

TRIMIS-Army Technical Report 1-6



PHARMACY MANUAL SYSTEMS

CONDITION-ACTION DIAGRAM FLOWCHARTS

US ARMY TRIMIS AGENCY Walter Reed Army Medical Center Washington, DC 20012



August 1976

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The charts are a graphic depiction of the steps involved in providing the full range of pharmaceutical services likely to be required by a large military medical center. The charts include provisions for identifying and determining eligibility of patients requiring medication, resolving any problems encountered, and dispensing and delivering medication in whatever manner is required. Processes are also outlined for maintaining inventory control, providing quality control and drug information support, and for supporting the manufacturing and prepackaging processes necessary for the preparation and packaging of speciality products.

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*These mnemonics are not intended for use as general identifiers, but are used in these charts for indexing and cross-referencing purposes.

ACKNOWLEDGMENTS

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PURPOSE

The purpose of the Pharmacy Manual Systems' condition—action flowcharts is to present an easily understood overview of one goal system of manual operations required to support innovative pharmaceutical services and drug distribution systems. It is suggested that the best use for the flowcharts would be as the basis for an introduction or short course which will prompt an extensive internal audit and analysis of current pharmacy operations. Such an analysis should bring to light problems, the resolution of which can have a substantial impact on the ability of the pharmacy to support and be involved in improved patient care techniques.

BACKGROUND

There is a wide diversity in the services offered in pharmacy operations throughout the military medical departments, ranging from the simple dispensing functions of the small outpatient pharmacy in a military health clinic to the wide variety of specialty pharmaceutical services offered in the large military medical center. A comprehensive pharmacy system must be capable of supporting many services including outpatient predispensing, inpatient drug distribution, sterile product scription preparation, and inventory control functions. The system must be flexible enough to provide support for facilities that have a single centralized pharmacy as well as support for facilities that have a system of decentralized drug distribution with many pharmacies operating throughout the medical facility. Therefore, the pharmacy manual operational systems, as depicted in these charts, include features that may not be implemented at all hospitals and clinics. However, a subset of these systems should suffice for any given treatment facility regardless of specialization or workload.

LIMITATIONS

The charts were developed to address the requirements of a 1280-bed military medical center which also supports a large outpatient population. The system includes the many types of services required from a large active institutional pharmacy and was designed for a decentralized pharmacy operation which supports several inpatient dispensing pharmacies operating throughout the hospital and two large volume outpatient pharmacies, The implementatin of such manual systems requires an adequate number of personnel with the appropriate combination of professional and technical skills.

Most of the functions depicted in the charts are being, or will be, modeled at Walter Reed Army Medical Center. Many of the functions are operational at various military medical centers and Army hospitals. However, the charts describe a goal manual system which is not fully implemented at any known military hospital at this time. The charts are intended as a guideline to improving manual operation and are not intended to be adopted as a standing operating procedure by any single hospital. Development of facility specific charts is encouraged as a meaningful approach to system planning for individual pharmacies which meet local requirements.

OBJECTIVES

The objective of the modern pharmacy practice is to provide the patient or professional staff with the potent medications necessary to treat or diagnose human problems, to provide adequate instructions or information for administering the medication, and to monitor the patients overall drug therapy program to insure that it is free from pharmacological hazards.

In order to provide responsive services the pharmacy must perform a multitude of procedures on a routine basis. The objective of each of the major process cycles are outlined in the following paragraphs.

1. Outpatient Pharmacy Cycle

- a. Provide outpatients with medications necessary to treat their problems.
- b. Provide professional drug therapy counselling to ambulatory patients.
 - c. Assist care providers in resolving medication problems.

2. Inpatient Pharmacy Cycle

- a. Prepare and deliver IV admixtures and other sterile products and unit dose medications to the wards/units on a scheduled basis.
- b. Provide timely response to STAT medication requests and orders which are received out of synchronization with the regularly scheduled deliveries.
 - c. Assist care providers in resolving medication problems.

Non-patient-specific Supply Cycle

Provide drug items to non-pharmacy-controlled dispensing points (i.e., wards, clinics, Emergency kits, CPR carts, MOD cabinets, etc.).

4. Inventory Control

- a. Assure that medication stocks of formulary items are maintained at normal operating levels in the satellite dispensing pharmacies as well as in the central support pharmacy to provide maximum availability of drug items.
- b. Obtain medications that are either not on hand or not normally stocked when necessary for specific therapy or diagnosis.

5. Manufacturing/Prepacking Cycle

- a. Manufacture those items that are not available from commercial sources, or which must be compounded within the pharmacy for other reasons.
 - b. Repackage bulk stock into more usable package sizes.

6. Pharmacy Quality Control

Insure that the highest possible standards are maintained in the pharmacy service. This function includes monitoring of the quality of products, accuracy and calibration of equipment, and the expertise of and techniques used by all pharmacy personnel.

7. Drug Information Function

- a. Maintain and provide on request information pertinent to drug therapy to patients and care providers.
 - b. Maintain a formulary of effective drugs and dosage forms.

OVERVIEW

The charts are a graphic depiction of the steps involved in providing the full range of pharmaceutical services likely to be required by a large military medical center. The charts include provisions for identifying and determining eligibility of patients requiring medication, resolving any problems encountered, and dispensing and delivering medication in whatever manner is required. Processes are also outlined for maintaining inventory control, providing quality control and drug information support, and for supporting the manufacturing and prepackaging processes necessary for the preparation and packaging of speciality products.

EXPECTED BENEFITS

- 1. Improved management control and service responsiveness.
- 2. Centralized administrative and supply support.
- 3. Uniform and complete workload data collection.
- 4. Greater flexibility and support capability.
- Greater staff knowledge of ward/clinic operations and procedures.
- Improved record retrieval, documentation, and roster generation.
- 7. Improved utilization of professional, supportive and physical facility resources.
- 8. Improved patient and professional satisfaction.

SUBSYSTEM INTERFACES

The major interface is with the Wards and Clinics System which is responsible for prescribing, ordering, and, in the case of inpatients, administering medications. Other interfaces with Laboratory, Radiology, Logistics, Food Service, and Patient Administration provide the information, exchange support, and services required to provide comprehensive pharmaceutical services.

AMENDABILITY TO APD SUPPORT

These charts represent the first step in detailing the requirement for a computer supported pharmacy system. The charts may be used to determine the processing requirements of an automated pharmacy system. These will assist the developer of an automated pharmacy system in detecting potential or existing problem areas, and can be used to help resolve the problems. Although the system can be implemented without any computer support, it is designed to detail the manual requirements and procedures of the computer assisted pharmacy system specified by the TRIMIS Pharmacy Subsystem technical workbook (TTW, Section 15).

PHARMACY ABBREVIATIONS

APS Automated Prescription System semi-automated oral solid

dispensing units.

ASHP American Society of Hospital Pharmacists

COMMO Communications

Consult Consultation

CPR Cart Cardio-pulmonary Resuscitation Cart

DA Department of the Army

DC'D Discontinued

DD Department of Defense

ER Kit Emergency Kit

FDA Food and Drug Administration

HQ Headquarters

ID Identification

Info Information

IV Intravenous

Lab Laboratory

Med Medication

MMM Medical Materiel Manager

OIC Officer in charge

PAD Patient Administration Division

P & C Purchasing and Contracting

RN Registered Nurse

RNWD Renewed

RX Prescription

SF Standard Form

STAT Immediate

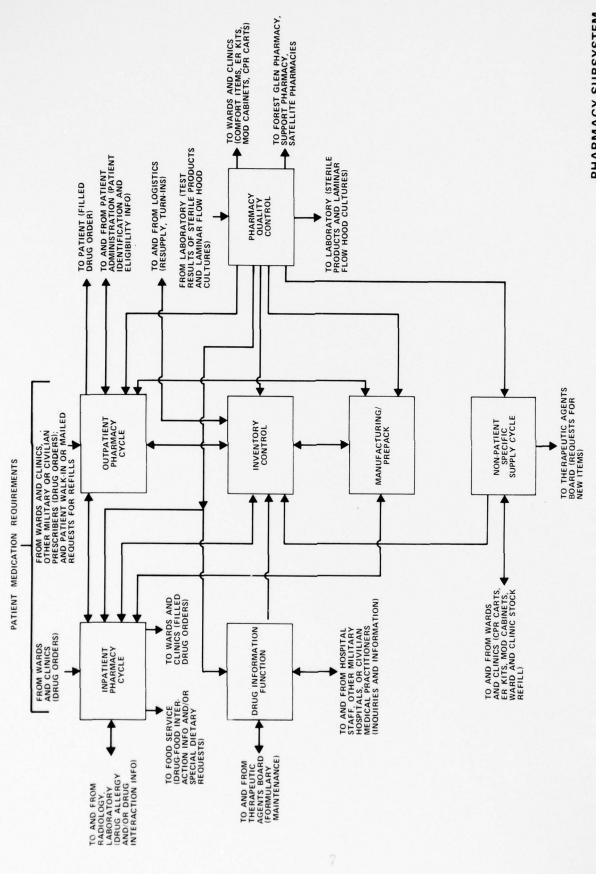
TAB Therapeutic Agents Board; tablet

Tech Technician

USP United States Pharmacopeia

W/- with

WRAMC Walter Reed Army Medical Center



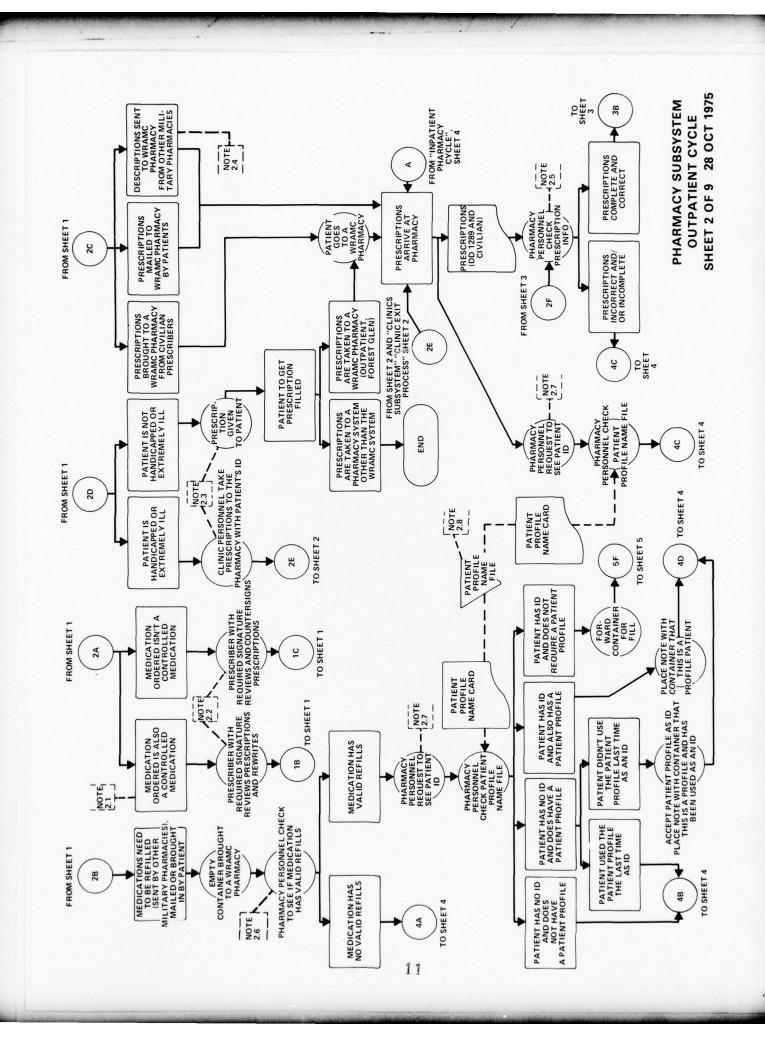
PHARMACY SUBSYSTEM FUNCTIONAL OVERVIEW 28 OCT 75

- elements to be included on this form are: patient's name, address, phone number, date of order, medication name & strength, dosage instructions, amount of medication, number of refills authorized, prescriber's signature, and, if applicable, printed prescriber's name, rank, corps and BNDD or SSN number. Only one medication may be ordered per form. The prescriber will also indicate on the prescription if this patient should be added to the pharmacy's Patient Profile series (mostly chronic care patients).
- 1.2 This prescriber is an individual who can prescribe any medications which are not controlled or which are not on a restricted use list.

 This individual would be an Amosist, a nurse clinican/practitioner, physician's assistant, etc. Each prescriber of this type has a predetermined list of medications he/she can prescribe without a doctor's countersignature (under this condition the prescriber has full prescribing privileges). These lists are periodically reviewed and updated by the Therapeutic Agents Board. In certain cases a prescriber with full prescribing privileges can be considered a prescriber requiring a countersignature (i.e., he/she writes for an investigational medication).
- 1.3 This is a prescriber who can prescribe most medications including controlled medications (but excluding restricted medications) without the approval of any other prescriber.

NOTES ON OUTPATIENT PHARMACY CYCLE FLOW CHARTS SHEET 1 (CONTINUED)

- 1.4 The restricted medications are either limited to a specific service or doctor, or require the signature of the chief of the prescribing doctor's service or signature of a specifically authorized professional person. An example of the first case is an investigational medication (restricted by doctor) or dermatology medications (restricted to Dermatology Service).
- 1.5 A countersignature is required when the medication is designated to require a countersignature by the Therapeutic Agents Board (TAB) and the hospital commander or by the hospital commander alone. Types of countersignatures would be Chief of Service, doctor of a specific service, or a specific doctor.
- 1.6 The exit clerk checks to see that the patient's name, address, phone number, and (if applicable) age of patient are annotated on the prescription(s). The exit clerk will also check to assure that the prescription is signed and if applicable, the printed prescriber's name, rank, corps, and BNDD or SSN number is in the signature block when a controlled drug is prescribed.



- 2.1 Those medications to be controlled as indicated by the Drug Enforcement Administration (DEA), Army Regulations, and/or the hospital commander.
- 2.2 If, after reviewing the prescription(s), the reviewing prescriber disagrees with the ordering prescriber, he will not countersign or rewrite the prescription(s) and the process stops. The reviewing prescriber must concur with the ordering prescriber before he will countersign or rewrite the prescription(s). The reviewing prescriber may also have the option of writing prescription(s) for other medications when he is in disagreement with the ordering prescriber. The rewriting of a prescription is necessary if it is for a controlled medication. When a controlled medication is prescribed the prescription requires the printed name, rank, corps and BNDD or SSN number for each signature which appears on the prescription (due to lack of space the prescription must be rewritten).
- 2.3 After normal duty hours for the outpatient pharmacy, the
 4th floor pharmacy will support the outpatient prescription
 1oad. The main differences between the usual outpatient cycle and
 the after duty hours cycle are: (1) If the patient is handicapped
 or extremely ill either the clinic personnel (or escort, messenger)
 can bring the prescription(s) to the 4th floor pharmacy or clinic

NOTES ON OUTPATIENT PHARMACY CYCLE FLOW CHARTS SHEET 2 (CONTINUED)

personnel can send the prescription via the Telelift (when working) to the 4th floor (2) If the patient is not handicapped or extremely ill the clinic personnel can send the patients with the prescription(s) to the 4th floor pharmacy or they can still send the prescription(s) via the Telelift (when working) to the 4th floor (requires clinic staff to explain the patient's medication instructions before dispensing).

2.4 Some military pharmacies in the Military District of Washington (MDW) area have a prescription fill agreement with WRAMC. If they don't have the medicine, they can send the prescriptions to WRAMC and see if WRAMC stocks the medication. These prescriptions are usually transported by couriers or on ambulance runs.

2.5 The information checked is patient's name, address, phone number, date of prescription, medication name, strength, dosage instructions, amount of drug (not to exceed 30-day amount), number of refills (not to exceed 5), prescriber's signature, and, if applicable, printed prescriber's name, rank, corps, BNDD or SSN number. If more than one prescription, check for contraindications between prescribed medications. Any of the above elements could be incomplete or incorrect and require some action to resolve.

2.6 An invalid refill request is recognized when: (1) a refill is brought in too soon, (2) a refill is requested on a prescription over 6 months old, and, (3) there are no refills left. If a prescription is for a needed chronic care medication, the pharmacy will dispense only enough medication to insure maintenance until the patient can see a prescriber.

NOTES ON OUTPATIENT PHARMACY CYCLE FLOW CHARTS SHEET 2 (CONTINUED)

2.7 The identification (ID) necessary is the patient's official ID card (DD Form 2A and others) and not the outpatient clinic ID card. If the patient has forgotten his official ID card, the outpatient clinic card may be accepted for ID one time only. Whether the clinic card is accepted or not, the patient's name will be placed on a list to be forwarded to the appropriate authorized office (PAD or other) in order to determine if patient is actually still authorized medical care. The patient's name will also be placed on this list if he/she has no ID, but his/her prescription will not be filled. He/she will be sent to the to the authorized office for a certificate of eligibility for medical care.

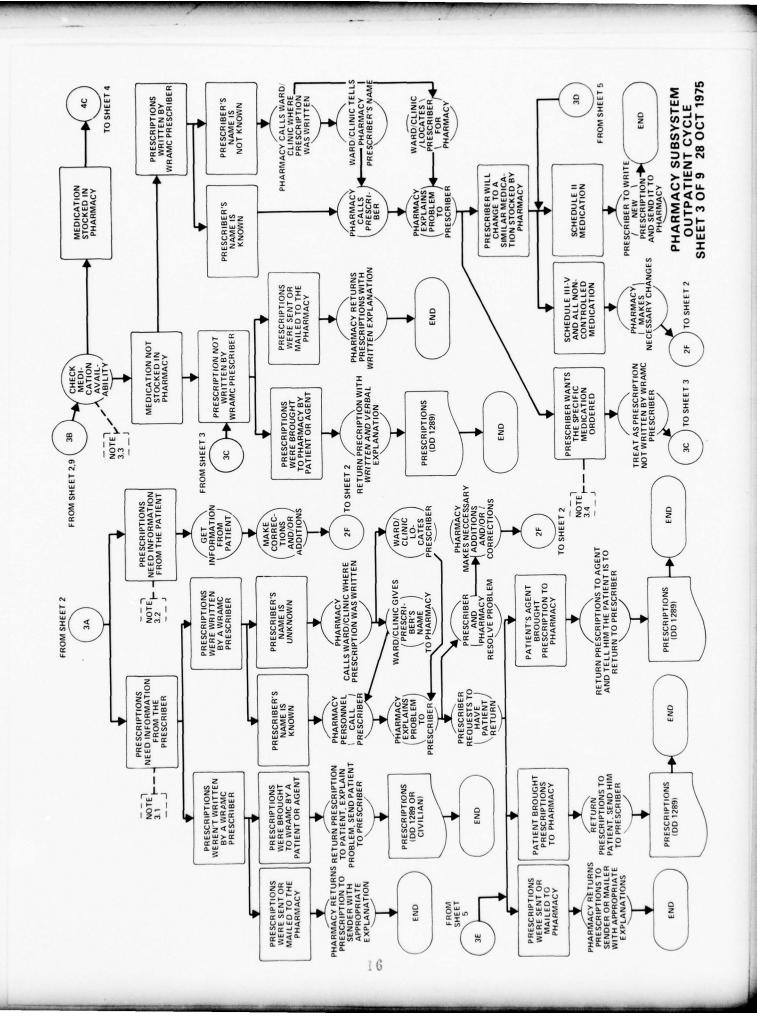
If the patient has been to WRAMC before with no official ID and has been told it is required, or has presented an expired ID and been asked to get a new one but didn't do so, he/she will be asked to go to the appropriate authorized office for a certificate stating he/she is authorized medical care before the prescription will be filled.

If the patient has a refill or has a patient profile and forgot his/her ID, the pharmacy will accept the refill and profile as a one time only ID. If the medication request comes from another military pharmacy, it is assumed that the patient is eligible for medical care. If it comes by mail it is assumed for the first fill that patient is eligible, and eligibility will be confirmed when the completed Profile questionnaire is sent back with the medication.

