

on small businesses; the benefits and utility of the rule in its current form and, if amended, in its amended form; the continued need for the rule; the complexity of the rule; and whether, and to what extent, the rule overlaps, duplicates, or conflicts with other Federal, State, and local government rules. OSHA also asked for comments on new developments in technology, economic conditions, or other factors affecting the ability of covered firms to comply with the standard. Furthermore, OSHA asked for comments on alternatives to the rule that would minimize significant impacts on small businesses while achieving the objectives of the Occupational Safety and Health Act.

### Conclusions and Recommendations

OSHA's Section 610 review of the MC Standard finds the following:

- There is a continued need for the Standard.
- The Standard does not impose an unnecessary or disproportionate burden on small businesses or on industry in general.
- Although the Standard does impose costs, these costs are essential to protecting worker health.
- This lookback review did not identify any industries in which the Standard diminished the industries' viability.
- There is no indication that employers are unable to comply due to the complexity of the Standard.
- The Standard does not overlap, duplicate, or conflict with other state or federal rules.
- Economic and technological trends have not reduced the need for the Standard.
- No public commenter felt the MC Standard should be rescinded. Several of the comments underscored the hazards associated with exposure to MC and that it is feasible to comply with the Standard. Other comments contained specific suggestions for how compliance with the Standard could be improved through compliance assistance, and how worker health could be improved through information on the toxicity of substitutes for MC use.

OSHA's review of the MC Standard under EO 12866 finds the following:

- The Standard remains justified and necessary in light of ongoing hazards and fatalities.
- In general, the Standard is compatible and not duplicative with other state or federal rules.
- The Standard remains consistent with E.O. 12866 because it has produced the intended benefits (i.e.,

protecting workers' health), and has not been unduly burdensome.

OSHA concludes that the MC Standard has protected workers from adverse health effects resulting from exposure to MC in the workplace. In terms of economic impacts, the MC Standard does not impose an unnecessary or disproportionate burden on small businesses or on industry in general. Although the Standard does impose costs, these costs are essential to protecting worker health. This lookback review did not identify any industries in which the MC Standard diminished the industries' viability.

OSHA recommends the following:

- The MC Standard should continue without change.
- According to public comments, lack of information and training are the most common barriers in the construction industry for compliance with the MC Standard. Therefore, OSHA recommends reviewing its compliance assistance materials to determine the need for updates. OSHA also recommends reviewing the adequacy of how these materials are disseminated and additional means for reaching affected populations.
- The use of substitutes for MC has increased in certain industries. These substitutes may pose their own health hazards. Therefore, based on public comments, OSHA will consider putting out guidance recommending that, before a substitute for MC is used, the toxicity of that substitute should be checked on the EPA and NIOSH Web sites (<http://www.epa.gov> and <http://www.niosh.gov>, respectively).

**Authority:** This document was prepared under the direction of David Michaels, PhD, MPH, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue, NW., Washington, DC 20210. It is issued under Section 610 of the Regulatory Flexibility Act (5 U.S.C. 610) and Section 5 of Executive Order 12866 (58 FR 51735, October 4, 1993).

Signed at Washington, DC, on April 26, 2010.

**David Michaels,**

*Assistant Secretary of Labor for Occupational Safety and Health.*

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## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 1

RIN 2900-AN42

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

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Veterans Affairs (VA) proposes to amend its regulations regarding access to VA facilities to control the promotion of drugs and drug-related supplies at VA facilities and the business relationships between VA staff and sales representatives promoting drugs and drug-related supplies. The purposes of the proposed rule are to reduce or eliminate any potential for disruption in the patient care environment, manage activities and promotions at VA facilities, and provide sales representatives with a consistent standard of permissible business practice at VA facilities. It would also facilitate mutually beneficial relationships between VA and such sales representatives.

**DATES:** Comments must be received by VA on or before July 6, 2010.

**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 proposes to amend 38 CFR part 1 to regulate access to VA medical facilities by sales representatives (including account managers and clinical liaisons) 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 proposed § 1.220(a), is a network of all VA health care 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>. The proposed rule would prescribe Department-wide rules that must be followed at the VISN and local levels. We note that the proposed rules are consistent with past VA policy and practice.

