Arnall Golden Gregory LLP

Client Alert

Contact Attorneys Regarding This Matter:

Alan G. Minsk
404.873.8690 – direct
alan.minsk@agg.com

Diana Rusk Cohen
404.873.8108 – direct
diana.cohen@agg.com

Arnall Golden Gregory LLP
Attorneys at Law

171 17th Street NW
Suite 2100
Atlanta, GA 30363-1031

One Biscayne Tower
Suite 2690
2 South Biscayne Boulevard
Miami, FL 33131

2001 Pennsylvania Avenue NW
Suite 250
Washington DC 20006

www.agg.com

VA Issues Final Rule on Drug Promotion by Pharmaceutical Representatives

The Department of Veterans Affairs (VA) recently issued a final rule amending its regulations regarding access to VA facilities by pharmaceutical company representatives. As discussed in the *Federal Register* preamble to the final rule, the amended regulations are intended to reduce or eliminate any potential for disruption in the patient care environment, manage activities and promotions at VA facilities, and provide pharmaceutical company representatives with a consistent standard of permissible business practices at VA facilities.[1] The new rule, which focuses on permissible promotional practices for drugs and drug-related supplies, is limited in scope to "on-site, in-person" promotional and educational visits to VA medical facilities by pharmaceutical company representatives.[2] The rule becomes effective April 4, 2012.

Definitions of Key Terms

The rule defines certain key terms that are used in describing permissible promotional practices at VA facilities. We note here terms and definitions that are pertinent to understanding how the new rule operates.

- ***Criteria-for-use*—**"clinical criteria developed by the [VA] at a national level that describe how certain drugs may be used." VA's criteria for use are available to the public on the agency's website.[3] Local VA authorities may institute exceptions to these national criteria, as needed, for operational reasons.
- **Drug-related supplies—**"supplies related to the use of a drug, such as test strips … inhalers, spacers, insulin syringes, and tablet splitters."
- **New molecular entity—**"a drug product containing an active ingredient that has never before received U.S. Food and Drug Administration approval."
- **Non-promotable drugs—**"drugs designated by VA as non-promotable." A list of drugs or drug-related supplies classified by VA as non-promotable is available on the agency's website and may be requested by contacting the Chief of Pharmacy Services at the applicable VA medical facility. VA notes that it will rarely define a drug as non-promotable and currently does not have any drugs classified as such on its website.

1 77 Fed. Reg. 12997, 12997 (March 5, 2012). The *Federal Register* notice is available at http://www.gpo.gov/fdsys/pkg/FR-2012-03-05/pdf/2012-5279.pdf.
2 The rule does not apply to the distribution of information and materials through other means (i.e., other than on-site, in-person visits).
3 www.pbm.va.gov

- **Pharmaceutical company representative—**"any individual employed by or contracted to represent a pharmaceutical manufacturer or retailer." VA has defined this term broadly to make clear that employees of pharmaceutical companies, contracted or otherwise, must follow the procedures in the new rule.
- **VA National Formulary (VANF) drugs—**"any drug or drug-related supply that appears on the VA National Formulary." The VANF is available on the agency's website and may also be requested by contacting the Chief of Pharmacy Services at the applicable VA medical facility.

Permissible Promotional Practices

The rule addresses the requirements for on-site promotion at VA facilities in terms of three categories of drugs and drug-related supplies:

1. VA National Formulary (VANF) drugs and drug-related supplies and non-VANF drugs and drug-related supplies with criteria-for-use;
2. non-VANF drugs and drug-related supplies without criteria-for-use; and
3. new molecular entities.

The rule permits on-site promotion for all three drug types if certain criteria are met.

For VANF and non-VANF products with criteria-for-use, on-site promotion at VA facilities is permissible if all of the following apply:

- The drugs or drug-related supplies are discussed, displayed, and represented "accurately."
- The promotion has "significant educational value" and does not divert VA staff from other on-duty activities, such as patient care.
- The drug or drug-related supply has not been classified by VA as non-promotable.

On-site promotion of non-VANF products without criteria-for-use is also permissible if all the above criteria are met *and* the promotion is specifically permitted by the Veterans Integrated Service Network (VISN) Pharmacist Executive, or Chief of Pharmacy Services, or designee.[4] Similarly, new molecular entities may be promoted on-site if these criteria are met and if the VISN Pharmacist Executive, Chief of Pharmacy Services, or designee grants specific permission. In the case of new molecular entities, permission is automatically revoked if the product is subsequently designated as non-promotable. Additionally, permission will be reconsidered if the new molecular entity is subsequently denied VANF status.

Educational Programs

The new rule also discusses educational programs, specifying the types of programs that qualify as educational and delineating the content and allowable distribution practices for any materials to be used at such

4 The final rule does not provide detail on the process for obtaining such permission.

a program. For purposes of the VA rule, an educational program is any "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 Chief of Pharmacy Services or from whoever has been delegated such approval authority under local facility policy. To facilitate prior approval, all materials for a proposed educational program must be provided at least 60 days before the proposed program date or distribution of the materials.

