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Client Alert

FDA & Life Sciences Practice Group

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Department of Veterans Affairs Issues Final Rule on In-Person, On-Site Promotion of Drugs and Drug-Related Supplies

On March 5, 2012, the Department of Veterans Affairs (VA) released a Final Rule governing "on-site, in-person promotional activities, including educational activities" by pharmaceutical company representatives at VA medical facilities. Department of Veterans Affairs, Drug and Drug-Related Supply Promotion by Pharmaceutical Company Representatives at VA Facilities, Final Rule, 77 Fed. Reg. 12997 (Mar. 5, 2012); 38 C.F.R. § 1.220. The Final Rule modifies 38 C.F.R. part 1 and becomes effective on April 4, 2012.

The Final Rule was part of VA's effort to establish a set of national VA-wide rules governing on-site promotion at VA facilities to replace the current network of rules created at the local and regional VA Integrated Service Network (VISN) levels. Any inconsistent local policies are preempted by the Rule. VA's purpose in creating the rule was "to reduce or eliminate any potential for disruption in the patient care environment, manage activities and promotions at VA facilities, and provide pharmaceutical company representatives with a consistent standard of permissible business practice at VA facilities." Its objective was to protect patient safety, the integrity of VA's National Formulary and criteria-for-use, and the amount of time that VA clinicians have to commit to their patients.

In the preamble to the Final Rule, VA expressly clarified that the rule governed only physical access to VA medical facilities and that "information and materials can be distributed through other means than in-person at a VA medical facility."

Criteria for Drugs Eligible for On-Site, In-Person Promotion

The Final Rule describes the circumstances under which pharmaceutical representatives may promote drugs on the VA National Formulary (VANF) and drug-related supplies,[i] as well as drugs that are not on the VANF (non-VANF), but for which VA has developed criteria-for-use (available at www.pbm.va.gov).[ii]

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Under the Final Rule, on-site, in-person promotion will be allowed for VANF drugs and drug-related supplies and non-VANF drugs with criteria-for-use and drug-related supplies if: (1) the drugs or drug-related supplies "are discussed, displayed, and represented accurately;" (2) the promotion "has significant educational value and does not divert VA staff from other activities" that they would otherwise be performing while on duty; and (3) the drug or drug-related supply is not non-promotable.[iii] New molecular entities and non-VANF drugs and drug-related supplies that do not have criteria-for-use may only be promoted if they meet these three criteria and are specifically permitted by the VISN Pharmacy Executive, Chief of Pharmacy Service, or a designee.[iv] We note that currently no drugs are classified as "non-promotable."

Requirements Governing On-Site Educational Programs

Under section 1.220(f) of the Final Rule, 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 and a "suitability" determination from a designated official at the facility at least 60 days before the program, unless VA agrees to a different date. Materials that are "part of a risk evaluation and mitigation strategy ["REMS"] or other duty imposed by the Food and Drug Administration ["FDA"]" will be deemed suitable, but still must be submitted to the designated official for approval. Other materials will be deemed suitable if the designated official determines that the materials meet the following requirements:

- Industry sponsorship (*e.g.*, staple goods, personnel, financing) is disclosed in the introductory remarks and in the announcement brochure for the event;
- Direct comparisons of industry-sponsored and non-sponsored sources of data on FDA-approved uses are disclosed in the introductory remarks and in the announcement brochure;
- The educational program does not solicit protected patient health information or patient participation in pharmaceutical-company sponsored programs, except as required by Federal laws and regulations, such as pursuant to a REMS required by FDA;
- Patient education materials, unless FDA-required labeling, do not contain the name or logo of the manufacturer and are not used to promote a specific medication, unless the VA Pharmacy Benefits Management Service determines that the logo is inconspicuous and legal requirements make removal impractical;
- Education programs and associated materials for a drug, drug-related supply, or a new therapeutic indication for a drug that is on the VANF but not yet reviewed by VA must be submitted to the facility's Chief of Pharmacy Services or designee; and
- Educational programs and associated materials focusing primarily on non-VANF drugs or drug-related supplies without criteria-for-use are permitted only if they meet the criteria for promotion and if specifically permitted by the VISN Pharmacy Executive, Chief of Pharmacy Service, or a designee.