VA proposes this rule to prescribe the circumstances under which sales representatives from pharmaceutical companies promoting drugs and drug-related supplies may be granted access to VA facilities. This rule is necessary to limit such access to those circumstances that benefit VA from an educational standpoint, while avoiding potential disturbance to patient care and ensuring compliance with standards of ethical conduct. Pharmaceutical sales representatives have heavy interaction with local VA staff each year, and this rule will ensure that their activities do not negatively affect the quality of patient care. The proposed rule would also assist these sales representatives by providing clear standards, applicable to all VA facilities nationwide, which are consistent with current practices at most VA facilities. The proposed rule would require the Chief of Pharmacy or other official responsible for such decisions to approve educational programs and materials presented or furnished by these sales representatives, so as to ensure that those programs and materials focus on clinician education as opposed to marketing of drugs and drug-related supplies. The proposed rule would generally deny sales representatives access to patient care areas in VA facilities to ensure patient privacy, and would require them to make appointments at the facilities they intend to visit as opposed to open and unrestricted access. Further, the proposed rule would prohibit sales representatives from furnishing any food to VA staff or gifts above the de minimis value set forth in the standards of ethical conduct for Federal employees, and would prohibit VA employees' personal acceptance of drug samples.

We propose to designate this rule as § 1.220. Currently, § 1.218, regarding security and law enforcement at VA facilities, describes general behavior that is prohibited on the grounds of VA property. Proposed § 1.220, would govern the behavior of particular individuals (sales representatives) on the grounds of VA medical facilities, but is not a security and law enforcement

provision as it is not our intention to prescribe a fine for failure to comply with this rule. (VA is required to provide for a fine and/or imprisonment for violations of the security and law enforcement provisions at § 1.218 (38 U.S.C. 901)).

In proposed paragraph (a), we would set forth definitions applicable to this section. In particular, we would use current policy and practice to define "Criteria-for-use" as clinical criteria describing how certain drugs may be used in VA. The criteria-for-use are, and will continue to be, posted on VA's Web site at <http://www.pbm.va.gov>. The definition would note that local exceptions may apply "for operational reasons." An example of the need for a local exception might be if a particular facility within a VISN (*e.g.*, a Community-Based Outpatient Clinic (CBOC)) did not have a physician with the required expertise about a particular drug to prescribe. Under the exception, a primary care provider might direct that the drug be prescribed at a different facility within the VISN (*e.g.*, a VA hospital) where a suitable physician could be found. We note that such exceptions at the local level are not posted on our Web site, or elsewhere, because they are subject to change and because they do not have any general effect on the approval of the drug for use within VA. For example, if the particular facility hires a physician with the required expertise to administer the drug within its approved criteria for use, or if a physician within the facility obtains such expertise through training. We also note that such exceptions have no effect on the use of the drug elsewhere within the VISN. Thus, these exceptions do not have a broad or national effect on pharmaceutical companies.

We would broadly define "drugs" and "drug-related supplies" because we intend these terms to be inclusive of all items typically promoted by pharmaceutical sales representatives. Similarly, paragraph (a) would define "VA medical facility" as "any property under the charge and control of VA used to provide medical benefits." These broad definitions would ensure that the proposed rule applies to the largest possible number of sales representatives and VA medical facilities, including but not limited to hospitals, CBOCs, nursing homes, and domiciliaries.

We would define "VA National Formulary (VANF) drugs and/or drug-related supplies" as "any drug or drug-related supply that must be available for prescription at all VA medical facilities," and would provide the public with a means to obtain the most current

list of such drugs or drug-related supplies. Non-VANF drugs or drug-related supplies would be defined as drugs or drug-related supplies that are not included on the list of VANF drugs or drug-related supplies.

Proposed paragraph (b) would set forth the general rule applicable to the promotion of drugs and drug-related supplies. It would state that notwithstanding § 1.218(a)(8), regarding soliciting, vending, and debt collection on VA property, VA would allow promotion in VA medical facilities of VANF and non-VANF drugs or drug-related supplies if the promotion is consistent with criteria-for-use, the drug is not classified as non-promotable, and the promotion is otherwise consistent with the proposed rule and with facility initiatives. It would clearly be against the interests of VA and our patients to allow a promotion that did not meet these three criteria, which are consistent with past policy and practice. This rule would be an exception to § 1.218(a)(8) because that rule bars solicitations "of any kind" on VA property, and otherwise precludes behavior (such as posting signs and distributing literature) that would be specifically authorized by § 1.220.

