

**MDRD Manual of Operations**  
**Volume 1, Chapter 6**  
**The Pharmacy Chapter**

**TABLE OF CONTENTS**

	<b>PAGE</b>
Section 6.1	Responsibilities of the Drug Distribution Center.....1.6.1
Section 6.2	Responsibilities of the Clinical Center Pharmacies.....1.6.2
Section 6.3	Communication.....1.6.2
Section 6.4	Supply Procedure for Clinical Centers.....1.6.3
Section 6.5	Inventory Records.....1.6.3
Section 6.6	Prescription Filling at the Clinical Center.....1.6.3-4

**APPENDICES**

Appendix 1	Procedure for Ordering Supplements.....1.6.5
	Figure 1. Pharmacy Order Form Worksheet.....1.6.6-7
	Figure 2. Pharmacy Order Form.....1.6.8
	Figure 3. Prescription Form.....1.6.9
	Figure 4. Prescription Refill Record.....1.6.10
	Figure 5. Mixture Dispensing Scheme.....1.6.11
	Figure 6. Drug Accountability Record.....1.6.12

MANUAL OF OPERATIONS

Volume I

Chapter 6

THE PHARMACY CHAPTER

**Section 6.1** RESPONSIBILITIES OF THE DRUG DISTRIBUTION CENTER

Responsibilities of the Drug Distribution Center will include:

1. Procurement and distribution of the MDRD Keto Acid mixture packets and tablets, multivitamin supplements, and keto acid flavoring for the study. (Note: Calcium and iron supplements and blood pressure medications are not supplied by the Drug Distribution Center.)
2. Inventory control and storage of the supplements.
3. Design and implementation of a distribution system for the supplements.
4. Communication with the appropriate members of the MDRD study team about issues relating to supplements used in the study.
5. Providing information to clinical center pharmacists and other team members about pharmacy-related issues pertaining to the study.
6. Maintaining adequate records to fulfill requirements of Federal and State regulatory agencies and requirements of the MDRD protocol.
7. Administrative functions such as forecasting, budgeting, and communication with other central laboratories and clinical centers regarding the supplements listed in (1).

## Section 6.2 RESPONSIBILITIES OF CLINICAL CENTER PHARMACIES:\*

Clinical center pharmacies will be responsible for:

1. Ordering keto acids, flavor packets, and multivitamin supplements from the Drug Distribution Center for patients at the clinical center.
2. Filling prescriptions for MDRD study patients.
3. Maintaining records as required by the protocol and applicable regulations.
4. Submitting periodic reports to the Drug Distribution Center concerning the above activities.

\* NOTE: While not legally required, storage and dispensing of supplements by a licensed Pharmacy at Clinical Centers is recommended.

## Section 6.3 COMMUNICATION

Telephone communications with the Drug Distribution Center should be directed to:

Edward H. Jones, Pharm.D.

(216)-444-4303

or

Janet A. Ungar, R.Ph.

(216)-444-4311

Written inquiries should be addressed to Dr. Jones at:

Hospital Pharmacy

The Cleveland Clinic Foundation

9500 Euclid Avenue

Cleveland, Ohio 44195-5102

All orders should be placed by using the forms and instructions shown in Figures 1 and 2.

#### **Section 6.4 SUPPLY PROCEDURE FOR CLINICAL CENTERS**

Initially, the DDC will send a 90-day supply of vitamins and keto acid mixture to each clinical center pharmacy based on usage. After the initial shipment, pharmacists at the clinical centers will be responsible for maintaining supply levels at their centers. Orders may be placed with the Drug Distribution Center according to a 60-day cycle.

#### **Section 6.5 INVENTORY RECORDS**

Clinical center pharmacies will maintain inventory records of the MDRD Keto Acids and MDRD multivitamin tablets. The form and procedure for this will be the Investigational Drug Accountability Record used by the National Cancer Institute (form NIH-2564) (Figure 6). Electronic records are acceptable in place of the NIH form as long as a hard copy report can be produced when needed.

