HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Mr. Barry A. Wilson
Chief Pharmacy Officer
Family Care Health Centers
401 Holly Hills
St. Louis, MO 63111

Re: Docket No. 2003P-0288/CP1

Dear Mr. Wilson:

This letter responds to your citizen petition received on June 20, 2003, requesting an interpretation of the phrase "pharmacies of hospitals or other health care entities" as used in section 503 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 353). In particular, you request that the Food and Drug Administration (FDA) deem the pharmacy located in the Family Care Health Center (FCHC) a pharmacy of a "health care entity" for the purposes of receiving and dispensing prescription drug samples. We have responded in the past to similar inquiries. For the reasons stated below, your petition is granted.

The Prescription Drug Marketing Act of 1987 (PDMA) was enacted on April 22, 1988, and was modified by the Prescription Drug Amendments of 1992 (PDA) on August 26, 1992. The PDMA, as modified by the PDA, amended various sections of the Act to, among other things, establish requirements for the distribution of human prescription drug samples. The PDMA made it unlawful, according to section 503(c)(1) of the Act, for any person to "sell, purchase, or trade or offer to sell, purchase, or trade any drug sample." In addition, section 503(d) of the Act bars any person from "distribut[ing] any drug sample." There are exceptions, however, to this prohibition. According to section 503(d)(2)-(3), a manufacturer or authorized distributor of a drug may distribute samples but only (1) to licensed practitioners or (2) upon request of a licensed practitioner, to "pharmacies of hospitals or other health care entities." Similarly, according to section 503(d)(1), the prohibition on drug sample distribution does not preclude the dispensing of prescription drug samples to patients by a (1) licensed practitioner, (2) health care professional acting at the direction and under the supervision of a licensed practitioner, or (3) "pharmacy of a hospital or of another health care entity" that is acting at the direction of a licensed practitioner. Our regulations implementing the PDMA (21 CFR part 203) codified the drug sample distribution requirements and restrictions.

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According to your petition, the FCHC is an outpatient facility that provides medical treatment to the St. Louis community. In addition, the FCHC houses a pharmacy (the FCHC pharmacy). The FCHC and the FCHC pharmacy are owned and operated by the Federally Qualified Community Healthcare Center (Petition at 1-2). Based on telephone conversations with you on August 10 and September 3, 2003, we understand that you would like for physicians practicing at the FCHC to be able to order samples from the manufacturer for delivery to the FCHC pharmacy in accordance with the regulations referenced above.

Section 503(d) of the Act does not require a pharmacy to be a *hospital pharmacy* in order to receive and dispense prescription drug samples. The Act permits pharmacies of hospitals *or other health care entities* to receive and dispense prescription drug samples. According to § 203.3(q), a *health care entity* is "any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor." Therefore, as a provider of medical treatment on an outpatient basis, the FCHC is a *health care entity*, and it follows that the FCHC pharmacy is the pharmacy of a health care entity. The FCHC pharmacy may receive and dispense prescription drug samples under section 503 of the Act. The FCHC pharmacy and its employees remain subject, however, to section 503(c) of the Act, which prohibits the sale, purchase, or trade or offer to sell, purchase or trade any prescription drug sample.

For the reasons described above, your petition is granted. As the pharmacy of an entity that provides medical treatment, the FCHC pharmacy is the pharmacy of a health care entity for the purposes of section 503 of the Act.

Sincerely yours,

John M. Taylor, III
Associate Commissioner
for Regulatory Affairs

cc: Kevin Kinkade R.Ph,
Executive Director
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