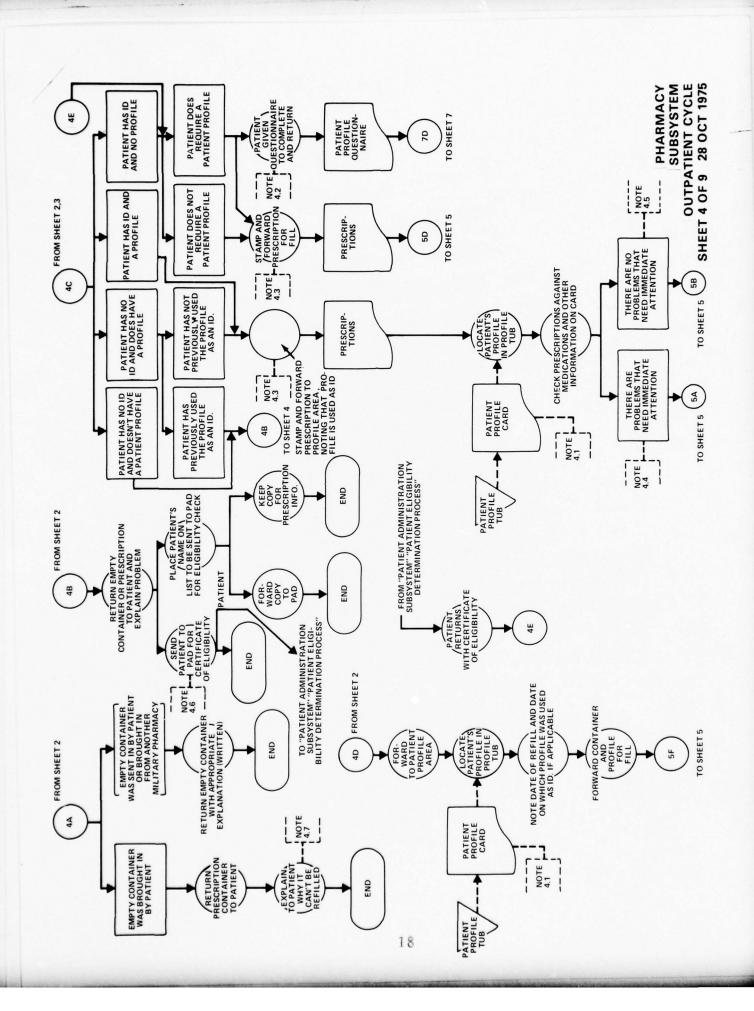
2.8 The Patient Profile Name File is a rotary file consisting of the

NOTES ON OUTPATIENT PHARMACY CYCLE FLOW CHARTS SHEET 2 (CONTINUED)

names of all patients with a patient profile maintained by the pharmacy. It is kept in alphabetical order. If a patient's name appears on this file, the file can be used as a one (1) time ID and if used as such it is noted on patient's file card. After normal duty hours this file is taken to the 4th floor pharmacy along with the Patient Profiles (file tub) and is brought back to the outpatient pharmacy the next duty morning.

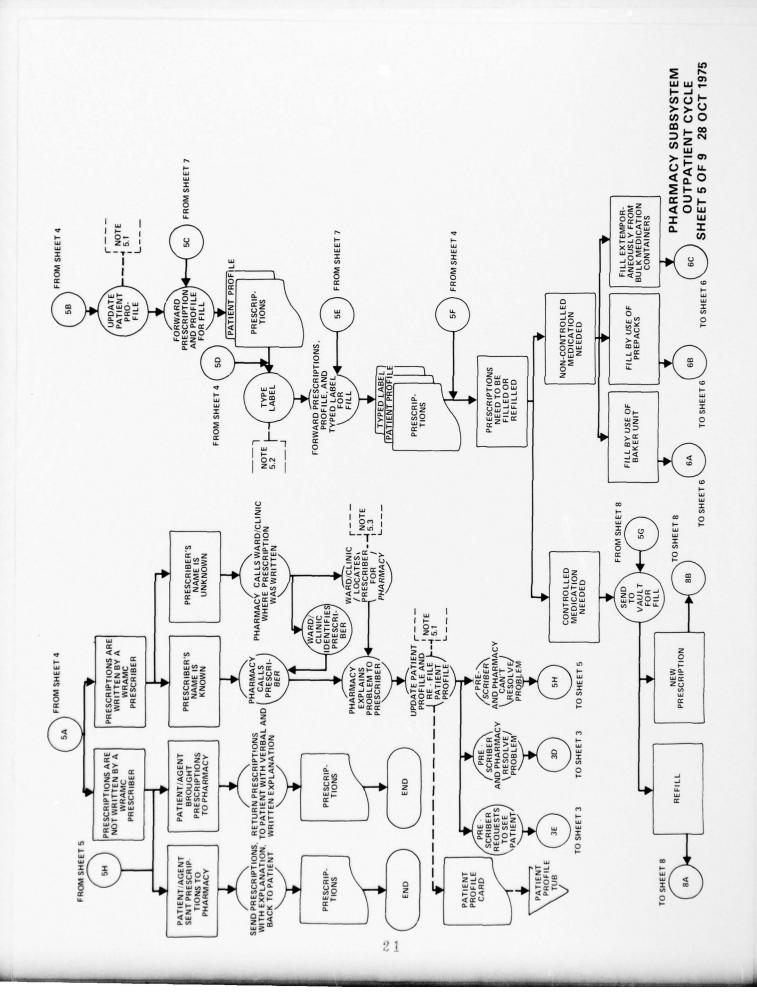


- 3.1 Information which requires action by the prescriber is either pertinent to the medication (instructions, strength, or name) or pertinent to the prescriber's signature block (the required signature, the printed name, rank, corps or BNDD or SSN number) and possible contraindication between prescribed medications and/or other drugs.
- 3.2 Information that can be routinely obtained from the patient includes patient's name, address, phone number, and, if known, prescriber's name and ward or clinic where the prescription was written.
- 3.3 If a medication is temporarily out of stock, the prescription is returned to the patient with the explanation that the medication is temporarily out of stock and the date the medication is due in. If the medication is not stocked or even if it is just temporarily out of stock, the patient will be informed that he/she can obtain the medication in a civilian pharmacy (at his/her own expense) or at some other military pharmacy (WRAMC will maintain area hospital formulary file copies to facilitate determination of other military pharmacies where the drug(s) may be stocked).
- 3.4 Selected non-formulary items can be special ordered for a single patient if the prescriber and the department chief feel this specific medication is required (TAB will routinely review all such actions).

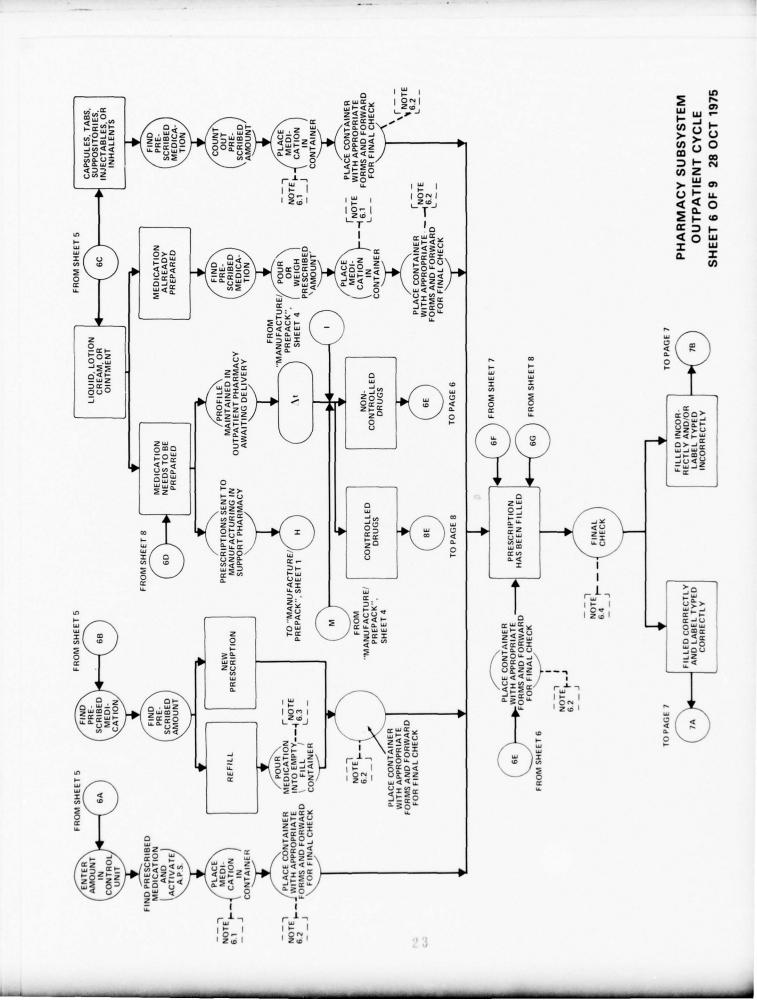


- 4.1 The data elements on the patient profile card are: patient's name, address, phone number, social security number, ID card number, sponsor's social security number, sponsor's ID card number, patient's age, weight, sex, race, family members (names), patient's sensitivities/allergies, medications routinely used, all doctors routinely seen, and any special medical problems. This information is gathered initially from the Patient Profile Questionnaire given to the patient when it is first decided to keep a profile on the patient. It is routinely updated during any following visits. After duty hours, the Patient Profiles (in a "tub" file) are taken up to the 4th floor pharmacy and returned to the outpatient pharmacy the next duty morning. The patients selected for patient profiles are chronic care, problem-user, or prescriber selected patients.
- 4.2 The patient may either turn in the completed questionnaire when picking up medications (encouraged), send it in (self-addressed, postage paid envelope provided) or bring it in at a later time.
- 4.3 The prescription is stamped with a numbering machine (e.g., Bates) when it has been determined it will be filled. If the prescription is for a controlled medication, it will be stamped at a later time with a specific Schedule II or Schedule III-V numbering machine (Bates machines with different number sequences).

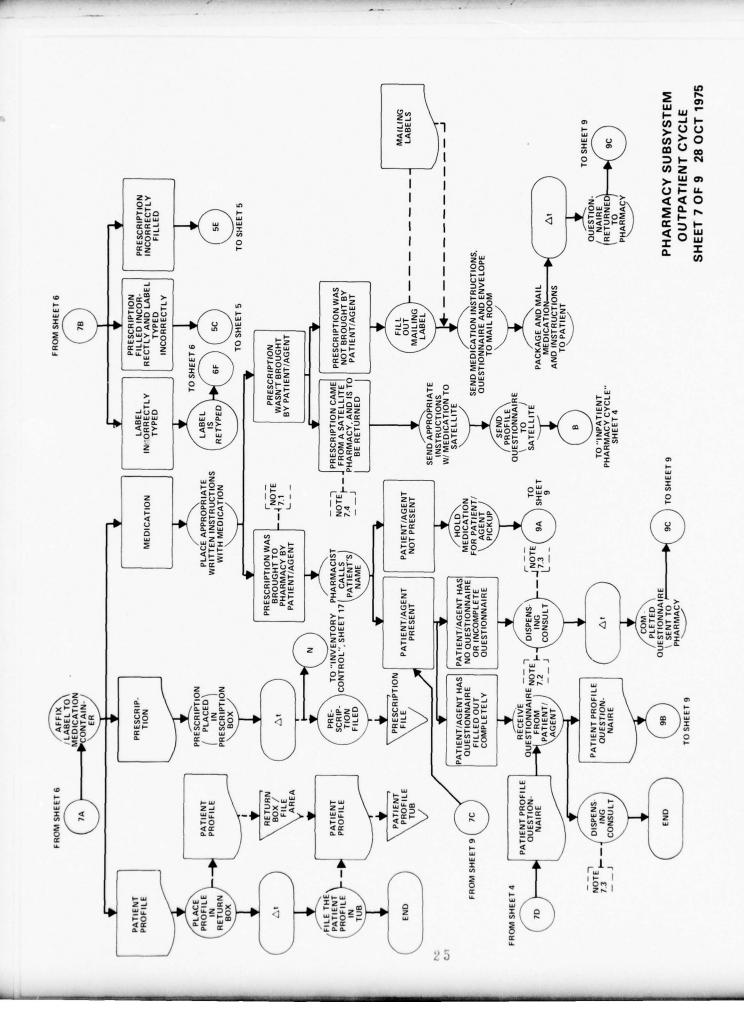
- 4.4 These problems would be (1) duplicate medications (both exact or pharmacologic category), (2) major contraindications, or (3) possible enzyme/metabolic problems.
- 4.5 These are problems which can be resolved by instructing the patient to take contraindicated medications a certain period of time apart to eliminate the problem. This instruction takes place by counselling the patient at the pharmacy when he/she picks up his/her medication.
- 4.6 The patient is requested to obtain a certificate of medical care eligibility from the Patient Administration Office (PAD). The patient may or may not return to the pharmacy. In the case where the patient does not return, the encounter is ended. In either case the patient may proceed through a PAD medical care eligibility process.
- 4.7 The patient is advised that the refill cannot be accomplished because: (1) the refill has been brought in too soon, (2) a refill is requested on a prescription that is over 6 months old, or (3) there are no refills left. Further, the patient is advised that if the medication need still exists, then prescription should be renewed by a visit to the prescriber.



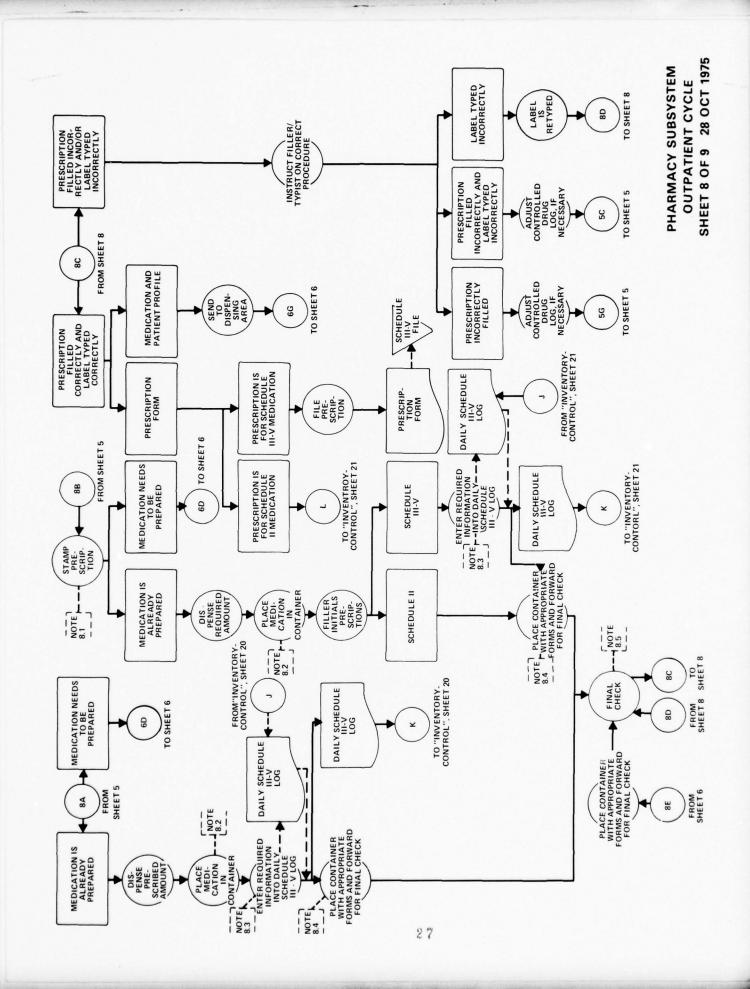
- 5.1 If there are no problems, the new medication(s) prescribed are added to the profile along with the date and number of refills authorized. If there are problems, the new medication(s) prescribed are added to the profile with a notation of the problem, how handled (contacted prescriber, etc.), and resolution of problem (instructed patient, new prescription, etc.).
- 5.2 The data elements on a label are patient's name, address (if necessary), date label originally typed, dosage instructions, medication name, strength, amount to be dispensed, number of refills (1 for one, 1-2 for two, 1-2-3 for three, etc.), prescriber's name and dispensor's initials.
- 5.3 If prescriber is not readily identifiable, pharmacy personnel will make every attempt to locate and/or identify him/her. If, however, he/she can not be identified, the prescription will not be filled and the patient will be asked to return to the clinic to see another care provider.



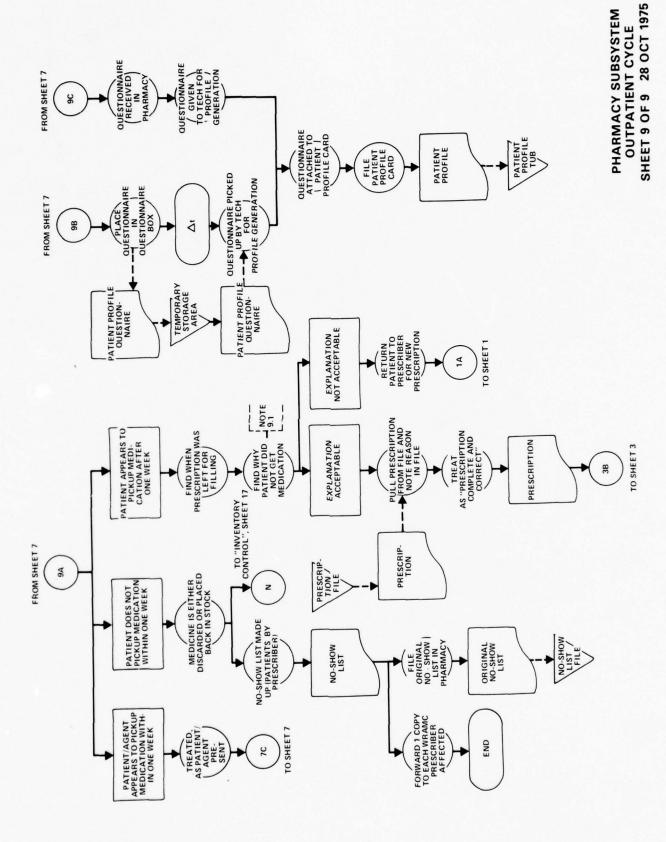
- 6.1 If prescription is a refill, place medication in the returned empty glass container and add a new cap. If a new prescription, place medication in new container. The Child Safety Packaging Act requires a new container for refills if plastic bottles are used. If the container appears to be contaminated, it will be replaced with a new container (requires a new label to be typed).
- 6.2 The appropriate forms are the prescription form and/or the patient profile card, as applicable.
- 6.3 If the medication is a liquid or cream, the medication is not transferred to the empty refill container and both the old empty container (has label indicating refills) and the new prepack container will be dispensed to the patient (with brief duplicate label).
- 6.4 The prescription is routinely checked to make sure the right medication and the right amount are given. The label is checked to be sure it is correctly typed. The patient profile card is checked to see if any additional information needs to be relayed to the patient. If medication is a contraindicated medication, the patient profile card is checked for information that needs to be relayed to the patient. This check must be made by a registered pharmacist.



- 7.1 This includes prescriptions sent from satellite pharmacies which are to be held at the outpatient pharmacy for patient pickup.
- 7.2 If the patient has an uncompleted questionnaire and cannot wait to finish it, the pharmacist gives the patient a postage paid, self-addressed envelope and instructs the patient to mail the questionnaire in when he/she does complete it.
- 7.3 Patient is given medications with complete written instructions. He/she will also be given verbal instructions, and will be questioned as to whether or not he/she fully understands them. If the patient is not fluent in the English language, special arrangements will be made to assure that he/she understands the instructions.
- 7.4 Discharged Patients and Patients on a pass will have their prescriptions sent down to the outpatient pharmacy from one of the satellites (such prescriptions can be filled and returned to the satellite to be dispensed on the ward or the patient can pick up medications at the outpatient pharmacy when leaving WRAMC).

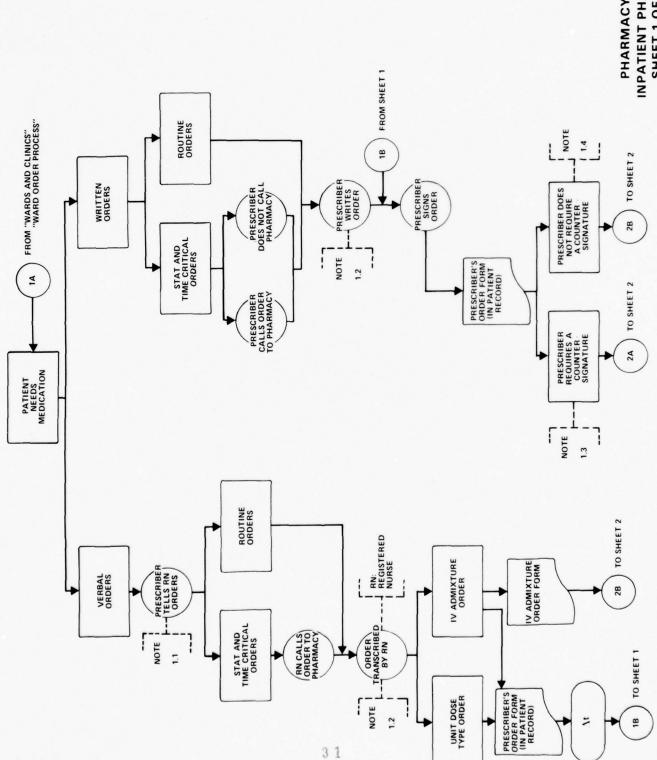


- 8.1 There are two numbering machines in the vault: one for Schedule II and one for Schedule III-V medications. Besides adding the prescription number, sequenced by the machine, a date stamp is also used to annotate the date the prescription was filled.
- 8.2 If the prescription is a refill, place the medication in the returned empty glass container and add a new cap. If a new prescription, place the medication in an unused container.
- 8.3 The data elements listed in the log are prescription/voucher number, name & strength of medication, amount dispensed, and date. This log is totaled by individual medication at either the beginning or ending of each work day for posting to controlled medication logs.
- 8.4 The appropriate forms are the prescription form and/or the patient profile card, as applicable.
- 8.5 The prescription is checked to make sure the right medication and the right amount are given. The label is checked to be sure it is correctly typed. The patient profile is checked to see if any additional information needs to be relayed to the patient. This check is made by a registered Pharmacist.



SHEET 9

9.1 In order to determine if the explanation is acceptable, the patient's age, the situation, the medication, and the contents of the patient profile (if applicable) are considered.



