

# P & T News

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## ESSENTIAL ELEMENTS OF COMPLETE, SAFE, AND ACCURATE INPATIENT MEDICATION ORDERS

As part of our ongoing educational mission, the Pharmacy and Therapeutics Subcommittee would like to assist in orienting new faculty and house staff physicians, dentists, and other prescribers to the guidelines for complete, safe, and accurate medication order writing. This review should also serve as a reminder for all UIHC prescribers previously exposed to these guidelines: **completion of all "essential elements" of medication orders will assure that they will be safely, accurately, and promptly interpreted; the care you take will ultimately benefit your patient.** This issue of the *P&T News* will review the guidelines for writing inpatient medication orders.

In 2004 UIHC created a single hospitalwide policy that details how to completely, safely and accurately prescribe medications for inpatients and patients receiving treatment in the ambulatory care clinics. This policy [1.23, "Prescribing Medications for Hospitalized Patients (Inpatients) and Clinic Patients"] is posted on the UI Hospitals and Clinics Policies and Procedures Web Site and is accessible to UIHC staff via IPR using the "Web Links" button.

Inpatient medication orders are to be written on the structured medication order form (A-1a) shown on page 2. The following elements should be considered when writing inpatient medication orders:

### **Safety First: Handwriting Legibility and Use of Abbreviations**

Several national organizations, including the American Medical Association, the Institute of Medicine, the Institute for Safe Medication Practices, and the Joint Commission for Accreditation of Healthcare Organizations, have warned healthcare providers about the association between poor prescriber handwriting and medical errors. Medication orders written hurriedly and illegibly force other care providers to seek order clarifications or inadvertently lead the care provider to erroneously interpret the order and give medication in a manner not intended by the prescriber. To avoid errors caused by illegibly written orders, the following should be observed:

- ◆ All aspects of handwritten medication orders must be **clearly written using a ballpoint pen**. Felt tips and fountain pens do not generate sufficient pressure to transmit the order to the carbon copy from which Pharmacy interprets and dispenses.
- ◆ Care should be taken when prescribing drugs with **look-alike names**, especially when handwritten (examples include Inderal vs. Isordil, tramadol vs. trazodone, or Humulin vs. Humalog). Drug names should be legibly printed.
- ◆ **Avoid the use of drug name abbreviations and minimize the use of medical abbreviations** as these may be misread or misinterpreted (for example, "qod" may be misinterpreted as "qid," resulting in a significant drug overdose). As a safety precaution, the UIHC has developed a list of dangerous medical abbreviations that may **not** be used in the course of patient care (see Table 1); prescribers will be required to rewrite any orders using a dangerous medical abbreviation included in this list. Write instructions in complete English.
- ◆ **Prescriber signatures and CLP codes should be clearly legible**, not simply recognizable.

Additional information about safely writing medication orders may be reviewed at the Institute for Safe Medication Practices web site ([www.ismp.org](http://www.ismp.org)).



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**A-1a DOCTORS' ORDERS**

Remove TOP copy to send to Pharmacy

• File most recent sheet of this number on bottom •

1. Write firmly, this form has many copies.
2. Affix date and signature to each set of orders.
3. Write orders to change or discontinue a current order on next blank line.
4. Medication orders must include the four character (alpha-numeric) prescriber's code.
5. Medication orders for this patient expire as stated in the "Prescribing Medications for Hospitalized Patients" section of the current UIHC Formulary and Handbook.

DATE **7-10-06** PATIENT CARE UNIT **4JCW**

HOSP # **88-12345-0**

NAME **Dane Jones** **(A)**

BIRTH DATE **7-4-1973**

ADDRESS **Anytown, IA 51234**

IF NOT IMPRINTED, PLEASE PRINT DATE, HOSP. #, NAME AND LOCATION.

