

(4) To seek permission to transit the Safety Zone, the Captain of the Port or her representative can be contacted via Sector Delaware Bay Command Center (215) 271-4940.

(5) This section applies to all vessels wishing to transit through the Safety Zone except vessels that are engaged in the following operations: (i) Enforcing laws; (ii) servicing aids to navigation, and (iii) emergency response vessels.

(6) No person or vessel may enter or remain in a safety zone without the permission of the Captain of the Port;

(7) Each person and vessel in a safety zone shall obey any direction or order of the Captain of the Port;

(8) The Captain of the Port may take possession and control of any vessel in the safety zone;

(9) The Captain of the Port may remove any person, vessel, article, or thing from a safety zone;

(10) No person may board, or take or place any article or thing on board, any vessel in a safety zone without the permission of the Captain of the Port; and

(11) No person may take or place any article or thing upon any waterfront facility in a safety zone without the permission of the Captain of the Port.

(d) *Definitions.* (1) The Captain of the Port means the Commanding Officer of Sector Delaware Bay or any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port to act on her behalf.

(e) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the Safety Zone by Federal, State, and local agencies.

Dated: February 3, 2012.

Todd C. Wiemers,

Captain, U.S. Coast Guard, Alternate Captain of the Port Delaware Bay.

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900-AN42

Drug and Drug-Related Supply Promotion by Pharmaceutical Company Representatives at VA Facilities

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This final rule amends the Department of Veterans Affairs (VA) regulations regarding access to VA facilities by pharmaceutical company

representatives. The purposes of the rule are to reduce or eliminate any potential for disruption in the patient care environment, manage activities and promotions at VA facilities, and provide pharmaceutical company representatives with a consistent standard of permissible business practice at VA facilities. The amendments will facilitate mutually beneficial relationships between VA and pharmaceutical company representatives.

DATES: *Effective Date:* This final rule is effective April 4, 2012.

FOR FURTHER INFORMATION CONTACT:

Louis E. Cobuzzi, PBM Services (119), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420; (202) 461-7362. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: Under 38 U.S.C. 303, the Secretary of Veterans Affairs is responsible for “the proper execution and administration of all laws administered by the Department and for the control, direction, and management of the Department.” The Secretary has authority to prescribe all rules necessary to carry out the laws administered by the Department, such as section 303 regarding control and management of the Department. *See* 38 U.S.C. 501(a). VA has implemented this authority, as it pertains to management of VA facilities, in 38 CFR part 1.

VA amends 38 CFR part 1 to regulate access to VA medical facilities by pharmaceutical company representatives promoting drugs and drug-related supplies. Currently, many policies regarding access to VA facilities are established and maintained at the local level, either by Veterans Integrated Service Network (VISN) leaders or by administrators at particular facilities. A VISN, which we define in § 1.220(b), is a network of VA medical facilities located in a particular region. There are 21 such regions, and the areas that they service can be found at <http://www.vacareers.va.gov/networks.cfm>. On May 11, 2010, we proposed VA-wide rules that would be followed at the VISN and local levels.

We received five comments on the proposed rule. Although we make a few modifications based on these comments and some organizational changes for improved clarity, we otherwise adopt the rule as proposed for the reasons discussed in the May 11, 2010, notice. A detailed consideration of the comments follows.

Requests for New Definitions

In response to the comments concerning the scope of § 1.220 as a whole, we have added a “Scope” paragraph, designated as paragraph (a), that states: “This rule governs on-site, in-person promotional activities, including educational activities, by pharmaceutical company representatives at VA medical facilities. It does not apply to the distribution of information and materials through other means.” This note clarifies that the rule governs only physical access to VA medical facilities and that information and materials can be distributed through other means than in-person at a VA medical facility. Consistent with this clarification of the scope of the rule, we have revised the heading of § 1.220 to “On-site activities by pharmaceutical company representatives at VA medical facilities.” Because we inserted a new paragraph (a) and made other organizational changes to the rule, the paragraph designations used in the proposed rule have changed. Throughout this rulemaking we cite to both the proposed rule paragraph designation and the final rule paragraph designation.

We note that we have made a technical revision to correctly refer to the “official National Formulary.” The proposed rule had referred to the “official National Formulary of the United States,” which is not the correct title of the National Formulary.

A commenter stated that the proposed rule does not clearly define “educational programs and materials.” The commenter stated that proposed paragraph (d) “appears to apply to programmed events with an educational, rather than promotional, purpose * * * and the materials associated with such events.” To clarify the applicability of proposed paragraph (d), now designated as paragraph (f), we have added the following: “An educational program is a pre-scheduled event or meeting during which a pharmaceutical company representative provides information about a drug or drug-related supply.” We have also modified the word “materials” where it appears in paragraph (f) with the word “associated” to make clear that the materials discussed in paragraph (f) are those materials intended for use in connection with an educational program. We note that this definition applies only to this section and does not apply to the similar terms as used by other U.S. Government agencies, such as the Food and Drug Administration (FDA), in their regulations or guidances.

The commenter also argued that proposed paragraph (d), now designated as paragraph (f), may be susceptible to a broad interpretation that would cover “most promotional materials,” such as documents that instruct patients on how to take their medication or educate physicians about the side-effects associated with particular medications. This commenter, as well as others, appears to be concerned with the general breadth and scope of proposed paragraph (d), and we agree that these can be clarified. The purpose of proposed paragraph (d) was to monitor materials distributed on VA grounds in connection with an educational program. As explained in the proposed rule, we have concerns that a VA patient will obtain such materials and misinterpret them, which could interfere with that patient’s clinical course of treatment. As explained above, we revised the rule so that this paragraph clearly applies to educational programs and the materials associated therewith. On-site distribution of materials outside the context of an educational program is addressed in paragraph (h)(6) of the final rule, as discussed later in this rulemaking.

One commenter suggested that VA delete proposed paragraph (d) entirely because there is insufficient clarity about what constitutes “programs,” noting that the rule could restrict the provision of educational materials mandated by the FDA. To address this comment, we have explicitly stated in current paragraph (f) that “[t]he approval authority will deem suitable any educational program and associated materials if it is part of a risk evaluation and mitigation strategy or other duty imposed by the Food and Drug Administration.” However, we note that even such educational programs must be submitted to the approval authority for review to ensure appropriate scheduling and that such educational program is indeed an obligation imposed by the FDA. We also note, as explained later in this preamble, that the required notice for an educational program may be given on a shortened basis in certain cases.

Also related to proposed paragraph (d), commenters requested that VA define “summary of the program and all materials” and “well in advance of the proposed date.” VA’s intent is to require that all educational programs and associated materials be submitted, and the inclusion of the word “summary” caused confusion in this regard, so we removed the word “summary” from the paragraph. For “well in advance of the proposed date,” we have changed the phrase in current paragraph (f) to read:

“at least 60 days before the proposed date of the educational program or distribution of associated materials, unless VA agrees in an individual case to a different date.” We believe that this gives VA adequate notice, while allowing for flexibility in cases where the pharmaceutical company cannot provide 60 days advance notice and VA agrees that, in a particular case, we do not need the full 60 days to review the materials.

A commenter requested that VA define “non-promotable,” as used in proposed paragraph (b)(2), because the word could be interpreted subjectively, and therefore may not be applied consistently in the field. Commenters also requested that VA publish a list of non-promotable drugs. We agree that it will be useful to pharmaceutical company representatives to provide information about where to find a list of such drugs. Thus, we define non-promotable drugs as “drugs designated by VA as non-promotable” and inform the public that a list of such drugs will be available upon request or on VA’s Web site at <http://www.pbm.va.gov>. We have also removed the following sentence from proposed paragraph (b)(2), now designated paragraph (c)(3): “A list of the drugs or drug-related supplies classified by VA as non-promotable is available at www.pbm.va.gov, or may be requested by contacting the local office of the Chief of Pharmacy Services.” This sentence is no longer necessary because virtually identical language has been used in the definition for non-promotable drugs.

