MANAGING MEDICATION SAMPLES

A Volunteers in Health Care Guide

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Preface

October, 2001

This manual was developed to provide information to free clinics regarding regulations and subsequent exemptions to parts of those regulations issued by the Food and Drug Administration (FDA) in December, 2000. These regulations address the donation of physician samples to charitable institutions.

The National Free Clinic Task Force, simultaneous with the production of this manual, entered into discussions with FDA about the regulations and their potential effect on free clinic operations. As a result of that meeting the Food and Drug Administration has taken the issue under consideration. In addition, in August, 2001 Congressman Richard Burr (R-NC) and Congressman Gerald Kleczka (D-WI) introduced H.R. 2740, the Drug Access Act of 2001, which proposes to overturn the applicable FDA regulations for free clinics. [1]

For more information on the proposed legislation or the National Free Clinic Task Force's efforts in this area, please contact the National Free Clinic Task Force, which has been working with the bill's sponsors:

Mark Cruise, vafc@bellatlantic.net
Virginia Association of Free Clinics
Richmond, Virginia

Glenn T. Pierce, gtpierce@worldnet.att.net
ABCCM Medical Ministry
Asheville, North Carolina

Marty Hiller, marty@thefreeclinic.org
Free Clinic of Greater Cleveland
Cleveland, Ohio

Patricia White, healthright@aol.com
West Virginia Health Right, Inc.
Charleston, West Virginia

John Mills, jgmills@earthlink.net
North Carolina Association of Free Clinics
Winston-Salem, North Carolina

To contact the bill's sponsors:

Congressman Burr's office
Staff contact: Jenny Hansen (202)225-2071

Congressman Kleczka's office
Staff contact: Maria Castillo (202)225-4573

1 *As of November, 2003, Congressman Burr's office stated that the bill had not made progress and the FDA had not yet overturned the FDA regulations for free clinics.*

Understanding Drug Sample Regulations

Are you confused about how to stay in compliance with drug sample regulations? Maintaining a system for drug samples can be challenging for free clinics due to limited resources and the complexity of sample regulations. Volunteers in Health Care has developed this document as a resource for volunteers and staff of free clinics or other pharmaceutical access programs on regulations passed by the Food and Drug Administration (FDA) regarding drug samples.

It is important to keep in mind that drug samples are regulated at both the federal and state levels. The main purpose of this document is to provide guidance regarding the federal regulations, but you will also find information about how to learn more about your state regulations. Remember to comply with both federal AND state regulations regarding drug samples.

This document was created by Katheryne Richardson, PharmD, after discussions with pharmacists and administrators of free clinics and other programs providing pharmaceutical access for the uninsured or underserved. Volunteers in Health Care would like to thank the programs that gave of their time in order to make this *Managing Medication Samples: A Volunteers in Health Care Guide* possible. In addition, Volunteers in Health Care would like to thank the FDA for reviewing and providing input to this document.

VIH

Volunteers in Health Care(VIH) is a national resource center for health care providers and programs serving the uninsured, with a special focus on programs using volunteer clinicians. Our mission is to promote and support organized, community-based health care initiatives with one-on-one technical assistance, consulting services, the creation of hands-on tools and the sharing of service models, experiences and information. Through its three program areas-volunteer supported medical services, oral health and pharmaceutical access-VIH maintains a body of expertise upon which community programs can draw. This manual is one of several products available through Volunteers in Health Care. If you would like more information about Volunteers in Health Care, please call 1-877-844-8442 or log onto our website, www.volunteersinhealthcare.org

ABOUT THE AUTHORS

Katheryne Richardson, Pharm.D. is a pharmacy consultant who has recently consulted for the federal Pharmacy Affairs Branch and Volunteers in Health Care. She received her Doctor of Pharmacy degree from the University of Kentucky College of Pharmacy and has worked for the Bureau of Prisons and the Department of Defense. She has also had experience volunteering as a pharmacist at free clinics in Lexington, KY and Jacksonville, FL.

Janet Walton, M.A. is Deputy Director for Volunteers in Health Care. Ms. Walton has an MA in sociology from Harvard University and has worked extensively in the health care field. She has programmatic responsibility for VIH and leads the organization in its strategic development. Prior to her work at VIH she served as senior staff to the Director of Public Health in Boston and as an independent consultant for municipal, state and private organizations providing health care to vulnerable populations.