- 1.1 It may be possible for the prescriber to consign the ordering to the commo clerk. If this happens, the actions remain the same as if the order is consigned to the nurse (used only with commo clerks who have demonstrated they can routinely address this capability).
- 1.2 The orders are written on a three-part no carbon required (NCR) form. The data elements required to be on this form are: patient's name, ward, bed number, medication name(s) and strength(s), date of order, dosage form, dosage instructions (including time of administration), prescriber's signature, and transcriber's signature (if applicable). This form is a multiple item form (it can be used for more than one medication order). The orders are routinely written in the patient's record. If the order is for an IV-Admixture solution, another form is also filled out by the registered nurse or commo clerk and the three-part (NCR) form is used to validate the IV-Admixture order. The data elements on this form are: patient's name, ward, bed number, prescriber's name, transcriber's name, time solutions are due, vehicle & amount, additive name(s) and strength(s) or amount(s). This is a single item order and only one vehicle and required additive(s) are written per order form (but can be for multiple bottles, e.g., every 8 hours).
- 1.3 This prescriber is an individual who can prescribe any medications, which are not on a restricted use list. This individual would be an

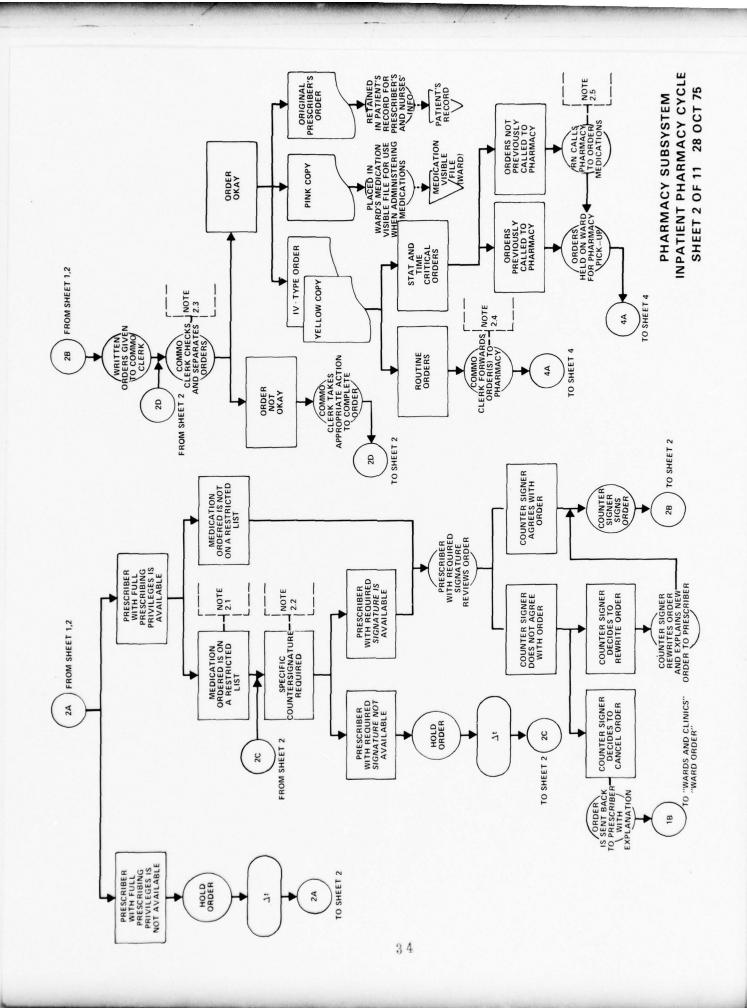
NOTES ON INPATIENT PHARMACY CYCLE FLOW CHARTS SHEET 1 (CONTINUED)

Amosist, a nurse clinician/practitioner, physician's assistant, etc.

Each prescriber of this type has a predetermined list of medications he/she can prescribe without needing a doctor's countersignature.

These lists are periodically reviewed and updated by the Therapeutic Agents Board (Pharmacy and Therapeutics Committee for Navy and Air Force). In certain cases a prescriber with full prescribing privileges can be considered a prescriber requiring a countersignature (i.e., he/she writes for a restricted medication).

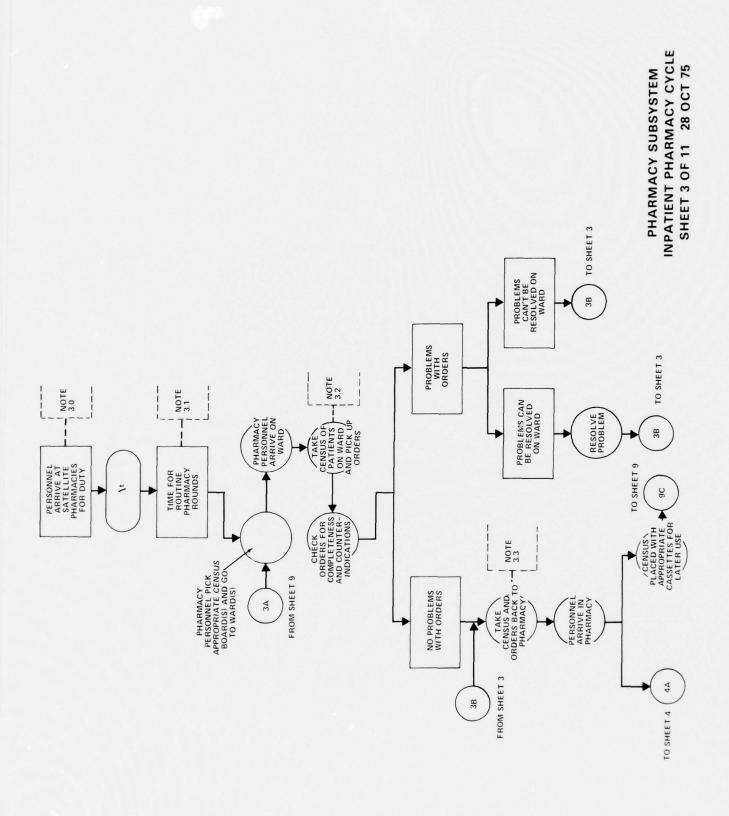
1.4 This is a prescriber who can prescribe any medications (including controlled medications but excluding restricted medications) without the approval of any other prescriber. In certain cases a prescriber requiring a countersignature can be considered a prescriber with full prescribing privileges (i.e., the prescriber writes for a medication on his/her list).



- 2.1 Restricted medications are either limited to a specific service or doctor, or require the signature of the chief of the prescribing doctor's service or another authorized professional person. An example of the first case is an investigational medication (restricted by doctor) or dermatology medication (restricted to Dermatology Service). An example of the second case would be certain antibiotics (e.g., carbenicillin), albumin, or parenteral hyperalimentation formulations.
- 2.2 The countersignature is required when the medication is designated to require a countersignature by the Therapeutic Agents Board (TAB) and the hospital commander or by the hospital commander alone. The types of countersignatures are Chief of Service, doctor of a specific service, or a specific doctor.
- 2.3. The commo clerk checks to see that the order(s) is complete (name, date and location). The commo clerk also separates the copies, retaining the original in the patient's record, possibly placing the pink copy in the ward's Medication Visible File, and forwarding the yellow copy to the pharmacy.
- 2.4 The order(s) can be forwarded in three ways: (1) placed in the Telelift, (2) hand carried by messenger, (3) picked up by pharmacy personnel during normal rounds and/or when delivering Stat and Time Critical medications.

NOTES ON INPATIENT PHARMACY CYCLE FLOW CHARTS SHEET 2 (CONTINUED)

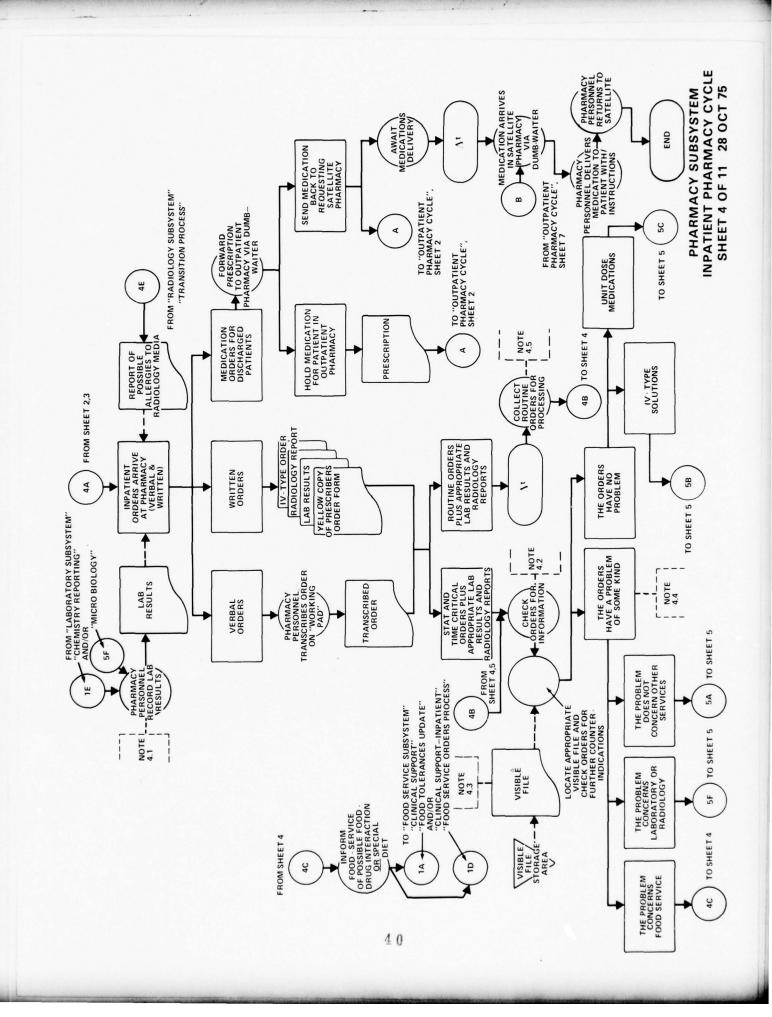
2.5 This may be accomplished by a commo clerk only when this individual has demonstrated competence for this activity.



- 3.0 At the beginning of each working day, the 4th floor pharmacy will return to the 5th, 6th, and 7th floor pharmacies the sterile product suspense "hourly" files and the Visible Patient Medication files (these files are returned with all original orders plus any new orders). At the end of each working day the 5th, 6th, & 7th floor pharmacies will send their sterile products "hourly" file and Visible files to the 4th floor (which will handle all patient orders during the night).
- 3.1 Every day the satellite pharmacy personnel will make periodic rounds of the wards on their floor to check for catch-up orders required and current patient locations. After the satellite pharmacies on the 5th, 6th, & 7th floors close for the night, the 4th floor pharmacy will provide services to all wards in the hospital.
- 3.2 In taking the census (patient location), pharmacy personnel check to see who is still on the ward, what bed they are in, who has been discharged, who is on leave, who will be discharged before next scheduled unit dose cassette delivery, and who will be placed on leave before the next scheduled unit dose delivery. If a new patient has arrived on the ward (admission or transfer), cassette drawer labels will be prepared for that patient. The elements on the label will be patient's name, bed number and all allergies (if any).

NOTES ON INPATIENT PHARMACY CYCLE FLOW CHARTS SHEET 3 (CONTINUED)

3.3 On the way back to the pharmacy an initial sorting of the orders takes place. Normally this sort will separate orders by ward, and also separate Stat and Time Critical orders from routine orders. Separation of problem orders from non-problem orders may occur. In addition, as established per Standing Operating Procedure (SOP), orders requiring specific drug(s) for laboratory and/or radiology tests will be screened and the drug(s) delivered to the wards (secondary orders) as appropriate to support diagnostic procedures.

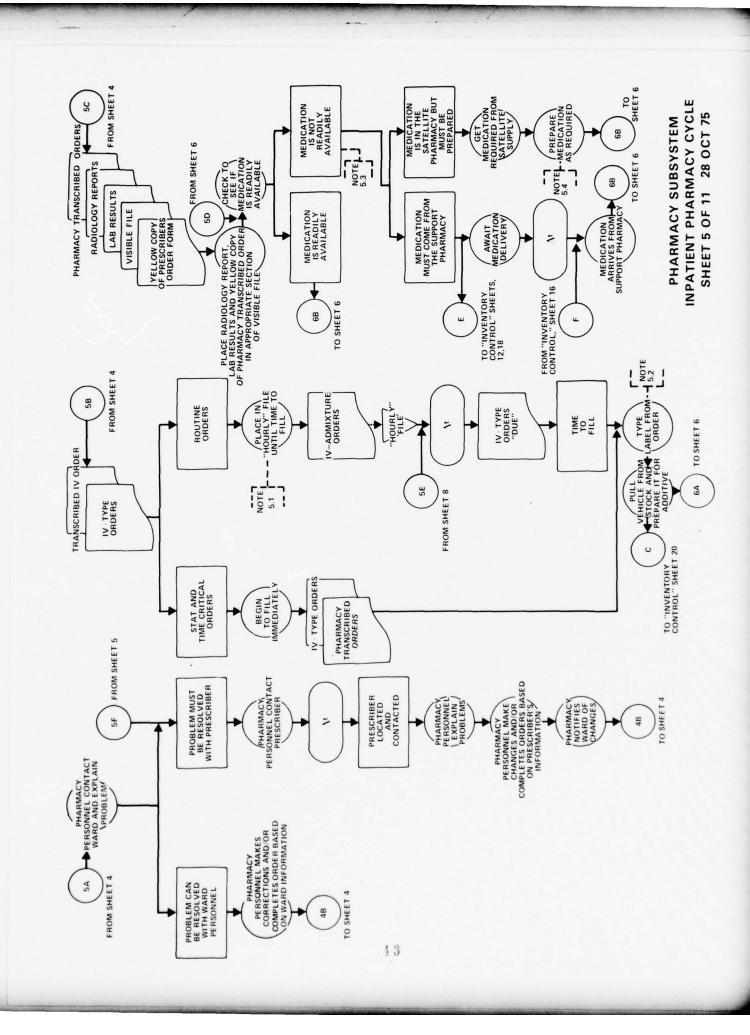


- 4.1 The results/reports the pharmacy is interested in are BUN, Creatinine, antibiotic C/S, PTT, etc.
- 4.2 The information checked (if a prescriber's order form) is patient's name, ward, bed number, medication name & strength, dosage instructions (including time), prescriber's signature, transcriber's signature, countersignatures as required, and contraindications between items on this order form. If an IV-Admixture order, check for patient's name, ward, prescriber's and transcriber's names, time(s) due, vehicle, amount of vehicle, additive(s) with strengths and amounts and possible contraindications between items on this order form. Also check to see if medication is stocked in the pharmacy system.
- 4.3 There is a separate patient medication Visible File maintained by the Pharmacy for each ward. Each file has a separate section for each bed on the ward and each section contains all current orders written for the patient in that specific bed, plus appropriate Lab and Radiology reports.
- 4.4 The types of problems possible are: no name or wrong patient's name, no bed number or wrong bed number, no ward or wrong ward, no date (these are handled by contacting the commo clerk on the ward); or medication/dosage form/instruction either: (1) are not on the order,
- (2) the information is not consistent (handled/resolved normally with clerk or throught prescriber), or (3) there are contraindications between medications on the same order or previous orders (resolved with prescriber).

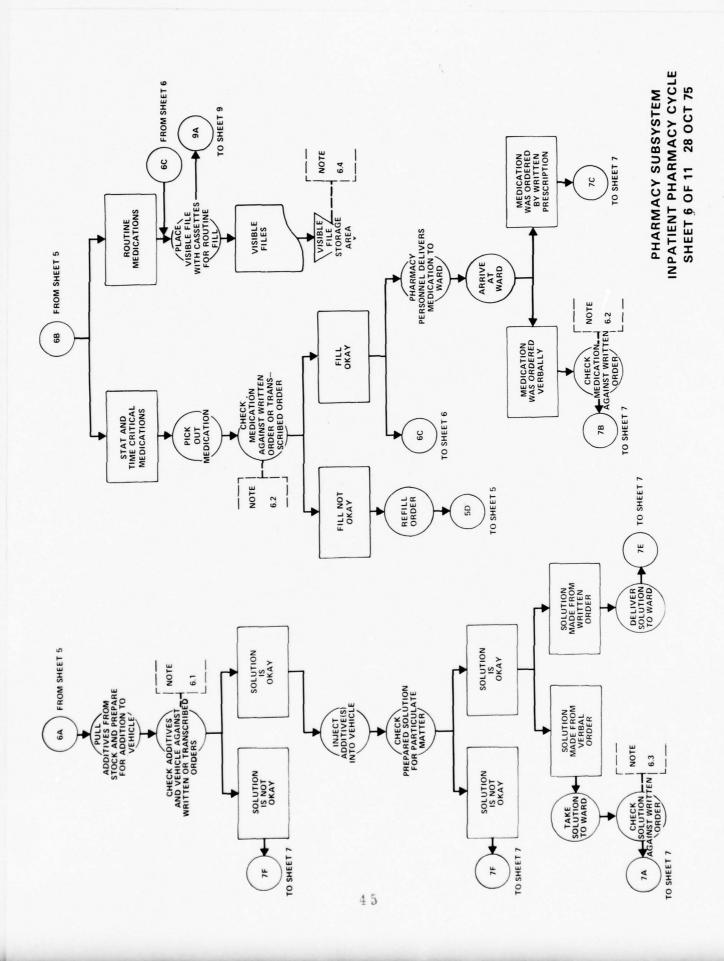
NOTES ON INPATIENT PHARMACY CYCLE FLOW CHARTS SHEET 4 (CONTINUED)

The pharmacy will also inform prescribers, when applicable, that a medication a patient is taking is capable of changing the Lab results significantly; or that radiology has reported that the patient is possibly allergic to Iodine, etc. Pharmacy will also inform prescriber if ordered medication is not stocked in pharmacy system, Lab of problem medications, and Food Service of drugs which have a potential for drug-dietary interaction. Also, Food Service will be notified that intake of the medication by the patient requires special dietary considerations (a specific beverage or food, e.g., orange juice or milk).

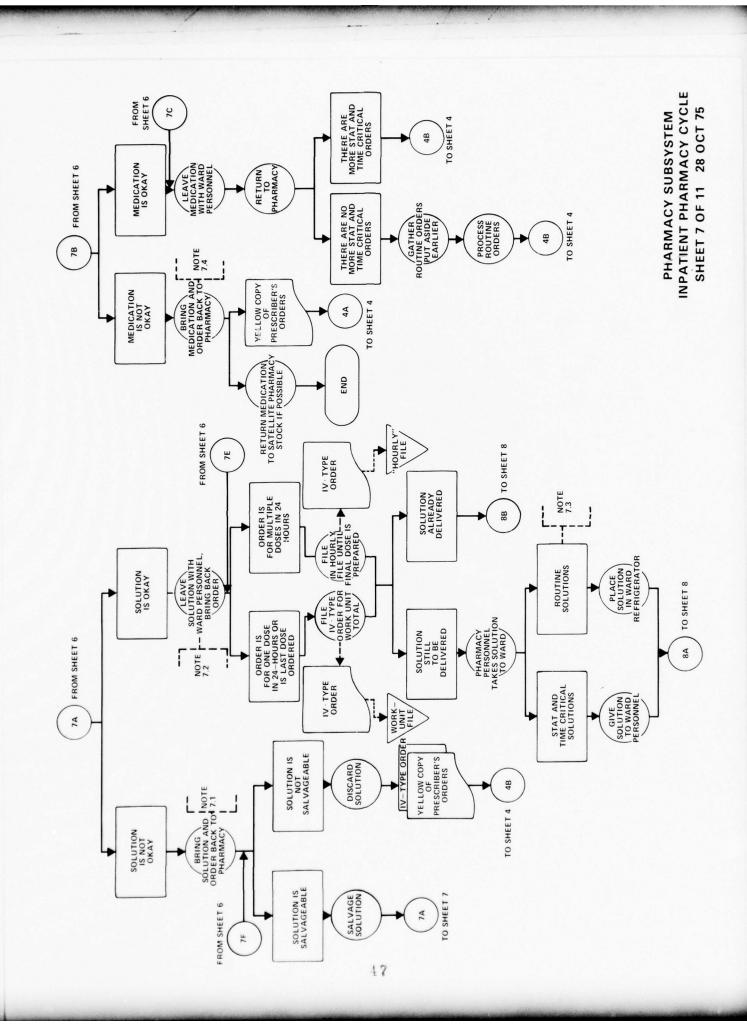
4.5 There may or may not be a time delay in the collection of routine orders for processing. All Stat and Time Critical orders are processed first if there are any. If there are none, then routine orders are immediately collected and processed.



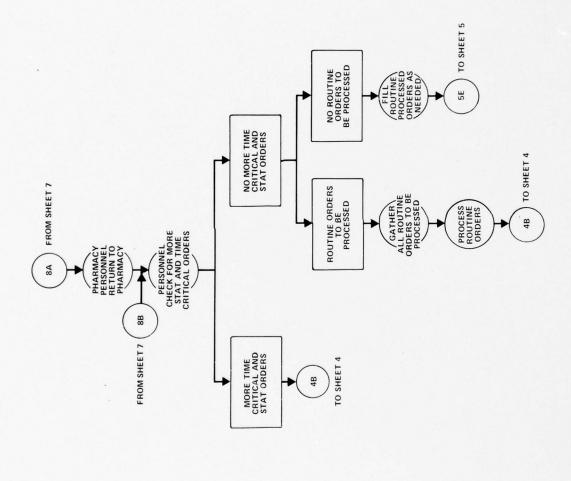
- 5.1 The "hourly" file is the suspense file for the sterile products (IV admixtures, etc). It is set up by hour of administration. Each order is placed in a time slot reflecting the appropriate time due. Time to fill will vary from one hour to one-half hour before scheduled administration based on the amount of time required to fill and type of order.
- 5.2 The data elements included on the label are patient's name, ward, date & time prepared, discard date & time, initials of person preparing solution, vehicle & amount, additive(s) with amount or strength, special instructions, and when a series of bottles is to be administered, the number of the bottle (e.g., first, second, ... etc),
- 5.3 The reasons for the medication not being readily available are:
- (1) medication not stocked in satellite pharmacy, (2) satellite temporarily out awaiting re-supply from support pharmacy,
- (3) medication not available in unit dose packaging (e.g., unusual or short lived injections for unit dose), and (4) medication which must be compounded in either the satellite or the support pharmacy.
- 5.4 The amount prepared depends on the medication, the patient (adult or child) and the diagnosis. When the order is a Stat or Time Critical order, only enough dosages will be prepared to last until the next cassette delivery. If the order is routine, a certain number of dosages is prepared (i.e., 2-3 days supply).