We disagree with additional comments suggesting that VA should develop a mechanism that allows pharmaceutical manufacturers to participate in the determination of whether a drug is non-promotable. We reject the commenters’ suggestions in order to maintain the safety of our patients, and so that we can continue to make quick, important clinical responses to scientific and medical developments related to pharmaceutical products. VA must independently determine which drugs to designate as non-promotable. In determining whether a drug is non-promotable, VA considers many factors, including price, a determination that a certain drug has no clinical benefit, or a finding that promotional materials exceed the clinically determined specific use of a drug—such as when VA makes a clinical decision to utilize a drug for a narrow purpose. For example, there may be a drug or new molecular entity that does not appear on the VA National Formulary (VANF), which VA uses to

treat patients for diseases that VA would otherwise be unable to treat. In such instances, VA must continue to maintain strict adherence to its criteria-for-use and prevent undesired promotion of a drug. Therefore, VA must be able to designate a drug as non-promotable in order to enforce any attempt by pharmaceutical company representatives to systematically promote the use of a certain drug for uses outside of those sanctioned by VA. Finally, we note that VA will rarely, if ever, classify a drug as non-promotable. In fact, we currently do not have any drugs classified as non-promotable, as reflected on our Web site at <http://www.pbm.va.gov>.

Commenters suggested that VA define “facility initiative,” as used in proposed paragraph (b)(4). We understand that this term may create some confusion, and rather than define the term, we have revised the regulation text so that it no longer uses that term and instead fully explains the requirements. Specifically, in new paragraph (c)(2), we clarify the meaning of the requirements that we set forth in proposed paragraphs (b)(3) and (4). We require that the promotions must have “significant educational value and must not inappropriately divert VA staff from other activities that VA staff would otherwise perform during duty hours, including patient care and other educational activities.” This language accurately clarifies intent of the previous “facility initiatives” language. We reject an additional request that VA identify the decision-maker who determines whether these requirements for promotion are met under the rule. VA respects the need for its various facilities to be permitted to initiate creative responses to the needs of their specific patient population, as well as surrounding communities. Moreover, different facilities will have different management resources available to make these determinations. We will continue to allow each facility to delegate to the appropriate staff member to make this determination.

Commenters recommended that VA define “promote” or “promotion” in order to clarify that safety discussions and scientific exchanges are not included in the rule. Commenters also suggested that we clarify whether medical or clinical liaisons are specifically excluded from being considered promoters. We understand that employees of pharmaceutical companies attempting to visit VA facilities work in different capacities and possess varying levels of expertise. We also understand that this could lead to confusion about application of the rule. We clarify this issue by defining a

“pharmaceutical company representative” as “any individual employed by or contracted to represent a pharmaceutical manufacturer or retailer.” By defining pharmaceutical company representative broadly, we remove any ambiguity as to whether an employee of a pharmaceutical company, contracted or otherwise, should follow the procedures set out in this rule. Clinical liaisons may freely discuss the benefits of a medication manufactured or sold by their employer simply by following the requirements set out under this rule. We also note again that pharmaceutical company representatives are free to provide safety and scientific information through means other than on-site, in-person, visits to VA facilities.

Commenters suggested that VA define the terms “manufacturer sponsored program,” “promotional materials,” “patient education materials,” and “individual departments.” We disagree with the commenters’ suggestions because the meaning of each of these terms is clear in the context of the rule. They are accepted terms of art in the industry that are well understood by pharmaceutical company representatives and VA staff. Commenters also suggested that VA define the term “marketing activities” as used in proposed paragraph (d)(2). We have decided to remove this paragraph referencing “marketing activities” because we believe that the requirements for educational program and associated materials are adequately described in the rest of proposed paragraph (d), now designated paragraph (f).

Requests for Modifications to Proposed Definitions

Commenters suggested that VA modify the definition of “drugs” to clarify the meaning of chemicals, the impact on drugs used for medical research, the basis for decisions based on drugs, and who that decision-maker will be. To address these comments, we have decided to adopt the definition of “drug” used in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*). We modified the definition only to remove internal cross-references. By doing so, we hope to eliminate the confusion expressed by the commenters. As we stated in the preamble to the proposed rule, we intend the term “drug” “to be inclusive of all items typically promoted by pharmaceutical sales representatives,” and thus have adopted the definition used by Congress in the Federal Food, Drug, and Cosmetic Act. We note that nothing in this regulation is intended to conflict with

FDA’s regulation regarding the promotion of investigational new drugs, see 21 CFR 312.7.

Several commenters recommended modifications to the definition of “drug-related supplies” because they assert that it is unclear whether VA intends to include medical devices in this definition. We believe that the term as defined properly and clearly covers those devices required to use a given drug in accordance with the prescribed use, but we have added as examples of such supplies inhalers, spacers, insulin syringes, and tablet splitters. These devices are generally given out by VA pharmacies in our patient setting, as opposed to other offices within VA facilities.

One commenter stated that including test strips and testing devices is not justified because the rule is “aimed at promotion of particular pharmaceuticals and pharmaceutical representatives.” Whether a representative is promoting a drug or a testing device associated with a drug, it is important that VA be able to limit the effects of such promotion on patient care. Again, we make no changes based on these comments.

Several commenters also requested clarification of the definition of “criteria-for-use.” One commenter suggested that VA adjust the definition to require compliance only with VA’s national criteria-for-use standards, and do away with the authorization of exceptions at the local level. We disagree with these suggestions and will continue to provide local VA facilities the ability to make necessary decisions that are in the best interest of their patients with regard to criteria-for-use, based on geographic or other factors specific to the patient population at each VA facility. We also clarify that this rulemaking does not alter the well-established practice for learning about national and local criteria-for-use and the VANF. At the local level, pharmaceutical company representatives will continue to request criteria-for-use from the appropriate VA employee at the appropriate VISN Office, or the Office of the Chief of Pharmacy Services. We further note, in response to comments regarding mature brands, that all national criteria-for-use requirements are listed on VA’s Web site.

One commenter suggested that VA exclude medical residents from being considered “health professional students” under proposed paragraph (f)(5), now designated paragraph (h)(3), because residents have prescribing power and therefore should receive drug information. We reject this suggestion because we believe that it would be

inappropriate to allow, as a general rule, drug marketing to target health professional students who are still in training. Such marketing is designed to promote the sale of a particular product, and not to educate health professionals about a variety of pharmaceutical products. In addition, under the rule, VA has the flexibility to allow all trainees including residents to receive marketing information at the discretion of the VA staff member providing clinical supervision. In this regard, we changed the language in paragraph (h)(3) to “the staff member providing clinical supervision” rather than simply “clinical staff member.” We believe this revision adds clarity.

Finally, we note that we are changing a reference used in the definition for “VA National Formulary (VANF) drugs and/or drug-related supplies.” We are changing “local office of the Chief of Pharmacy Services” to the “VA medical facility’s Chief of Pharmacy Services.” This is simply a technical edit that makes this clause consistent with the language added in definitions discussed above, and provides more clarity to the public. We make a similar change to proposed paragraphs (e)(1), now designated paragraph (g)(1) and proposed paragraph (f)(2), now designated paragraph (h)(1). Specifically, we change references to “local policies” and “local office of the Chief of Pharmacy Services” to “medical center policy” and “VA medical facility office of the Chief of Pharmacy Services.”

Requests for Clarification

For clarity, we have restructured the content of proposed paragraphs (b) and (c) regarding the basic requirements for promotion, into newly designated paragraphs (c), (d), and (e). The proposed rule addressed the requirements for promotion in terms of three categories of drugs and drug-related supplies: (1) VANF drugs and drug-related supplies, and non-VANF drugs and drug related supplies with criteria-for-use; (2) non-VANF drugs and drug-related supplies without criteria-for-use; and (3) new molecular entities. This final rule continues to address drugs and drug-related supplies in terms of these three categories, however, to make the requirements associated with each of these three categories of drugs or drug-related supplies more clear, we have broken the rule out into separate paragraphs addressing each category of drug or drug-related supply. The substance of these sections remains virtually the same with organizational changes for clarity. Paragraph (c) provides the requirements for

promotion of VANF drugs and drug-related supplies, and non-VANF drugs and drug related supplies with criteria-for-use. Paragraph (d) provides the requirements for promotion of non-VANF drugs and drug-related supplies without criteria-for-use, which include an approval requirement on top of the three requirements under paragraph (c). Similarly, paragraph (e) provides the requirements for promotion of new molecular entities, which include an approval requirement on top of the requirements found under paragraph (c).

One consistent concern expressed by the commenters was the relationship between this rule and laws administered by the FDA. As explained throughout this rulemaking, we have made clarifications where commenters have noted the possibility of a perceived conflict. Thus, we have clarified that promotion must be consistent with FDA laws and VA criteria-for-use. We note that nothing in this regulation should be construed as permitting promotional or educational activities that are not in compliance with applicable FDA requirements.