#### **Section 6.6 PRESCRIPTION FILLING AT THE CLINICAL CENTER**

PRESCRIPTIONS WILL BE FILLED BY THE PHARMACY AT THE CLINICAL CENTER. Some procedures will vary to suit circumstances at the individual clinical center. The following procedures are suggested:

1. Figure 3 is completed by the physician and delivered to the pharmacist.
2. A 35-day supply of keto acid tablets or mixture should be dispensed on the first prescription filled. If the mixture is used, flavor packets should be provided. Refills may be for 30 days supply or another appropriate quantity corresponding to the patient follow-up schedule. The physician's prescriptions should be checked against the keto acid dispensing scheme (Figure 5) to verify the dose. Doses should not vary from protocol.

3. The prescription label should contain the patient's name, prescriber's name, prescription number assigned by the pharmacy, date of dispensing, directions to the patient, MDRD patient study number, and any other information required by state or local regulations.
4. MDRD multivitamins should be labeled as a prescription medication. It is suggested that containers of 100 tablets be dispensed.
5. Relevant information is to be recorded on the MDRD Prescription Refill Record Form (Figure 4). This includes item dispensed, date of filling, pharmacist's initials, lot number and expiration date of the item dispensed.
6. Each prescription filled is recorded on the Investigational Drug Accountability Record (Figure 6) for that item.

## APPENDIX 1

### PROCEDURE FOR ORDERING SUPPLEMENTS

#### Instructions:

1. Calculate order quantities according to the worksheet (Figure 1).
2. Enter quantities needed in the "QTY" column on the left side of the order sheet (Figure 2). Use black ink if possible.

3. Send order to MDRD Drug Distribution Center

Edward H. Jones, Pharm.D.  
c/o Hospital Pharmacy  
Cleveland Clinic Foundation  
9500 Euclid Avenue  
Cleveland, OH 44195-5102

Retain a photocopy if you wish.

4. Please send orders according to your schedule. (Schedules will be distributed in early 1989.) Try to minimize exceptions.
5. The DDC will fill your orders and return a copy of the order form to you as a packing list.
6. Enter quantity received on your copy and initial. Retain packing list for your records. Notify DDC of discrepancies in quantity, lot# or items shipped.

FIGURE 1

MDRD Clinical Center  
Pharmacy Order Form  
(Revision #1)

Worksheet For Calculating Order Quantities

KETO-ACID MIXTURE PACKETS

Pt# \_\_\_\_\_ # of Pks/Day \_\_\_\_\_ x 90 days = Amount needed \_\_\_\_\_

Pt# \_\_\_\_\_ # of Pks/Day \_\_\_\_\_ x 90 days = Amount needed \_\_\_\_\_

Pt# \_\_\_\_\_ # of Pks/Day \_\_\_\_\_ x 90 days = Amount needed \_\_\_\_\_

SUBTOTAL \_\_\_\_\_

- Amount On Hand (Subtract) \_\_\_\_\_

= Total Amount Needed \_\_\_\_\_

Figure 1  
(continued)

KETO-ACID TABLETS, TABLETS/DAY

Pt# \_\_\_\_\_ # of Tablets/Day \_\_\_\_\_ x 90 days = Amount needed \_\_\_\_\_

Pt# \_\_\_\_\_ # of Tablets/Day \_\_\_\_\_ x 90 days = Amount needed \_\_\_\_\_

Pt# \_\_\_\_\_ # of Tablets/Day \_\_\_\_\_ x 90 days = Amount needed \_\_\_\_\_

SUBTOTAL \_\_\_\_\_

- Amount On Hand (Subtract) \_\_\_\_\_

= Total Amount Needed \_\_\_\_\_

FLAVOR PACKETS (Specify flavors and amounts required) \_\_\_\_\_

MDRD MULTIVITAMINS

Number of patients in study \_\_\_\_\_ x 90 days

- Amount On Hand (Subtract) \_\_\_\_\_

= Amount Needed \_\_\_\_\_



Figure 2

MODIFICATION OF DIET IN RENAL DISEASE STUDY  
ORDER FORM FOR SUPPLEMENTS

FOR DDC USE  
SHIPPING  
DATE \_\_\_\_\_

MDRD DRUG DISTRIBUTION CENTER  
c/o Hospital Pharmacy  
Cleveland Clinic Foundation  
One Clinic Center  
9500 Euclid Avenue  
Cleveland, Ohio 44195-5102  
Phone: (216) 444-4303

Clinical Center Name: \_\_\_\_\_  
Street Address: \_\_\_\_\_  
City, State, Zip Code: \_\_\_\_\_  
Attention: \_\_\_\_\_  
Principal Investigator: \_\_\_\_\_