**DRUG AND IV ORDERS ONLY**

**DRUG ALLERGIES, TO BE COMPLETED BY PRACTITIONER ONLY**

- No Known Allergies  
 Specify **Penicillin** **(B)** **(E)** **(F)** **(G)**

DATE / TIME	DRUG OR I.V. SOLUTION	DOSE	ROUTE	INTERVAL/REMARKS
7-10-06 0630	<b>Furosemide</b> <b>(D)</b>	40mg	PO	daily
<b>(C)</b>	<b>Atenolol</b>	50mg	PO	daily
	<b>Enoxaparin</b>	40mg	subq	q 12 hours
	<b>D5 1/2 NS with 20mEq KCl/l</b>		IV	to run at 125ml/hr
	<b>Morphine</b>	4mg	IV	q 4 hrs PRN pain
	<b>Ace taminophen</b>	650mg	PO	q 4 hrs PRN pain
	<b>Metoclopramide</b>	10mg	IV	q 4 hrs PRN nausea
				<i>Open Smith V123</i>
7-12-06 0930	<b>Discontinue enoxaparin</b>			
	<b>Begin</b>			
	<b>Warfarin</b>	5mg	PO	daily
				<i>Open Smith V123</i> <b>(H)</b>

**SAMPLE**

**DIAGNOSTIC, THERAPEUTIC AND DIETARY ORDERS:**

Attending Physician Name: \_\_\_\_\_

ADMIT to (unit) \_\_\_\_\_

Date \_\_\_\_\_

Physician determined Level of Care, as reflected in documentation, (check one):

- ACUTE** (requires specialized care and daily MD intervention)  
 **\*RECOVERY** (less than 24 hours care after invasive procedure)  
 **\*OBSERVATION** (to monitor medical status for resolution within 24 hours, then discharge, or change to acute level of care)

**\*ANY CHANGE IN LEVEL OF CARE REQUIRES A NEW PHYSICIAN ORDER WITH TIME AND DATE.**  
 Questions, call Admisslon Bed Placement Cntr. 4-5000

**A**  
**1a**  
**B**  
**CLIN NOTES**  
**C**  
**LABORATORY**  
**D**  
**X-RAY EXAM**  
**E**  
**CONSULTATION**  
**F**  
**T**  
**SPEC. EXAM**  
**G**  
**THERAPY**  
**H**  
**PATHOLOGY**  
**I**  
**PT. QUES.**

## COMPLETION OF DESIGNATED SECTIONS OF THE A-1a DOCTORS' ORDER FORM

All medication orders must include: patient name, hospital ID number, birth date, patient care area, date order is written, patient allergies, medication name, dose, route of administration, dosing interval and any clarifying remarks, and the prescriber's signature.

(The capital letters at the beginning of each section refer to a specific section of the A-1a Doctors' Order example on page 2)

**A Patient name, hospital number, birthdate, patient care unit, and date.** This demographic information should be transmitted to the medication order by using the patient's addressograph plate.

**B Allergies.** Patient's medication allergies should be specified in this space. If there are no known allergies, please check the box next to "NKA-No Known Allergies."

**C Date.** As each series of medication orders is written, the date should precede the order. Prescribers are encouraged to include the time when writing medication orders.

**D Medication Column.** Medications should be ordered by the generic name, not by the proprietary or trade name. Hospital policy and the Joint Commission on Accreditation of Healthcare Organizations standards **permit the use of drug name abbreviations in medication orders only if the abbreviation has been specifically approved by the hospital and it appears on a published list.** "Coined" abbreviations such as HCTZ, AZT, PCN, TMP-SMX, and ddl are **not** acceptable abbreviations, may be misinterpreted, and may cause drug errors. Medication orders that contain nonapproved drug name abbreviations are not valid. Pharmacists are authorized to withhold dispensing and nurses are authorized to withhold administration of medications ordered via nonapproved abbreviations. The list of drug name abbreviations approved for use at UIHC is provided in the on-line *Formulary and Handbook* --- <http://www.healthcare.uiowa.edu/pharmacy/Formulary/Form/16ApprovedDrug.html>

If it is necessary to **modify or discontinue a medication order**, it is important that this be done on the next open line on the A-1a Doctors' Order Form. **Do not** alter an existing order which Pharmacy and Nursing have accepted onto their profiles. For example, if the existing order is for digoxin 0.25 mg PO daily, and you wish to change it to digoxin 0.125 mg PO daily, on the next open line write: "Discontinue digoxin 0.25 mg. Begin digoxin 0.125 mg PO daily."