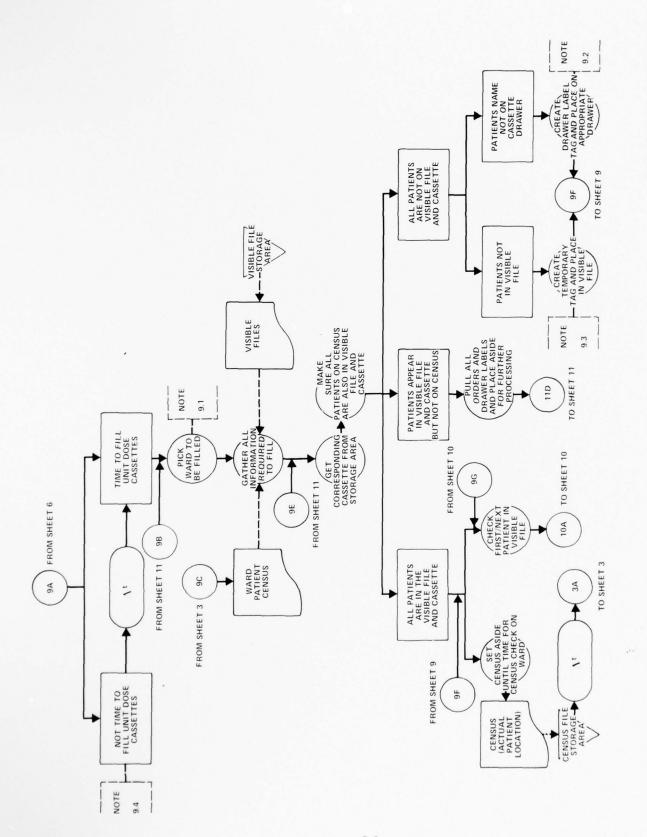


- 6.1 The solutions are checked to make sure the correct vehicle and volume of sterile fluid are on hand for the preparation of the order, and that the right additives and amounts of same are on hand for the preparation of the order.
- 6.2 Check order to make sure the medication, strength, and dosage form corresponds to the order.
- 6.3 The solutions are checked to make sure the correct vehicle and volume of sterile fluid were used in the preparation and that the right additives and amounts of same are on hand for the preparation.
- 6.4 The Visible Files are pulled per established procedure when Pharmacy personnel are ready to fill the unit dose cassettes.

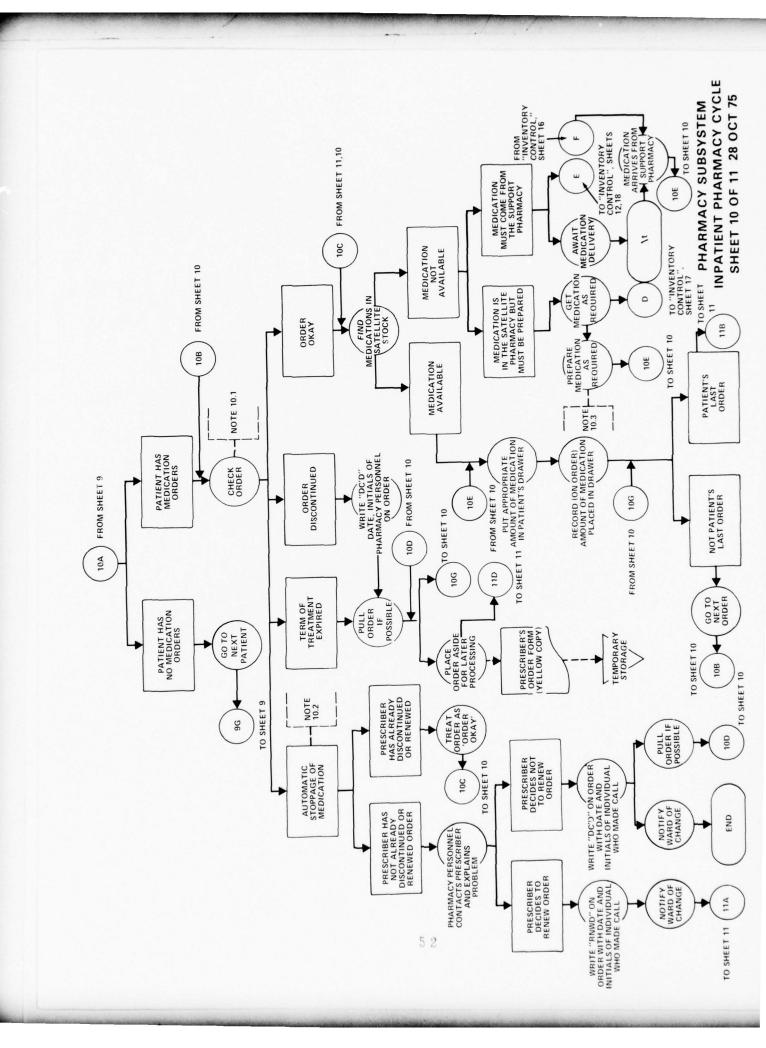


- 7.1 Stat orders would be called to pharmacy to allow reformulation to still meet the requirements of the actual written order in a suitable time frame.
- 7.2 If the order is not on the ward, the solution will be left and the order sent to the pharmacy when it is available (the pharmacist will verbally validate the order based on conversation with the prescriber or the nurse).
- 7.3 Many IVs will be delivered by Telelift during non-peak workload periods.
- 7.4 Stat orders would be called to the pharmacy to allow preparation and delivery in a suitable time frame.

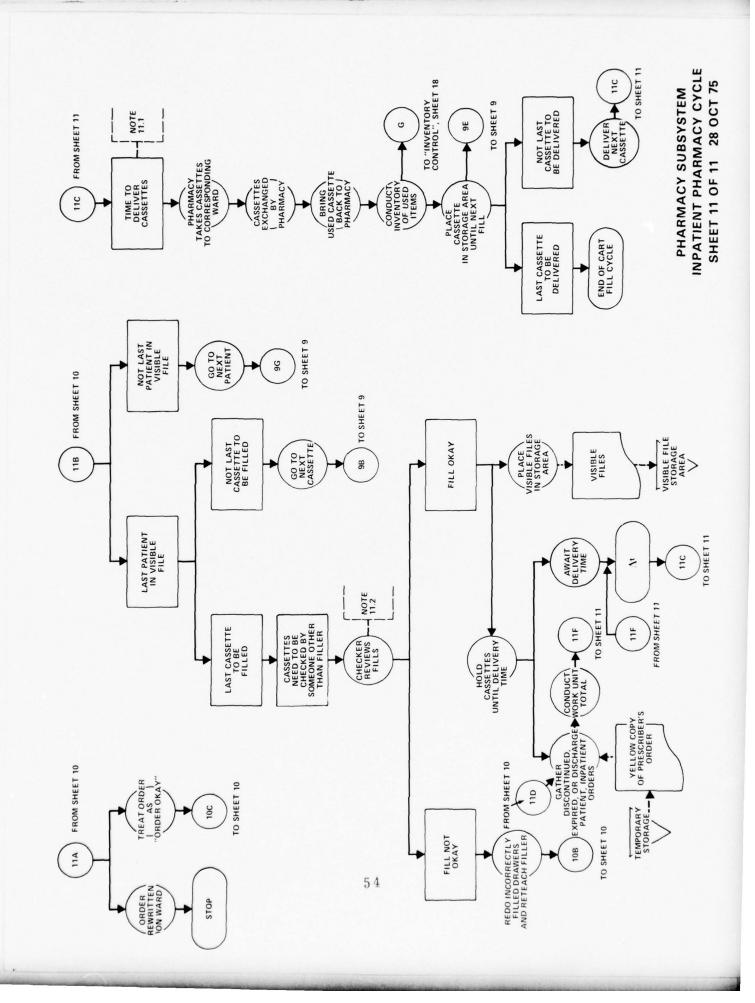




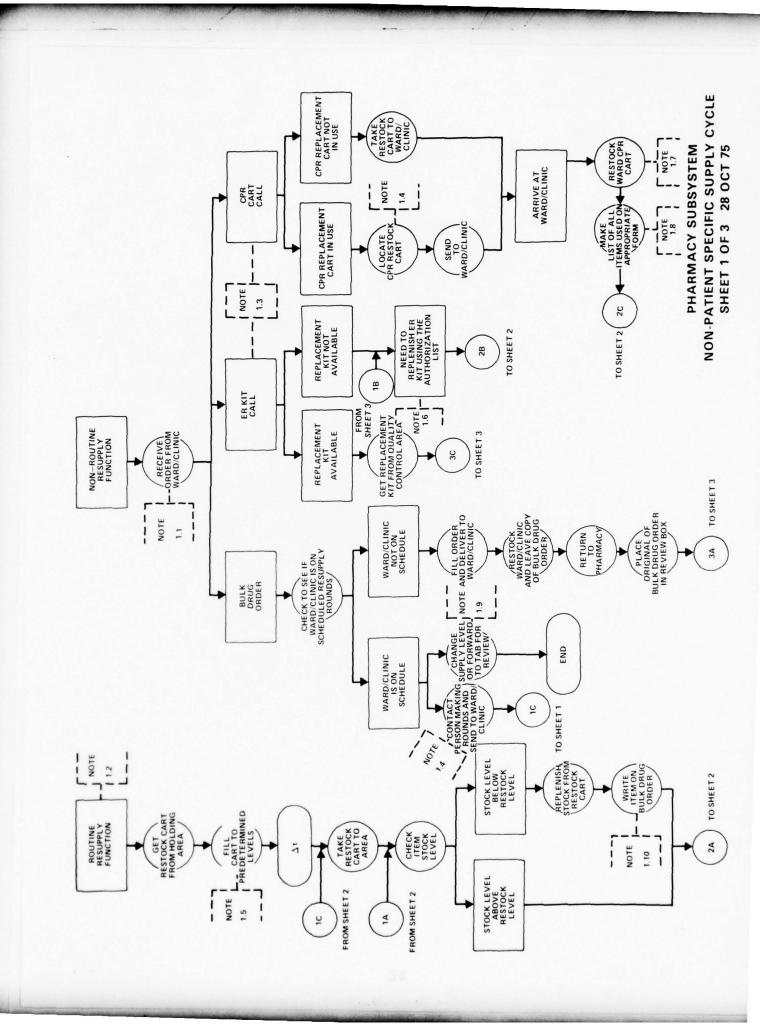
- 9.1 Each satellite has an established procedure as to which ward is filled first, second, third, ... etc. This is not a rigid schedule and may be changed according to patient loads.
- 9.2 The drawer label data elements are patient's name and first initial, bed number, and allergy/sensitivity (may be multiple labels if two or more drawers required).
- 9.3 The temporary label consists of patients name (last name first) and bed number.
- 9.4 The routine filling of unit dose cassettes may be interrupted to fill other Stat or Time Critical Orders.



- 10.1 The orders are checked for any automatic stop orders (ASO), any orders for which term of treatment is expired, or orders which were discontinued.
- 10.2 This is when a medication is stopped due to an established length of treatment. Medications of this type are narcotics, antibiotics, ... etc. The length of treatment is established by the TAB and the hospital commander, by the hospital commander, or by established nursing procedures.
- 10.3 The amount prepared depends on the medication, the patient (adult or child) and the diagnosis. When an order is a Stat or Time Critical order, only enough dosages will be prepared to last until the next cassette delivery. If the order is a routine order, a certain number of dosages is prepared (i.e., 2-3 days supply).



- 11.1 The delivery schedule is a procedure set-up by each satellite pharmacy and delivery is routinely made when convenient to the ward.
- 11.2 The checker reviews the entire fill to make sure the correct medications and amounts have been placed in the correct patient drawers. The check is accomplished one drawer and one patient at a time as in the original fill process.



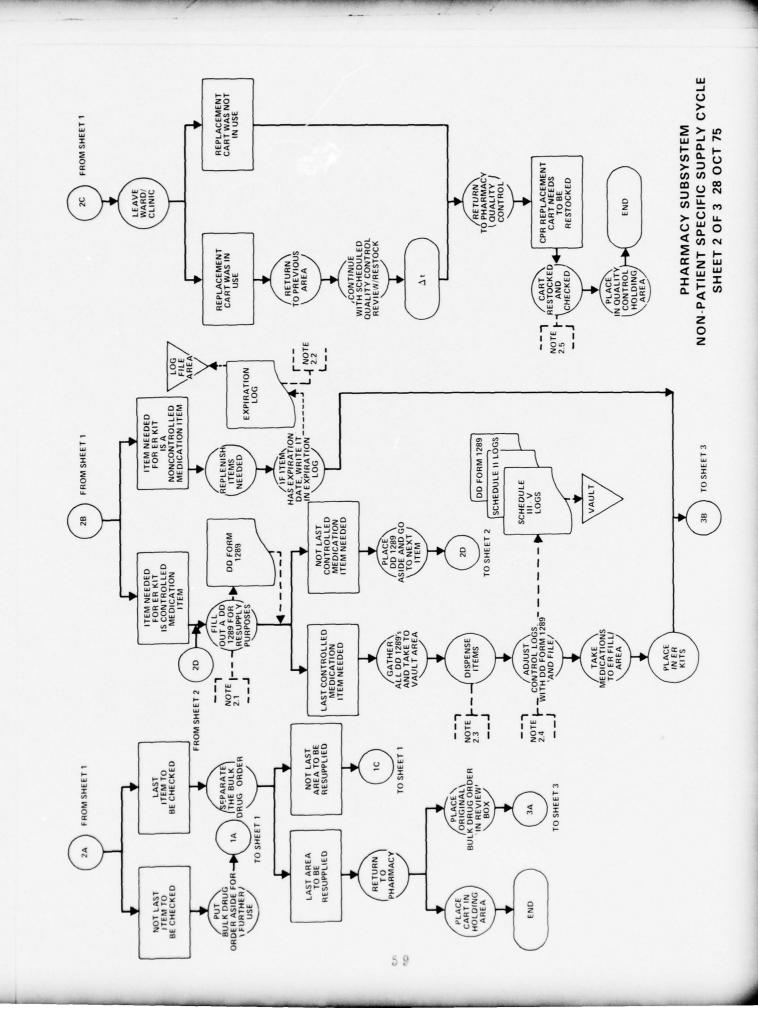
NOTES ON NON-PATIENT SPECIFIC SUPPLY CYCLE FLOW CHARTS SHEET 1

- 1.1 These orders are Bulk Drug Orders for ward/clinic stock or staff "comfort items" which have been used or are calls informing the pharmacy that the ER kit or CPR Cart has been used.
- 1.2 This process will provide automatic resupply for MOD cabinets, and ward/clinic stock. The MOD Cabinet is located in the ER/ASO area and is used after the outpatient pharmacy closes for the night. It will contain a predetermined group of all labeled treatment prepack items that will be routinely used in treating patients after outpatient pharmacy hours.
- 1.3 All ER kit and CPR Cart calls are handled by the Pharmacy
 Quality Control (QC) Team during the regular QC duty period and by
 the 4th floor pharmacy thereafter.
- 1.4 A Page Boy will be used to make locating cart personnel on rounds easier (assigned to Chief, Pharmacy Service).
- 1.5 The Ward/Clinic Restock Cart contains staff "comfort items", and bulk liquids and other necessary ward/clinic stock items authorized by TAB for ward/clinic use.
- 1.6 ER kits have a list posted on them of the items and amounts of each item to be placed or replaced in the kits. The kit being replenished is not the ER kit on the ward but the returned exchange

NOTES ON NON-PATIENT SPECIFIC SUPPLY CYCLE FLOW CHARTS SHEET 1 (CONTINUED)

kit in the pharmacy needing to be filled (extra kits are routinely available, CPR carts must be filled in place however).

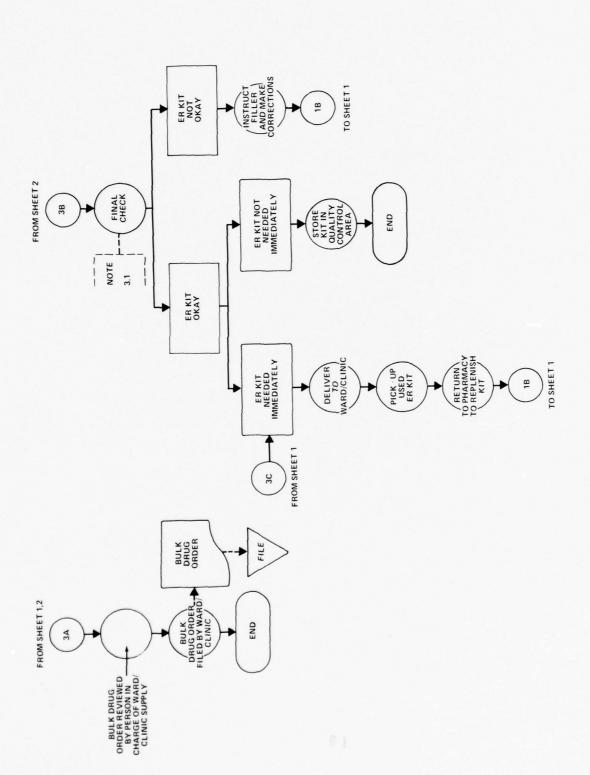
- 1.7 During the process of restocking; the expiration dated items, items on suspense list, and all items on the CPR Cart in question will be routinely checked (quality assurance).
- 1.8 Non-controlled stock will be placed on Bulk Drug Orders with expiration dates if applicable. Controlled stock will be placed on DD Form 1289 with expiration dates where applicable. In either case, the location will be placed in the space provided for patient's name or specific area space on the form used.
- 1.9 Newly requested ward/clinic stock items are reviewed and approved by TAB. The levels of such stock, unless considered excessive, may be increased/decreased as appropriate to the demands of patient care and changing patient mix.
- 1.10 The Bulk Drug Order has the following data: the specific area where the list was prepared, date order filled out, medication name and strength, dosage form, unit of issue, quantity requested, and signature of pharmacy staff person making order.



NOTES ON NON-PATIENT SPECIFIC SUPPLY CYCLE FLOW CHARTS SHEET 2

- 2.1 The DD Form 1289 is filled out as it would be for a normal prescription with the following changes: specific ER kit or CPR Cart is noted instead of patient's name, a registered pharmacist signs instead of a prescriber, no instructions are indicated on the form, and the RX symbol is lined out.

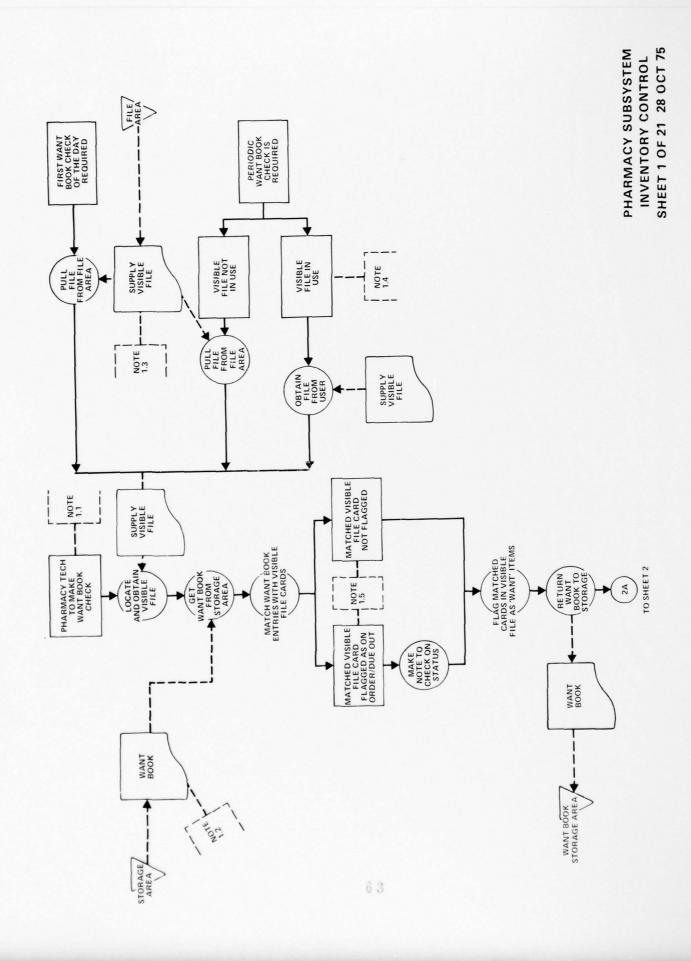
 Data elements which remain unchanged are as follows: medication name and strength, dosage form, and amount to be dispensed. Only one item can be ordered per DD 1289.
- 2.2 The data elements entered in the log are date of expiration, medication name and strength, dosage form, the location where the medication is being placed (i.e., ER kit number or CPR Cart location), manufacturer, and lot number.
- 2.3 The DD Form 1289 is stamped on the front with a prescription number (which becomes the voucher number). All the DD 1289's for one unit are filled at one time but are entered in the controlled drug log one at a time.
- 2.4 The information entered is date dispensed, quantity dispensed, voucher number, adjusted balance on hand, and person dispensing the item(s).
- 2.5 The information captured during the restocking and checking of CPR Replacement Carts is the same as in the case of ER kit refilling.