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Table of Contents

I. Federal Regulations

A. BACKGROUND AND EXEMPTIONS

In December, 2000 regulations regarding drug sample distribution and management developed by the FDA went into effect. These regulations, a consequence of the Prescription Drug Marketing Act of 1987, can be found in the Code of Federal Regulations: 21 CFR 203. One subsection, 21CFR203.39, addresses the issue of donation of drug samples to charitable institutions. After the regulations were published, several free clinics wrote to the FDA requesting to be exempted from these regulations. In response, the FDA agreed to permit free clinics to have three major exemptions from the drug sample distribution regulations, as long as the exemptions didn't interfere with state law. (See Appendix I for FDA letter of response.) This is an important point to remember: although free clinics are exempt from certain federal regulations they are still required to follow state law. The special exemptions from federal regulations for free clinics are as follows:

1. **Free clinics do NOT have to conduct an annual sample inventory or report.** This means that every year most other types of facilities are required to conduct a sample inventory and prepare a report, but free clinics are not required to do so. [203.39(g)]

2. **Free clinics may permit a person other than a *licensed practitioner* to examine the samples prior to dispensing or distribution.** This means that federal regulations do not require the pharmacist or licensed practitioner to actually conduct the examination, but that they may authorize another person to do this. An advantage of this exemption is that it will allow free clinics to efficiently use its volunteers. [203.39(c)]

3. **Free clinics need to include only the following information in the sample distribution log: drug brand name, lot number, quantity, and date of distribution, destruction, or dispensing.** [203.39(f)] There is conflicting information in the exemption letter from the FDA. Until this issue is resolved, it is recommended that you follow the wording in the letter regarding [203.39(e)]. The example log that is included with this document follows section [203.39(e)] until a clarification can be obtained.

Please note: If your organization is not a charitable health care facility as described in the FDA letter, these exemptions are not applicable to your organization (see *Frequently Asked Questions* and *Appendix I* for further information).

B. Federal Regulations for Drug Samples in Charitable Insitutions: A Checklist

Action	Who Performs Action	What to Check
Receiving Drug Samples 203.39(a), (b)	■ An authorized agent or employee of the charitable institution	**The sample...** ❑ Arrives in a sealed carton ❑ Is in its original, unopened packaging ❑ Has intact labeling
Inspecting Drug Samples 203.39(c), (d), (e), (f)	■ A licensed practitioner ■ A registered pharmacist ■ A person authorized by a licensed practitioner of the charitable institution	❑ Donation record accurately describes drug sample ❑ Expiration date is within limits ❑ Sample labeling is not mutilated, obscured, or detached from packaging ❑ Sample doesn't show evidence of storage or shipping conditions that might have affected its stability, integrity, or effectiveness ❑ Sample is still on the market and not subject to a recall ❑ Sample shows no evidence of contamination, deterioration, or adulteration ❑ If the sample does not pass the inspection, it should be destroyed or returned to the manufacturer and this information recorded in the log
Donating Drug Samples to another institution 203.39 (b), (c), (e), (f)	■ Collection by an authorized agent of the recipient charitable institution ■ Personal delivery by a licensed practitioner or an agent/employee of the donating charitable institution or by mail/common carrier	❑ Follow the 8 steps under *Inspecting Drug Samples* above ❑ Record donation information in the log ❑ Place samples in a sealed carton ❑ Adhere to any additional state regulations or guidelines before donating ❑ Donate the samples
Destroying, returning or dispensing Samples 203.39 (d)	■ State regulations will determine the authorized parties	❑ Record information in the log ❑ Consult state regulations/guidelines to determine the specific procedures for destroying, returning or dispensing samples

This information is based on 21 CFR 203.39 *Donation of drug samples to charitable institutions*, and the Request for Exemption from 21 CFR 203.39 dated December 7, 2000. Please contact the state board of pharmacy or medicine for any additional regulations or guidelines that pertain to particular states.

C. An Example of a Drug Sample Log

SAMPLE LOG* ___-___-___ UNTIL___-___-___

DRUG BRAND NAME & STRENGTH	MANUFACTURER	LOT #	QTY	DATE RECEIVED /ITL**	RECEIVED FROM: Name Address Phone #	DATE INSPECTED /ITL	DATE DESTROYED /ITL	DATE RETURNED /ITL	DATE DISPENSED OR DISTRIBUTED/ITL

* Keep this log for 3 years.

** ITL=Initials of person recording item on log. ITL for Date Inspected signifies that the following items were checked and satisfactory: expiration date, labeling, overall appearance, product name.

This information is based on 21 CFR 203.39 *Donation of drug samples to charitable institutions*, and the Request for Exemption from 21 CFR 203.39 dated December 7, 2000.
Please contact the state board of pharmacy or medicine for any additional regulations or guidelines that pertain to particular states.