The proposed rule had stated that educational programs and associated materials must conform to the requirements detailed in paragraphs (d)(1) through (9), now designated paragraphs (f)(1) through (6). A commenter recommended that we clarify in proposed paragraph (d) whether educational programs and associated materials will be deemed suitable if they satisfy those requirements. We accept this recommendation and have changed the language in the rule to reflect this clarification. Paragraph (f) now states: “[E]ducational programs and associated materials will be deemed suitable if the approval authority determines that they conform to the following requirements.” We have also removed the word “new” as a modifier for “drug” and “drug-related supply.” We believe that the use of the term “new drug” could confuse sales representatives because this is a term that is specifically defined by the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. 321(p). VA used the word “new” in the proposed rule to limit this sentence only to drugs and drug-related supplies that are “already on the VANF but ha[ve] not yet been reviewed by VA[.]” Because this clause already exists in the regulation text, the word “new” is extraneous and is removed.

Another comment suggested that VA clarify the “clear identification” requirements that had appeared in proposed paragraphs (d)(6) and (d)(7), in order to give companies proper notice about how to comply with the rule. As

explained below, we have replaced the “clear identification” requirement with a specific requirement that educational programs and associated materials regarding a drug, drug-related supply, or therapeutic indication be submitted to a specific approval authority. With respect to educational programs and associated materials regarding non-VANF drugs or drug-related supplies without criteria-for-use, we have cross-referenced the approval and other requirements found in newly designated paragraph (d). We note that the 60-day submission requirement applies to all proposed educational programs and associated materials.

One commenter requested that VA clarify that the provision of journal articles that increase the reader’s knowledge should be specifically exempted from the rule, or otherwise advise how journal articles may be provided in compliance with the rule. There exist multiple avenues for the distribution of journal articles and similar information and therefore we decline to make any change in response to this comment. First, we note that VA staff and patients are free to research and acquire any medical literature they see fit. Second, as noted above, we have clarified in new paragraph (a) that “[t]his rule governs on-site, in-person promotional activities * * *. It does not apply to the distribution of information and materials through other means.” Therefore, journal articles may be distributed in connection with on-site activities as long as the pharmaceutical company representative complies with the requirements of this rule. Further, nothing in this rule can or should be interpreted to prevent the distribution of such materials through means other than on-site, in-person distribution (e.g., through the mail). For further guidance, we note that parties distributing journal articles or other reprints that contain off-label uses should consult the FDA’s “Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices.”

We received multiple comments requesting clarification of the content of proposed paragraph (e), now designated paragraph (g), as it relates to the provision of free drugs by pharmaceutical company representatives. We agree with the comments that “donations” is a misleading phrase to use because it might connote charitable donation programs in which pharmaceutical companies participate. Therefore, we have removed all references to

“donations” and instead use the term “samples.” One commenter asked that VA clarify the meaning of the phrase “trial-use” and clarify the relationship between proposed paragraph (e)(2) and clinical trials. The phrase “trial-use” was intended to refer to the use of the samples on a trial basis. However, as the comment demonstrates, use of the word “trial” might connote formal clinical trials. Therefore, we have revised proposed paragraph (e)(2), now designated paragraph (g)(2), to remove the reference to “trial-use” and instead state that “[a]ll usage information pertaining to the intended use of these drugs or drug-related supplies must be forwarded to the VISN Pharmacist Executive or VISN Formulary Committee.”

Further comments on proposed paragraph (e)(2), now designated paragraph (g)(2), suggest that VA should clarify the conduct that constitutes compliance with this paragraph, and clarify whether VA employees may accept samples from their own personal, non-VA physicians. We have made minor revisions to the language of this section to clarify the requirements for drug samples. First, we clarify that the pharmaceutical company representative “must submit samples of drugs and drug-related supplies for approval to the person at the medical facility to whom such responsibility is delegated under local policy, usually the Director.” Second, we require that “[a]ll usage information pertaining to these drugs or drug-related supplies must be forwarded to the VISN Pharmacist Executive or VISN Formulary Committee.” Third, assuming approval of a drug or drug-related supply has been obtained, we require that “[a]ll samples of drugs or drug-related supplies must be delivered to the Office of the Chief of Pharmacy Services for proper storage, documentation and dispensing.” Third, this rule does not regulate the conduct of VA employees when receiving medical care from their own physicians, and nothing in this rule may be construed as regulating the private relationship between a VA employee and his or her personal doctor. Therefore, we make no change to the statement that “[d]rug or drug-related supply samples may not be provided to VA staff for their personal use.” Finally, we removed the clause “the intended use of” in reference to information that “must be forwarded to the VISN Pharmacist Executive or VISN Formulary Committee. We did not intend to limit “information” to the intended use of the drug; rather, we intended to require that pharmaceutical

companies forward appropriate information.

We also revised the last sentence of proposed paragraph (e)(1), now designated paragraph (g)(1), to remove the words “of travel” that had appeared in the proposed rule, because the statutory authority applies to all gifts in support of VA staff official travel, not just “[g]ifts of travel.”

Another comment requested that the prohibition on pharmaceutical company representative visits and the distribution of materials, in instances where VA staff or departments indicate that they wish not to be called on by pharmaceutical company representatives, should exclude visits and materials that are necessary for patient safety, such as product recalls or critical, substantive changes to warnings about particular medications. We decline to make any changes based on this comment. First, we note that most communications of this nature can be made more quickly and effectively through electronic or telephonic communication, and personal visits should not be required. Second, the rule does not prohibit on-site distribution of any patient safety materials to the VA medical facility office of the Chief of Pharmacy Services or similar other appropriate authority for distribution as necessary for patient safety. In other words, if necessary, important patient safety information can be provided in-person to the VA medical facility office of the Chief of Pharmacy Services or other appropriate authority for distribution by VA.

A similar comment suggested that VA include a patient-safety exception to the educational programs and associated materials requirement in proposed paragraph (d)(4), now designated paragraph (f)(3). Specifically, the commenter requested that the rule permit documents and discussions related to an FDA-required risk evaluation and mitigation strategy, as well as product safety warning and other labels. We recognize the value of the information and did not intend the rule to conflict with any FDA requirements. Therefore, we have revised the rule to specify the permissibility of solicitation of protected health information or patient participation in pharmaceutical company-sponsored programs when “required by Federal laws and regulations such as an educational program that is part of a risk evaluation and mitigation strategy required by the Food and Drug Administration.”

One commenter requested that VA clarify in proposed paragraph (f) whether pharmaceutical company representatives will be permitted to

leave materials for individuals or departments on the do-not-call list when they are on-site for a scheduled appointment with another provider. We have clarified in newly designated paragraph (h)(1) that pharmaceutical company representatives may not “leave any materials for” any individuals or departments on the do-not-call list. The reason for this prohibition is that leaving products in this manner may disrupt our medical professionals’ regular activities, particularly given that such professionals have put their names on a do-not-call list. Moreover, patients who see such products may be misled into believing that VA endorses the use of such product. As noted several times in this notice, nothing in this rule prohibits the transmission of materials by mail, and for the purposes of facilities management, we would prefer that materials be distributed in this manner.

A commenter requested that VA define or provide examples of a “medical center conference” in proposed paragraph (f)(6), now designated paragraph (h)(4), and provide an exception allowing pharmaceutical company representatives who sign a form or agreement to attend such conferences. We decline to define the term or provide examples because we believe this term is unambiguous. We reject the requested exception because patient-specific information may be discussed at medical center conferences, and an exception allowing pharmaceutical company representatives to attend these conferences would be inconsistent with VA’s vigorous protection of patient privacy. We note that we have revised the phrase “patient-specific material” to “information regarding individual patients.” We believe that this language more precisely reflects the intended notion of protection of patient privacy. In addition, we have reworded the paragraph so that it says that a “pharmaceutical company representative may not attend a medical center conference where information regarding individual patients is discussed,” where the proposed rule had said that a “sales representative is not allowed to attend a medical center conference where patient-specific material is discussed.” The new phrasing is consistent with now designated paragraph (g)(3) and does not change the meaning.

Another comment suggested that VA clarify that this rule is implemented in the spirit of supporting appropriate pharmaceutical company representative access to VA facilities and staff. We agree with the spirit of this comment.

VA fully intends to continue our positive relationships with pharmaceutical companies and pharmaceutical company representatives in the future. However, there is no need to revise the rule to add such a statement.