**E Dose Column.** Dosages should be prescribed in the metric system. The number of units of medications (e.g., 2 capsules) is only acceptable for combination products that are commercially available in only one strength. If a single ingredient medication is available in only one strength, it is still important to write that strength on the order. The terms "one tablet," or "one ampul," or only the volume amount for oral liquids, should *not* be used because the strength or concentration of the dosage unit periodically changes. A zero should *always* be placed before a decimal expression less than one to prevent misinterpretation of drug orders. For example, .5 mg may be mistaken for 5 mg, especially on carbon copies or when the decimal point is written on the line of the order form. The correct way to express this value is 0.5 mg. The leading zero alerts the pharmacist and the nurse if the decimal point is not visible. *Never* place a decimal point and zero after a whole number as the decimal point may not been seen. Write 5 mg, *not* 5.0 mg, as this may be mistakenly interpreted as 50 mg.

**F Route Column.** The route of administration is indicated in this column, e.g., PO or IM.

**G Interval and Remarks Column.** Indicate the schedule on which the medication is to be administered. This section should also be used when prescribing a specific number of doses or days of therapy. The "PRN" designation should include the medication's purpose (e.g., PRN sleep, PRN pain). The drug administration times at the UIHC are published in the on-line *Formulary and Handbook* --- <http://www.healthcare.uiowa.edu/pharmacy/Formulary/Form/DrugAdminTimes.html>

**H Signature.** Inpatient medication orders must be signed by authorized prescribers. **Medication orders are to include the four-character (alpha-numeric) prescriber's code.** Orders written by medical students must be reviewed and co-signed by a licensed physician or dentist. Designated physician assistants and advanced registered nurse practitioners delineated in specific protocols approved by the UIHC and their employing departments may sign orders for medications and treatments. The designation "PA" or "ARNP" must follow the signature of the prescribing physician assistant or advanced registered nurse practitioner, respectively, on all inpatient medication orders. Physician assistants may not write orders for Schedule II controlled substances which are listed in Iowa law as stimulants or depressants.

## Generic Substitutions

In accordance with Hospital Bylaws, the pharmacist is authorized to dispense and the nurse is authorized to administer generic brands of drugs approved for stock by the Pharmacy and Therapeutics Subcommittee whether or not it is the same brand specified in the medication order. If the generic medication stocked is not acceptable, the prescriber must note on the A-1a medication order that only the brand specified is acceptable. To obtain the desired brand of medication, the prescriber must also complete an Inpatient Special Order Request for a Non-Stock Drug (described below).

## Automatic Expiration of Medication Orders

- ◆ Medication order durations default to those predefined by the Pharmacy and Therapeutics Subcommittee at the time the order is entered in the pharmacy computer system<sup>1</sup> unless otherwise specified by the physician.
- ◆ All medication orders expire and must be rewritten when a patient is transferred to a different clinical service or when the patient returns from the operating or delivery room.
- ◆ Medication order duration defaults are separated into "hard stops" and "soft stops."

**Hard stops** are used for clinical situations where there is a significant potential for adverse effects to occur or other clinically undesirable effects if therapy is continued. A hard stop is a notification to the Licensed Independent Practitioner (LIP) that therapy is discontinuing based on policy and a new order is required to continue therapy. Examples of medications with hard stops are:

Drug	Predefined Order Duration	Rationale
Clozapine	7 days	FDA requirement for close monitoring.
Coagulation Factor VIIa (NovoSeven)	24 hours	Protocol requires close control.
Ketorolac injection	5 days	Potential for adverse effects with extended therapy.
Fenoldopam	48 hours	FDA use guidelines indicate up to 48 hours.
Dexmedetomidine	24 hours	FDA use guidelines indicate up to 24 hours.
Rasburicase injection	24 hours	High expense therapy; clinical data/experience indicate that one dose is usually sufficient.
Meperidine injection	48 hours	Potential for adverse effects with extended therapy.

LIPs are notified of the impending expiration of orders via an Expiring Orders Summary (EOS). The EOS is placed on the patient's chart at least 24 hours prior to the assigned expiration date/time. It is important that medication orders be rewritten in a timely manner before the end of their assigned expiration date.