II. State Regulations

A. BACKGROUND

Most states have unique regulations regarding drug samples. The state board of pharmacy and the state board of medicine will usually have some state regulations for drug samples in addition to the federal regulations. (For a list of state boards of pharmacy and medicine, see Appendix II).

In most states, drug samples are under the control of the prescriber. Thus, the state board of medicine will often have regulations about how its prescribers should handle samples. The state board of pharmacy is often limited in its ability to dictate what rules must be followed for samples. Often the state board of pharmacy will have a few rules regarding prescriber dispensing, and a few rules limiting or forbidding pharmacy possession and dispensing of drug samples. The main authority regarding drug samples is often left to the state board of medicine. Because there is considerable difference in the way states handle the authority for drug samples, it is a good idea to contact both the state boards of medicine and pharmacy to learn about specific state drug sample regulations.

If the free clinic desires or is required to obtain a pharmacy permit, the board of pharmacy's dispensing regulations will likely become the most relevant authority. Although each state is different, the presence of a pharmacy permit may determine whether or not the free clinic needs to follow dispensing requirements determined by the board of pharmacy. As an example, one state requires a pharmacy permit in order to repackage or dispense medications. Samples that are given to patients by prescribers in their sample packaging do not fall under this repackaging or dispensing requirement, and this action is not governed by the state board of pharmacy dispensing regulations. If the prescriber desires to sell medication to patients, charge a fee for this dispensing, or engage in medication repackaging (taking samples out of the original packaging and putting them into new packaging or bottles), the boards of pharmacy and medicine consider this act to be dispensing, and require the prescriber to follow the dispensing guidelines (mandating certain record-keeping and labeling requirements) promulgated by the board of pharmacy. This is just an isolated example of how one state handles drug samples and dispensing, and it is advisable to contact your state board of pharmacy to determine if your state has similar requirements.

After you receive a copy of the rules and regulations from the boards, you can remain informed about new pharmacy board policies by checking the board of pharmacy newsletter. Approximately 38 states publish their board of pharmacy newsletter online, and the documents may be retrieved on the following website: **http://www.nabp.org** and click on Foundation/State Newsletters and select your specific state.

B. QUESTIONS TO ASK THE BOARDS OF PHARMACY OR MEDICINE

If you are unsure of what questions to ask the state board of pharmacy or medicine, here are some suggestions:

1. Are there any other state entities besides the board of pharmacy or medicine that have regulations regarding drug samples? Sometimes other governing bodies will pass regulations regarding drug samples, and the board of pharmacy or medicine should be able to point you in the right direction if this is the case.
2. May I have a copy of the state board of pharmacy or the state board of medicine regulations that relate to drug samples?
3. Are there any specific regulations that I should know about regarding free clinics? (At least one state passed a specific regulation that transferred the authority regarding samples in free clinics from the board of pharmacy to another regulatory board.)
4. Who may dispense the sample—must the person be a licensed practitioner with a dispensing license?
5. What sort of information is the free clinic required to maintain regarding drug samples? This might include log books, computer records, patient or prescriber information.
6. Does the free clinic need a special license or permit to dispense samples to patients?
7. What patient and/or clinic specific information is required on the label of samples?
8. What information are patients required to receive with medications—is written material required? Who may provide this information?

A. FREQUENTLY ASKED QUESTIONS REGARDING DRUG SAMPLES

1 **What are the special exemptions from the federal Prescription Drug Marketing Act regulations for free clinics?**	Free clinics: ■ Do NOT have to conduct an annual sample inventory or report. ■ May permit a person other than a **licensed practitioner** to examine the samples prior to dispensing or distribution. This means that federal regulations do not require the pharmacist or licensed practitioner to actually conduct the examination, but that they may authorize another person to do this. ■ Need only include certain information in the sample distribution log. As the FDA will be further clarifying this exemption, it is recommended that clinics collect information indicated in the drug sample log included in this manual.
2 **What do we do if samples are lost, stolen, or missing?**	Notify the FDA within 5 working days. Contact: Office of Compliance Center for Drug Evaluation and Research U.S. Food and Drug Administration (301) 594-0101
3 **Can we give expired samples to parties that ship them overseas?**	No. The opinion of the FDA is that an expired sample drug is "adulterated," and the only appropriate actions to take would be destruction or return to the manufacturer.
4 **How do we find out about drug recalls?**	FDA issues general information about all new recalls it is monitoring through a weekly publication titled "FDA Enforcement Report" which is available by subscription from the Superintendent of Documents, Government Printing Office. For price and ordering information, contact the Government Printing Office, Washington, DC 20402, Telephone 202-512-1800; or fax to 202-512-2233. The latest issues of the FDA Enforcement Report are available FREE on FDA's Internet Website **http://www.fda.gov/opacom/enforce.html**