Proposed paragraph (c) would apply only to the promotion of non-VANF drugs or drug-related supplies without criteria-for-use. Such promotions are generally for new molecular entities or new indications for existing drugs, and such promotions must be regulated at the local level in order to allow for different clinical approaches. The promotion of new molecular entities would be permitted, but any decision allowing the promotion of such a drug would be reconsidered if the VANF committee reviews the drug and grants or denies VANF status. Because new molecular entities generally do not have a history of significant published studies in populations similar to the VA patient population and may not be part of an established drug class, it is important that the proposed rule allow VA medical professionals to become educated through the promotion of such drugs but, at the same time, ensure that promotions are consistent with National policy.

Proposed paragraphs (d) and (f) would be general rules applicable to educational programs and materials (paragraph (d)) and the behavior of sales representatives on the grounds of VA medical facilities (paragraph (f)). These rules would attempt to balance the benefits of such promotion against the need to maintain an appropriate clinical environment at VA facilities, safeguarding the peace and privacy of

patients and ensuring that VA personnel are able to perform their jobs without unnecessary interference. The rules would also avoid any appearance of bias for or against particular drug manufacturers by closely regulating the use of advertising material and display of brand names, logos, and sponsorships. An appearance of bias in a drug promotion situation could significantly undermine the trust of patients or the public in VA doctors. Proposed paragraph (e), in addition to furthering the policies described above that support paragraphs (d) and (f), would regulate the receipt of gifts and donations to ensure that VA maintains appropriate relationships with drug companies and suppliers.

In paragraph (g), we would set forth the consequences for noncompliance with this section. Any individual, or any company, that fails to comply with this section would be subject to limitations on the right to access VA facilities, which may include suspension of a sales representative's access privileges, or, in extreme cases, denying access to a company's entire sales force. Consistent with the Secretary's delegations of authority to the Under Secretary for Health and the Under Secretary's further delegation of authority to certain Veterans Health Administration officials, the proposed rule would authorize the director of the VA Medical Center of jurisdiction to issue appropriate orders restricting access to facilities under the director's control. This is the person who would be in the best position to determine whether any violation of the proposed rule requires restrictions on access to particular VA facilities or whether an opportunity for corrective action by the individual or company will suffice. In most cases, we expect that the infraction would be adequately addressed by the sales representative and no formal action would be required.

Procedurally, paragraph (g) would require the director to notify the sales representative or company of the violation and any proposed restrictions on access privileges before issuing any final order. The director would be required to provide notice to a company's sales manager if the proposed action would result in a denial of access privileges for the company's entire sales force. Affected persons and companies would have 30 days after the date of the notice to provide the director a response; however, during that 30-day period the proposed action would be enforced. This is necessary to ensure that noncompliance does not continue during the 30-day period. After considering the requirements of the

proposed rule, the circumstances of the improper conduct, and any response submitted by the sales representative or company, the director would either resolve the matter informally or issue a final order restricting access.

Under proposed paragraph (g)(4), in cases where the director issues a final order suspending or permanently barring a company's entire sales force, the director would be required to provide notice of the company's right to a one-time appeal of the matter to the Under Secretary for Health. Any such request for the Under Secretary's review would be submitted to the director that issued the order within 30 days of the date of the order. The director would then forward the initial notice, the company's response, the director's order, and the company's request for review to the Under Secretary for a final decision. The director's order would be enforced until the Under Secretary's review is complete. This mechanism provides important due process to companies seeking to appeal such final orders.

We note that in most cases, sales representatives are considerate of VA's needs and mission, and do not behave inappropriately. Accordingly, we do not envision that the proposed paragraph (g) would be invoked with regularity.

#### **Executive Order 12866**

Executive Order 12866 directs agencies to assess all 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, and other advantages; distributive impacts; and equity). The Executive Order classifies a regulatory action as a "significant regulatory action," requiring review by the Office of Management and Budget (OMB) unless OMB waives such review, if it is a 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 the Executive Order.

The economic, interagency, budgetary, legal, and policy implications of this proposed rule 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 proposed rule would have no such effect on State, local, or tribal governments, or on the private sector.