**Soft stops** are used for clinical situations where abruptly discontinuing therapy can adversely affect patient care. A soft stop is a notification to the LIP that therapy has reached a point where discontinuation of therapy should be considered. For soft stop medications with order durations of less than three days, there are direct communications from the pharmacist to the LIP to ensure that medications are not continued longer than clinically necessary.

**For soft stop medications with order durations of 3 days or longer, communications are sent to the LIP via IPR.** The LIP is presented with a prompt when the IPR Progress Notes are accessed. If the LIP is responsible for the therapy, the LIP will have the option to discontinue, continue, or modify the therapy, or defer the decision until specific clinical information is available. The LIP must write an order to discontinue the therapy. Examples of medications with soft stops are:

Drug	Predefined Order Duration	Rationale
Systemic antibiotics	7 days	Limit development of resistance; limit development of fungal overgrowth; limit development of <i>C. difficile</i> diarrhea; usual duration of therapy for many clinical situations; high-expense therapy; avoid inadvertent discontinuation of therapy.
Anti-retrovirals	30 days	Therapy is long-term; soft stop avoids "surprise" therapy discontinuations.
Anti-tuberculosis medications	30 days	Therapy is long-term; soft stop avoids "surprise" therapy discontinuations.
Nesiritide injection	48 hours	High-expense therapy requires close control.
Lansoprazole injection	72 hours	Oral therapy should be considered after 72 hours.
All other medications	30 days	Soft stop avoids "surprise" therapy discontinuations.

## Blanket Orders

The use of blanket orders is prohibited at UIHC. Blanket orders are general prescriber directions that do not provide specific information about the medication therapy prescribed (e.g., "continue previous medications," "resume preoperative medications," or "discharge on current medications"); with these types of orders, the medication name, dose, route, frequency, and/or indication for use is not stated. All medication orders must be written clearly including complete medication name, dose, route of administration and frequency of use.

<sup>1</sup>The pharmacy computer system is an on-line patient medication system. The system screens medication orders for dosages, drug interactions, allergies, and therapeutic duplications.

## Range Orders

Range orders are those medication orders which provide a range of options for administering a specific medication to a patient (e.g., "acetaminophen 325-650 mg every 4 hours PRN pain").

- ◆ Prescribers are encouraged to write specific orders that define the dose to be given and the maximum frequency of administration.
- ◆ Prescribers are encouraged to **not** write orders with a range of administration intervals, e.g., "acetaminophen 325 mg every 4 - 6 hours PRN pain." This type of order will be interpreted as being administered no more frequently than every four hours. Prescribers are encouraged to write orders that specify the minimum interval for medication administration ("acetaminophen 325 mg every 4 hours PRN pain").
- ◆ When range orders are written and there are no specific policies and procedures to govern dosing parameters, the nurse will use his/her clinical judgment to select the proper dosage and frequency of administration within the established range. This dosage/frequency selection will be made after careful assessment of the patient's clinical condition, taking into consideration the patient's response/lack of response to previous doses and the expected onset of action of the medication. Nurses should contact the prescriber if questions related to administration of the specific dose exist.
- ◆ Range orders lacking a medication therapy indication may represent a situation for potential medication misadventures. Nurses must use their clinical judgment in determining whether orders provide enough clarity to proceed with therapy. If questions exist related to specific medication therapies, the nurse must contact the prescriber prior to proceeding with medication administration.

## Verbal Orders

**Verbal orders for inpatient medications are discouraged**, and should be used infrequently as there is greater potential for medication errors when they are used. Verbal orders may only be used in cases of emergency or when the prescriber is unable to be present to write the necessary order and delaying administration of the medication or performing the treatment would be adverse to the patient's welfare. When a verbal order is received, it must be placed in print; after it is placed in print, the staff member must read back the order verbatim to the prescriber for verification of accuracy. Medication order recipients should read back the written order and request or provide correct spelling. The staff member will document the read back and verification process by recording "RBAV" and signing his/her name. All verbal orders must be signed by the prescriber delivering the order. The policy "Verbal Orders" is accessible to UIHC staff via IPR using the "Web Links" button (V.40; "Verbal Orders").