A. Frequently Asked Questions Regarding Drug Samples--continued

5 **Can we dispense samples in baggies as prepacks?**	Consult your state board of pharmacy for specific regulations on dispensing.
6 **Do we need a policy and procedure manual for handling samples?**	Federal regulations do not require free clinics to have a policy and procedure manual, but many states do.
7 **The federal regulations use the term "destroy" referring to samples. What is acceptable to them: throwing samples away, flushing them down the toilet, or burning them?**	The federal regulations do not specify what is considered acceptable regarding the destruction of samples. the FDA recommends that you contact either your state Environmental Protection Office (EPA) or your board of pharmacy for what is considered acceptable in your state.
8 **When the federal and state regulations conflict, what should we do?**	Follow the more strict regulation.
9 **Do the federal regulations provide guidance regarding sample dispensing/labeling requirements?**	State regulations determine this. Contact your state board of pharmacy or medicine for more information.
10 **Can we put samples with the same lot number and expiration date into prescription bottles for dispensing?**	The FDA does not object to combining samples with the same lot numbers for dispensing. However, when the packaging is changed (i.e., the sample packaging is removed and the medication put into another bottle) states usually consider this repackaging and will only permit a pharmacist or licensed prescriber to do this. Special labeling may be required, as well as a pharmacy permit. Check with your state board of pharmacy or medicine before combining lot numbers or repackaging samples.

A. Frequently Asked Questions Regarding Drug Samples--continued

11 Are there other federal regulations pertaining to samples that we need to know about?	Not that pertain to free clinics. There are other federal regulations regarding the manufacturer, and they may be found in CFR 203.30-38.
12 What constitutes a sealed container? When we conduct pick-ups from a physician's office can we put the samples in a cardboard box and wrap it with masking tape?	The FDA has not defined a "sealed container." However, the FDA emphasized that the purpose of a sealed container is to make sure that the recipient can tell if theft or damage has occurred to the samples. The FDA opined that a cardboard box wrapped with masking tape should be sufficient for purposes of a sealed container.
13 Are 203.39(e) and (f) the same?	VIH is currently waiting on FDA clarification.There is conflicting information in the exemption letter from the FDA. Until this issue is resolved, it is recommended that you follow the wording in the letter regarding [203.39(e)]. The example log that is included with this document follows section [203.39(e)] until a clarification can be obtained.
14 To be in compliance with the regulations do both the donor and recipient have to inspect the samples?	Both the donor and recipient should inspect the samples to be in compliance with the regulations.
15 How can we tell if a sample has been "stored or shipped under conditions that might affect its stability, integrity or effectiveness?" What might some of these conditions be?	Look for the following clues in tablets or packaging: melting, disintegration, wet, moldy, or crushed materials, torn packaging or tablets, missing tablets, discolored tablets or packaging

A. Frequently Asked Questions Regarding Drug Samples--continued

16 Does the authorization referred to in 203.39(c) have to be in writing? If so, does it have to name a specific individual or can it just name the function—e.g., pharmacy program volunteer?	The FDA does not require this authorization to be in writing, but recommends it. Including the specific individual's name and function would be preferable if the site is keeping a written record of authorization.
17 We are not a free clinic, we are a program that provides medication, including samples, to low-income people without prescription access. Do the free clinic exemptions apply to us?	The **exemptions** apply to free clinics only. However, the CFR 203.39 regulations apply to "charitable institutions." This is defined in CFR 203.3 (f) as "a nonprofit hospital, health care entity, organization, institution, foundation, association, or corporation that has been granted an exemption under section 501c (3) of the Internal Revenue Code of 1954, as amended."
18 We are a free clinic that gets a lot of samples directly from drug representatives. Do these regulations still apply? How do we address the sealed container requirement in these circumstances?	The regulations for sample donations still apply. However, the sealed container requirement does not have to be met when donations are received directly from drug representatives.
19 We contacted our local law enforcement to ask them what to do with expired samples. They told us we could throw them away in the garbage. Is this OK? If the board of pharmacy states something else, which one should we follow?	Contact your state board of pharmacy or your state Environmental Protection Agency office for the appropriate means of disposal of prescription samples. Local law enforcement may not be aware of specific disposal issues relating to prescription drugs. However, if two sources conflict as to the appropriate law or regulation, it is in your best interest to follow the more strict option.

B. HELPFUL HINTS REGARDING DRUG SAMPLES

1. Consider forming a task force or a committee to deal with issues pertaining to samples. It should include individuals such as the clinic director or appointee, a volunteer responsible for samples, a representative from the prescribing staff (physician, nurse, PA, etc.) and a pharmacist.

