

MARIAN CLINIC

November 28, 2000

Margaret O'Rourke, Senior Regulatory Expert
Center for Drug Evaluation Research
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Dear Ms. O'Rourke:

I am writing to request an exemption for Marian Clinic and other private non-profit clinics to the rules and regulations posted December 3, 1999 (volume 64, Number 232) (DOCID:fr03de99-20) that amends the PDMA regulations 21 CFR203.39.

Marian Clinic serves the low-income uninsured population of Shawnee County. Last year we had 7174 medical visits on our site. We try to help our patients obtain the medication prescribed by our volunteer doctors in three ways: (1) samples received from doctors' offices and pharmaceutical companies authorized by the doctor, (2) the indigent medication programs of pharmaceutical companies and (3) Marian Clinic paying the cost of the medicines from Medical Mart Pharmacy out of grant money. Last year we gave out 3746 samples and paid for 1039 prescriptions. The office person who helps with the indigent drug program says she spends about 14 hours per week helping 180 current patients with the application and maintenance in getting medicines from pharmaceutical companies.

Regarding the donated sample medications, each of two staff nurses spend 20% of their time sorting, dating and putting samples on the shelves of our locked medicine room. Nurses put together a month's supply of medicine without tampering or breaking the packages. If the lot numbers had to be noted that would be difficult to do since the medicine comes from different doctors' offices. When patients are seen by the doctors, the samples are ready for the patients. The date, amount and frequency that the patient should take of the medicine are noted on the patients' charts. The patients are given oral and written instructions and precautions concerning the prescribed medications.

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Roberta Krull, Russ Niver DDS, John Padilla, Marilyn Page, Carol Robertson,
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The proposed regulations for the acceptance, storage and distribution of drug samples by charitable institutions would be difficult for us to fulfill. We do not have a pharmacist on the premises other than the occasional University of Kansas pharmacy student who helps because of a mandatory volunteer requirement. The Clinic which is supported mainly by private money does not have the resources to hire additional staff to coordinate such an effort. I would be forced to stop accepting sample medicines from doctors in the community if the exemption is not granted to us.

To understand the full impact of how the proposed regulations could hamper our ability to help the medically underserved I believe you would need to see first-hand how we do what we do with limited staff and volunteers. I extend an open invitation for you or your representative to come visit our Clinic. I believe that in a worthy attempt to make the medicines safe for people an obstacle is created that would severely hamper our efforts to help the medically uninsured.

Sincerely,



Marilyn Page, LSCSW, PhD
Executive Director

CC: Governor Bill Graves
Senator Sam Brownback
Representative Dennis Moore
Secretary Clyde Graeber
Senator Sandy Praeger

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