#### **Paperwork Reduction Act**

The proposed 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 proposed rule would 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 proposed rule would not cause a significant economic impact on health care providers, suppliers, or other small entities. The proposed 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 proposed 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.

#### **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.

Approved: December 30, 2009.

**John R. Gingrich,**

*Chief of Staff, Department of Veterans Affairs.*

For the reasons set forth in the preamble, the Department of Veterans Affairs proposes to amend 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 Promotion of drugs and drug-related supplies at VA medical facilities.**

(a) *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](http://www.pbm.va.gov). Exceptions may be applied at the local level for operational reasons.

*Drugs* means pharmaceuticals or chemicals intended for use by a patient or, in some cases, for medical research.

*Drug-related supplies* means supplies related to the use of a drug, such as test strips or testing devices.

*New molecular entity* refers to an active ingredient that has never before been marketed in the United States in any form.

*Non-VANF drugs or drug-related supplies* are drugs or drug-related supplies that do not appear on the VA National Formulary.

*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 must be available for prescription at all VA medical facilities. A list of VANF drugs or drug-related supplies is available at [www.pbm.va.gov](http://www.pbm.va.gov), or may be requested by contacting the local office of the Chief of Pharmacy Services.

*Veterans Integrated Service Network (VISN)* means one of the 21 networks of VA medical facilities.

(b) *Permissible promotion of drugs and drug-related supplies.*

Notwithstanding § 1.218(a)(8), VA will allow promotion in VA medical facilities of VANF and non-VANF drugs or drug-related supplies if all of the following are true:

(1) The promotion is consistent with any existing criteria-for-use.

(2) The drug or drug-related supply has not been classified by VA as non-promotable. A list of the drugs or drug-related supplies classified by VA as non-promotable is available at [www.pbm.va.gov](http://www.pbm.va.gov), or may be requested by contacting the local office of the Chief of Pharmacy Services.

(3) The promotion is otherwise consistent with this section.

(4) The promotion is consistent with facility initiatives.

(c) *Promotion of non-VANF drugs and drug-related supplies without criteria-for-use.* Under paragraph (b) of this section, non-VANF drugs or drug-related supplies must be promoted consistent with any existing criteria-for-use. Non-VANF drugs without criteria-for-use may be promoted only if:

(1) Specifically permitted by the VISN Pharmacy Executive;

(2) Authorized by the Chief of Pharmacy with jurisdiction over the VA medical facility at which the promotion occurs; and

(3) In a case where a VISN Formulary Leader has permitted the promotion of a new molecular entity prior to any decision regarding its VANF status, such permission must be reconsidered if the new molecular entity:

(i) Is subsequently granted VANF status but is labeled non-promotable; or

(ii) A decision is made to deny VANF status.

(d) *Educational programs and materials.* All educational programs and materials must be approved by the person at the VA medical facility to whom such approval responsibility has been delegated under local policy, usually the Chief of Pharmacy Services. A summary of the program and all materials must be provided well in advance of the proposed date so that a determination of the program's suitability can be made. Programs and materials must conform to the following guidelines:

(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 program.

(2) Marketing activities cannot be conducted during an educational program.

(3) Promotional materials are not to be placed in any patient care area.

(4) Programs or materials must not offer patients an opportunity to participate in manufacturer sponsored programs and/or require the furnishing of Protected Health Information.

(5) Patient education materials must not contain the name or logo of the pharmaceutical manufacturer or be used for promotion of specific medications; 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. Even if such materials are approved by the VA National Formulary committee, the materials must otherwise be approved by the local facility in accordance with paragraph (d) of this section.

(6) Programs or materials regarding a new drug, drug-related supply, or a new therapeutic indication for a drug, which is already on the VANF but has not yet been reviewed by VA, must be clearly identified as such.

(7) Programs or materials focusing primarily on non-VANF drugs or drug-related supplies are discouraged; such programs or materials, as well as programs or materials regarding VANF drugs or drug-related supplies with restrictions, must be clearly identified as such.