2. Develop a formulary, or a specific list, of samples that your clinic accepts. There is an advantage to knowing exactly which medications you will stock. This may enable the clinic to have labels and patient information pre-printed and in stock.

3. Solicit computer software companies and ask if they will donate services or products to help streamline your labeling and record-keeping needs.

4. Post bulleted lists of state and federal requirements in the sample room or cabinet so volunteers have access to it.

5. Develop a policy and procedure manual that will help ensure consistent processes regarding sample procedures for your institution.

6. Consider starting a periodic volunteer "sample" day where volunteers spend a few hours logging and checking samples.

7. Consider approaching your state board of pharmacy, board of medicine, or other regulatory body to explore special exemptions for free clinics regarding sample regulations.

IV. An Inside Look at Sample Programs

Three free clinics interviewed for this manual provided information on their experiences with complying with the new FDA regulations. This section describes their experiences and offers advice on ways to meet the most common challenges.

A. FREE CLINIC #1

This clinic maintains its samples in a locked room that it refers to as the pharmacy. Its system is organized around an on-going log that is maintained in the clinic's laptop computer. The log consists of an alphabetical list of drug names, based on the drug's brand name. The medication samples are kept on shelving in the pharmacy in categories such as "antibiotics" or "pediatrics," which enable volunteer clinicians and pharmacy volunteers to easily locate the appropriate sample. A current printout of the computerized log sheet is printed maintained in the pharmacy on a clipboard. The printout contains columns for the drug's name (brand and generic), strength, package size, number of samples currently available, number of samples added to stock, number of samples dispensed, and number of expired samples removed.

Medication samples are received in sealed containers in the clinic, and a volunteer enters the sample name, strength, and quantity on the printed log sheet in the pharmacy, and checks to make sure the expiration date is within the limits. Volunteers write expiration dates in bold ink on each sample package for easy identification. The pharmacy volunteer is careful to record the sample drug name and other log information on the printed log, and is instructed to ask medical personnel if unsure of how to fill out the log sheet. The volunteer then places the sample on the shelf under the appropriate category. The pharmacy manager collects the printed log sheet bi-weekly and enters the information into the computer. After entering the update, the pharmacy manager places an updated printed log-sheet in the pharmacy. If the medication log shows that a certain sample is getting low, the pharmacy manager notifies the clinic's case manager who in turn expresses that need to the doctors and pharmaceutical company representatives.

Volunteer clinicians come to the pharmacy and ask for a specific drug. The pharmacy volunteer checks the printout to make sure that the drug is currently in the inventory. Once it is determined that the sample is in stock, the pharmacy volunteer shows the clinician where the sample is located on the shelf. The pharmacy volunteer gives the clinicians a bag if a large number of packages are being dispensed and records the drug name, strength, quantity and clinician name on the log sheet. The pharmacy volunteers serve to point the volunteer clinician in the right direction, not to dispense the medications. The clinicians are responsible for packaging, labeling, checking the sample and counseling the patient. The pharmacy volunteers are responsible for helping clinicians locate available medications, stocking medications by category, keeping the pharmacy clean and neat, recording the activity of samples (arrival, dispensed, expired, etc.), and actually removing expired medications from the shelves.

Pharmacy volunteers remove the samples that have expired and place them in a box clearly marked EXPIRED. They will be disposed of by the pharmacy manager in accordance with good medical practice, which is determined by the state board of pharmacy for this clinic. The board of pharmacy for this state has suggested that clinics use a "return" service (also called a "reverse distributor," this is a company that returns expired samples to the manufacturer for a fee that the clinics pay). The companies typically charge per pound, but sometimes the companies will charge a fee based on the number of medications destroyed. One company that was contacted charged a fee of $3.00/pound. For more information, contact local pharmacies or wholesalers to obtain names of various companies. The state board will also permit clinics to use methods such as incineration to destroy the samples, but if this method is selected, the board warns that OSHA regulations must be followed. The board recommends that a return service be used as opposed to trying to comply with the OSHA regulations.

Clinicians and pharmacy volunteers are both instructed to report any problems, suggestions, questions or concerns about the pharmacy to the pharmacy manager. This clinic is preparing to implement a new system that uses a donated computer program to assist with package labeling and inventory requirements. This new computerized system will help relieve the clinicians of manually labeling the samples. The clinic has put together a task force to make sure that the sample program meets the needs of the volunteer clinicians and the patients, as well as complies with state and federal requirements. The clinic director feels that the system for dealing with samples is working to provide the only means that many patients have to obtain pharmaceuticals.