The Final Rule does not contain an express exemption for journal articles, as requested by one commenter. VA explained that it did not add such an exemption because "[t]here exist multiple avenues for the distribution of journal articles." VA reasoned that staff and patients are free to research and acquire any medical literature they need, that journal articles may be distributed in connection with on-site activities in accordance with the Final Rule's requirements, and that "nothing in this rule can or should be interpreted to prevent the distribution of such materials through means other than on-site, in-person distribution (*e.g.*, through the mail)." However, VA advised parties to consult FDA's Good Reprint Practice Guidance when distributing articles concerning off-label uses.[v]

Provision of Gifts, Drugs, and Other Promotional Items

Gifts. Under the Final Rule, pharmaceutical companies are not permitted to give and VA employees are not permitted to receive "any item (including but not limited to promotional materials, continuing educational materials, textbooks, entertainment, and gratuities) that exceeds the value permissible for acceptable under government ethics rules." The Standards of Ethical Conduct for Employees of the Executive Branch generally prohibit Executive Branch employees from accepting any gift "or other item of monetary value" from "any person or entity seeking official action from, doing business with, or conducting activities regulated by the employee's agency, or whose interests may be substantially affected by the performance or the nonperformance on the employee's duties."[vi] However, an exception to the prohibition allows employees to accept "unsolicited gifts having an aggregate market value of $20 or less per source per occasion" as long as the aggregate market value of gifts received from any one person does not exceed $50 in a year.[vii]

Items that may not be given to VA employees may potentially be donated to a medical center library or individual facility for use by all employees in accordance with the facility's policy. Gifts of travel support for VA staff official travel may be accepted subject to advanced legal review.

Meals. The Final Rule also states that food items of any type or any value may not be provided to VA staff, including volunteers and without compensation employees, and pharmaceutical company representatives may not bring food items into the VA facility for use by non-VA staff.

Samples. Samples of drugs and drug-related supplies must be submitted by the pharmaceutical company representative to a designated official at the facility for approval, and all "usage information" pertaining to the drug or drug-related supply must be sent to the VISN Pharmacist Executive or VISN Formulary Committee. Samples must be delivered to the Office of the Chief of Pharmacy Services "for proper storage, documentation, and dispensing," and drugs and drug-related supplies may not be provided to VA staff for personal use.

Conduct of Pharmaceutical Company Representatives

In order to engage in permissible promotional activities under the Final Rule, pharmaceutical representatives must schedule an appointment before each visit "[i]n order to minimize the potential for disruption of patient care activities." During these visits, representatives may not leave promotional materials or make meeting requests with other VA staff, although representatives are permitted to respond to requests initiated by VA staff during the visit. VA facilities may develop "do-not-call lists" of individuals and departments who may not be contacted and for whom materials may not be left by pharmaceutical representatives. Pharmaceutical representatives are not permitted to use the paging system to locate VA employees, but use of beepers is allowed if specifically requested by the VA employee. Representatives are also prohibited from marketing to medical, pharmacy, nursing, and other health profession students, including residents, unless approved by and conducted in the presence of staff members providing clinical supervision.

To protect patient privacy, pharmaceutical representatives may not attend medical center conferences where individual patient information is discussed or presented,[viii] and representatives generally may not wait for scheduled appointments or make presentations in patient-care areas.[ix] Materials may only be distributed on-site at the time and location of the scheduled appointment or educational program; materials may not be left in patient care areas because patients may be confused by manufacturer-sponsored brochures that are inconsistent with VA's drug therapy management processes and the materials may create a perceived VA bias for or against certain products.

Penalties for Non-Compliance

If the Director of the VA medical center of jurisdiction determines that a company representative failed to comply with the rules governing on-site promotion at VA facilities, the Director may limit, suspend, or revoke the visiting privileges of the representative by written order, but may not issue a fine. The Director will notify the representative of the non-compliance and any interim disciplinary action taken. The representative's supervisor may also be notified in the case of multiple instances of misconduct. Representatives will have 30 days to provide a response to the notice, after which the Director will issue a final written order to the representative or supervisor confirming the action taken. The final written order must include a summary of the circumstances of the violation, a listing of the specific provisions of the section that the representative violated, the bases for the Director's determination of what action to take, and, if the notice suspends or permanently revokes visiting privileges of multiple representatives, notice concerning the right of review of the order. Pharmaceutical companies may request review of a final written order by the Under Secretary of the VA by written request within 30 days of the order, although VA will enforce the final written order while the order is under review.