PHARMACY SUBSYSTEM
NON-PATIENT SPECIFIC SUPPLY CYCLE
SHEET 3 OF 3 28 OCT 75

NOTES ON NON-PATIENT SPECIFIC SUPPLY CYCLE FLOW CHARTS SHEET 3

3.1 This check is made by someone other than the filler and the review assures that the right medications and amounts are placed in each kit or in the CPR Replacement cart inventory.

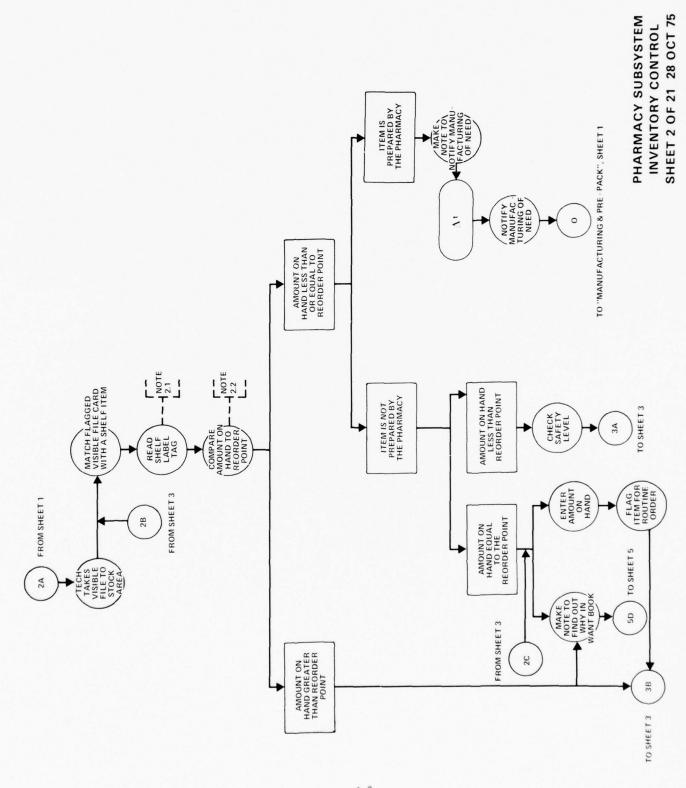


NOTES ON MANUAL INVENTORY CONTROL FLOW CHARTS SHEET 1

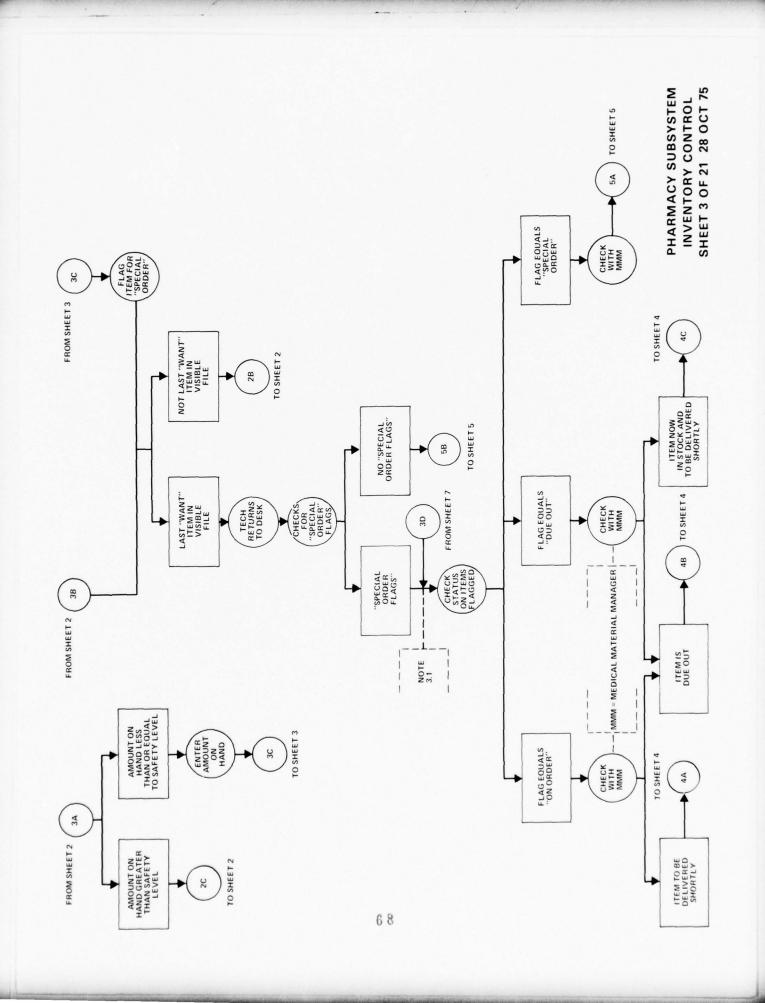
- 1.1 This want book check is made at the start of the day and at periodic intervals thereafter.
- 1.2 The want book contains the list of items that for one reason or another cannot be found in the supply area, or which have been noted as below their reorder point. The want book is always kept in the same place in the supply area. The data elements placed in the want book are the medication name and strength, dosage form, and the ID of the person who noted the shortage.
- 1.3 The Supply Visible File is a stock code listing of all the items required in order to operate the pharmacy. The data elements listed in the Visible File are: the item name (if medication, generic and trade names), medication strength (if applicable), dosage form (if applicable), National Stock Number (NSN), operating maximum stock level*, reorder point*, safety level, amount on hand, amount due out, amount received, date ordered, date received, date due in*, unit of issue, order document number, supplier* (Logistics, wholesaler [Gilpin or District] purchasing & contracting, or other sources [loans], storage notes, manufacturer(s) lot number, expiration date*, unit price*, quality control information*, and descriptive data. Starred (*) items are data elements that are to be entered in pencil to facilitate changes/updates.
- 1.4 The visible file, when in use, can be located in three places in most cases: (1) in the stock area being used for inventory,

NOTES ON MANUAL INVENTORY CONTROL FLOW CHARTS SHEET 1 (CONTINUED)

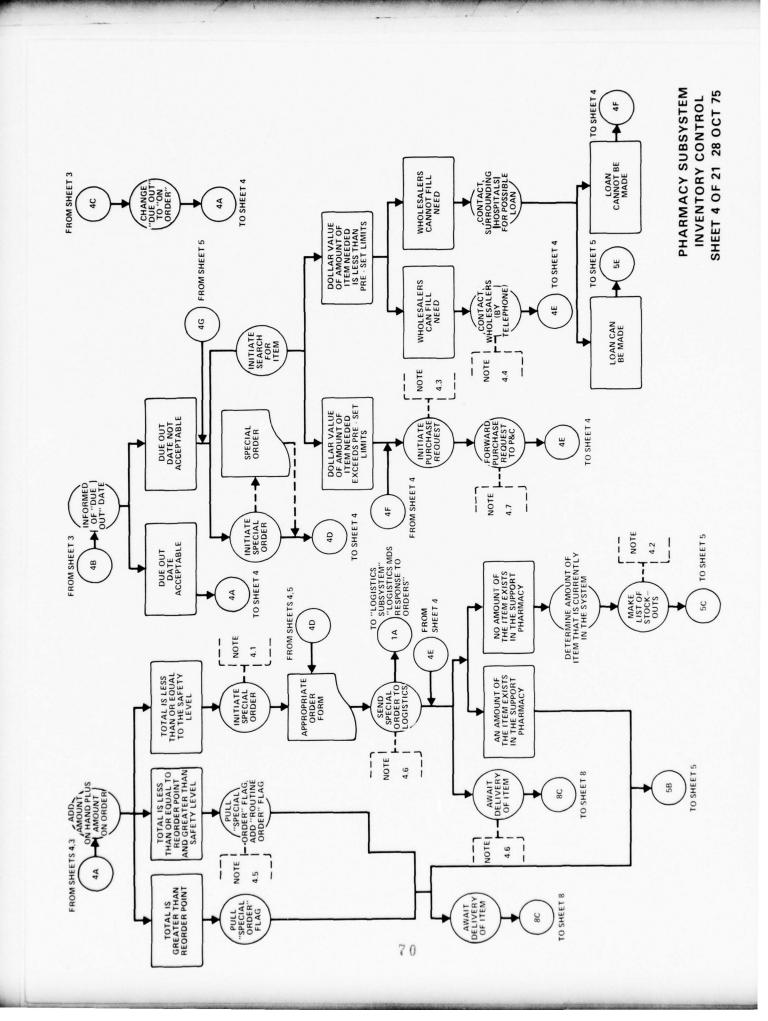
- (2) in the stock receipt area being updated while receiving supplies, or (3) in the office area being used to check the stock control parameters.
- 1.5 The flags referred to are small pieces of colored plastic. We foresee the need for 5 different flags: (1) item was placed in want book, (2) need for routine order, (3) item is on order, (4) item is due out to Logistics, and (5) item needs special order.



- 2.1 The Shelf Label (a magnetic strip with a paper label face) is placed on the outer edge of the shelf under the item. The data elements on the label are the item name (if medication, generic & trade names), unit of issue, descriptive data, operating/maximum stock level, reorder point, safety level, and if a medication, strength and dosage form.
- 2.2 In the case of a controlled item, the comparison is made using the DA form 3862 (Controlled Substances Stock Record). The data elements on a DA form 3862 are item name (if medication, generic & trade), medication stength and dosage form, columns for date of transaction, quantity received, voucher number, person receiving or dispensing item, quantity dispensed and balance on hand.



3.1 For Connector 3D, this path is not dependent upon the occurrence of a "special order" Flag.



4.1 The order is prepared on a DA Form 2765 if the item is not a controlled medication item (note R or K). The data elements on this card are National Stock Number, unit of issue, unit price, document register number, priority, demand, cost detail account number, organization code, quantity requested, item description, total price, material category code, and Julian date.

If the item ordered is a controlled medication item, a

DA Form 2765-1 is used. The data elements are the same as the

DA Form 2765 plus the addresses of the facilities handling the

items, which are clearly shown to facilitiate an audit.

If the order is for a non-standard item which is not prestocked, a DA Form 3161 is used. The data elements on this form are: issue/turn-in, request number, from requesting activity to issuing activity, date required, priority, accounting & funding data, stock number, description, coding of material, unit of issue, quantity, unit price, total cost, justification, date ordered, ordering officer, date received, receiving officer, total cost per sheet, and total cost per order.

The designation that the order is a special order (immediate need), or routine order (normal need) is always entered in the priority blocks using a predetermined code.

4.2 The list is documented for ready reference in a note book and consists of the following information; medication name,

NOTES ON MANUAL INVENTORY CONTROL FLOW CHARTS SHEET 4 (CONTINUED)

medication strength, dosage form, date due in, amount of drug in pharmacy system, and locations with the amount at each location.

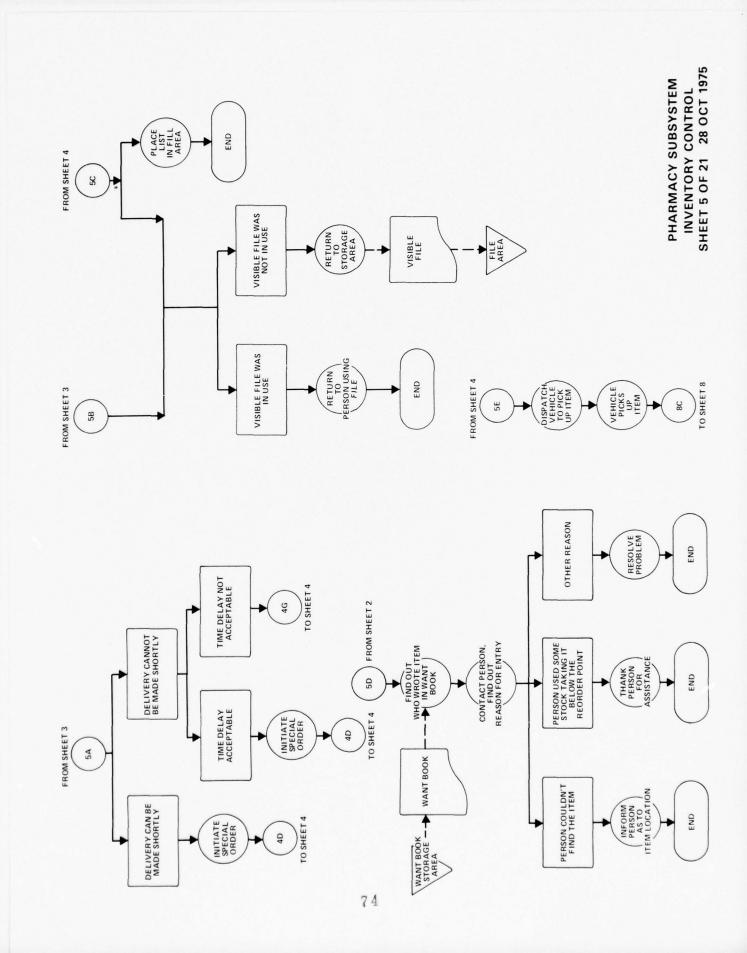
- 4.3 The request is accomplished on a DA Form 3953. The data elements are: date of order, purchased for (which pharmacy—support or Forest Glen), date needed, authorization for request, description of supplies, quantity, unit of issue, estimated unit and total price, source or vendor, how item is used, date of signature, name and signature of initiating officer, and accounting classification.
- 4.4 The pharmacy will alternate wholesale orders between Gilpin and District Wholesalers when applicable (wholesaler usually known to carry item being ordered).
- 4.5 Other flags, if present, are not removed.

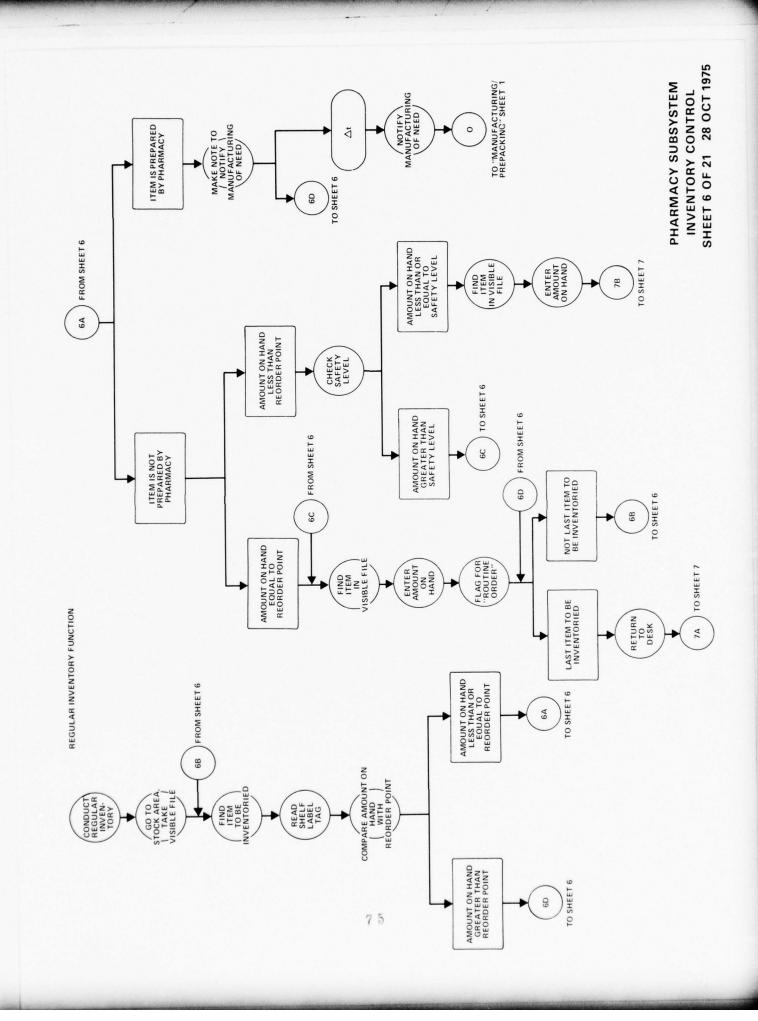
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4.6 The special order, on either DA Form 2765 or DA Form 2765-1, is routed to the Medical Material Manager (MMM) through the Hospital Logistics System (HLS). The MMM functions are outside the HLS functional responsibilities. For this reason the MMM manual functions will not be flowcharted by Logistics. The Medical Material Manager's handling determination of the special order is communicated through HLS. This routing process will not be flowcharted since no action is taken by HLS other than forwarding the handling determination to the customer.

NOTES ON MANUAL INVENTROY CONTROL FLOW CHARTS SHEET 4 (CONTINUED)

4.7 The functions of Purchasing and Contracting (P and C) are outside the Hospital Logistics System functional responsibility. For this reason P and C functions will not be flowcharted by Logistics.





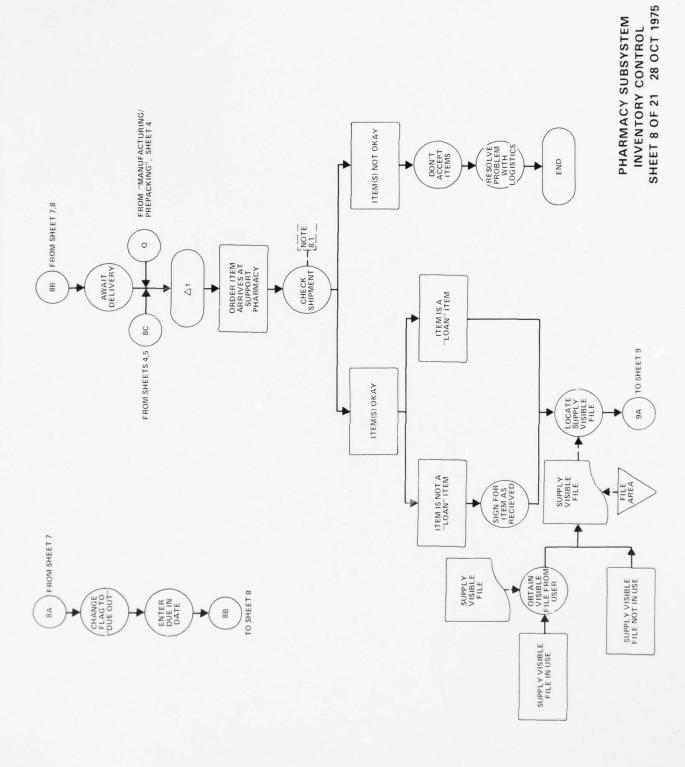
TO SHEET 3

NO FLAGS

FROM SHEET 6

PHARMACY SUBSYSTEM INVENTORY CONTROL SHEET 7 OF 21 28 OCT 75

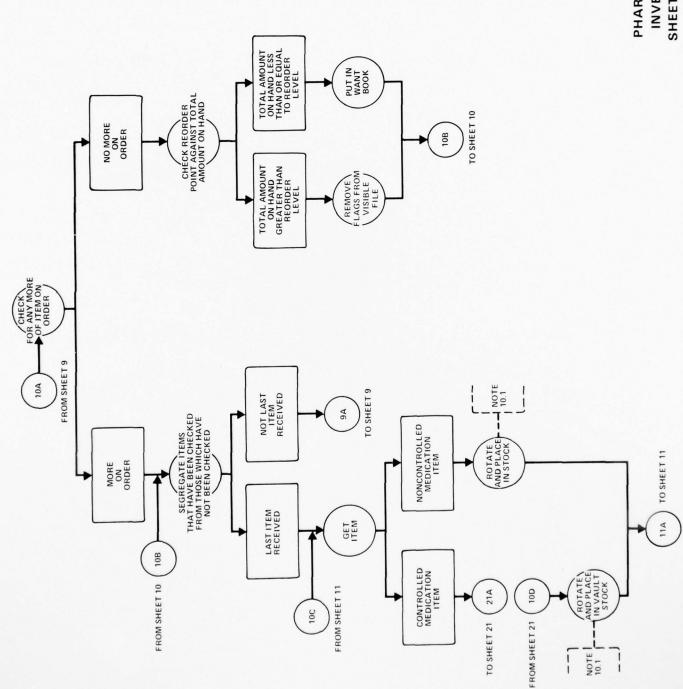
7.1 The routine order is routed to the Medical Material Manager (MNM) through the Hospital Logistics System (HLS). The MMM functions are outside the HLS functional responsibilities. For this reason the MNM manual functions will not be flowcharted by Logistics. The Medical Material Manager's handling determination of the routine order is communicated through HLS. This routing process will not be flowcharted since no other action is taken by HLS.



8.1 The shipment is checked for broken or damaged containers, sealed containers which have been opened, damaged items sent from Logistics, partial order fills, wrong item sent, or expired item sent.