Comments That Provisions of the Rule are Redundant, or are Governed by Other Law or Guidance

As discussed earlier in this rulemaking, some commenters indicated that portions of the rule are unnecessary because the regulated behavior is also subject to other laws and/or regulations. For example, one comment stated that we need not regulate the provision of gifts or food to VA employees, because pharmaceutical company representatives are already subject to other ethical guidelines that address the behavior of pharmaceutical company representatives in this regard. We make no changes based on these comments. Such other laws and/or regulations are consistent with our regulation, and certainly restating the requirements in our own regulation does not adversely affect anyone, notwithstanding the commenters’ characterization of these provisions as being “redundant.” Moreover, centralizing the relevant information in a single regulation will have administrative benefits. Other commenters objected to portions of the rule that they perceived as conflicting with or being duplicative of other laws and regulations. We address these comments below.

The limitations on the pharmaceutical company provision of food and gifts to VA employees are consistent with Standards of Ethical Conduct applicable to Executive Branch Employees, and restating the requirements in our own regulation provides clarity and does not adversely affect anyone, notwithstanding the commenters’ characterization of these provisions as being “redundant.” To the extent that industry ethical standards impose similar requirements on their sales representatives, we note that such restrictions may be revised by industry. Moreover, centralizing the relevant information in a single regulation will have administrative benefits. One commenter stated that the rule’s criteria-for-use requirements can conflict with the FDA’s approval of certain prescribing information, also known as “labeling.” We make no changes based on these comments. While FDA approves drugs for certain purposes or uses based on the population at large and potential uses for the drug, VA further considers how a certain drug may be best-used for the benefit of our

unique patient population. While VA criteria-for-use may be more specialized or tailored than FDA-approved labeling, such criteria-for-use will not contradict FDA-approved labeling. If a pharmaceutical company representative believes that VA criteria-for-use contradicts FDA-approved labeling, that representative should seek clarification from the VISN Pharmacist Executive, or Chief of Pharmacy Services, or designee.

One commenter stated that VA should consider alternatives to the requirement that VA officials in the field review all educational programs and associated materials because the materials are already regulated by FDA, and the review requirement would place a large administrative burden on VA facilities. Another commenter requested that VA exclude from the rule educational materials that FDA does not require companies to disseminate, but does require to be submitted for FDA review, because a second layer of review is redundant and may undermine FDA's expertise if VA reaches a conclusion that differs from FDA. We decline to make any changes based on this comment. Pharmaceutical company representatives should only be distributing material that conforms with Federal laws and regulations including those administered by the FDA. Whether an educational program and associated materials are appropriate for a scheduled event is a narrower question. For example, a pharmaceutical company representative may seek approval for an educational program regarding a diabetes drug, but also wish to include materials related to a blood pressure drug. The VA approval authority could deny approval of the materials based on the inclusion of irrelevant material. However, this denial would not be a second review of the content of the FDA-approved material.

One commenter recommended that VA provide an appropriate staff member with discretionary authority to permit manufacturer-sponsored programs due to their potential benefit to patients. We reject this recommendation because the final rule presents pharmaceutical company representatives and companies with a clear procedure, described in proposed paragraph (d), now designated paragraph (f), to obtain approval for such programs at VA facilities. VA facilities' highest priority must at all times be to provide direct care to its patients, and must have the ability to limit the quantity and timing of programs so as not to impede clinicians' ability to provide care. It is inevitable that limited openings and competing programs will require that VA facilities determine which option is most

clinically appropriate for its patients. For example, a VA facility may schedule a program detailing a new flu vaccination just before the start of flu season because it is timely and will impact a greater number of patients at their individual facility, rather than host a requested program about prenatal care. We note that the program about prenatal care need not be rejected outright and may be considered for a future date. Paragraph (f) will ensure that the clinical interests of VA's patients at each facility remain the most important factor in determining whether to permit educational programs and materials at VA facilities.

Another comment suggests that the requirement in proposed paragraph (d)(5), now designated paragraph (f)(4), that allows qualified VA pharmacy staff to grant exceptions to the logo display limitations may lead to unequal application in the field and should be removed. We disagree with this comment. Each VA medical facility must consider the needs of its individual patient populations in reaching determinations about educational materials, and we do not intend to limit their discretion by requiring VAMC acceptance or rejection of such materials. We note as well that the rule has specific standards that will prevent or minimize the potential for unequal application in the field, which include that the logo or name need not be removed if it is inconspicuous or if legal requirements (e.g., trademark requirements) make removal impractical. As explained previously, we have also added the statement that "this requirement does not apply to labeling required by the Food and Drug Administration," so as to ensure that this provision of the regulation does not conflict with FDA laws and regulations.

One commenter objected to the prohibition on labeling drug samples as "samples," because that restriction contradicts with the Prescription Drug Marketing Act, which requires samples to be labeled as such. We agree with this comment and have removed the prohibition on labeling drug samples as "samples."

Recommended Policy Changes

One commenter requested an exception for the distribution of information about new molecular entities to certain VA decision-makers, including the VISN Pharmacist Executives, Chiefs of Pharmacy, specialty physicians and formulary decision-makers for each VAMC and VISN. As discussed above, the rule does in fact authorize the promotion of new molecular entities under proposed

paragraph (c)(3), now designated paragraph (e). New molecular entities may be promoted at the discretion of a VISN Pharmacist Executive, Chief of Pharmacy Services, or designee. We do not believe it is necessary—or the best use of VA's resources—to limit the Executive's discretion in selecting a designee, or to require in all VISNs that the individuals described by the commenter be authorized to make this decision.

We have revised the definition of "new molecular entity" in proposed paragraph (a). The proposed rule defined the term as "an active ingredient that has never before been marketed in the United States in any form," which would be a virtually impossible standard to measure, as there is no clear way to determine whether an ingredient has "ever" been marketed "in any form." Therefore, we have revised the definition of the term to read: "a drug product containing an active ingredient that has never before received U.S. Food and Drug Administration approval." Because VA lacks the expertise of FDA to independently analyze new molecular entities for safety and other purposes, we rely on those determinations already made by FDA regarding such entities. This revision should clarify some of the commenters' confusion as to the definition of new molecular entities, and in addition no longer defines the term in connection with marketing.

A separate comment was that VA should not require authorization by VISN Pharmacist Executives or the Chief of Pharmacy for promotion of non-VANF drugs, because each VA Medical Center could potentially adopt a different administrative approach, which may lead to educational disparity among VA staff. We reject this suggestion and continue to grant each VISN the flexibility to determine whether the promotion of a non-VANF drug is appropriate given the needs of its unique patient population. Adopting a single national policy regarding the promotion of non-VANF drugs would negatively impact patient care because VA medical centers must consider the specific needs of their patient population based on unique geographic and other demographic factors. For example, drugs such as certain antibiotics can and should be treated differently for rural and urban populations in order to maximize the effectiveness of the drug. Other examples would include facilities located in communities in which a particular illness is more prevalent, such as certain respiratory infections, or facilities that focus on the treatment of

a specific disease or disability. A single national policy would prove too rigid to meet the needs of VA patients at the local level.

Another commenter stated that VA should presumptively disallow educational programs and materials focusing on non-VANF drugs or drug-related supplies because promotion of such drugs can undercut the legitimacy of VA's medical formulary. We do not agree with the commenter to the extent that the comment can be read to suggest that non-VANF drugs without criteria-for-use should never be promotable. We believe that the provisions of newly-designated paragraph (d) contain sufficient safeguards on promotion of such drugs and drug-related supplies.

On the other hand, one comment suggested that VA not discourage the dissemination of educational programs or associated materials that focus on non-VANF drugs or drug-related supplies, because physicians only stand to better serve their patients by having access to such information. We have made several modifications to the rule to clarify the requirements for educational programs and associated materials regarding (1) a drug, drug-related supply, or new therapeutic indication for a drug that is already on the VANF, but has not yet been reviewed by VA; or (2) non-VANF drugs or drug-related supplies without criteria-for-use. Specifically, we have revised the substance of proposed paragraph (d)(6), now designated paragraph (f)(5), to require submission and approval of educational programs and associated materials regarding a drug, drug-related supply, or therapeutic indication to the VA medical facility's Chief of Pharmacy Services or designee. In turn, we removed the requirement that such educational programs and materials be clearly identified as discussing a new drug, drug-related supply, or therapeutic indication. We believe that submission to and approval by the Chief of Pharmacy Services or designee will ensure that such educational programs and associated materials are suitable. Similarly, we have revised the substance of proposed paragraph (d)(7), now designated paragraph (f)(6), to permit educational programs and associated materials regarding non-VANF drugs or drug-related supplies without criteria-for-use only if those drugs or drug-related supplies may be promoted under newly designated paragraph (d), which contains the requirements for promotion of non-VANF drugs or drug-related supplies without criteria-for-use. This revision removes the language from the proposed

rule stating that such educational programs and associated materials "are discouraged." Again, we believe that the review and approval procedures for these educational programs will ensure that these educational programs and associated materials are suitable.