Shipping Address (if different from above):

Clinical Center Name: \_\_\_\_\_  
Street Address: \_\_\_\_\_  
City, State, Zip Code: \_\_\_\_\_  
Attention: \_\_\_\_\_

ORDER DATE \_\_\_\_\_

			FOR DDC USE ONLY					
QTY.	UNITS	ITEM	QTY FILLED	FILLED BY	LOT NUMBER	EXP.	QTY REC'D	REC'D BY
	50's	Keto-Acid Mixture Packets						
	100's	Keto-Acid Mixture Tablets						
	100's	MDRD Multivitamins						
	100's	Enalapril 5mg Tablets						
	100's	Enalapril 10mg Tablets						
	400 gm Cans	Flavoring-Golden Punch						
	400 gm Cans	Flavoring-Orange						

NOTE: Keto-Acid Mixture Tablets and Packets require refrigeration.

Order Submitted By: \_\_\_\_\_  
Pharmacist Signature

FIGURE 3  
PRESCRIPTION FORM  
MODIFICATION OF DIET IN RENAL DISEASE STUDY

Patient Name: \_\_\_\_\_ Patient Number: \_\_\_\_\_

Patient Weight (SBW) \_\_\_\_\_ Kg

Name of Clinical Center: \_\_\_\_\_

Needed By Patient: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

Will Pick Up in Pharmacy: \_\_\_\_\_ (YES) \_\_\_\_\_ (NO) Deliver To: \_\_\_\_\_

**Check Medications Required**

\_\_\_\_\_ 1. Keto-Acids 2.8g (2.8g/10kg/DAY) 35 day supply  
Refills (30 day supply) as needed for 1 year.

\_\_\_\_\_ 2. MDRD Multi-Vite (R & D Labs) #100  
Sig: Take 1 tablet every day.  
Refills as needed for 1 year.

\_\_\_\_\_  
Physician \_\_\_\_\_ Date \_\_\_\_\_

Refer questions about this prescription to the MDRD drug distribution center at  
(216) 444-4303.

I request that the above medications not be dispensed in child resistant packaging.

\_\_\_\_\_  
Physician \_\_\_\_\_ Date \_\_\_\_\_

THIS SPACE FOR SAMPLE LABELS

FIGURE 4  
MDRD PRESCRIPTION REFILL RECORD

[illegible]

**MORD STUDY**  
**KETO-ACID MIXTURE DISPENSING SCHEME**

	40 kg	50 kg	60 kg	70 kg	80 kg	90 kg
<b>Packets:</b>						
30 day	120 Packets	150 Packets	180 Packets	210 Packets	240 Packets	270 Packets
Supply	Send 30 4 packets/day	Send 30 5 packets/day	Send 30 6 packets/day	Send 30 7 packets/day	Send 30 8 packets/day	Send 30 9 packets/day
<b>Packets:</b>						
35 day	140 Packets	175 Packets	210 Packets	245 Packets	280 Packets	315 Packets
Supply	Send 35 4 packets/day	Send 35 5 packets/day	Send 35 6 packets/day	Send 35 7 packets/day	Send 35 8 packets/day	Send 35 9 packets/day
<b>Tablets:</b>						
Supply for	630 Tablets	630 Tablets	630 Tablets	1260 Tablets	1260 Tablets	1260 Tablets
29 days	15 tablets/day	18 tablets/day	21 tablets/day	25 tablets/day	29 tablets/day	33 tablets/day
or more*						

**CALCULATIONS AS FOLLOWS:**

1. All weights are standard body weight.
2. Dosage based on 1 packet/10 kg/day.
3. An additional 5.0 kg will be rounded up; less than 5.0 kg will be rounded down. For example, a weight of 65.0 kg rounds up to 70 kg while a weight of 64.9 kg rounds down to 60 kg.

\* Remember to subtract to adjust for the amount the patient has on hand.

# Investigational Drug Accountability Record

Name of Institution

Protocol No. (NCI)

Drug Name, Dose Form and Strength

Protocol Title

Dispensing Area

Investigator

Line No.	Date	Patient's Initials	Patient's I.D. Number	Dose	Quantity Dispensed or Received	Balance Forward	Manufacturer and Lot No.	Recorder's Initials
						Balance		
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								
15.								
16.								
17.								
18.								
19.								
20.								
21.								
22.								
23.								
24.								