the company publishing the brochure is too conspicuous, or even if approved by the PBM, if the local facility does not approve it for whatever reason. Instead of creating and applying uniform standards applicable to all facilities or instituting a centralized approval process, the Proposed Rule allows individual facilities to reject brochures that adhere to FDA guidelines and trump approval of brochures by the PBM for no particular reason. As a practical matter, this means a company could be forced to print special versions of its brochures to satisfy individual preferences. Further, without standards, facilities can arbitrarily accept one company's brochure and reject another's, which fosters the perception that decisions are irrational and improperly motivated. As previously discussed, we recommend that this provision be deleted and that approval of medical education literature be centralized and presumptively granted to material prepared in accordance with FDA guidelines.

b. Non-Promotable Drugs

In addition to giving local pharmacy management absolute control over medical staff access to information on new drugs and non-formulary drugs without a Criteria-for-Use, one of the most troubling aspects of the Proposed Rule is the ease with which a drug can be designated by a facility as non-promotable. Even a drug on the VA National Formulary can be designated as non-promotable if the local Chief of Pharmacy determines promotion is inconsistent with facility initiatives, presumably because he or she wants to discourage familiarity with the drug and potentially greater use because of its cost. Because the term promotion is vague and could include clinical information provided by medical liaisons, designation of a drug as non-promotable by a facility could bar any exchange of any information between medical professionals concerning the particular drug. Although the VA may save money in the short term, patients who could benefit from these drugs may suffer and incur additional health care costs in the long term if their doctors are

unfamiliar with all available options or with a particular use of a drug and are deliberately kept in the dark.

Furthermore, the Proposed Rule references a website listing drugs classified as non-promotable, but the circumstances when a drug might be designated non-promotable are subject to constant change as there are no regulatory standards. Moreover, because section 1.220(b) seems to give individual facilities unfettered discretion to block promotion (discussion) of formulary drugs or approved uses of non-formulary drugs if inconsistent with facility initiatives, and there are no standards for determining whether a drug meets this criteria, there is nothing to prevent arbitrary or wholesale treatment of drugs as non-promotable. We recommend this provision be deleted. Alternatively, we recommend the term promotion be defined to exclude clinical information and that standards be established for designating a drug as non-promotable notwithstanding its formulary status and use consistent with the Criteria-for-Use. Further, we recommend that the decision to classify a drug as non-promotable be made only by the national PBM, in order to standardize the practice and not undermine the rule.

c. Adherence Is Not Compulsory for All Facilities

The Proposed Rule is intended to standardize the rules governing on-site conduct of pharmaceutical manufacturer representatives and their access to VA medical staff. It also purports to improve the relationship between the VA and drug manufacturer representatives. However, the rule is not a two-way street. By codifying policy, and imposing regulatory restrictions, it denies facilities flexibility in implementing more lenient policy with respect to representative visits, medical education, and provision of information, while simultaneously granting facilities discretion to impose greater restrictions. Additionally, because the Proposed Rule does not require VA facilities to permit access under the conditions specified in the rule, they are free to bar any visits. In short, the Proposed Rule offers no improvement over the current situation with respect to VA medical personnel access to information about a pharmaceutical manufacturer's drugs through personal exchanges with company representatives. Further, although the Proposed Rule says the VA does not intend to impose sanctions for violating security/trespass rules if a representative discusses with a medical staff member a prohibited topic, such as a new study involving a non-formulary drug, it does not preempt policies of other VA facilities, such as that adopted by the VA San Diego Healthcare System (Memorandum 119-06), that treat those who discuss such topics as criminal trespassers. In order to standardize the rules governing representative visits, we urge the VA to preempt local policies, and prohibit its facilities from barring on-site visits by drug company representatives who agree to abide by the Proposed Rule and imposing sanctions not provided for in the Proposed Rule.

6. The Disciplinary Provisions of the Proposed Rule Fail to Provide Due Process to Sales Representative and Companies

The CGP believes that the provisions of section 1.220(g) of the Proposed Rule fail to provide adequate due process to individuals and companies accused of noncompliance with the rule. Given that these sanctions can be imposed for violating speech restrictions, which, as discussed, we believe are impermissible to begin with, and can affect an individual's livelihood, paragraph (g) should allow all company representatives notified of noncompliance with the rule (directly or through a supervisor) to continue operating during the 30-day response period. The proposed Rule acknowledges that provisions exist for protecting the VA against conduct that violates its security regulation, and that activity governed by the Proposed Rule is unlikely to pose a security risk. Thus, in the absence of such a threat, there is no need to impose sanctions for noncompliance with speech-related restrictions before the representative or the company has an opportunity to be heard. We recommend that suspension of detailing privileges of either an individual or a sales force only become effective after the company has been given an opportunity to respond to any notice of noncompliance. Visits with VA medical staff may be a privilege and not a right, but the suspension of detailing privileges should be subject to the same due process afforded individuals before a security clearance can be suspended or contractors before eligibility for award can be suspended.

Further, if a restriction on detailing privileges is imposed against an individual or a company sales force, the restriction should be limited to the VA facility in which the noncompliant activity occurred. Because the standards of conduct and approval requirements are vague and may vary from facility to facility, acts of an individual at one facility that are deemed to be noncompliant should not result in "the imposition of a VISN-wide or VA-wide" restriction or exclusion of the entire sales force of a company without clear guidelines explaining what types of acts can lead to certain penalties. We urge the VA to reconsider the fairness of these provisions in light of the consequences for affected representatives and companies and the necessity to provide adequate due process.

7. The Proposed Rule Unfairly Penalizes One Group of FSS Contractors by Prohibiting their Account Representatives from Marketing Certain Contract Items

Manufacturers of brand drugs and biological products are required by the Veterans Health Care Act, 38 U.S.C. 8126, to offer the drugs for sale to the VA on the Federal Supply Schedule ("FSS"). Under a delegation of authority from the General Services Administration ("GSA"), the VA negotiates and administers FSS contracts covering drugs and biological products in accordance with GSA program rules. Pursuant to those rules, the VA's goal is to obtain the contractor's commitment to charge the VA its most favored customer price regardless of terms, even though the VA does not commit to purchase any more

than $25,000 under the contract. For innovator drugs and biological products, the contract price can be even lower if the most favored customer price is below the federal ceiling price. The consideration for the commitment to sell at the FSS price is the size of the federal market opportunity. Accordingly, in order for contractors to reap the value of their bargain and obtain federal sales, it is expected that they will actively market to their federal customers. Indeed, both GSA and the VA remind FSS contractors that the government does not guaranty FSS contract sales and it is the responsibility of the contractors to generate sales through direct marketing of user agencies. However, for those contract items the VA designates as non-promotable, the Proposed Rule would eliminate any possibility of marketing directly to the VA.

The CGP is greatly concerned that the good faith basis for the FSS program - low prices in exchange for marketing opportunity- is completely undermined by a rule that denies contractors the ability to market products offered on the FSS to their principal customer. Other than the time, place and manner restrictions on doing business on VA property that apply to visits by all contractors, the CGP is unaware of any regulatory prohibition on marketing of other goods or services available on the FSS that the agency decides it does not like, and we question whether it is permissible to discriminate by imposing such marketing restrictions on select contractors and select items under the FSS program. We urge the VA to consult with GSA before finalizing a rule that conflicts with the FSS program and appears to deny FSS contractors the benefit of their contracts.

Thank you again for the opportunity to share our concerns about the Proposed Rule and for considering these comments.

Sincerely,

Larry Allen

Larry Allen,
President