Update: As of November, 2003, the clinic administrator noted that since the original case study summary was written, the clinic discovered that the state pharmacy regulatory agency had very specific drug sample record-keeping and reporting requirements for clinics (especially impacting clinics with multiple delivery sites). Since the clinic had extended its sample program to its other delivery sites, the clinic administrator determined that the clinic would actually meet the state requirements with less trouble if the sample data was tracked manually (as opposed to implementing a computer system). The reason this made sense was that the clinic had several care sites that provided services on different days, and trying to enter multi-site data into a computer would have been time-prohibitive. The clinic and its sites report that their "old" sample system still works well and assists patients in need of medications.

In addition to their sample system, the clinic has recently started to purchase a limited amount of prepacked generic drugs. The clinic administrator feels that samples are appropriate for many patients, but noticed two trends: 1.) patients are often switched many times between sample medications, depending on what sample is available at that patient visit, and 2.) that patient are rarely able to afford the sample medication if the patient has to buy the drug at a retail pharmacy. As a possible solution, the clinic administrator is implementing a generic drug program for a limited amount of antibiotics and chronic medications in hopes that the generic drugs will serve the patients well and provide excellent continuity of care.

In addition, the clinic works with a federally qualified health center in the area to try and provide permanent medical homes for the free clinic patients. This results in allowing the patients to access 340B priced medications (a federally-mandated drug discount program only available to certain qualified health centers), and patients are generally able to afford these 340B priced medications.

B. FREE CLINIC #2

Samples are brought to the clinic at different dates and times, and taken to the clinic director or other volunteer that is present. The samples are briefly checked by volunteers to make sure they arrive in a sealed container, and that the expiration date is still valid. The clinic used to accept samples that arrived in non-sealed containers, but will no longer accept such samples due to the federal regulations. The clinic also used to accept expired samples, but the clinic will no longer accept them due to the fact that the clinic will then be responsible for their destruction or return to the manufacturer. If the samples are expired or are not in a sealed container, the clinic will not even take the samples into the clinic, and explains the reasoning to the party donating them so that similar situations may be avoided in the future. After this initial inspection, the clinic director or other volunteer then records the donating party's name, address and phone number in a log book, and takes the sample to a locked room.

Once a month, a small number of volunteers (3-5 people) spend about 3 hours logging the samples into a logbook, and verifying information. The volunteers check to make sure that the samples are in the original, unopened container, the labeling is intact, the sample hasn't been recalled, and that the sample's overall appearance indicates that it hasn't deteriorated or been damaged. The volunteers then record this information in the logbook and organize the samples on the shelves by brand name. The volunteers used to consolidate samples (take different lot numbers of the same drug and combine them into the same bottle) because it saved space on the shelves, but no longer do this because of federal and state regulations.

The samples remain on the shelves until the physician dispenses them to the patient. In the state where the clinic is located, all of the physicians who dispense samples are required to have a dispensing license. As a result of this, the clinic director requires any physician who wishes to volunteer at the clinic to maintain a state issued dispensing license. The physician volunteers are responsible for recording the patient information at the clinic and labeling the medication (with the instructions, patient name, drug name, drug strength, instructions, quantity, date and physician name). The clinic hopes to someday implement a computerized system (rather than hand written) that allows the clinic name, address, and phone number to be printed on the prescription label to fulfill state dispensing requirements.

Once a month volunteers return to conduct a "sample day," and spend about 3 hours logging in new samples and checking old samples to make sure the dates and appearances are still valid.

Overall, the clinic volunteers feel that they are helping patients a great deal by maintaining a system of processing samples. The clinic director has commented that although the federal and state regulations at times seem to be a burden, the clinic has implemented new policies as a result of these regulations. Some of these new policies include accepting only in-date samples in sealed containers, maintaining the original packaging, no longer combining sample bottles of different lot numbers, and requiring physicians to maintain dispensing licenses. These new policies have made a positive impact on the clinic's sample system by allowing it to be safe and easier to account for samples. The clinic director stated that it has been very helpful to meet with other volunteer clinic directors to discuss regulations and strategies for implementing safe and effective sample systems for patients.

C. FREE CLINIC #3

This free clinic has listed some challenges and possible solutions to situations it faces on a daily basis.

