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Title 38, Parts 0, 1, 2, 12, 14-16,  
18-20, 25-26, 38-45, 48-49, 74-75

*General*

**Veterans Benefits Administration**

Supplement No. 105

Covering period of *Federal Register* issues  
through April 1, 2012

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# GENERAL INSTRUCTIONS

Custom Federal Regulations Service™

## Supplemental Materials for *Book A*

Code of Federal Regulations

Title 38, Parts 0, 1, 2, 12, 14-16, 18-20, 25-26, 38-45, 48-49, 74-75

*General*

## Veterans Benefits Administration

Supplement No. 105

5 April 2012

Covering the period of Federal Register issues  
through April 1, 2012

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**Book A, Supplement No. 105  
April 5, 2012**

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A-13 to A-16	A-13 to A-16	Book A Index
1.INDEX-7 to 1.INDEX-8	1.INDEX-7 to 1.INDEX-8	Part 1 Index
1.218-7 to 1.301-1 <i>(note §1.220 is added between §1.218 and §1.300)</i>	1.218-7 to 1.301-1	§1.220

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## HIGHLIGHTS

### Book A, Supplement No. 105 April 5, 2012

**Supplement Highlights references:** Where substantive changes are made in the text of regulations, the paragraphs of *Highlights* sections are cited at the end of the relevant section of text. Thus, if you are reading §3.263, you will see a note at the end of that section which reads: “Supplement *Highlights* references—6(2).” This means that paragraph 2 of the *Highlights* section in Supplement No. 6 contains information about the changes made in §3.263. By keeping and filing the *Highlights* sections, you will have a reference source explaining all substantive changes in the text of the regulations.

**Supplement frequency:** This Book A (*General*) was originally supplemented twice a year, in April and October. Beginning 1 August 1995, supplements will be issued *every month* during which a final rule addition or modification is made to the parts of Title 38 covered by this book. Supplements will be numbered consecutively as issued.

#### **Modifications in this supplement include the following:**

1. On 5 March 2012, the VA published a final rule, effective 4 April 2012, to amend its regulations regarding access to VA facilities by pharmaceutical company representatives. Change:
  - Added §1.220.



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*End of Section Title Index*

(1) VA administration directors will issue policies and operating procedures governing the proper exercise of arrest and other law enforcement actions, and limiting the carrying and use of weapons by VA police officers. VA police officers found qualified under respective VA administration directives and duly appointed heads of facilities for the purposes of 38 U.S.C. 902, will enforce these rules and regulations and other Federal laws on VA property in accordance with the policies and operating procedures issued by respective VA administration directors and under the direction of the head of the facility.

(2) VA administration directors will prescribe training for VA police officers of the scope and duration necessary to assure the proper exercise of the law enforcement and arrest authority vested in them and to assure their abilities in the safe handling of situations involving patients and the public in general. VA police officers will successfully complete prescribed training in law enforcement procedures and the safe handling of patients as a condition of their retention of statutory law enforcement and arrest authority.

(3) Nothing contained in the rules and regulations set forth in paragraph (a) of this section shall be construed to abrogate any other Federal laws or regulations, including assimilated offenses under 18 U.S.C. 13, or any State or local laws and regulations applicable to the area in which the property is situated. (Authority: 38 U.S.C. 901-905)

[50 FR 29226, July 18, 1985]

*Next Section is §1.220*

**§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](http://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](http://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)

[77 FR 13007, Mar. 5, 2012]

**Supplement *Highlights* reference(s):** 105(1).

*Next Section is §1.300*

### Parking Fees at VA Medical Facilities

#### §1.300 Purpose.

Sections 1.300 through 1.303 prescribe policies and procedures for establishing parking fees for the use of Department of Veterans Affairs controlled parking spaces at VA medical facilities. (Authority: 38 U.S.C. 501(a), 8109)

[53 FR 25490, July 7, 1988]

#### §1.301 Definitions.

As used in §§1.300 through 1.303 of this title:

- (a) *Secretary* means the Secretary of Veterans Affairs.
- (b) *Eligible person* means any individual to whom the Secretary is authorized to furnish medical examination or treatment.
- (c) *Garage* means a structure or part of a structure in which vehicles may be parked.
- (d) *Medical facility* means any facility or part thereof which is under the jurisdiction of the Secretary for the provision of health-care services, including any necessary buildings and structures, garage or parking facility.
- (e) *Parking facilities* includes all surface and garage parking spaces at a VA medical facility.
- (f) *Volunteer worker* means an individual who performs services, without compensation, under the auspices of VA Voluntary Service (VAVS) at a VA medical facility, for the benefit of veterans receiving care at that medical facility. (Authority: 38 U.S.C. 8109)

[53 FR 25490, July 7, 1988]