## Dose Standardization

For selected **parenteral antibiotics** utilized in adult patients and pediatric patients weighing 20 Kg or more, standardized doses have been established. When an antibiotic order is received for a nonstandard dose size, the dose will be rounded to the nearest standard size. The prescriber and the nurse will subsequently be notified. In situations in which the prescriber determines that the patient's dosage requirements cannot be met by a standard dose size, a "PATIENT ORDER FOR NONSTANDARD ANTIBIOTIC DOSES" (Form 602a) must be completed by the prescriber in addition to the usual A-1a Doctors' Orders Form. Upon receipt of this order, the "nonstandard" doses will be prepared and dispensed. Consult the on-line *Formulary and Handbook* --- <http://www.healthcare.uiowa.edu/pharmacy/Formulary/Form/04Parenteral.html> and <http://www.healthcare.uiowa.edu/pharmacy/Formulary/Form/05PedParenteral.html> for lists of the standard antibiotic doses.

## Parenteral Nutrition Orders

Medication orders for adult and pediatric parenteral nutrition solutions are written on separate medication order forms (A-1a—AVN for Adults; A-1a—PVN for Pediatrics; A-1a—NVN for Neonates). These orders must be written daily.

**Parenteral nutrition orders for adult patients (A-1a—AVN for Adults) must be written by 1500 hours** so that orders may be received by the Pharmacy no later than 1500 hours daily. Solutions are hung at 2100 hours.

If there are extremely unusual situations, an order for parenteral nutrition can be compounded up to 2100 hours. Pharmacy requires a minimum of two hours to compound a parenteral nutrition solution. Orders for parenteral nutrition cannot be processed after 2100 hours. In these situations, 10% dextrose with electrolytes should be used until a 12-hour bag of nutrition solution can be prepared for a 0900 hours dose the following morning.

**Parenteral nutrition solution orders for pediatric and neonatal patients (A-1a—PVN for Pediatrics, A-1a—NVN for Neonates) must be written daily by 1100 hours** so that orders may be received by the Pharmacy by 1300 hours. Solutions are hung at 1800 hours. Orders received after 1300 hours may not be available until after 2100 hours.

## Special Order Drugs

If a drug needed for a specific patient is not stocked by Pharmacy, and no alternative stocked drug is suitable, the drug will be acquired on a one-time basis as a Special Order Drug. In order to initiate the acquisition of a Special Order Drug, the prescriber must write a chart order in the usual fashion, indicating that the drug should be special ordered. Additionally, an Inpatient Special Order Drug Request (Form 602) stating the reason that the Special Order Drug is needed in lieu of other drugs stocked must be completed, signed by the patient's attending physician, and sent to Pharmacy. Most Special Order Drugs can be procured within 48 hours. If unusual circumstances make it imperative that a Special Order Drug be obtained in less than 48 hours, the prescriber must contact Pharmacy directly so that emergency measures can be arranged.

## Restricted Stock and Protocol Drugs

There are several drugs that have been approved for stock by the Pharmacy and Therapeutics Subcommittee with specific restrictions on their use. **Restricted Stock Drugs** are identified in the drug monograph section of the Formulary; the conditions of the restriction are also included in the monograph. Drugs approved for stock by the Pharmacy and Therapeutics Subcommittee for use according to specific criteria are termed **Protocol Drugs**; they are identified in the drug monograph section of the Formulary. See page 8 for additional information on protocol drugs.

## Personal Medication Supplies

If patients admitted to UIHC bring **personal medication supplies** (including herbal or alternative medicines) with them, these drugs are not administered to the patient while at the hospital, but rather are collected by Nursing personnel and, preferably, returned to the patient's family, or stored in a secure manner and returned to the patient at the time of discharge. Special circumstances (as defined by the responsible physician or dentist) may indicate that the patient's medications should be administered at UIHC; for example, birth control pills or medication that is not available at UIHC. Under these circumstances, it is the responsibility of the pharmacist to examine the medications for proper identification, labeling, and condition prior to permitting the drugs to be administered to the patient. When it is decided that personal medications brought from home by the patient are to be administered by hospital personnel, the physician or dentist is required to specify this intent in the patient's chart at the time the medication is prescribed. Prescribers should keep in mind that there is a potential risk of medication errors with the use of non-formulary medications as hospital staff may be unfamiliar with dosing and administration.