CHALLENGE	SOLUTION
1. The drug room where we store samples is disorganized and the volunteers can't find samples they are looking for.	**1.** A formulary, or a list of medication samples that the clinic stocks, can be prepared and posted on the door. The list will ideally contain the drug name, strength, major use, and the location on the shelf, i.e., the shelves will be labeled with letters or numbers or even by drug class for easy location. Another good idea is to separate the topical samples from the oral samples. Most pharmacies do this as a matter of safety.
2. The clinic receives so many drug samples that they pile up in the corner and there is no time to go through them before they expire. Often, once we check in the samples they have already expired. Expired samples have to be returned to the manufacturer in our state, and the clinic has to pay a fee to do this.	**2.** Appoint an accountable person that will be responsible for checking in the samples. That person should ask to make sure that the samples are in date, and that the samples are drugs that the clinic will actually use BEFORE accepting them. This situation presents another reason why a formulary is a good idea. Having a list of samples you accept will make it easier for the person accepting the samples on the clinic's behalf.
3. We are eligible for 340B pricing, but we are unable to get a pharmacy permit due to lack of funding and professional staff. We are looking for a way to access the 340B pricing.	**3.** If your clinic is eligible for 340B pricing (a federal drug discount program), there are some options you have. One option is to contract with a local pharmacy to provide your services. Another option that will hopefully soon become a reality is to use a pre-pack service to purchase drugs, and to make sure that the pre-pack service sells at 340B prices. The Prime Vendor, Bergen Brunswig, is in the process of developing such a program. For more information about 340B pricing, visit **http://www.hrsa.gov/odpp**.

C. Free Clinic #3 Challenges--Continued

Challenge	Solution
4. Our clinic can't find a volunteer pharmacist.	**4**. Most states have associations of pharmacists, and there are even local chapters that may be in your immediate area. Contact your state pharmacy association and ask for help. Another possible source would be a college of pharmacy. Even if the college is not located in your immediate area, there may be students who would be willing to volunteer, or the college may know of local pharmacists.
5. Our patients are sometimes eligible for pharmaceutical assistance programs, but we are unable to keep up with the paperwork.	**5.** Volunteers in Health Care maintains **http://www.RxAssist.org**, which is an on-line source of information and pharmaceutical assistance program application forms. In addition, VIH also offers a computer program called RxAssist Plus, which helps to track patients and applications. Contact VIH for more information (1-877-844-8442).
6 It is very time consuming and tedious for us to check the expiration dates on our samples.	**6**. A suggestion that you might want to try: when initially checking the samples in, the expiration date should be checked. When this initial check is conducted, consider putting a small, round, colored sticker on the sample to designate the expiration date. These stickers can be obtained at any office supply store. Assign a color to each month, i.e., FEB 04 could be blue, and MARCH 04 could be red. That way, instead of scanning each sample package to try and read the tiny expiration dates, a volunteer can run a check periodically to pull all the "red" samples.
7. We store our samples in the attic, but a pharmacist informed us that the heat in the attic could harm the samples.	**7.** It is important to try and avoid storing samples in a hot area or an area susceptible to water damage where the samples are likely to be damaged. Storage of samples is a problem in free clinics. A small investment in good shelving in the drug closet can help efficiently organize the space you have. Also, only accepting samples that your patients will likely use will help control excess drug sample storage problems.

Appendices

Appendix I

TEXT OF FDA LETTER SENT TO FREE CLINICS

December 7, 2000

Re: Request for Exemption from 21 CFR 203.39

Dear Sir/Madam:

This is in response to your letter requesting an exemption from the requirements of *the Prescription Drug Marketing Act (PDMA)* regulations, part 203.39, that became effective December 4, 2000

We have evaluated the request and have decided that, unless required otherwise by applicable State law, in the exercise of its enforcement discretion, FDA does not intend to object if non-profit, charitable health care facilities and associated pharmacies, such as free clinics that receive, store, and dispense prescription drug samples as part of their function of providing free health care to indigent, uninsured, and underinsured community populations do not comply with 21 CFR 203.39(g), which states as follows:

203.39(g): Each recipient charitable institution shall conduct, at least annually, an inventory of prescription drug sample stocks and shall prepare a report reconciling the results of each inventory with the most recent prior inventory. Drug sample inventory discrepancies and reconciliation problems shall be investigated by the charitable institution and reported to FDA.

FDA supports the provision of needed medical care to indigent, uninsured, and underinsured patient populations, and understands the critical issue of limited financial and human resources in achieving this health care goal.