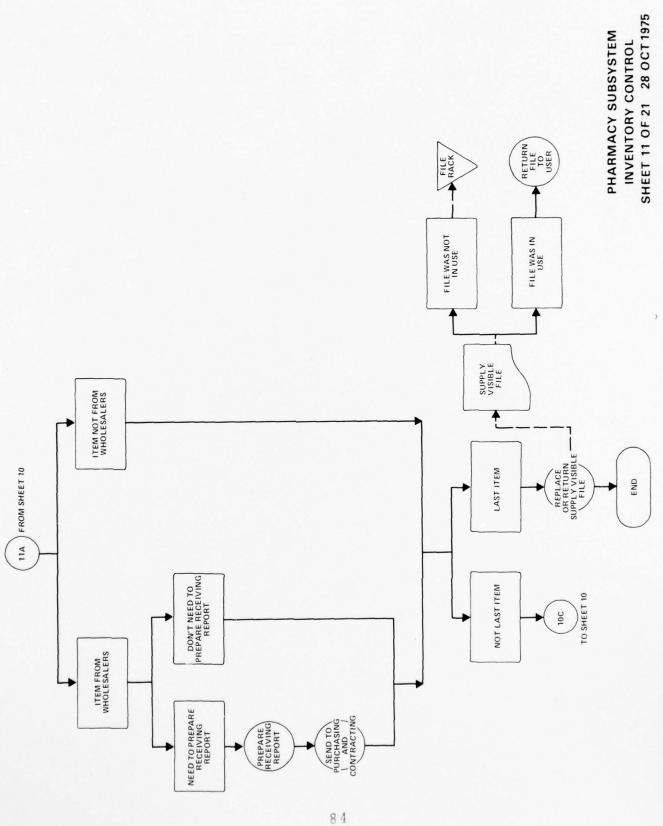
PHARMACY SUBSYSTEM INVENTORY CONTORL SHEET 9 OF 21 28 OCT 75

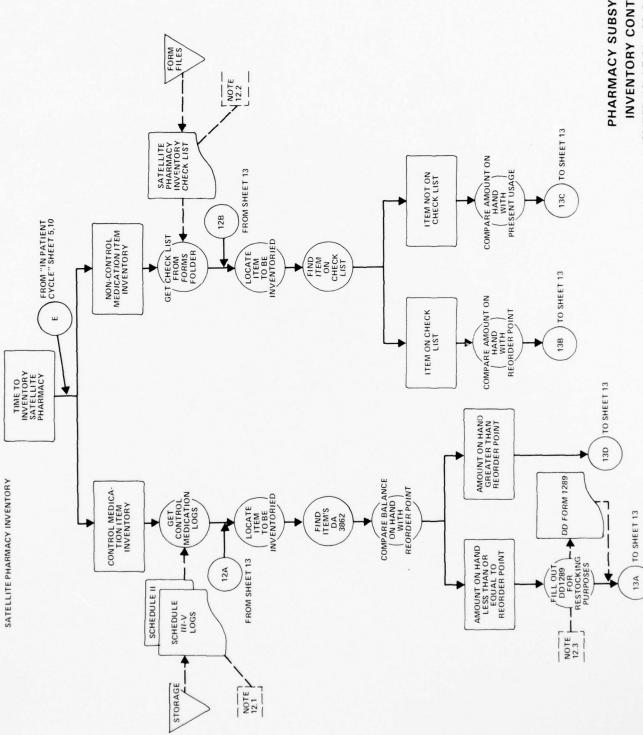
- 9.1 The entries made on the card are date received, quantity received, expiration date, manufacturer, and lot number. If the item is being loaned to the pharmacy (for repayment to lender at a later time) the information also entered is the amount of loan and from where the item came for repayment purposes. The amount will be circled to signify item was borrowed.
- 9.2 The "loan repayment" will not be made if such action would necessitate a special order for item.
- 9.3 The entries are the date of "repayment" and the initials of the person authorizing "repayment".



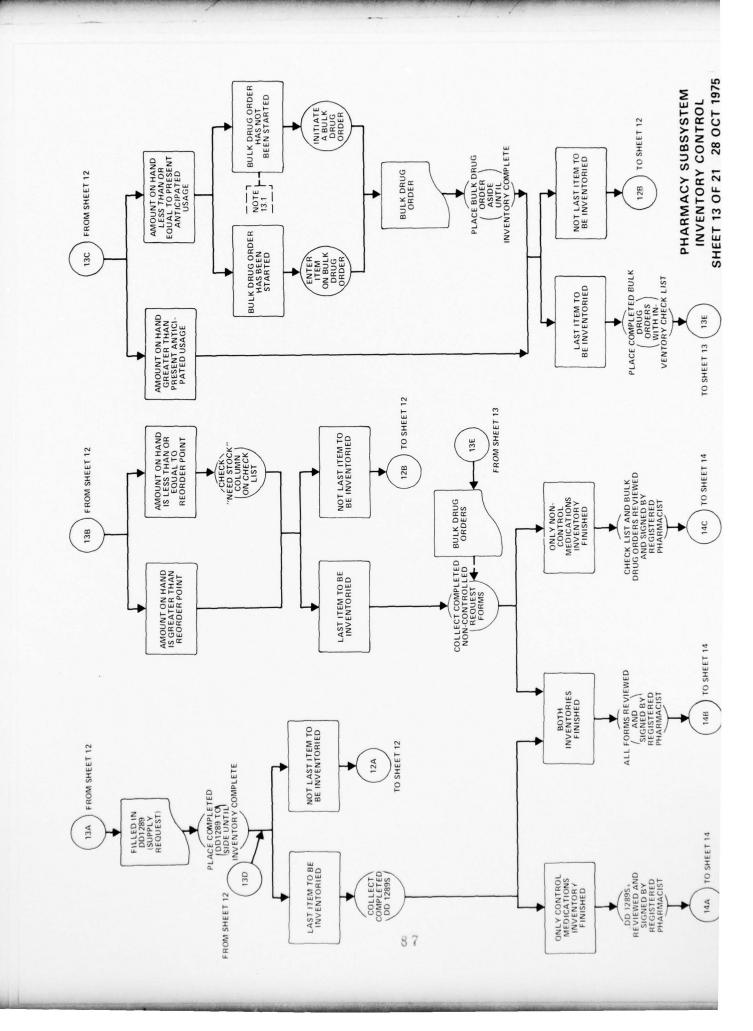
SHEET 10

10.1 The stock is rotated so that first in is first out (FIFO) with exception of dated items, which will be rotated to be dispensed prior to expiration date regardless of date of receipt if at all possible.

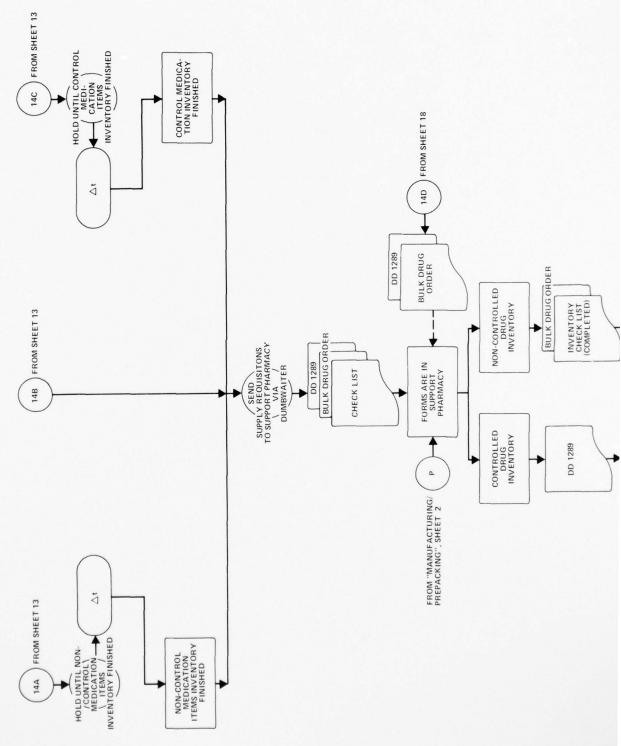


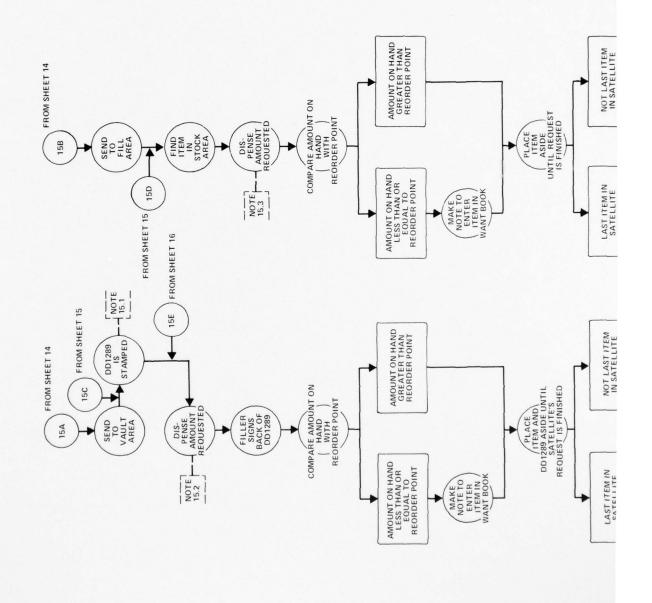


- 12.1 The control logs consist of DA Form 3862 (Controlled Substances Stock Record). The data elements are medication name, medication strength, dosage form, reorder point, maximum stock level, and columns for date of transactions, quantity received, quantity dispensed, balance on hand, and person receiving or dispensing item.
- 12.2 The Satellite Pharmacy Inventory Check List consists of only those items used in each specific satellite pharmacy (i.e., 5th floor pharmacy will not stock all medications that are specifically used on the 6th or 4th floors). The data elements on this list are medication name, medication strength, dosage form, reorder point, need stock column (amount of stock to be sent to the satellite is predetermined), and signature of the pharmacist in charge. Two copies of this form are prepared (orginial and carbon).
- 12.3 The DD Form 1289 is filled out as it would be for a normal prescription with the following changes: specific satellite instead of patient's name, pharmacist signs instead of a prescriber, Rx symbol is lined out, and no instructions (directions, signa) are indicated on the form. The use of these data elements remains unchanged: medication name & strength, dosage forms, and amount to be dispensed. Only one item can be ordered per DD Form 1289.

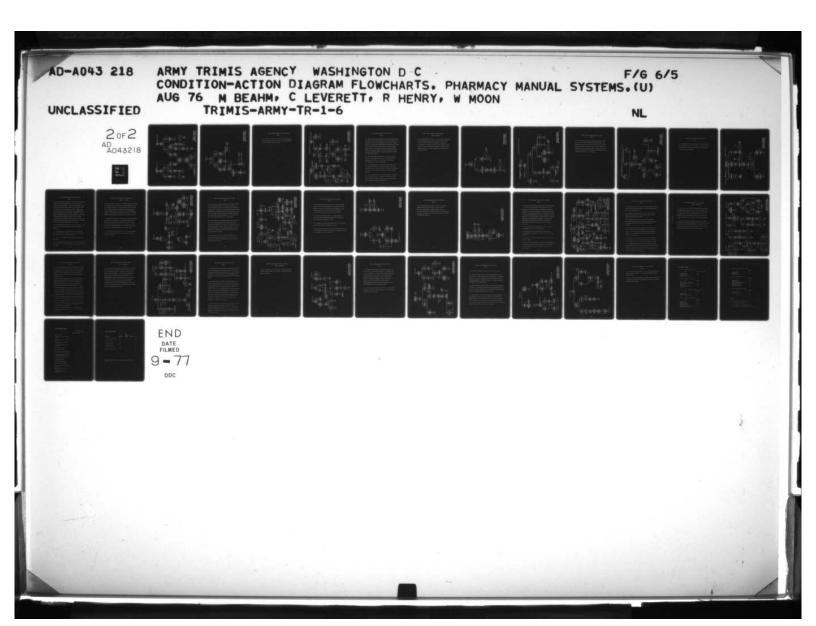


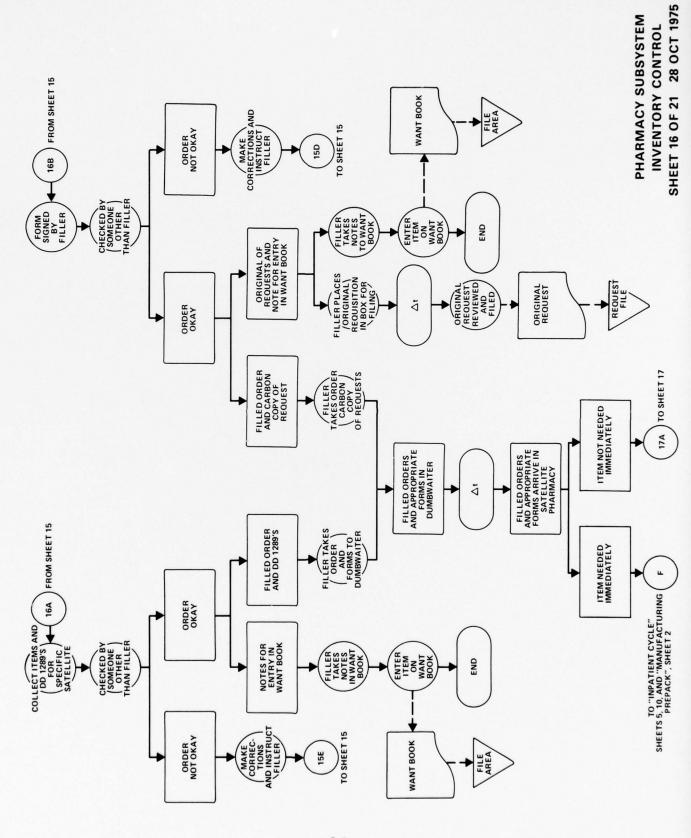
13.1 The completed Bulk Drug Order (DA Form 8-236) includes the following data elements: the specific satellite pharmacy, date of order, medication name & strength, dosage form, unit of issue, quantity requested, and signature of pharmacist.

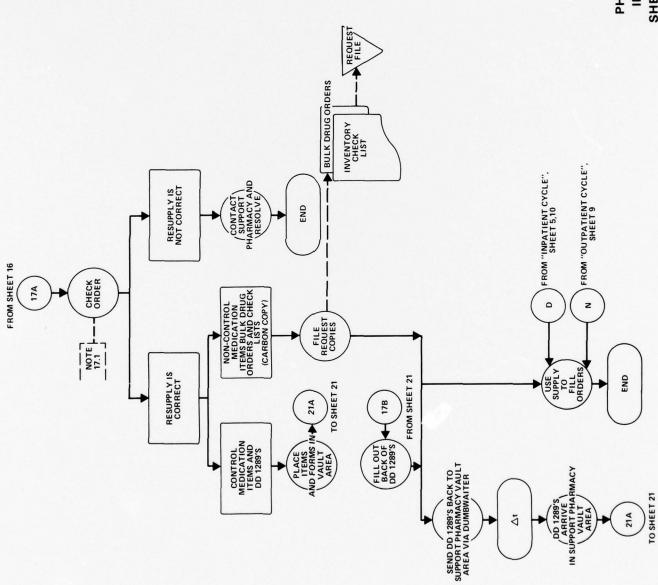




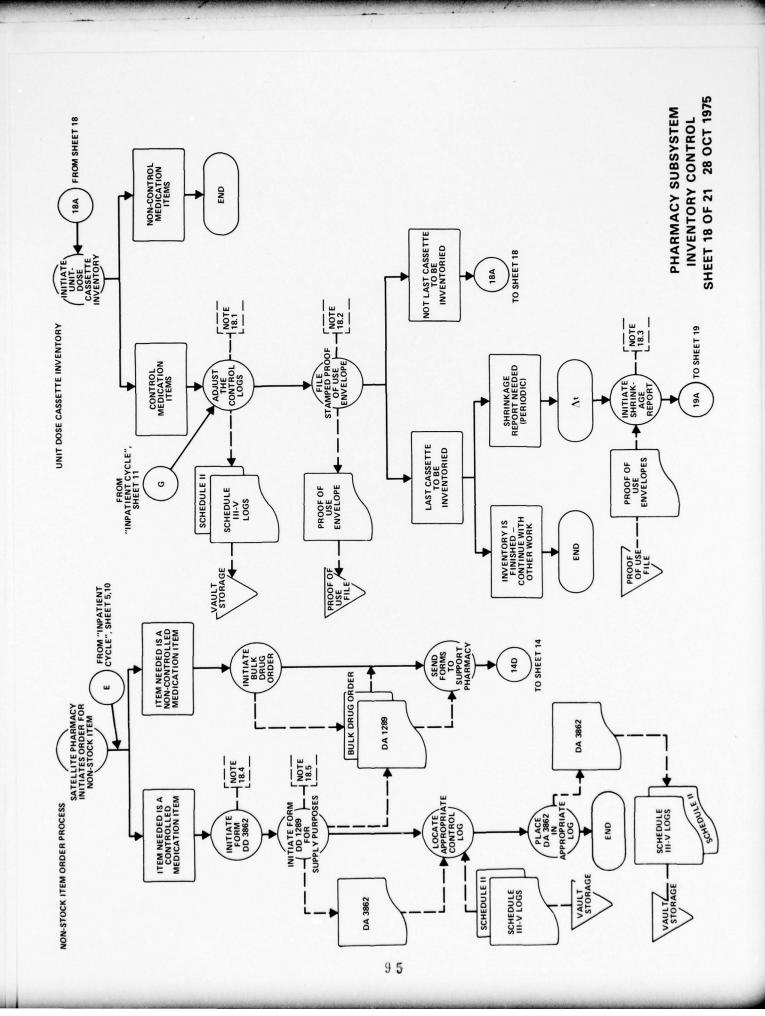
- 15.1 The DD Form 1289 is stamped on the front with a prescription number (which becomes the voucher number). It is also imprinted on the back with a proof of receipt stamp with blanks for the name of the person receiving the medication, the date & hour received, person dispensing, and the area where the medication as received. All DD 1289s for one satellite are processed at one time (one prescription at a time).
- 15.2 If the amount requested can't be dispensed for some reason, the filler will dispense as much as possible and adjust the amount requested to reflect the amount dispensed and initial this change.
- 15.3 When filling from the check list, a mark is drawn through the stock stock amount on the list after each item is dispensed. If filling from the Bulk Drug Order, a check mark is placed next to the amount requested unless amount dispensed is different from the amount requested; the amount actually dispensed is written next to the amount requested.







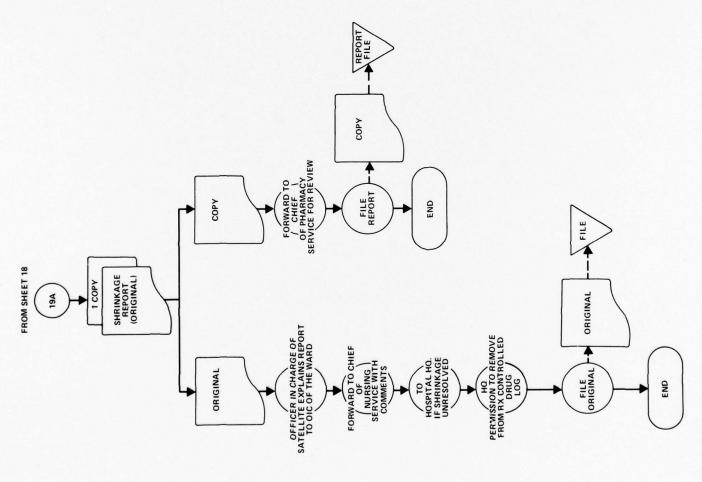
17.1 The order is checked to insure that it is for this pharmacy, the items delivered are what were ordered, no broken or damaged items are present, and items are in date.

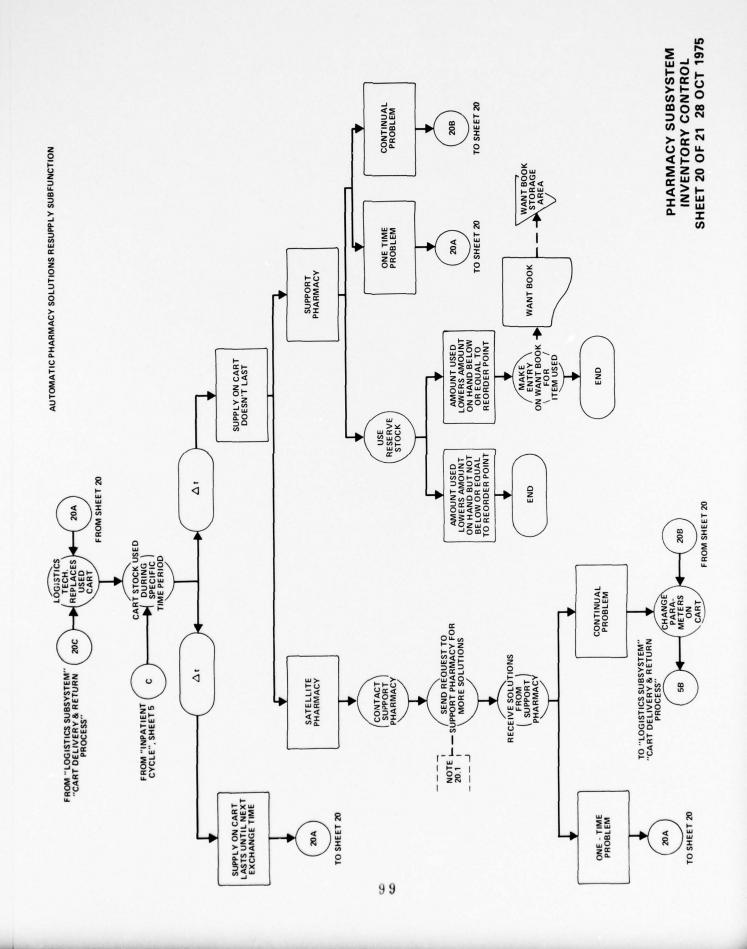


- 18.1 Check by ward to determine how many of each controlled medication item were used and decrease the balance on hand by that number (e.g., if four patients on ward 4 received/consumed 2,1,1,2 capsules of Chloral Hydrate, the Chloral Hydrate balance would be decremented by 6 for ward 4). Also, the proof of use envelopes are numbered in sequence and these numbers are used as the voucher numbers (e.g., taking the previous example, for the voucher numbers you would use the notation 1200-1203 to voucher the decreased balance). The person adjusting the balance also enters his/her initials.
- 18.2 The data elements on the proof of use envelope are patient's name, bed number, prescriber's name, nurse who administers dosage, date given, and time given. If the dosage was contaminated or destroyed, note this, sign and witness same.
- 18.3 The Shrinkage Report lists those controlled medications used but not given to patient, such as dropped doses, etc. This report will have two copies, the original (going to the Chief, Nursing Service thru the OIC of the ward) and a copy (going to the Chief, Pharmacy Service).
- 18.4 The data elements placed on the DA Form 3862 are: medication name & strength, dosage for , reorder point, maximum stock level, date of transaction, quantity received, quantity dispensed, balance on hand, and person receiving or dispensing item.

