



Kansas Association
for the
Medically Underserved
The State Primary Care Association

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November 20, 2000

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

Dear Ms. O'Rourke:

This letter is being directed to you in response to rules and regulations posted December 3, 1999 (volume 64, Number 232) (DOCID:fr03de99-20) that amends the PDMA regulations 21 CFR203.39 and sets up regulations for the acceptance, storage and distribution of drug samples by charitable institutions.

I am writing to request an exemption for the more than 30 private non-profit clinics that currently provide services to the uninsured in our state. As director of The Kansas Association for the Medically Underserved, which is a State association of non profit primary care clinics and federally qualified health centers in the state of Kansas and the Primary Care Association for the State of Kansas, I can honestly say these new regulations will cause undue burden on staff, most particularly in those clinics that are primarily staffed by volunteer support.

For the past 10-15 years, Kansas has worked diligently to create a comprehensive primary care system of care for the uninsured in Kansas. This system includes approximately 30 non-profit primary care clinics. Sixteen of these clinics receive funding from the Kansas Department of Health and Environment, through state legislation that was enacted in 1991. Additionally there are 8 are federally funded Community Health Centers, or Federally Qualified Health Centers (FQHC's) who receive funding from the Health Resources Service Administration (HRSA), four primary care clinics, who are located in local health departments and the remainder, who are supported through contracts with local non profit hospitals or other community or faith based organizations.

Each day, all across the state, physicians deliver samples to these clinics and health centers, where in 1999 over 70, 000 individuals received services. For over 70% of the patients, who are the uninsured, these samples represent the only medications they are able to receive. For many of the clients, samples represent the first month's supply of prescribed medication while staff prepare papers to enroll the patient in the various medically indigent drug programs of participating pharmaceutical companies.

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Kansas Health Centers - A Good Investment

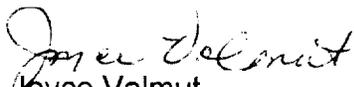
Within any given month professional staff, who work or volunteer for these health care organizations, all non-profit 501(c)3 primary care clinics and health centers, may distribute 3 to 400 different kinds of medication each month.

Although we agree that regulations and standards are necessary to assure safe delivery of medications, we believe that these regulations go beyond what is necessary and are therefore asking for exemption since the resources to complete the requirement of this proposal would be prohibitive to most clinics or health centers.

In the city of Topeka alone, which is a city of about 120,000, it is not unusual for 30 or 40 physicians to donate as many as 500 different types of samples to clinics. This means one clinic could receive as many as 2000 samples of medications each month. These samples are delivered in large boxes or shopping bags. They have not been sorted prior to delivery. Lot numbers are mixed together, some in the same packages. Once delivered professional staff check, sort and shelve samples that are appropriate for the patients they serve. Out of date medications are destroyed according to proper procedure. Every precaution is taken to assure that packages are not tampered with or broken. In many instances, clinics have called on local pharmacists to provide them with assistance in setting up their sample supply room, however none of the clinics or FQHC's have funds to hire pharmacists as the regulations call for. It takes approximately 50% professional staff time just to sort through the samples and keep the clinic stock up to date. In order to complete the requirements as proposed in this regulation, at least one full time staff person would need to devote all of their time to this task and a computerized program would need to be developed to assure the type of tracking and the inventory described is completed accurately.

We believe it is unrealistic to expect non-profit clinics or health centers to take on this additional burden, especially in light of the fact that these clinics and health centers are already strapped for resources and have already taken on the moral and legal burden of care for a population of people that is itself, without resources and especially in light of the fact that no evidence supports unsafe practices where medications are involved within these facilities.

We therefore implore you to exempt these charitable institutions.


Joyce Volmut
Executive Director

CC: Governor Bill Graves
Senator Sam Brownback
Senator Pat Roberts
Representative Jerry Moran
Representative Jim Ryun
Representative Todd Tiarht
Representative Dennis Moore
Secretary Clyde Graeber
Senator Sandy Praeger