



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY 17 2004

Food and Drug Administration  
Rockville MD 20857

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Mr. Andrew P. Twyman  
Deputy Assistant Secretary  
Office of Mental Health  
State of Louisiana Department of Health and Hospitals  
1201 Capitol Access Road  
P.O. Box 4049  
Baton Rouge, Louisiana 70821-4049

Re: Docket No. 2004P-0036/ CP1

Dear Mr. Twyman:

This letter responds to your citizen petition received on January 21, 2004, 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 outpatient clinic pharmacies operated by the Louisiana State Office of Mental Health (LSOMH) pharmacies of a *hospital or other 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) and (3) of the Act, 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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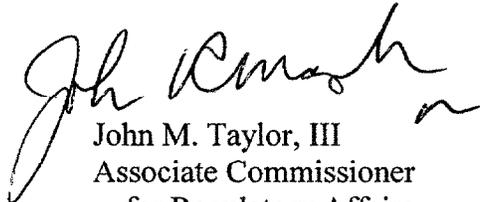
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According to your petition, LSOMH operates outpatient clinics, which provide medical treatment to patients. The outpatient clinics house pharmacies, also operated by LSOMH, which exclusively serve LSOMH patients (LSOMH pharmacies). LSOMH would like for the pharmacies to be able to receive and dispense prescription drug samples in accordance with the PDMA and implementing 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 LSOMH outpatient clinics are *health care entities*, and it follows that the LSOMH pharmacies are pharmacies of a health care entity. The LSOMH pharmacies may receive and dispense prescription drug samples under section 503 of the Act. The LSOMH pharmacies and their 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 pharmacies of entities that provide medical treatment, the LSOMH pharmacies are pharmacies 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