First Amendment Concerns

In response to a comment that VA's requirement of permission before promotion of non-VANF drugs with no criteria-for-use would violate the First Amendment, VA explained that its requirement did not violate the First Amendment because it knows of "no right to discuss products with Government officials acting in their official capacity." VA explained that it is not "in any way restricting pharmaceutical company representatives from communicating these views to members of the public . . . in a proper forum for free speech," which VA hospitals are not. VA also explained that an important rationale for supporting the rule was "the need to maintain and enhance patient safety" because the drugs are placed on the VANF "through a rigorous and scientifically-based process, in which patient safety is paramount with cost being a secondary consideration."

Implications for Pharmaceutical Manufacturers

VA's Final Rule strictly regulates on-site promotion of drugs and drug-related supplies at VA facilities. Although aspects of the Final Rule are consistent with current practices at many VA facilities, some provisions will likely require manufacturers to change existing compliance policies that govern interactions at VA facilities. In addition, companies should note that even though the rule often deems FDA-reviewed materials to meet VA's requirements, the materials must still be submitted to VA for review in many cases (*e.g.*, materials that will be distributed as part of an educational program). Finally, it appears that some provisions of the Final Rule will require further action on the part of VA facilities to be fully implemented, such as the specific process that manufacturers should use to seek approval of educational programs and associated materials, as well as some of the particular requirements related to that process, such as the types of information that would be acceptable sources of "non-sponsored sources of data or other analytical information . . . for FDA-approved uses of a particular drug." VA may issue specific guidance regarding the food prohibition and other restrictions on the conduct of pharmaceutical company representatives at VA facilities, so manufacturers should continue to monitor this issue for any such working guidance that it disseminates.

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[i] "Drug-related supplies" are "supplies related to the use of a drug" and include "devices required to use a given drug in accordance with prescribed use," *e.g.*, inhalers, spacers, insulin syringes, and tablet splitters.

[ii] Criteria-for-use are "clinical criteria developed by the [VA] at a National level that describe how certain drugs may be used." A list of current criteria-for-use is available at www.pbm.va.gov. In the Final Rule, VA explained that "[w]hile FDA approves drugs for certain purposes or uses based on the population at large and potential uses of the drug, VA further considers how a certain drug may be best-used for the benefit of our unique patient population," so "[w]hile VA criteria-for-use may be more specialized or tailored than FDA-approved labeling, criteria-for-use will not contradict FDA-approved labeling."

[iii] The list of non-promotable drugs is available by request or on VA's website at www.pbm.va.gov. VA stated in the Final Rule that it disagrees with comments that pharmaceutical manufacturers should participate in the determination of whether a drug is non-promotable because VA needs to maintain the safety of its patients by preserving its ability to make quick, important clinical responses to scientific and medical developments independently. Specifically, VA "must be able to designate a drug as non-promotable in order to enforce any attempt by pharmaceutical company representatives to systematically promote the use of a certain drug for uses outside of those sanctioned by VA." In deciding whether a drug is non-promotable, "VA considers many factors, including price, a determination that a certain drug has no clinical benefit, or a finding that promotional materials exceed the clinically determined specific use of a drug — such as when VA makes a clinical decision to utilize a drug for a narrow purpose." VA stated that it "will rarely, if ever, classify a drug as non-promotable" and noted that currently there were no drugs classified as non-promotable.

[iv] A "new molecular entity" is "a drug product containing an active ingredient that has never before received [FDA] approval."

[v] *See* U.S. Food and Drug Administration, Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (2009), http://www.fda.gov/regulatoryinformation/guidances/ucm125126.htm.

[vi] 5 C.F.R. § 2635.101(b)(4); *see also* 5 C.F.R. pt 2635.

[vii] 5 C.F.R. § 2635.204(a).

[viii] We note that VA declined to define the term "medical center conference" on the basis that the term is unambiguous.

[ix] These areas include: patient rooms and ward areas where patients may be encountered, clinic examination rooms, nurse stations, intensive care units, operating room suites, urgent care centers, emergency rooms (but not staff offices located in them), and ambulatory treatment centers.