One commenter requested that VA require direct comparison between industry-sponsored and non-sponsored sources in any disclosure. We agree with this comment with respect to educational programs and associated materials and added a new paragraph (f)(2) requirement that such a comparison be made where both industry-sponsored and non-sponsored sources of information exist for FDA-approved uses of a particular drug. We believe that such a comparison will provide VA staff with the ability to review the full range of data that exists for a particular drug within the limits established by FDA through comprehensive research, which will enable them to make the best decisions for VA patients. This commenter also suggested that VA educational material requirements should include a uniform format for disclosure of industry sponsorship. Additionally, the commenter recommended that VA regulate the format of disclosures in accordance with findings that maximize the effectiveness of disclosures on reducing the influence of marketing over physicians' decision-making. VA acknowledges the potential advantages to a uniform format and increased knowledge about the impact of disclosures, but these recommendations are beyond the scope of this particular rulemaking.

One commenter suggested that VA change the requirement that educational programs and materials must not contain company names or logos, stating that the requirement in proposed paragraph (d)(1) that such materials disclose any industry sponsorship, directly conflicts with proposed paragraph (d)(5), which states that no company names or logos may appear on patient educational materials. We make no changes based on this comment and note that the provision in proposed paragraph (d)(1) relates to introductory remarks and announcement brochures for educational programs. In contrast, proposed paragraph (d)(5) pertains to patient education materials. Therefore, we do not agree that any conflict exists between the two provisions. We note that proposed paragraphs (d)(1) and (5) are now designated as paragraphs (f)(1) and (4).

With respect to the limitation in proposed paragraph (d)(5), now designated paragraph (f)(4), on name

and logos on patient educational materials, one commenter argued that smaller drug manufacturers will be unable or unwilling to produce literature specifically for VA due to cost. We note again that this rule applies only to in-person activities, and that companies (large or small) who do not wish to comply with paragraph (f) are free to continue to distribute their materials through other means. Nevertheless, we have inserted a sentence to clarify that proposed paragraph (d)(5), now designated as paragraph (f)(4), concerning logos, "does not apply to labeling required by the Food and Drug Administration."

According to one commenter, VA should permit physicians to grant meetings with pharmaceutical company representatives in patient care areas, particularly where working with a physician in a patient care area is necessary. We make no changes based on this comment. VA is committed to protecting patient privacy and generally does not find it appropriate for a pharmaceutical company representative to attend a meeting in a patient care area. However, we note that at many VA medical facilities, the offices for key VA staff members working in the emergency rooms are physically located within the emergency room itself. We do not intend to prevent qualified VA staff from holding meetings with pharmaceutical company representatives in their offices simply because the office is within the emergency room. We therefore have clarified that the patient-care area of the emergency room does not include staff offices that may be located in the emergency room by adding a parenthetical to that effect after "emergency rooms" in the list of "patient-care areas" under paragraph (h)(5), which was proposed paragraph (f)(7).

Another commenter suggested that VA should permit brochures in patient waiting areas because there is no disruption to treatment, and recommended that literature meeting FDA requirements should be presumptively permissible, and the display of a company's logo should not be restricted. We decline to permit brochures in patient waiting areas and have moved this prohibition from the section of the rule discussing educational programs and associated materials to the section of the rule discussing conduct of pharmaceutical company representatives more generally to clarify that distribution of such educational material is limited not only in connection with an educational program. This provision is now located

at paragraph (h)(6) and states: "Pharmaceutical company representatives may only distribute materials on-site at the time and location of a scheduled appointment or educational program. In no circumstances may materials be left in patient care areas." We believe that the prohibition on placement of materials in patient care areas is necessary because manufacturer-sponsored brochures may not be consistent with VA's drug therapy management processes and could lead to confusion. VA occasionally determines that for the purposes of its patient population, the best use of a given drug may be for a specific use, rather than the broad array of conditions that FDA may have approved the drug for. Therefore, patients may become confused if promotional materials appear inconsistent with the VA clinician's appropriate use of the drug. Providing brochures in patient waiting areas could also create a perceived VA bias for or against certain products.

A commenter asserted that proposed paragraph (d)(3) would have a negative effect on patient care by preventing distribution of materials regarding Patient Assistance Programs (PAPs). Proposed paragraph (d)(3) stated that "[p]romotional materials are not to be placed in any patient care area." As explained above, this provision was moved to a different part of the rule, is now designated as paragraph (h)(6), and states: "Pharmaceutical company representatives may only distribute materials on-site at the time and location of a scheduled appointment or educational program. In no circumstances may materials be left in patient care areas." Patients who are using a particular drug and who require information distributed specifically to them through a PAP will not be affected by this paragraph; however, the distribution of such materials will have to be performed in accordance with the regulation. Under the regulation, PAP-related materials may be distributed directly by a pharmaceutical representative on-site pursuant to a scheduled appointment or approved educational program, or indirectly via mail. This will have no negative impact on patient care because VHA has always ensured, and will continue to ensure, that patients obtain any information necessary for their care.

A commenter asserted that the rule can be read to apply to drug company provision of items in connection with research trials. We emphasize that the marketing or in-person solicitation of any approved drug is governed by this regulation. This will have no impact,

however, on the process for approving research protocols; it simply affects when and how materials concerning drugs are marketed on-site at VA facilities.

Finally, a commenter raised a concern that the regulation will undermine the ability of Federal Supply Schedule (FSS) contractors to market products that are on the FSS. Placement of a product on the FSS merely affects the price that VA will pay for the product. It has no impact on the in-person solicitation or promotion of that drug within VHA facilities. Whether or not a drug is on the FSS should not authorize a company's sales representative to behave differently from representatives of drugs that are otherwise recognized or approved for distribution to VA patients.

Comments Regarding the Disciplinary Process

We received a number of comments regarding the proposed disciplinary process, including a suggestion to remove proposed paragraph (g) in its entirety. We make no changes to the disciplinary process based upon the comments because such a process is necessary to protect patient safety, as well as VA staff's ability to provide the highest quality services to patients. We also note that VA does not intend to impose sanctions except as necessary to prevent future impropriety. However, it is important that we maintain the ability to do so. Although we decline to change the disciplinary process described in the proposed rule, we have made organizational changes to the disciplinary section of the rule to more clearly describe the process. Specifically, proposed paragraph (g) has been designated as paragraph (i) and now includes headings. We revised the heading of the entire paragraph from "Failure to properly promote drugs or drug-related supplies within VA" to "Non-compliance" because this heading is both more concise and accurate. We have also made non-substantive language changes for purposes of clarity. For example, we have removed the terminology referring to "sales force" and "regional managers" and instead use the defined term "pharmaceutical company representative" in the interest of clarity and consistency. In addition, we have removed the phrase "commercial visits" and refer only to "visits" as the modifier "commercial" is unnecessary.

A commenter suggested that VA clarify in the supplementary information of this rulemaking that most often problems between VA and pharmaceutical company

representatives will be resolved informally and that formal action should be limited. We agree with this comment and further note that VA seeks to continue the traditionally amicable nature of interaction with pharmaceutical company representatives and companies at both the national and local levels. We make no changes to the regulation based upon the comment.

Another commenter stated that VA should provide clear guidance on which circumstances would justify a penalty to an entire sales force as opposed to an individual representative, as well as what would justify a penalty extending to other VA facilities. The commenter also requested clarification on what is meant by "permanent revocation of commercial visiting privileges." We do not believe that the provisions are ambiguous. VA will analyze violations on a case-by-case basis. The rule provides sufficient notice of the acceptable and unacceptable behavior of pharmaceutical company representatives on VA property, and the distribution of materials while on VA property. The rule also provides sufficient direction as to the process that VA will follow when we are required to formally address non-compliant behavior. However, in response to the request for greater clarity, we have revised the rule so that rather than refer to "instances of widespread misconduct" in proposed (g)(3), paragraph (i)(2) now refers to "multiple instances of misconduct." The word "widespread" could be misinterpreted to refer to the geographical location of the misconduct, rather than the recurrence of misconduct.