## Medication Order Review

A pharmacist will review all medication orders, and in those instances in which a consultation about a drug order is required, the pharmacist will discuss the issue directly with the prescriber.

For further information on prescribing inpatient medications, please refer to the on-line *Formulary and Handbook* -- <http://www.healthcare.uiowa.edu/pharmacy/Formulary/Form/15Prescribing.html> -- or call Dave Weetman, Assistant Director for Acute Pharmaceutical Care.

**Table 1. Dangerous Medical Abbreviations**

DANGEROUS MEDICAL ABBREVIATIONS		
Abbreviation	Common Error	Appropriate Action
IU	Mistaken as "IV" (intravenous) or 10 (ten).	Write international unit(s)
MgSO <sub>4</sub>	Misinterpreted as morphine sulfate, resulting in the wrong medication being administered.	Write magnesium sulfate
MS / MSO <sub>4</sub> / MSO <sub>4</sub>	Misinterpreted as magnesium sulfate, resulting in the wrong medication being administered.	Write morphine
Q.D. / QD / q.d. / qd	Mistaken for Q.O.D./qod, resulting in an inappropriate dosing schedule.	Write daily
Q.O.D./QOD/q.o.d./qod	Mistaken for Q.D./qd, resulting in an inappropriate dosing schedule.	Write every other day
T I W	Misinterpreted as "three times a day" or "twice a week."	Specify days of the week
U / u	Mistaken as a zero or 4 (four), resulting in an overdose. Also mistaken for "cc" (cubic centimeters).	Write unit(s)
µg	Mistaken for "mg" (milligrams) when written, resulting in an overdose.	Write microgram(s) or mcg

In accordance with hospital policy, chemotherapy drug name abbreviations are never permitted to be used. The abbreviations in the following table are particularly prone to misinterpretation if used in printed communications and must always be avoided:

DANGEROUS CHEMOTHERAPY ABBREVIATIONS	
Abbreviation	Complete Drug Name To Be Written/Printed Out
2-CDA	Cladribine
5-FU	Fluorouracil
6-MP	Mercaptopurine
CPT-11	Irinotecan
IL-2	Aldesleukin
VP-16	Etoposide
CDDP	Cisplatin
MTX	Methotrexate

## DECIMAL NUMBERS AND ZEROS

Medication doses may be misinterpreted when decimal numbers are not written out properly. The following actions should be taken to ensure that doses are written clearly and completely:

- Never use a "trailing zero" (e.g., 10.0 mg) after a decimal point, because the decimal point may not be seen by others, leading to a significant drug overdose (e.g., 10. 0 mg is seen as 100 mg).
- Always use a "leading zero" (e.g., 0.1 mg) before a decimal point, because the decimal point may not be seen by others, also leading to a significant drug overdose (e.g., .1 mg is seen as 1 mg).

## Administration of Medications Not Procured by the Department of Pharmaceutical Care

The Department of Pharmaceutical Care has been asked whether medications brought into the hospital by patients or care providers for administration by University of Iowa Hospitals and Clinics staff within the facility (such as within an ambulatory care clinic) is permitted. In general, the administration of such medications at UIHC is not permitted.

Patient safety may be severely compromised when medications not obtained by the Department of Pharmaceutical Care are administered within the hospital (exceptions for the use of patients' own medications may be reviewed in section U. of UIHC policy I.23, Prescribing Medications for Hospitalized Patients (Inpatients) and Clinic Patients (see <http://policies.uihc.uiowa.edu/Governing%20Body%20Directives/Section/I.23.pdf>). Drugs and chemicals not obtained directly by the hospital through known, secure pharmaceutical vendors are at potential risk of being stored outside acceptable environmental conditions (e.g., not maintained under refrigeration, if required for stability); being exchanged for counterfeit products (e.g., drugs in which there is a significant "street value"); or coming from a source where quality and purity are not assured (e.g., drugs purchased via the Internet from a foreign country). The use of such products may directly injure patients or lead to under treatment.

