

PETITION
to
Food and Drug Administration

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Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Action Requested

Petitioner Family Care Health Centers requests the Food and Drug Administration to interpret §503 of the Federal Food, Drug, and Cosmetic Act (codified at 21 U.S.C. §353)--specifically, the following language of §503(d)(3)(A)(i) and (ii):

“(A) Drug samples may only be distributed-

- (i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or
- (ii) at the written request of such a licensed practitioner, to *pharmacies of hospitals or other health care entities.*”
emphasis added.]

Petitioner specifically requests its pharmacy, located in an outpatient facility owned and operated by the Petitioner, a Federally Qualified Community Health Center, be deemed a “ pharmacy of an other health care entity” within the meaning of §503 and be allowed to inventory and dispense drug samples to its patients, many of whom are indigent, where:

- The pharmacy in the Family Care Health Center is owned and operated by the Federally Qualified Community Healthcare Center, and is directed by the same management as the community healthcare center.

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- The pharmacy in the community healthcare center has a system in place for carefully managing the samples, as further discussed below
- The patients of the Healthcare Center are the indigent, uninsured and under-insured of the St. Louis, Mo. inner city. Many of whom
- would go without medication except for the use of samples.

Statement of Grounds

General Background. Family Care Health Center is a Federally Qualified Community Healthcare Center. The mission of the Healthcare Center is to provide patient care to all in the community, including care for the medically indigent.

Family Care Health Center is also a *§501(c)(3)* tax-exempt organization under the Internal Revenue laws and regulations, and is a participant in the federal 340 B drug program to the benefit of the indigent patients treated.

Drug Samples at Family Care Health Centers' Pharmacy. The Federally Qualified Community Healthcare Center owns and operates a pharmacy located in the Healthcare Center. Physicians on the staff of Family Care Health Centers request and receive drug samples (i.e., sign for them) and the samples are stored and dispensed by physicians from a physician sample room. The Federally Qualified Community Healthcare Center wishes to have these samples stored in and dispensed from their new pharmacy which would track drug samples.

The advantages of the pharmacy handling the samples includes the following:

1. Better storage conditions
2. Better evaluation as to acceptable condition of the samples when received.
3. Better record keeping of samples.
4. Better statistics on use of samples.
5. Better ability to handle recalls of samples. The pharmacy has a mechanism for contacting patients in the event of a medication recall
6. A more complete patient drug profile can be maintained.
This is essential to checking for drug-drug, drug-alcohol and drug-food interactions, as well as duplicate & incompatible therapy.
7. Better and more professional labeling of samples, including caution and warning labels, detailed patient drug information sheets containing indications, warnings, contraindications, cautions, administration information, side-effect information, etc.

8. Better utilization of samples.
9. Counseling by a registered pharmacist.
10. Dispensed by prescription only and at no charge.

Earlier this year an inquiry was made of the inspector from the Missouri State Board of Pharmacy who had visited and made an initial inspection of the Healthcare Center pharmacy as to having the physicians donate their samples to the pharmacy. The inspector replied the pharmacy could not have samples and any samples found in the pharmacy would be seized. When asked about another healthcare provider which was allowed to keep samples, the inspector indicated that this other facility was part of a hospital system but that the petitioner had no such hospital connection. Due to this, no samples have been placed in the pharmacy.

Subject: Question Date: Wed, 02 Apr 2003 10:33:51 -0600 Status: Normal To: m.kidd@juno.com

Dear Mike Kidd:

The pharmacy is partially open handling our indigent patients and uninsured patients while we wait for a medicaid provider number so we can handle the large number of medicaid patients we have.

We are a Federally Qualified Community Health Center who will only serve patients of our health center and no outside patients. Approximately 96% of our patients are either uninsured or on medicaid.

Presently our physicians have drug company samples sent directly to them. They would like to have the pharmacy handle the dispensing of their samples. This would be done in a manner similar to that used at St. Louis ConnectCare.

Samples would only be dispensed to our indigent and uninsured patients. They would be dispensed free, with no charge to the patients. We would inventory the samples when received and keep a log of the samples given out, including lot numbers for easy recall if necessary. We would only dispense samples when requested by the physician on a prescription. We would keep the sample prescriptions in a separate file for easy review by you. All Sample prescriptions would be indicated with an "S" on them or however you felt best.

Basically we would handle the samples as they are handled at St. Louis ConnectCare. If you had any suggestions as to how to handle the samples, we would certainly adapted our procedures to your suggestions.

The advantages of the pharmacy handling the samples includes the following:

1. Better storage conditions
2. Better evaluation as to acceptable condition of the samples.

3. Better record keeping of samples.
4. Better statistics on use of samples.
5. Better ability to handle recalls of samples.
6. A more complete patient drug profile can be maintained.
7. Better and more professional labeling of samples.
8. Better utilization of samples.
9. Better check for drug-drug, drug-food, drug-alcohol interactions.

I would be happy to discuss this with you and of course, we would take no action pending your approval.

Thank you for your time and consideration.

Yours very truly,

Barry A. Wilson

**Subject:Re: Question Date:Fri, 4 Apr 2003 13:58:33 -0600 Status:Normal From:Michael A Kidd
<m.kidd@juno.com>**

The only way a pharmacy can have samples is if they are affiliated with a hospital. Connectcare was affiliated with Regional hospital I believe. I do not believe you can have samples at your pharmacy.

Feel free to contact Kevin Kinkade R.Ph, Executive Director of the Missouri Board of Pharmacy at P.O.Box 625 Jefferson City, Mo. 65102 if you want something in writing regarding this.

Mike Kidd R.Ph. inspector

Petitioner believes that its pharmacy falls within the "or other health care entities" language of Section 503 (d)(3)(A)(ii) as the pharmacy is a pharmacy of an(other) health care entity, naming the Federally Qualified Community Healthcare Center.

Additional Information

The Missouri State Board of Pharmacy can be reached at:

**Missouri Board of Pharmacy
3605 Missouri Boulevard
P. O. Box 625
Jefferson City, MO 65102
(573) 751-0091 Telephone
(573) 526-3464 FAX**

Environmental Impact Statement (EIS):

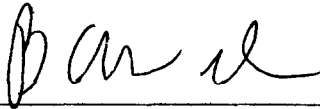
Petitioner claims a categorical exclusion from the environmental impact statement (EIS) requirement, for purposes of its petition requesting that the Food and Drug Administration interpret § 503 of the Federal Food, Drug, and Cosmetic Act, pertaining to the distribution of drug samples by a Federally Qualified Community Healthcare Center-owned pharmacy.

The categorical exclusion is claimed pursuant to 21 C.F.R. § 25.31, entitled "Human Drugs and Biologicals," and more specifically, 21 C.F.R. § 25.31(h), "Issuance, revocation, or amendment of a standard for a biologic product."

To the petitioner's knowledge, no extraordinary circumstances exist,

Certification

To the best of my knowledge, this petition includes all information relevant to the petition, favorable or not.



Signature

Barry A. Wilson
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