A commenter stated that proposed paragraph (g), now designated as paragraph (i), denies pharmaceutical companies due process, and suggests that VA require the opportunity for a hearing before revoking a representative or company's ability to speak with physicians at a VA facility. Another commenter requested that VA only limit restrictions to the specific VA facility in which the noncompliance with this rule occurred. We make no changes to the rule based on these comments. Due process concerns are not present here because revocation of visiting privileges would not deprive a pharmaceutical company representative of a constitutionally protected property interest. Further, we believe that the processes described in paragraph (i) are reasonable. Under paragraph (i), a pharmaceutical company representative and/or his or her supervisor is given notice of the noncompliance and the Director's interim action, a 30-day

window to respond to such notice, and a final written order detailing the circumstances of the violation and the reasons for the final action. Further, a pharmaceutical company is also given an opportunity for review of that final written order by the Under Secretary for Health. We have added to the first sentence of paragraph (i)(3) the word "either" to further clarify that the Director's final order must "either" confirm the action in the notice "or" specify another action.

Other related comments stated that VA should be required to notify the company of the noncompliance of one of its representatives. We believe that the burden to notify the company is properly placed on the pharmaceutical company representative. However, this rule does provide that VA will notify the appropriate manager or supervisor of the pharmaceutical company representative in instances where VA has found multiple instances of misconduct by an individual or multiple representatives.

One commenter asked that penalties "[g]enerally * * * not be enforced during the notice period." Again, the regulation provides clear notice of what behaviors are unacceptable. The type of enforcement that would occur during the notice period would be restriction of an individual pharmaceutical company representative's access to a facility or facilities. We believe that this minimal restriction must be enforced during the notice period in order to prevent recurrence or escalation of the behavior at issue.

Additionally, we disagree with one commenter's assertion that the activities governed under this rule do not pose a security risk. VA has three primary objectives in limiting the privilege of pharmaceutical company representatives' promotional activities in VA facilities. First, our primary purpose in creating this rule is the protection of our patients' safety. Second, we seek to protect the integrity of VA's National Formulary and criteria-for-use. Third, we aim to protect the amount of time that VA clinicians have to commit to their patients. We believe that actions by pharmaceutical company representatives that violate any of the provisions of this rule threaten these goals.

Finally, a commenter asked whether a permanent revocation could be subject to subsequent review. We note again that such revocation may be appealed by the pharmaceutical company representative or company to the Under Secretary for Health within 30 days of the order for revocation.

Legal Arguments

One commenter contends that the proposed rule would violate the First Amendment protection of free speech by requiring that drugs and drug-related products, which are non-VANF and which have no criteria-for-use, may be promoted only if "the promotion is specifically permitted by the VISN Pharmacist Executive, or Chief of Pharmacy Services or designee."

Specifically, the commenter maintains that the proposed rule's procedure for obtaining permission to promote such drugs and drug-related products results in a content-based restriction on free-speech which "denies patients the benefit of their doctor's most informed judgment on what is the right approach for their individual situation." The commenter states that VA has not explained how the above approval requirements are related to the goals enunciated in the proposed rule and advocates for decision authority to be given to VA medical departments and practitioners rather than pharmacy management.

We do not agree with the contention that the proposed procedures violate the First Amendment guarantee of free speech and thus reject the commenter's recommendations that VA give the decision authority to medical staff departments and practitioners rather than to pharmacy management. We do, however, believe that it is necessary to clarify the basis for these procedures.

First, this additional procedural requirement on promotion of non-VANF drug and drug-related supplies without criteria-for-use in VA hospitals is not a restriction of First Amendment free speech rights. We know of no right to discuss products with Government officials acting in their official capacity.

Specifically, the commenter does not contend that certain government property, which is open to other speakers, has been closed to pharmaceutical company representatives for use in communicating with private individuals or public officials not acting as such who might be willing to listen to them. Rather, the commenter appears to be claiming that pharmaceutical company representatives have an entitlement to a Government audience, VA physicians, so that they can express their views on non-VANF products without criteria-for-use. VA does not have an affirmative duty under the Constitution to listen to these views, nor is the Department in any way restricting pharmaceutical company representatives from communicating these views to members of the public, including VA physicians

in their personal capacity, in a proper forum for free speech. VA hospitals are not such a forum.

Additionally, there is an important rationale supporting our proposal for more restrictive procedures for promotion of non-VANF drugs without criteria-for-use to VA doctors at VA facilities. That rationale is primarily based on the need to maintain and enhance patient safety. The VANF is a list of drugs that are approved either for general use or with specific criteria-for-use. They are placed on the VA National Formulary through a rigorous and scientifically-based process, in which patient safety is paramount with cost being a secondary consideration.

In this process, VA's Medical Advisory Panel (MAP), which includes physicians from both VA and the Department of Defense, and the VISN Pharmacist Executives (VPE) Committee reviews drugs and drug related supplies, including new molecular entities to determine their appropriate use in the VA patient population. An evidence-based process is used to determine such appropriate use, with the primary factors being patient safety and therapeutic value; improved access to pharmaceuticals; promotion of a uniform pharmacy benefit; and reduction in the acquisition cost of drugs when feasible. The VANF supplants the local and VISN formularies which previously existed. This migration to a National Formulary has allowed VA to rely more uniformly on evidence-based drug evaluations further enhancing patient safety.

The MAP and VPEs also contribute valuable experience and expertise in meeting the unique medication therapy needs of Veterans on an ongoing basis. For example, VA uses this expertise to closely manage a drug marketed for smoking cessation due to the potential for significant adverse drug events in patients with certain clinical characteristics that are over represented in the VA patient population. Drugs that are not approved for the National Formulary, also known as non-formulary drugs, may still be prescribed in specific instances via VA's formal non-formulary request process.

As a participant in the process to determine which drugs will appear on the VANF, and the appropriate uses for each, the VISN Pharmacist Executive, in consultation with the local Chief of Pharmacy, who has ultimate responsibility for prescribing practices at his or her facility, are the officials best-suited to determine when to allow promotion of Non-VA VANF products without criteria-for-use. Having an official with region-wide responsibility

for prescribing also better serves VA's ability to maintain uniform prescribing practices, which, as discussed above, has allowed VA to rely more uniformly on evidence-based drug evaluations.

Under the proposed rule, pharmacy management, the VA professionals with the detailed knowledge and expertise to make the decision on promotion of drugs that are non-VANF without criteria-for-use would be given the authority to make the decision. They would be acting in accord with input received from VA physician members of the MAP based on their review of available evidenced-based drug evaluations and thus best protect VA patients.

Another commenter requested that VA "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." We make no changes based on this comment. First, this rule specifically precludes the application of VA's general prohibition against solicitations to pharmaceutical company representatives' promotion of drugs. VA strictly prohibits solicitation under 38 CFR 1.218(a)(8), yet this rule permits promotion, including educational activities, by pharmaceutical company representatives within the parameters set forth in the rule. Second, this rule sets precisely those "time, place and manner conditions" that the commenter requested. If the pharmaceutical company representative complies with the provisions of this rule, then an on-site, in-person visit will be granted. We note that pharmaceutical company representatives are not communicating with a public audience when speaking with VA staff in their professional capacities. On-duty VA staff, including health professionals charged with the duty to care for VA's patients, must be able to work without disruptions, and VA appropriately limits the public's access to VA facilities and staff to protect the safety and privacy of VA patients.

Commenters suggested that VA consult with the United States General Services Administration before implementing a rule that may interfere with contracts between VA and companies under the FSS rate, at which companies are willing to sell in exchange for marketing opportunities. We note that in the instance that this regulation interferes with any existing contracts, the terms of those contracts will continue to be honored. However, VA is not aware of any contracts that exist with any pharmaceutical

companies that contain provisions like those mentioned by the commenter and we therefore make no changes to the rule at this time.

