

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321-4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves establishing a safety zone around a fireworks display. The fireworks are launched from land and the safety zone is intended to keep mariners away from any fall out that may enter the water. Therefore this rule is expected to be categorically excluded, under section 2.B.2. Figure 2-1, paragraph 34(g), of the Instruction.

A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6 and 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.T05-0293 to read as follows:

§ 165.T05-0293 Safety Zone; Reedville July 4th Celebration, Cockrell's Creek, Reedville, VA.

(a) *Regulated Area.* The following area is a safety zone: specified waters of Cockrell's Creek located within a 420 foot radius of the fireworks display at approximate position 37°49'54" N/ 076°16'44" W (NAD 1983) in the vicinity of Reedville, VA.

(b) *Definition.* For the purposes of this part, Captain of the Port Representative means any U.S. Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain

of the Port, Hampton Roads, Virginia to act on his behalf.

(c) *Regulations.* (1) In accordance with the general regulations in 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port, Hampton Roads or his designated representatives.

(2) The operator of any vessel in the immediate vicinity of this safety zone shall:

(i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard ensign.

(ii) Proceed as directed by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard ensign.

(3) The Captain of the Port, Hampton Roads can be reached through the Sector Duty Officer at Sector Hampton Roads in Portsmouth, Virginia at telephone Number (757) 668-5555.

(4) The Coast Guard Representatives enforcing the safety zone can be contacted on VHF-FM marine band radio channel 13 (165.65Mhz) and channel 16 (156.8 Mhz).

(d) *Enforcement Period:* This regulation will be enforced on July 2, 2010 from 8 p.m. until 10 p.m.

Dated: April 24, 2010.

M.S. Ogle,

Captain, U.S. Coast Guard, Captain of the Port, Hampton Roads.

[FR Doc. 2010-11087 Filed 5-10-10; 8:45 am]

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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; republication.

SUMMARY: The Department of Veterans Affairs (VA) is republishing the proposed rule document that was published on May 5, 2010, in the **Federal Register** to provide the address that the public needs to submit their comments. In that document, we inadvertently omitted the **ADDRESSES** section for public comments. As a convenience to the public, instead of merely publishing a correction document, we are republishing the entire proposed rule with the

ADDRESSES section and a new 60-day comment period. These are the only two changes made to the proposed rule.

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 12, 2010.

ADDRESSES: Written comments may be submitted through <http://www.Regulations.gov>; by mail or hand delivery to the Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Ave., NW, Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. Comments should indicate that they are submitted in response to "RIN 2900-AN42—Drug and Drug-Related Supply Promotion by Pharmaceutical Company Sales." Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461-4902 (this is not a toll-free number) for an appointment. In addition, during the comment period, comments may be viewed online through the Federal Docket Management System at <http://www.Regulations.gov>.

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: On May 5, 2010, VA published this proposed rule in the **Federal Register** at 75 FR 24510, with an error. We inadvertently omitted the **ADDRESSES** section for public comments. We are republishing the proposed rule with the address information where the public can submit their comments and with a new 60-day comment period.

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 website, 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, 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.

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 December 30, 2009, 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: May 7, 2010.

Robert C. McFetridge,

*Director, Regulation Policy and Management,
Office of the General Counsel.*

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 <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, 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, 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)
[FR Doc. 2010-11170 Filed 5-10-10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 80

[EPA-HQ-OAR-2007-1158; FRL-9147-5]

RIN 2060-A071

Regulation of Fuels and Fuel Additives: Alternative Affirmative Defense Requirements for Ultra-Low Sulfur Diesel and Gasoline Benzene Technical Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: EPA is issuing a proposed rule to amend the diesel sulfur regulations to allow refiners, importers, distributors, and retailers of highway diesel fuel the option to use an alternative affirmative defense if the Agency finds highway diesel fuel samples above the specified sulfur standard at retail facilities. This rule also proposes to amend the gasoline benzene regulations to allow disqualified small refiners the same opportunity to generate gasoline benzene credits as that afforded to non-small refiners.

DATES: Comments: Comments must be received on or before June 10, 2010. Under the Paperwork Reduction Act, comments on the information collection provisions must be received by OMB on or before June 10, 2010.

Hearings: If EPA receives a request from a person wishing to speak at a public hearing by May 26, 2010, a public hearing will be held at a time and location to be announced in a

subsequent **Federal Register** notice. To request to speak at a public hearing, send a request to the contact in **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2007-1158, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.

- *E-mail:* a-and-r-docket@epa.gov.

- *Fax:* (202) 566-9744

- *Mail:* Air and Radiation Docket, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

- *Hand Delivery:* EPA Docket Center, Room 3334, EPA West Building, 1301 Constitution Avenue, NW., Washington, DC, Attention Air Docket ID No. EPA-HQ-OAR-2007-1158. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Comments should be submitted according to the detailed instructions in the **ADDRESSES** section of the corresponding Direct Final Rule located in the "Rules" section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Jaimee Dong, Compliance and Innovative Strategies Division, Office of Transportation and Air Quality, Office of Air and Radiation, Environmental Protection Agency, Mail Code 6405J, 1200 Pennsylvania Avenue, Washington, DC 20460; *telephone number:* (202) 343-9672; *fax number:* (202) 343-2800; *e-mail address:* Dong.Jaimee@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Why is EPA issuing this proposed rule?

EPA is issuing a proposed rule to amend the diesel sulfur regulations to allow refiners, importers, distributors, and retailers of highway diesel fuel the option to use an alternative affirmative

defense if the Agency finds highway diesel fuel samples above the specified sulfur standard at retail facilities. This rule also proposes to amend the gasoline benzene regulations to allow disqualified small refiners the same opportunity to generate gasoline benzene credits as that afforded to non-small refiners.

We have also published a direct final rule to make these same amendments in the "Rules and Regulations" section of this **Federal Register** because we view this as a non-controversial action and anticipate no adverse comment. We have explained our reasons for this action in the preamble to the direct final rule.

If we receive no adverse comment, we will not take further action on this proposed rule. If EPA receives adverse comment on a distinct provision of this rulemaking, we will publish a timely withdrawal in the **Federal Register** indicating which provisions of the direct final rule we are withdrawing. The provisions that are not withdrawn will go into effect on the effective date noted in the **DATES** section of the direct final rule, notwithstanding adverse comment on any other provision. We would address all public comments in any subsequent final rule based on this proposed rule.

We do not intend to institute a second comment period on the action. Any parties interested in commenting must do so at this time.

The regulatory text for the proposal is identical to that for the direct final rule and is published in the "Rules and Regulations" section of this **Federal Register**.

II. Does this action apply to me?

Entities potentially affected by this action include those involved with the production, importation, distribution, marketing, or retailing of diesel fuel and production of gasoline. Categories and entities affected by this action include:

Category	NAICS Codes ^a	SIC Codes ^b	Examples of potentially regulated entities
Industry	324110	2911	Petroleum Refiners.
Industry	422710	5171	Diesel Fuel Marketers and Distributors.
Industry	484220	4212	Diesel Fuel Carriers.

^aNorth American Industry Classification System (NAICS).

^bStandard Industrial Classification (SIC) system code.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action; however, other types of entities not listed in the table could also be affected. To determine

whether your entity is affected by this action, you should examine the applicability criteria of Parts 79 and 80 of title 40 of the Code of Federal Regulations. If you have any questions regarding applicability of this action to

a particular entity, consult the person in the preceding **FOR FURTHER INFORMATION CONTACT** section.