Free clinics are required to comply with sections (c) and (f) of 203.39 as set forth below:

203.39(c): A donated drug sample shall not be dispensed to a patient or be distributed to another charitable institution until it has been examined by a licensed practitioner or registered pharmacist at the recipient charitable institution to confirm that the donation record accurately describes the drug sample delivered and that no drug sample is adulterated or misbranded for any reason, including, but not limited to, the following:

1. The drug sample is out of date;
2. The labeling has become mutilated, obscured, or detached from the drug sample packaging;

3. The drug sample shows evidence of having been stored or shipped under conditions that might adversely affect its stability, integrity, or effectiveness;

4. The drug sample is for a prescription drug product that has been recalled or is no longer

5. The drug sample is otherwise possibly contaminated, deteriorated, or adulterated. This requirement protects the health and safety of the patient receiving the donated sample drug product. Due to limitations on the professional resources of free clinics, FDA does not intend to object if a person authorized by a licensed practitioner affiliated with the free clinic performs the examination described under this section, unless otherwise required by applicable state law or regulation.

203.39(f): Each recipient charitable institution shall maintain complete and accurate records of donation, receipt, inspection, inventory, dispensing, redistribution, destruction, and returns sufficient for complete accountability and auditing of drug sample stocks.

FDA does not intend to object if the record of sample distributions by free clinics is limited to the brand name of the drug product, the lot number, quantity, and date of distribution or dispensing, unless otherwise required by applicable state law or regulation.

Free clinics are required to comply with the following sections of 21 CFR 203.39:

203.39(a): A drug sample donated by a licensed practitioner or donating charitable institution shall be received by a charitable institution in its original, unopened packaging with its labeling intact.

This requirement ensures that the dispensing professional is provided with a fully labeled drug product in its approved packaging. This permits the clinic and the health care professional to identify the drug product, its dosage strength, its lot number for tracking and recall purposes, and to determine if the packaging of the product indicates that the product may have been exposed to conditions that may have rendered it unfit for human use.

203.39(b): Delivery of a donated drug sample to a recipient charitable institution shall be completed by mail or common carrier, collection by an authorized agent or employee of the recipient charitable institution, or personal delivery by a licensed practitioner or an agent or employee of the donating charitable institution. Donated drug samples shall be placed by the donor in a sealed carton for delivery to or collection by the recipient charitable institution.

This requirement ensures that donated sample products are delivered to the clinic in a controlled manner that would indicate whether damage or pilferage occurred to the package during shipment.

203.39(d): The recipient charitable institution shall dispose of any drug sample found to be unsuitable by destroying it or by returning it to the manufacturer. The charitable institution shall maintain complete records of the disposition of all destroyed or returned samples.

This section simply requires that, following examination of all donated drug samples by the recipient clinic as described under 203.39 (c), all drug samples that do not appear suitable for human use are either destroyed or returned to the manufacturer, and a record made of the drug samples that were destroyed or returned.

203.39(e): The recipient charitable institution shall prepare at the time of collection or delivery of a drug sample a complete and accurate donation record, a copy of which shall be retained by the recipient charitable institution for at least 3 years, containing the following information:

1. The name, address, and telephone number of the licensed practitioner (or donating charitable institution);

2. The manufacturer, brand name, quantity, and lot or control number of the drug sample donated; and

3. The date of the donation.

FDA believes that it is essential for free clinics that use donated prescription drug samples to keep complete and accurate records of all donated samples received by the clinic. These records allow traceability of the drug samples and will provide the basis from which free clinics can determine whether any significant loss or any theft or diversion of samples has occurred.

203.39(h): A recipient charitable institution shall store drug samples under conditions that will maintain the samples' stability, integrity, and effectiveness, and will ensure that the drug samples will be free of contamination, deterioration, and adulteration.

Generally, following the labeling and compendial requirements for storage and handling of a particular prescription drug helps to assure the safety and efficacy of the drug sample. This requirement serves to protect the health and safety of the patient population.

203.39(i): A charitable institution shall notify FDA within 5 working days of becoming aware of a significant loss or known theft of prescription drug samples.

Free clinics must notify FDA when they become aware that prescription drug samples have been stolen or a significant amount of samples cannot be accounted for.

These reports, and any questions, may be directed to: Margaret O'Rourke at: 301-594-0101 (orourke@cder.fda.gov).

Sincerely yours,

/s/

David J. Horowitz, Esq.
Acting Director
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Appendix II

STATE BOARDS OF MEDICINE & PHARMACY

CONTACT INFORMATION FOR STATE BOARDS OF MEDICINE AND PHARMACY

Contact Information for State Boards of Medicine
Federation of State Medical Boards (FSMB)
P.O. Box 619850
Dallas, TX 75261-9850
(817) 868-4000
http://www.fsmb.org/

Contact Information for State Boards of Pharmacy
National Association of Boards of Pharmacy (NABP)
700 Busse Hwy
Park Ridge, IL 60068
(847) 698-6227
http://www.nabp.net/

Volunteers in Health Care
111 Brewster Street
Pawtucket, RI 02680
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Fax 401-729-2955
www.volunteersinhealthcare.org