One commenter recommended that VA preempt local policies that may treat pharmaceutical company representatives who discuss prohibited topics as criminal trespassers. We decline to make any changes to the rule based on this comment for the following reasons. Currently, § 1.218, regarding security and law enforcement at VA facilities, describes general behavior that is prohibited on the grounds of VA property, and authorizes criminal sanctions in certain circumstances. Under § 1.218, persons who are not authorized to enter or remain on VA property are subject to a fine and/or a term of up to 6 months in prison. Under this final rule, § 1.220, VA may ultimately suspend or revoke visiting privileges for a pharmaceutical company representative or multiple representatives. Any such determination could be appealed to the Under Secretary for Health under paragraph (i)(5). If such suspension or revocation were imposed, then those representatives would not be authorized to enter VA property and would be subject to the sanctions listed in § 1.218(b).

At the same time, we note that this rule does indeed preempt all existing local policies that contradict this rule, as requested by the commenter. If the policy described by the commenter violates the rule then it is no longer lawful or effective; however, we have not been able to authenticate the memorandum described by the commenter.

A commenter suggested that VA "adopt[] a uniform format for disclosure of industry sponsorship." We are unsure what is intended by this comment, but it appears that the commenter is requesting that VA adopt formats adopted by the Journal of the American Medical Association. We believe that this rule provides clear national guidance on disclosures, and the policies expressed in the rule are based on the particular needs of VA. As a government-run, national health care provider employing a wide variety of medical professionals and treating primarily our nation's veteran population, we believe that it is appropriate to adopt specific guidelines relevant to our national practice. We make no changes based on this comment.

Effect of Rulemaking on Local Policies

Some commenters recommended that VA explicitly preempt local policies

with this rulemaking, or clarify that the new national policy will replace all existing local policies and provide substantive guidelines to the field. The commenters do not provide, and we are not aware of, any examples of official VA statements of policy (such as directives or handbook provisions) that conflict with this rule. If we were aware of such conflicts, we would specifically rescind such statements. Further, this regulation as a matter of law preempts any inconsistent local policies.

To the extent that VA employees in the field require further guidance than that provided in the rule, VA will issue policy directives and handbooks. This rule does not prevent the issuance of such guidance if such guidance is not in conflict with this rule. In fact, the existence of this regulation will provide VA a legal basis to issue and implement such non-regulatory guidance.

Title 38 of the Code of Federal Regulations, as revised by this final rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary rules or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Executive Order 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a "significant regulatory action," which requires review by the Office of Management and Budget (OMB), as "any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere

with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order."

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined and it has been determined to be a significant regulatory action under Executive Order 12866.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any given year. This final rule has no such effect on State, local, or tribal governments, or on the private sector.

Paperwork Reduction Act

This final rule does not contain any collections of information under the Paperwork Reduction Act (44 U.S.C. 3501–3520).

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This final rule will not cause a significant economic impact on health care providers, suppliers, or other small entities. The rule generally concerns the promotion of drugs by large pharmaceutical companies and only a small portion of the business of such entities concerns VA beneficiaries. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Catalog of Federal Domestic Assistance Numbers

The Catalog of Federal Domestic Assistance numbers and titles are 64.009 Veterans Medical Care Benefits, 64.010 Veterans Nursing Home Care and 64.011 Veterans Dental Care.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the

Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on October 4, 2011, for publication.

List of Subjects in 38 CFR Part 1

Administrative practice and procedure, Archives and records, Cemeteries, Claims, Courts, Crime, Flags, Freedom of Information, Government employees, Government property, Infants and children, Inventions and patents, Parking, Penalties, Privacy, Reporting and recordkeeping requirements, Seals and insignia, Security measures, Wages.

Dated: February 29, 2012.

Robert C. McFetridge,

Director of Regulation Policy and Management, Office of the General Counsel, Department of Veterans Affairs.

For the reasons set forth in the preamble, the Department of Veterans Affairs amends 38 CFR part 1 as follows:

PART 1—GENERAL PROVISIONS

- 1. The authority citation for part 1 continues to read as follows:

Authority: 38 U.S.C. 501(a), and as noted in specific sections.

- 2. Add § 1.220 to read as follows:

§ 1.220 On-site activities by pharmaceutical company representatives at VA medical facilities.

(a) *Scope.* This rule governs on-site, in-person promotional activities, including educational activities, by pharmaceutical company representatives at VA medical facilities. It does not apply to the distribution of information and materials through other means.

(b) *Definitions.* For the purposes of this section:

Criteria-for-use means clinical criteria developed by the Department of Veterans Affairs (VA) at a National level that describe how certain drugs may be used. VA's criteria-for-use are available to the public at www.pbm.va.gov. Exceptions may be applied at the local level for operational reasons.

Drug or drugs means:

(1) Articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them;

(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

(3) Articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(4) Articles intended for use as a component of any article specified in paragraphs (1), (2), or (3) of this definition.

Drug-related supplies means supplies related to the use of a drug, such as test strips or testing devices, inhalers, spacers, insulin syringes, and tablet splitters.

New molecular entity refers to a drug product containing an active ingredient that has never before received U.S. Food and Drug Administration approval.

Non-promotable drugs are drugs designated by VA as non-promotable on <http://www.pbm.va.gov>. A list of the drugs or drug-related supplies classified by VA as non-promotable may be requested by contacting the VA medical facility's Chief of Pharmacy Services.

Non-VANF drugs or drug-related supplies means drugs or drug-related supplies that do not appear on the VANF.

Pharmaceutical company representative means any individual employed by or contracted to represent a pharmaceutical manufacturer or retailer.

VA medical facility means any property under the charge and control of VA used to provide medical benefits, including Community-Based Outpatient Clinics and similar facilities.

VA National Formulary (VANF) drugs and/or drug-related supplies means any drug or drug-related supply that appears on the VA National Formulary (VANF). The VANF is available at www.pbm.va.gov, or may be requested by contacting the VA medical facility's Chief of Pharmacy Services.

Veterans Integrated Service Network (VISN) means one of the networks of VA medical facilities located in a particular region as designated by VA.

(c) *Promotion of drugs and drug-related supplies.* Notwithstanding § 1.218(a)(8), VA will allow promotion of VANF drugs and drug-related supplies, and non-VANF drugs and drug-related supplies with criteria-for-use, on-site and in-person at VA medical facilities if all of the following are true:

(1) Drugs or drug-related supplies are discussed, displayed and represented accurately;

(2) The promotion has significant educational value and does not inappropriately divert VA staff from other activities that VA staff would otherwise perform during duty hours, including patient care and other educational activities; and

(3) The drug or drug-related supply has not been classified by VA as non-promotable.

(d) *Promotion of non-VANF drugs and drug-related supplies without criteria-for-use.* Non-VANF drugs and drug-related supplies without criteria-for-use may be promoted only if the requirements of paragraphs (c)(1) through (3) of this section are met and the promotion is specifically permitted by the VISN Pharmacist Executive, or Chief of Pharmacy Services, or designee.

(e) *Promotion of a new molecular entity.* A new molecular entity may be promoted only if the requirements of paragraphs (c)(1) through (3) of this section are met and the promotion is specifically permitted by the VISN Pharmacist Executive, or Chief of Pharmacy Services, or designee. Such permission will be automatically revoked if the new molecular entity is subsequently designated non-promotable. Such permission must be reconsidered if the new molecular entity is denied VANF status.

(f) *Educational programs and associated materials.* For purposes of this section, an educational program is a pre-scheduled event or meeting during which a pharmaceutical company representative provides information about a drug or drug-related supply. All educational programs and associated materials must receive prior approval from the person at the VA medical facility to whom such approval authority has been delegated under local policy, usually the Chief of Pharmacy Services. All materials associated with a proposed educational program must be provided at least 60 days before the proposed date of the educational program or distribution of associated materials, unless VA agrees in an individual case to a different date, so that a determination of their suitability can be made. The approval authority will deem suitable any educational program and associated materials if it is part of a risk evaluation and mitigation strategy or other duty imposed by the Food and Drug Administration. Otherwise, educational programs and associated materials will be deemed suitable if the approval authority determines that they conform to the following requirements:

(1) Industry sponsorship must be disclosed in the introductory remarks and in the announcement brochure. Sponsorship includes any contribution, whether in the form of staple goods, personnel, or financing, intended to support the educational program.

(2) If industry-sponsored and non-sponsored sources of data or other analytical information exist for FDA-

approved uses of a particular drug, a direct comparison between the two sources must be disclosed in the introductory remarks and in the announcement brochure.

(3) The educational program does not solicit protected health information or patient participation in pharmaceutical company-sponsored programs, except as may be required by Federal laws and regulations such as an educational program that is part of a risk evaluation and mitigation strategy required by the Food and Drug Administration.