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

(1) *General.* No sales 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 local policies. Gifts of travel 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) *Donations of drugs and drug-related supplies.* Drug samples and free drug-related supplies must be approved by the person at the medical facility to whom such responsibility is delegated under local policy, usually the Director. Information pertaining to the trial use of these drugs or drug-related supplies must be forwarded to the VISN Pharmacy Executive or VISN Formulary Committee. Drugs or drug-related supplies donated for the intended purpose of patient use must be delivered to the Office of the Chief of Pharmacy Services for proper storage, documentation and dispensing. These donated items must not be labeled "sample," "professional sample," or similar words, unless VA grants an

exception in the interests of patient care. Drug or supply samples may not be provided to VA staff for their personal use.

(3) *Donations of food.* Sales 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). This constraint applies to all sales representatives who have business relationships with VA Clinical Services.

(f) *Conduct of sales representatives.* In addition to any other rules in this section, sales representatives (i.e., promoters) of drugs and drug-related supplies must conform to the following:

(1) *Sales representatives must provide accurate information.* Sales representatives must ensure that all drugs or drug-related supplies are discussed, displayed and represented accurately, in accordance with any applicable Food and Drug Administration and VANF guidelines and restrictions.

(2) *Contacts are to be by appointment only.* In order to minimize the potential for disruption of patient care activities, a sales representative must schedule an appointment before each specific visit. Access to VA medical facilities by a sales representative without an appointment is not permitted under any circumstances. VA medical facilities may develop a list of individuals or departments that do not wish to be called-on by sales representatives. A sales representative must not attempt to make appointments with individuals or departments on the list. The list may be obtained at the local office of the Chief of Pharmacy Services.

(3) *Contacts with VA staff without an appointment.* A sales representative visiting a VA medical facility for a scheduled appointment may not initiate requests for meetings with other VA staff; however, sales representatives may respond to requests initiated by VA staff during the visit.

(4) *Paging VA employees.* The sales 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.

(5) *Marketing to students.* Sales 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, their clinical staff member.

(6) *Attendance at conferences.* A sales representative is not allowed to attend a medical center conference where patient-specific material is discussed or presented.

(7) *Patient care areas.* Sales 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) Emergency rooms;

(vii) Urgent care centers; and

(viii) Ambulatory treatment centers.

(g) *Failure to properly promote drugs or drug-related supplies within VA.*

(1) A sales representative's commercial visiting privileges at one or more VA medical facilities may be restricted by the written order of the director of the VA medical center of jurisdiction if the director determines the sales representative failed to comply with the requirements of this section. The director will notify the representative of the noncompliance and of the director's proposed action under paragraph (g)(3) of this section. The director will also notify the manager or other appropriate supervisor of the sales force if there have been instances of widespread misconduct by an individual, or by multiple representatives of the same sales force, and the director proposes to suspend or permanently revoke the sales force's commercial visiting privileges at one or more VA medical facilities. The notice will offer 30 days to provide a response; however, the proposed action will be enforced effective the date of the notice.

(2) At the end of the 30-day period for a response, or after the director receives a timely response, the director may, as appropriate to prevent future noncompliance, issue a written order suspending or permanently revoking the sales representative's or sales force's commercial visiting privileges, impose a lesser sanction, or decide that no further action is required. 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 sales representative or sales force, any response submitted by the sales representative or sales force manager, and any prior orders issued or other actions taken with respect to similar

acts of misconduct. Any final 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 sales representative or sales force violated, and the bases for the director's determination regarding the appropriate remedial action.

(3) Actions that may be imposed under this section include limitation, suspension, or permanent revocation of commercial visiting privileges at one or more VA medical facilities. Instances of widespread misconduct by an individual or multiple sales representatives may result in the imposition of a VISN-wide or VA-wide limitation, suspension, or revocation of commercial visiting privileges of the entire sales force of a given manufacturer, if necessary to prevent further noncompliance. The director will provide the sales representative or sales force manager written notice of any final order issued under this section.

(4) Notice concerning a final order suspending or permanently revoking an entire sales force's commercial visiting privileges shall include specific notice concerning the right to appeal the director's order to the Under Secretary for Health. The sales force manager or other corporate representative may request the Under Secretary's review within 30 days of the date of the director's order by submitting a written request to the director. The director shall forward the initial notice, any response, the final order, and the request for review to the Under Secretary for a final VA decision. VA will enforce the director's 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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## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 62

RIN 2900-AN53

#### Supportive Services for Veteran Families Program

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Proposed rule.