Once materials are submitted, VA will base its determination of suitability on several factors. All educational programs and associated materials that are part of a Risk Evaluation and Mitigation Strategy (REMS) or other duty imposed by FDA will be deemed suitable. Otherwise, educational programs and materials must conform to the following to be deemed suitable:[5]

- Industry sponsorship must be disclosed in opening remarks and in the announcement brochure.[6]
- If industry-sponsored and non-sponsored sources of data or other analytical sources of 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.
- The program must not solicit protected health information or solicit patient participation in pharmaceutical company-sponsored programs, unless required as part of REMS or another federal law or regulation.
- In general, patient education materials may not contain the name or logo or the pharmaceutical manufacturer or be used for promotion of a specific medication. This requirement may be waived in cases where the VA Pharmacy Benefits Management Service determines that the logo or name is inconspicuous and legal requirements (e.g., trademark law) make removal impractical. The VA also notes that this requirement does not apply to any FDA-required product labeling.[7]
- If the program or materials focus on a drug, drug-related supply, or new drug indication that is already on the VANF, but has not yet been reviewed by VA, the materials must be submitted to the VA medical facility's Chief of Pharmacy Services or Designee.

Gifts, Samples, and Other Promotional Items

The rule restricts giving of gifts, stating that pharmaceutical company representatives may not give any item to a VA employee or facility if that item exceeds the limits set forth by government ethical rules, currently set at $20 per gift.[8] The rule also outlines required procedures for distribution of product samples. Pharmaceutical company representatives must submit samples of drugs and drug-related supplies for approval to

5 The final rule does not discuss procedures or protocol in cases where the agency fails to make a suitability determination within 60 days.

6 VA defines sponsorship to include "any contribution, whether in the form of staple goods, personnel, or financing, intended to support the educational program." 38 C.F.R. § 1.220(f)(1).

7 The *Federal Register* notice repeatedly states that all promotions must be consistent with FDA laws and that nothing in the rule should be construed as permitting promotional activities that are not in compliance with applicable FDA requirements.

8 See 5 C.F.R. § 2635.204(a) ("An employee may accept unsolicited gifts having an aggregate market value of $20 or less per source per occasion, provided that the aggregate market value of individual gifts received from any one person … shall not exceed $50 in a calendar year.")

the director of the VA Medical Center or other person who has responsibility for approval according to local facility policy. All usage information pertaining to the samples must be forwarded to the VISN Pharmacist Executive or VISN Formulary Committee, and all samples must be delivered to the Office of the Chief of Pharmacy Services for proper storage, documentation, and dispensing. Drug or drug-related samples may not be provided to VA staff for their personal use. Additionally, pharmaceutical company representatives may not provide food items of any type or value to VA staff or volunteers, or bring food items into VA medical facilities for use by non-VA staff (e.g., employees of affiliates).

Pharmaceutical Representative Conduct and Sanctions for Noncompliance

In addition to the restrictions already noted, the VA rule outlines expected conduct for pharmaceutical representatives and sets forth applicable sanctions in cases where the representative or company has failed to comply with any requirement in the new rule.

- Pharmaceutical company representatives may not access a VA medical facility without an appointment under any circumstances. Facilities may also develop no-contact lists of individuals or departments. Representatives must not try to contact, make an appointment with, or leave materials for any person or department on such lists. Pharmaceutical company representatives may only distribute materials on-site at the time and location of a scheduled appointment or educational program, and are strictly prohibited from leaving materials in patient care areas. Additionally, a pharmaceutical company representative visiting a VA facility for a scheduled meeting may not leave promotional materials or initiate requests for meetings with other VA staff who are not participants in the prescheduled meeting; however, representatives may respond to requests initiated by VA staff during the visit.
- Pharmaceutical company representatives 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.
- Pharmaceutical company representatives may not market to medical, pharmacy, nursing, or other healthcare profession students, including residents. The rule allows the clinical supervisor for such students and residents to make an exception and approve student marketing, if it will be conducted in the clinical supervisor's presence.
- Pharmaceutical company representatives may not attend any VA medical center conference where individual patient information will be discussed.
- Pharmaceutical company representatives may not wait for scheduled appointments or make presentations in patient care areas, such as exam rooms, nurses stations, intensive care units, operating room suites, urgent care centers, emergency rooms (excluding staff offices therein), ambulatory treatment centers, and patient rooms and wards where patients may be encountered.

Failure to comply with the above standards or with any other requirement of the new VA rule may result in limitation, suspension, or revocation of the VA visiting privileges of the pharmaceutical company representative. In cases on noncompliance, the director of the VA medical center will notify the representative and

the supervisor of the misconduct and any immediate action to be taken in response. The company will then have 30 days to provide a response. At the end of the 30-day period, the director will issue a final written notice either confirming any final action to be taken or stating that no further action is required. In determining the appropriate action—limitation, suspension, or permanent revocation of visiting privileges—the director will consider the circumstances surrounding the violation, any prior misconduct, and the company and/or representative's response.

Conclusion

The new VA rule delineates very specific protocols that must be followed for pharmaceutical company representatives to obtain and maintain on-site access to healthcare professionals at VA facilities. Companies that fail to comply with these detailed rules risk revocation of rights to future promotion at VA medical centers. Given the highly detailed and stringent nature of the new rule, the potential for violations is high if appropriate steps are not taken to learn the rule and train representatives accordingly.