(4) Patient educational materials must not contain the name or logo of the pharmaceutical manufacturer or be used for promotion of a specific medication, unless the VA Pharmacy Benefits Management Service determines that the logo or name is inconspicuous and legal requirements (e.g., trademark requirements) make their removal impractical. However, this requirement does not apply to labeling required by the Food and Drug Administration.

(5) Educational programs and associated materials regarding a drug, drug-related supply, or a new therapeutic indication for a drug that is already on the VANF but has not yet been reviewed by VA, must be submitted by the pharmaceutical company or pharmaceutical company representative to the VA medical facility's Chief of Pharmacy Services or designee.

(6) Educational programs and associated materials focusing primarily on non-VANF drugs or drug-related supplies without criteria-for-use are permitted only if those drugs or drug-related supplies may be promoted under paragraph (d) of this section.

(g) *Providing gifts, drugs or other promotional items to VA employees or facilities.*

(1) *General.* No pharmaceutical company representative may give, and no VA employee may receive, any item (including but not limited to promotional materials, continuing education materials, textbooks, entertainment, and gratuities) that exceeds the value permissible for acceptance under government ethical rules (5 CFR 2635.204(a)). However, such items may be donated to a medical center library or individual department for use by all employees, in accordance with medical center policy. Gifts in support of VA staff official travel may be accepted by the Department subject to advance legal review in accordance with 31 U.S.C. 1353, 41 CFR part 304, and VA policy regarding such gifts.

(2) *Samples of drugs and drug-related supplies.* Pharmaceutical company representatives must submit samples of

drugs and drug-related supplies for approval to the person at the medical facility to whom such responsibility is delegated under local policy, usually the Director. All usage information pertaining to these drugs or drug-related supplies must be forwarded to the VISN Pharmacist Executive or VISN Formulary Committee. All samples of drugs or drug-related supplies must be delivered to the Office of the Chief of Pharmacy Services for proper storage, documentation and dispensing. Drug or drug-related supply samples may not be provided to VA staff for their personal use.

(3) *Donations of food.* Pharmaceutical company representatives may not provide food items of any type or any value to VA staff (including volunteers and without compensation employees) or bring food items into VA medical facilities for use by non-VA staff (e.g., employees of affiliates).

(h) *Conduct of pharmaceutical company representatives.* In addition to the other provisions in this section, pharmaceutical company representatives must conform to the following:

(1) *Contacts must be by appointment only.* In order to minimize the potential for disruption of patient care activities, a pharmaceutical company representative must schedule an appointment before each visit. Access to VA medical facilities by a pharmaceutical company representative without an appointment is not permitted under any circumstances. VA medical facilities may develop a list of individuals or departments that may not be called-on by pharmaceutical company representatives. A pharmaceutical company representative must not attempt to make appointments with, or leave any materials for, individuals or departments on the list. The list may be obtained at the VA medical facility office of the Chief of Pharmacy Services. A pharmaceutical company representative visiting a VA medical facility for a scheduled appointment may not leave promotional materials for, or initiate requests for meetings with, other VA staff; however, pharmaceutical company representatives may respond to requests initiated by VA staff during the visit.

(2) *Paging VA employees.* A pharmaceutical company representative may not use the public address (paging) system to locate any VA employee. Contacts using the electronic paging system (beepers) are permissible only if specifically requested by the VA employee.

(3) *Marketing to students.* Pharmaceutical company

representatives are prohibited from marketing to medical, pharmacy, nursing and other health profession students, including residents. Exceptions may be permitted when approved by, and conducted in the presence of, the staff member providing clinical supervision.

(4) *Attendance at conferences.* A pharmaceutical company representative may not attend a medical center conference where information regarding individual patients is discussed or presented.

(5) *Patient care areas.* Pharmaceutical company representatives generally may not wait for scheduled appointments or make presentations in patient-care areas, but may briefly travel through them, when necessary, to meet in a staff member's office. Patient-care areas include, but are not limited to:

- (i) Patient rooms and ward areas where patients may be encountered;
- (ii) Clinic examination rooms;
- (iii) Nurses stations;
- (iv) Intensive care units;
- (v) Operating room suites;
- (vi) Urgent care centers;
- (vii) Emergency rooms (but not staff offices that may be located in them); or
- (viii) Ambulatory treatment centers.

(6) *Distribution of materials.* Pharmaceutical company representatives may only distribute materials on-site at the time and location of a scheduled appointment or educational program. In no circumstances may materials be left in patient care areas.

(i) *Non-compliance.*

(1) *General.* The visiting privileges of a pharmaceutical company representative or multiple representatives may be limited, suspended, or revoked by the written order of the Director of the VA medical center of jurisdiction if the Director determines the pharmaceutical company representative(s) failed to comply with the requirements of this section.

(2) *Notice of interim action.* The Director will notify the pharmaceutical company representative of the noncompliance and of the Director's interim action under paragraph (i)(4) of this section. The Director will also notify the supervisor of the pharmaceutical company representative(s) if there have been multiple instances of misconduct. The notice will offer 30 days to provide a response; however, the interim action will be enforced effective the date of the notice.

(3) *Final written order.* At the end of the 30-day period for a response, or after the Director receives a timely response,

the Director will issue to the pharmaceutical company representative and supervisor a final written order either confirming the action taken as indicated in the notice, or specifying another action to be taken under paragraph (i)(4) of this section. The written order may also state that the Director has determined that no further action is required. Any final written order issued by the Director shall include a summary of the circumstances of the violation, a listing of the specific provisions of this section that the pharmaceutical company representative(s) violated, and the bases for the Director's determination regarding the appropriate action. Notice concerning a final written order suspending or permanently revoking the visiting privileges of multiple pharmaceutical company representatives shall include specific notice concerning the right to review of the Director's order by the Under Secretary for Health.

(4) *Actions.* Actions that may be imposed under this section include limitation, suspension, or permanent revocation of visiting privileges at one or more VA medical facilities. In determining the appropriate action, the Director shall consider the requirements of this section, the circumstances of the improper conduct, any prior acts of misconduct by the same pharmaceutical company representative, any response submitted by the pharmaceutical company representative or their supervisor under paragraph (i)(2) of this section, and any prior written orders issued or other actions taken with respect to similar acts of misconduct.

(5) *Review.* The pharmaceutical company may request the Under Secretary's review within 30 days of the date of the Director's final written order by submitting a written request to the Director. The Director shall forward the initial notice, any response, the final written order, and the request for review to the Under Secretary for a final VA decision. VA will enforce the Director's final written order while it is under review by the Under Secretary. The Director will provide the individual who made the request written notice of the Under Secretary's decision.

(Authority: 38 U.S.C. 501)

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 80

[EPA-HQ-OAR-2011-0542; FRL-9642-3]

RIN 2060-AR07

Regulation of Fuels and Fuel Additives: Identification of Additional Qualifying Renewable Fuel Pathways Under the Renewable Fuel Standard Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: EPA published a direct final rule on January 5, 2012 to amend the Renewable Fuel Standard program regulations. Because EPA received adverse comment, we are withdrawing the direct final rule.

DATES: Effective March 5, 2012, EPA withdraws the direct final rule published at 77 FR 700, on January 5, 2012.

FOR FURTHER INFORMATION CONTACT:

Vincent Camobreco, Office of Transportation and Air Quality (MC6401A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564-9043; fax number: (202) 564-1686; email address: camobreco.vincent@epa.gov.

SUPPLEMENTARY INFORMATION: EPA published a direct final rule on January 5, 2012 (77 FR 700) to amend the Renewable Fuel Standard program regulations. The amendments would have expanded Table 1 of § 80.1426 to identify additional renewable fuel production pathways and pathway components that could be used in producing qualifying renewable fuel under the Renewable Fuel Standard program. We stated in that direct final rule that if we received adverse comment by February 6, 2012, that we would publish a timely withdrawal in the **Federal Register**. We subsequently received adverse comment on several of the changes included in the revised Table 1 of § 80.1426. Since the regulatory amendment in the direct final rule was a single Table including all changes, withdrawal based on the adverse comments we have received requires withdrawal of the entire revised Table. EPA intends to address all comments in a subsequent final action, which will be based on the parallel proposed rule also published on January 5, 2012 (77 FR 462).

As stated in the direct final rule and the parallel proposed rule, we will not