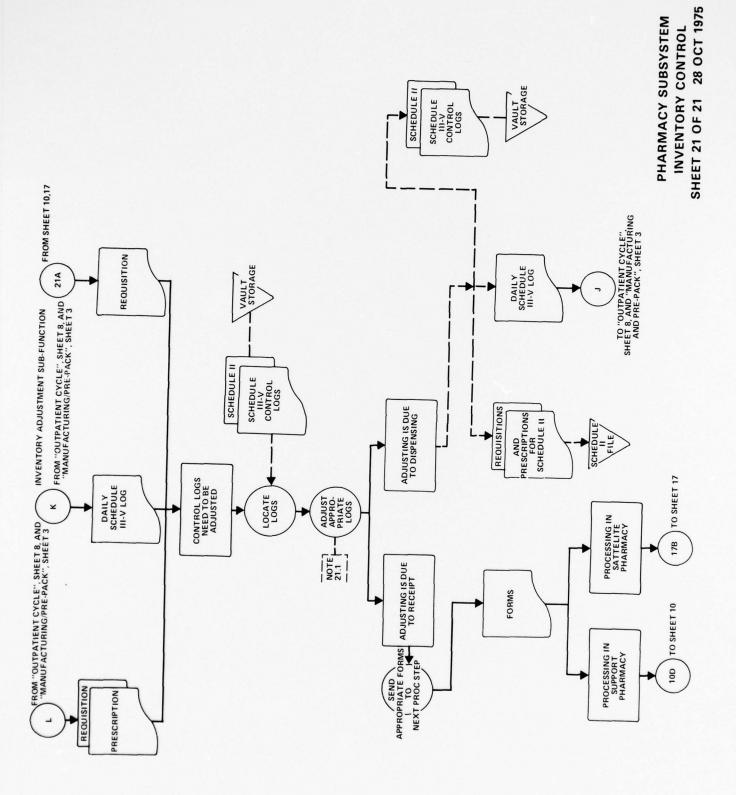
NOTES ON MANUAL INVENTORY CONTROL FLOW CHARTS SHEET 18 (CONTINUED)

18.5 The DD Form 1289 is filled out as it would be for a prescription with the following changes: specific satellite is noted instead of a patient's name, pharmacist signs instead of a prescriber, no instructions are indicated on the form, and Rx symbol is lined out. The use of these data elements remain unchanged: medication name & strength, dosage form, and amount requested. Only one item can be ordered per DD 1289.



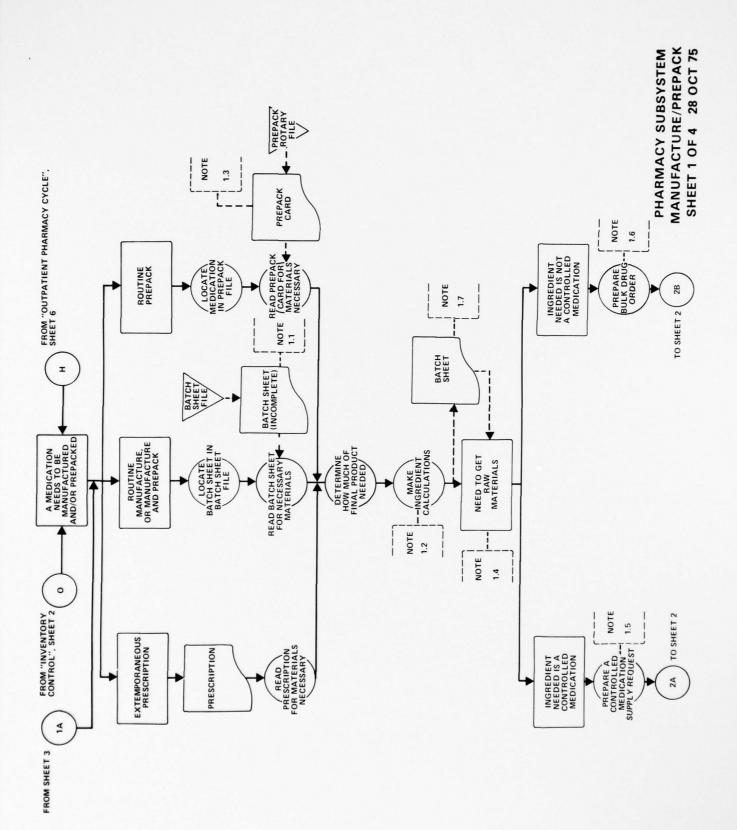


20.1 The request for additional sterile solutions from the support pharmacy will be made on a DA Form 8-236 (Bulk Drug Order). The data elements required are specific satellite pharmacy, the solution name, strength and/or amount per container, quantity required, and signature of person initiating the request. The order will be sent to the support pharmacy via the dumbwaiter and the solutions will be supplied to the satellite by the same route.



NOTES ON MANUAL INVENTORY CONTROL FLOW CHARTS SHEET 21

21.1 In adjusting the logs, the necessary information is placed in the appropriate columns on the DA Form 3862. The balance on hand is incremented or decremented by the amount placed in the credit or debit column as is appropriate.



NOTES ON MANUFACTURING/PREPACKING FLOW CHARTS

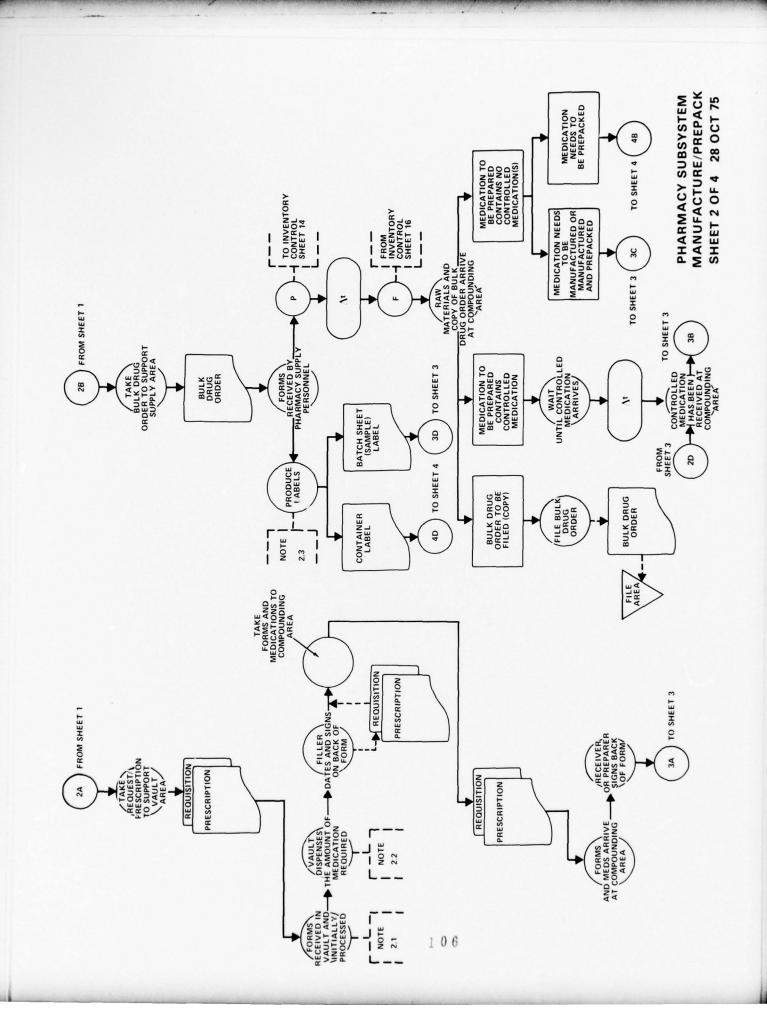
SHEET 1

- 1.1 The Master Batch Sheet contains the names of all the ingredients necessary to make the finished product. It also contains the formulas for making the product. The data elements permanent to the Batch Sheet are; product name, example amount, ingredients' names with example amounts, compounding instructions, an example label, and the amount & type of final containers. The data elements added during compounding include the following: manufacturer's name & lot number of ingredients being used, amount of ingredient used, initials of person procuring ingredients, initials of person verifying ingredients used, total amount of product prepared, and sample of the the label affixed to containers of the finished product. Batch sheets are copied by xerographic techniques, not hand copied.
- 1.2 After determining the amount of the final product wanted, a ratio is set up for use in calculating the amount of each ingredient necessary.
- 1.3 The data elements on this prepack card are: medication name and strength, amount per container, and type & size of container to be used. The file is likely to be a rotary file.
- 1.4 This will be both ingredients for compounding and containers for packaging.
- 1.5 The Controlled Medication Supply Request is a DD Form 1289 with the "Rx" crossed out. It contains similar data elements which include the following:

NOTES ON MANUFACTURING/PREPACKAGING FLOW CHARTS SHEET 1 (CONTINUED)

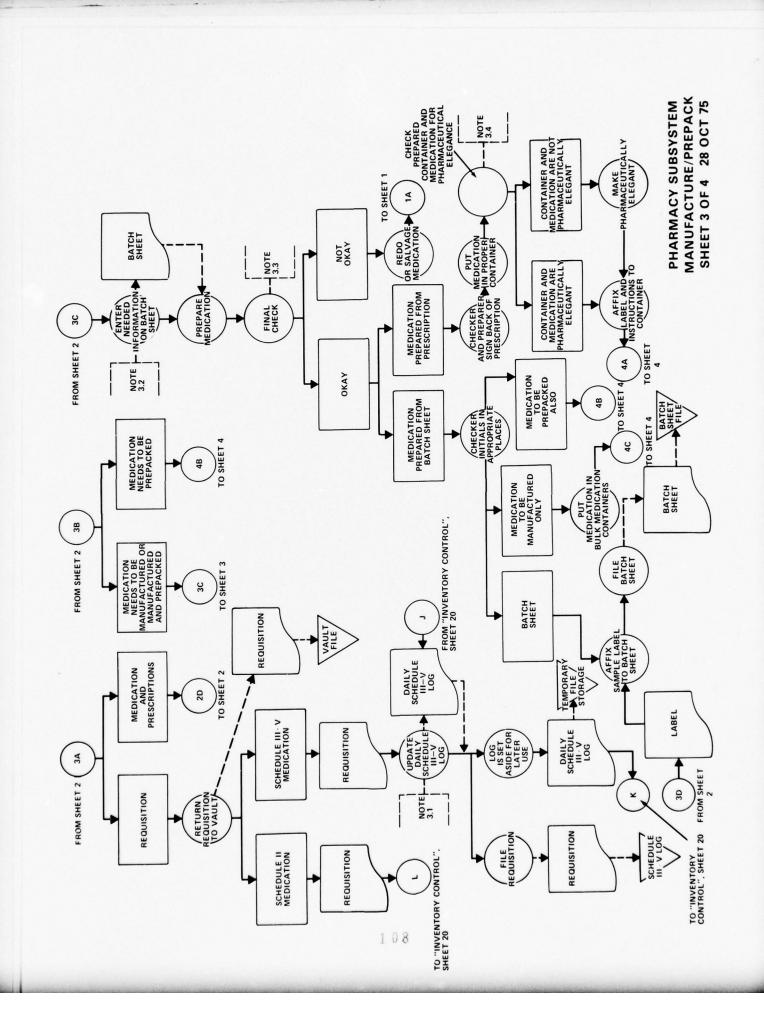
area to which medication is going (i.e., Manufacture/Prepack), medication name, strength, amount, and pharmacist ordering the medication. This is a single item requisition. Only one medication can be ordered per form. This form is used for routine manufacturing/prepacking and specific prescriptions are used as requisitions for an extemporaneous compound. If the requisition is made from a Batch Sheet, the original master Batch Sheet remains in the compounding administrative area.

- 1.6 The Bulk Drug Order (DA Form 8-236) has the following data elements: the specific area for delivery (i.e., Manufacture/Prepack), date of order, medication name, medication strength, dosage form, unit of issue, quantity requested, and signature of area supervisor. This is a 3-copy form. If the Bulk Drug Order is written from a Batch Sheet, the original Batch Sheet always stays in the compounding area.
- 1.7 The original copy of the Batch Sheet is held in the administrative area, while a Xerox copy accompanies the preparation(s) until the completion of processing.



NOTES ON MANUFACTURING/PREPACKING FLOW CHARTS SHEET 2

- 2.1 If the form is an actual prescription, the prescription number is used as the voucher number. If the form is a requisition, it will be stamped with the appropriate numbering machine (Schedule II or Schedule III V machine). At this time the Controlled Medication Supply Requests are also stamped on the back with a proof of receipt stamp. The receipt stamp has blanks for the following information:
- (1) name of person to make the preparation, (2) area of receipt,
- (3) date of receipt from vault and, (4) name of filler.
- 2.2 If medication is for an extemporaneously prepared prescription, the filler will accomplish the inventory updating at this time either in the Daily Schedule III-V Log or in the Schedule II Log. If entered in the Schedule II Log, the filler also notes that voucher was a prescription from a specific satellite pharmacy, so that an audit trail is established to support the formal controlled drug inventory which is made monthly.
- 2.3 The information on the labels includes: medication name and strength, amount per container, pharmacy lot number, expiration date, and any instructions determined necessary (for stockage and dispensing from MOD cabinet).

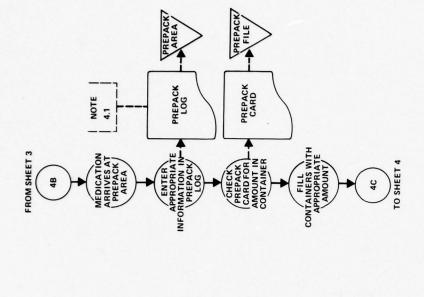


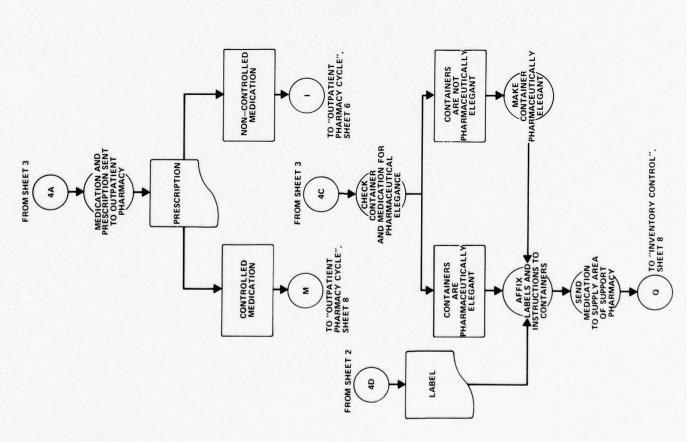
NOTES ON MANUFACTURING/PREPACKING FLOW CHARTS

SHEET 3

- 3.1 The data elements listed in the log are: prescription/voucher number, name and strength of medication, amount dispensed, and date dispensed. This log is totaled by individual medication at either the beginning or ending of each work day for posting to the controlled medication log for all Schedule III-V substances.
- 3.2 The information entered includes: initials of preparer, the actual amount of each ingredient to be used, and the manufacturer & lot number of each ingredient to be used.
- 3.3 The medication is checked against the Batch Sheet or prescription.

 The check must be made by a registered Pharmacist.
- 3.4 Make sure the container is clean and not slick or slippery and that the contained product is clear, clean, and evenly suspended or distributed as appropriate for the specific product.

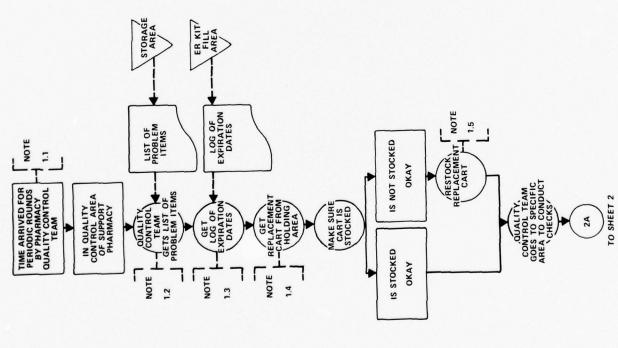




NOTES ON MANUFACTURING/PREPACKING FLOW CHARTS

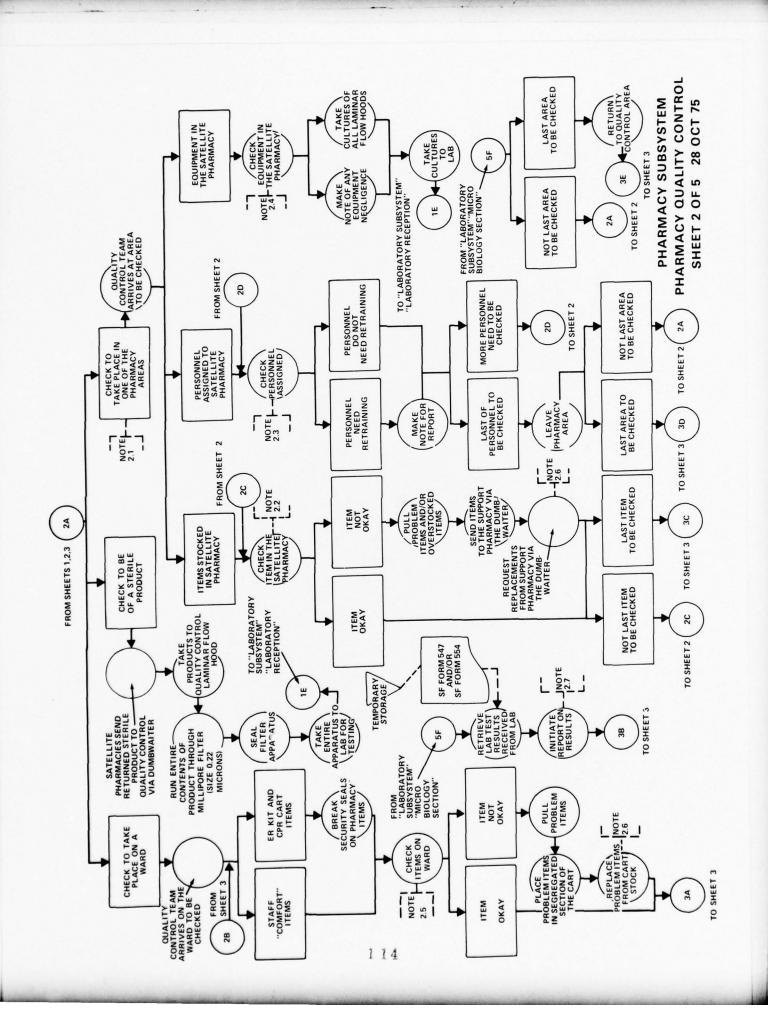
SHEET 4

4.1 The information routinely kept in the prepack log includes:
medication name & strength, amount per container, number of
containers, pharmacy prepack or manufacturing lot number, or
(if not manufactured by the pharmacy) manufacturer and manufacturer's
lot number. The prepack log will also contain a sample of the label
on the prepacked containers.



PHARMACY SUBSYSTEM PHARMACY QUALITY CONTROL SHEET 1 OF 5 28 OCT 75

- 1.1 These rounds are conducted by the pharmacy for two major reasons:
- (1) inspection for items which are past expiration date, to be suspended, or all on recall, and (2) surveillance of personnel in the pharmacy for retraining requirements as indicated by dispensing techniques. The Quality Control team is also responsible for filling of the ER kits and the CPR Carts, and for the preparation of training programs to be used in retraining to include contents (POI), type, and supervision of such retraining of personnel. The Quality Control team members will continually receive special training in the determination of problem items (items that might be defective for patient use).
- 1.2 This list contains items which are to be held in suspense, are past expiration date, or are on recalled status.
- 1.3 This log contains the expiration dates of all dated items currently located in the ER kits or CPR Carts by kit or cart numbers and location.
- 1.4 This cart is also used to replace emergency items used from the CPR Cart's supply.
- 1.5 These items are considered to be in inventory until dispensed as a replacement (a trade in the case of a suspended or expired item). A note on the Supply Visisble File will denote how much is on the replacement cart.

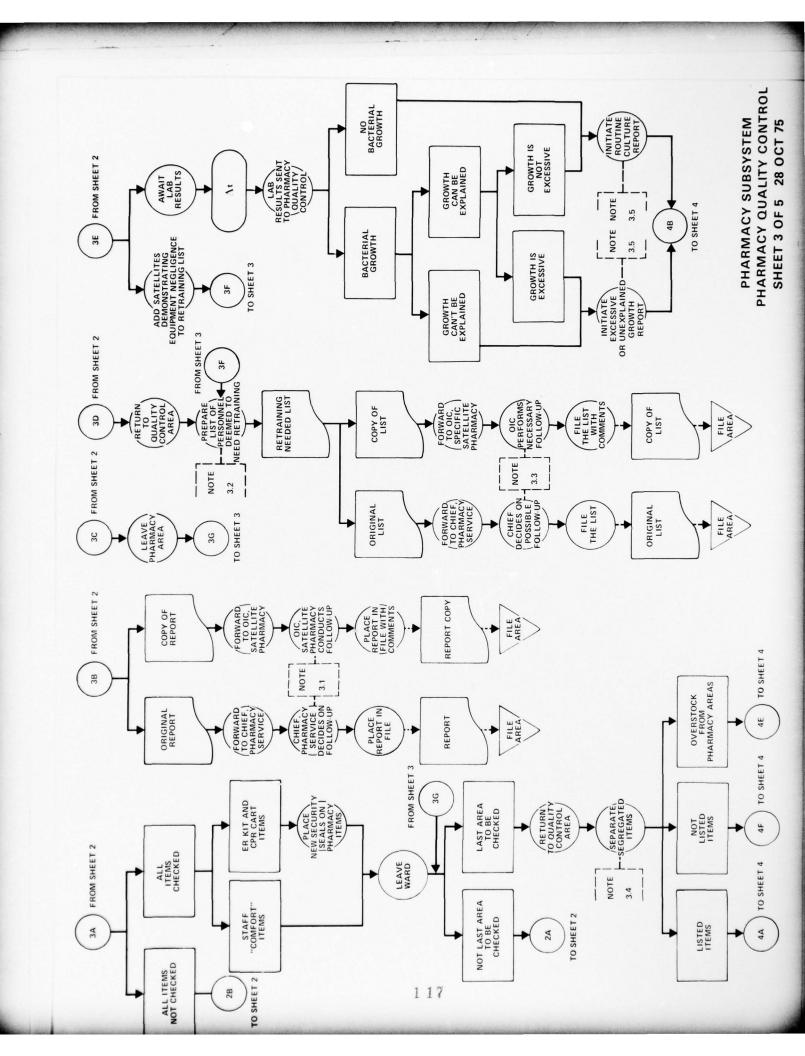


- 2.1 These areas will be the satellite pharmacies and will include the support pharmacy, Forest Glen pharmacy, the Manufacturing/Prepacking area, and the Quality Control area.
- 2.2 In addition to the normal checks, the stock levels, at each specific satellite pharmacy will routinely be checked in order to prevent over-stocking at any satellite.
- 2.3 The personnel are monitored for Aseptic technique and poor practices while performing their jobs. Military and civilian personnel, registered pharmacists and technicians are all routinely monitored.
- 2.4 All equipment is checked for cleanliness, all Laminar flow hoods are cultured for growth, and all equipment is checked for proper upkeep. Items will be checked for required preventive maintenance, and date of last performed preventive maintenance will be checked.

 Balances be will calibrated.
- 2.5 This check is to see if items are on the list of problem items or in the expiration log as due to soon go out of date. If the item is neither on the list or in the log, check for unexpected discoloration or unexpected precipitate, check for unlogged items which have an expiration date (if the item has an expiration date and has not been logged, but is still in-date, place the item in the log; if an item is out-of-date, pull the item), damaged containers, bad labeling or no labeling, and container contamination.

NOTES ON PHARMACY QUALITY CONTROL FLOW CHARTS SHEET 2 (CONTINUED)

- 2.6 This is a one for one trade that is documented in the Quality Control area later, regardless of item traded. If replacement item is dated, the expiration date, item, and location are entered into the expiration log. The location would be the ward if item is a replacement of ward stock "comfort", or CPR Cart item, and would be an ER kit number if the item is used as an ER kit replacement item.
- 2.7 This report will be by satellite pharmacy and will contain information concerning any bacterial growth. There will be two copies of the report: one to the Chief, Pharmacy Service and one to the officer in charge (OIC) of the specific satellite. The report will list the person who prepared the suspect sterile product.

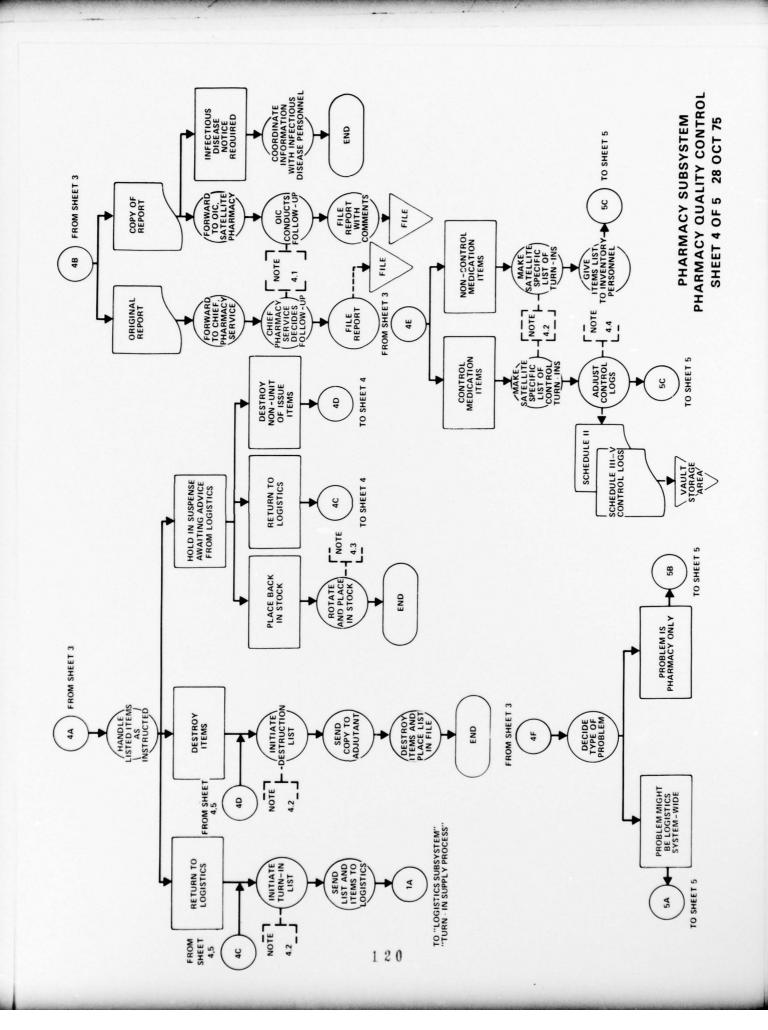


- 3.1 The Chief, Pharmacy Service, after communication with the OIC of the satellite, will decide on the type of follow-up he believes is necessary and relay that decision to the OIC of the satellite pharmacy who will conduct the follow-up. Satellite OIC's are encouraged to conduct routine continuing education programs and retraining sessions.
- 3.2 This list contains the names of all personnel who have been determined to require retraining. The names will be listed by specific satellite pharmacy. The list will be prepared with one original and as many copies as are needed (one copy per each satellite which has a person(s) requiring retraining). The OIC of each satellite pharmacy will signify compliance by signing the list and by stating that required training information and on the training (OJT) has been given to person in question. This list job will also be a part of the documentation in regards to possible future personnel actions. Also, specific satellites failing to service or use equipment properly will follow a similar procedure.
- 3.3 The Chief decides if personnel actions are required (such as change of MOS, complete retraining, etc). The officer in charge (OIC) makes sure appropriate training information is made available to personnel and takes an active part in training and continued close supervision of this individual.
- 3.4 These are the problem items pulled at the checked area and placed on the replacement cart, or the overstock from satellite pharmacy areas.

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NOTES ON PHARMACY QUALITY CONTROL FLOW CHARTS SHEET 3 (CONTINUED)

3.5 This report lists the results of the cultures, and the problems in each satellite by the individual satellite. The first half will list any unexplained growths or excessive explained growth (i.e., normal flora bacterial growth). The second half will deal with routine cultures or those cultures bearing no growth or little explained growth. There is one original report and as many copies as are needed to insure that the OIC of each satellite pharmacy concerned receives one copy. Coordination will routinely be accomplished with ward clinical personnel whenever a problem report in received. Further coordination with infectious disease personnel will also be accomplished as appropriate.

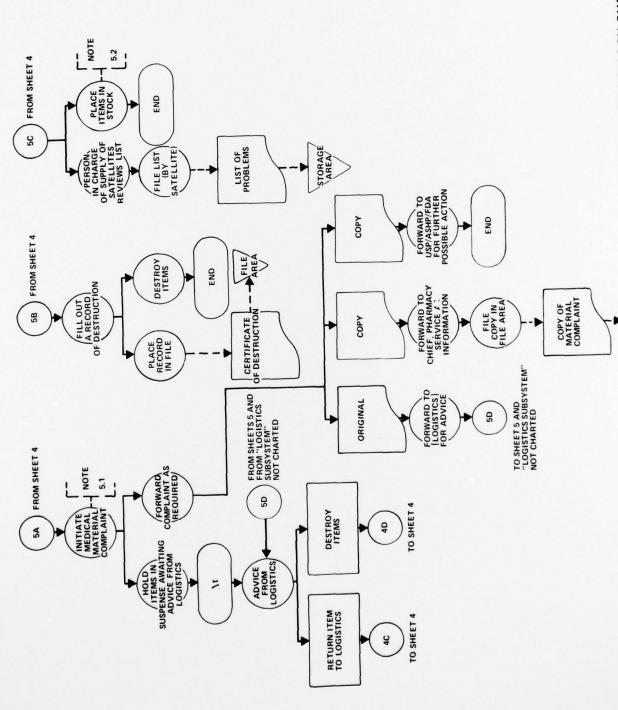


- 4.1 The Chief, Pharmacy Service decides what follow-up action is to be taken (retraining, etc.) and contacts the OIC of the satellite in question to inform the OIC of his/her decision. The OIC verifies that he/she conducted the follow-up action by documenting such on his/her copy of the report and forwarding same to the Chief, Pharmacy Service.
- 4.2 The list is made on a DA 3161 if a controlled medication is involved, turn-in is to Logistics, or items are to be destroyed. If it is non-controlled drug from a satellite and the support pharmacy, a Bulk Drug Order is used. No matter which form is used it is annotated as a turn-in. When controlled medication is involved, the document number is used as the voucher number. In the case of a turn-in, the receiving area keeps the original and the losing area gets a copy. When items are to be destroyed, the Adjutant gets a copy for headquarters approval prior to the destruction and the original of this approval goes to the pharmacy file (signals destruction) and is retained in the files
- 4.3 Stock is rotated so that first in is first out (FIFO) with the exception of dated items which must be rotated to be dispensed prior to expiration date if possible. Also, in this case, expiration dates are extended to coincide with information relayed by Logistics to the pharmacy (based on Bureau of Biologics, FDA, tests requested by USAMMA/DPSC).

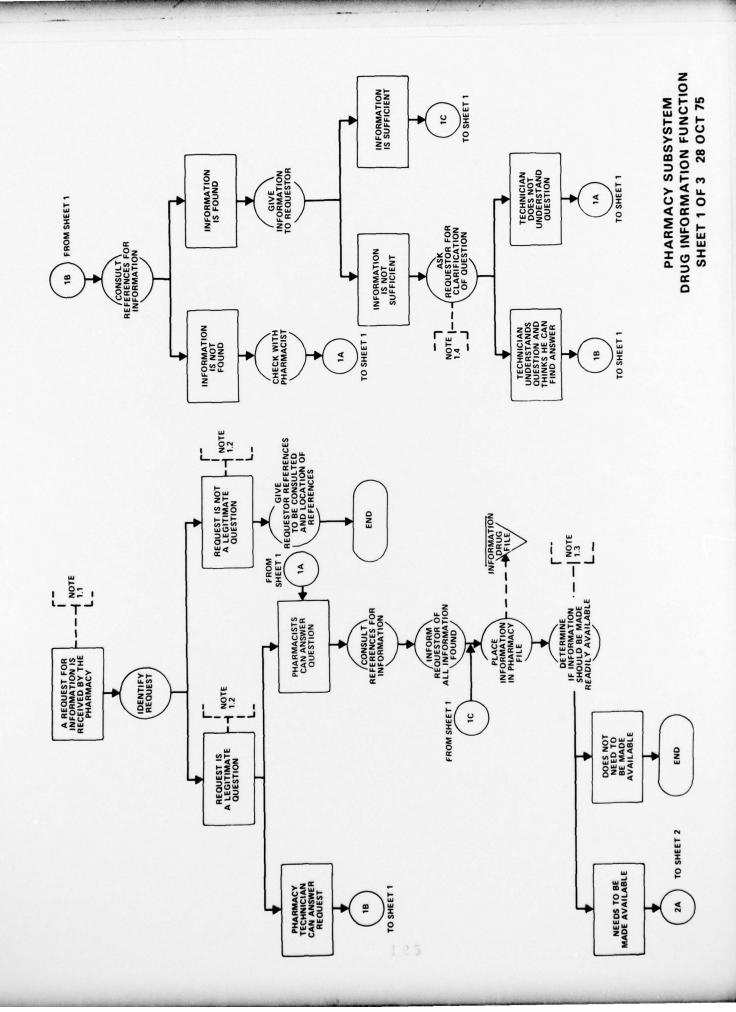
NOTES ON PHARMACY QUALITY CONTROL FLOW CHARTS SHEET 4 (CONTINUED)

4.4 The entries are made on a DA form 3862. Those entries are date received, quantity received, voucher number, and initials of person entering information.

AREA



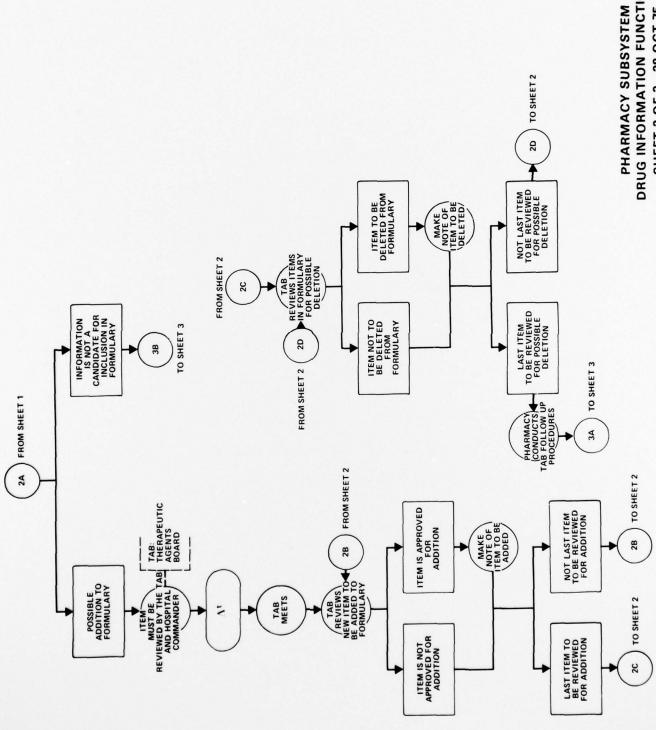
- 5.1 A Medical Material Complaint is initiated in compliance with AR 40-61 and is a notification of drug defect. The complaint can be one of two types: (1) a Type I, which is used if drug problem is life threatening or (2) a Type II, which is used if drug is unsuitable for use. The complaint is made in 3 copies; the original is forwarded to Logistics, one copy is placed in the pharmacy files, and one copy goes to the United States Pharmacopiea/American Society of Hospital Pharmacists/Foods and Drug Administration Drug Defect Reporting Program.
- 5.2 Stock is rotated so that first in is first out (FIFO) with the exception of dated items which must be rotated to be dispensed prior to expiration date if possible.



NOTES ON DRUG INFORMATION FUNCTION FLOW CHARTS

SHEET 1

- 1.1 A request for information can come from anyone in the hospital.
- 1.2 A legitimate request is one in which a specific question is asked that pertains to a specific patient or group of patients. A non-legitimate request is one in which the question is very broad in terms of time to be expended and pertains to no specific patient case but may be in support of a professional research interest area.
- 1.3 Should information regarding possible use be placed in the Formulary,
 The Bulletin of the Therapeutic Agents Board and Pharmacy Newsletter, or is
 it a one time request? Regardless of the decision, the information will be
 placed in the pharmacy files for likely future re-use.
- 1.4 If the technician cannot find the information or the information is not sufficient to meet the needs of the requestor, the technician will discuss the problem with the requestor and try to get a better understanding of the question. If after talking to the requestor the technician feels that he still cannot find sufficient information to answer the question, he will immediately refer the requestor to a pharmacist.



DRUG INFORMATION FUNCTION

NOTES ON DRUG INFORMATION FUNCTION FLOW CHARTS

SHEET 3

- 3.1 The pharmacy notifies Logistics by phone initially and follows this up with a DF for verification. This is handled by Pharmacy inventory control personnel.
- 3.2 This is to provide information to the hospital staff about the use of or regarding the new information available for drug items (all concerned professional staff members).

FILE DEPENDENCY SUMMARY

1. Process: Outpatient Cycle (OUTPAT)

| FILES | ACTIONS (See Legend*) |
|---------------------------|-----------------------|
| Patient Profile | AUR |
| Prescription File | AR |
| No Show File | A |
| Scheduled Medication Logs | U |
| | |

2. Process: Inpatient Cycle (INPAT)

| FILES | ACTIONS* |
|----------------------------------|----------|
| Ward Medication Visible File | A |
| Pharmacy Medication Visible File | AR |
| Patient Record | A |
| Census File | A |
| IV Admixture Hourly File | AR |
| Work Unit File | A |
| | |

3. Process: Non Patient Specific Supply Cycle (NPSS)

| FILES | ACTIONS* | | |
|---------------------------|----------|--|--|
| Expiration Log | A | | |
| Bulk Drug Order File | A | | |
| Scheduled Medication Logs | U | | |

4. Process: Inventory Control (INVEN)

| FILES | ACTIONS* | | |
|-----------------------------------|----------|--|--|
| Proof of use file | A | | |
| Want Book | RU | | |
| Supply Visible File | R | | |
| Original Request | A | | |
| Shrinkage Report File | A | | |
| Satellite Pharmacy Inventory List | R | | |
| Scheduled Medication File | R | | |

5. Process: Manufacture/Prepack (MANUF)

| FILES | ACTIONS* | | |
|----------------------|----------|--|--|
| Batch Sheet File | R | | |
| Prepack Card | R | | |
| Bulk Drug Order File | A | | |

6. Process: Quality Control (QC)

| FILES | ACTIONS* |
|--------------------------------|----------|
| Problem Items List | AR |
| Expiration Log | R |
| Certificate of Destruction | A |
| Unexplained Growth Report File | A |
| Laboratory Reports | A |
| Retraining Needed List | A |
| Material Complaint | A |

7. Process: Drug Information (INFO)

| FILES | ACTIONS* | | |
|-----------------------|----------|--|--|
| Formulay File | A | | |
| Information Drug File | A | | |

LENGEND

- R Process reads or examines data in file
- D Process deletes records from file
- A Process appends or inserts tecords into file
- U Process updates or modifies existing records in file

EXTERNAL INTERFACES SUMMARY

PHARMACY PROCESS

| | OUT- PAT | IN- PAT | IN- VEN | NPSS | QC | INFO |
|---|-------------|------------|------------|------|----|------|
| EXTERNAL INTERFACE | | | | | | |
| -Patient Eligibility Determination (PAD) | X | | | | | |
| -Receive Prescriptions (Wards and Clinics) | Х | Х | | | | |
| -Issue Items to Pharmaceutical Areas (W&C) | | | | Х | | |
| -Surveillance of Pharmaceutical Areas (W&C) | | | | | X | |
| -Filled Order to Patients | Х | | | | | |
| -Logistics MDS Response | | | X | | | |
| -Cart Delivery and Return (Logistics) | | | X | | | |
| -Turn in Supply Process (Logistics) | | | Х | | | |
| -Food Tolerances Update and/or Clinical Support (Food Service) | | Х | | | | |
| -Food Service Orders Process | | X | | | | |
| -Laboratory Reception | | | | | Х | |
| -Chemistry Reporting and/or Microbiology (Laboratory) | | Х | | | X | |
| -Transition Process (Radiology) | | Х | | | | |
| -Therapeutic Agents Board-Formulary Maintenance | | | | | X | |
| -Therapeutic Agents Board-Drug Information | | | | | Х | |
| -Professional Community-Drug Information | | | | | X | |

INDEX TO PHARMACY CHARTS

| PROCESS | MNEMONIC* | PHARMACY CHART NUMBER | No. of SHEETS | PAGE |
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| Inventory Control | Inven | 4 | 21 | 63 |
| Manufacture/Prepack | Manuf | 5 | 4 | 103 |
| Non-patient specific Supply Cycle | NPSS | 3 | 3 | 56 |
| Outpatient Pharmacy Cycle | Outpat | 1 | 9 | 8 |
| Pharmacy Quality Control | QC | 6 | 5 | 112 |

^{*}These are not intended for use as general identifiers but are only for use with these charts for indexing and cross-referencing purposes.