The Department of Pharmaceutical Care, under the auspices of the Pharmacy and Therapeutics Subcommittee, is ultimately responsible for the specifications of quality, quantity, and source of supply of all drugs, chemicals, biologicals, and pharmaceutical preparations used in the diagnosis and treatment of patients at University of Iowa Hospitals and Clinics. Specific policies for the procurement of only safe, effective, and high-quality drugs, chemicals, biologicals, and pharmaceutical products have been approved and may be reviewed at: <http://www.healthcare.uiowa.edu/pharmacy/formulary/Form/03Pharm.html>.

Some key points from these policies:

- The Department of Pharmaceutical Care is responsible for the procurement, distribution, and control of all drugs and pharmaceutical products used within the UIHC.
- Drugs used within the UIHC must be approved by the U.S. Food and Drug Administration (FDA) [i.e., FDA-approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) or have an Investigational New Drug (IND) application for use in an approved investigational drug study].
- All drugs, chemicals, biologicals, and pharmaceutical products shall meet the standards of quality of the United States Pharmacopeia-National Formulary, Accepted Dental Therapeutics, or other national standards.
- Compounded pharmaceutical products or bulk drugs prepared by an outside community or compounding pharmacy will not be used within the UIHC (including patient's personal medications brought into the UIHC).

These policies apply to inpatients and ambulatory patients receiving treatment within an ambulatory care clinic at the UIHC. The policies were implemented to ensure patient safety and limit the hospital's liability for adverse events or lack of efficacy associated with the administration of medications not obtained by pharmacy personnel. This stance is supported by the following:

**State regulations.** The Iowa Board of Pharmacy Examiners has decreed that policies and procedures governing the use and control of drugs brought into the institution must be implemented. Procedures must address identification of the drug and methods for ensuring the integrity of the product prior to permitting its use by patients.

**JCAHO requirements.** The Joint Commission on Accreditation of Healthcare Organizations standards state that a health system's pharmacy is responsible for ensuring the appropriate control of all medications used within the organization, including the selection, procurement and storage of those medications. Health systems must have a policy for how medications are procured. Acquisition of medications in a manner different from a health system's stated policy would not comply with JCAHO standards and could result in a citation.

**FDA regulations.** The FDA has long had concerns about large-scale pharmaceutical compounding conducted by "community" pharmacies, particularly when the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Federal Food, Drug and Cosmetic Act. Thus, no medication product compounded by a pharmacy outside the UIHC may be administered within the hospital.

Exceptions to the UIHC policies may be granted. Unique circumstances that warrant action outside these policies may be presented for review by the Chair of the Pharmacy and Therapeutics Subcommittee, UIHC legal counsel, and a senior Department of Pharmaceutical Care management representative. Requests should be submitted with a protocol outlining the intended use, source of the product, how the product will be obtained, where the product will be stored, and how the product will be dispensed and administered. Informed patient consent will be required before proceeding in such situations.

# WHAT ARE PROTOCOL DRUGS AND HOW ARE THEY ORDERED?

Currently, 27 drugs on the UIHC Formulary are considered "protocol drugs." These medications are denoted as such in the drug monograph section of the *Formulary*. Protocol drugs have been approved for use at UIHC for specific criteria that have been developed and approved by the Pharmacy and Therapeutics (P&T) Subcommittee (comprised of physicians, nurses, and pharmacists) in conjunction with the Antibiotic Advisory Subcommittee, Medication Use Evaluation Subcommittee, and the Medical Staff. These criteria have been established to ensure quality patient care (e.g., through the prevention of antibiotic resistance, avoidance of adverse events, etc.) and to encourage cost-effective therapy.

The agents included in this "protocol" classification include:

## Anti-Infectives:

- Amphotericin B Lipid Complex
- Aztreonam
- Caspofungin
- Ceftriaxone > 1 gram per day
- Cidofovir\*
- Daptomycin
- Levofloxacin Intravenous
- Linezolid
- Meropenem
- Quinupristin/Dalfopristin
- Tigecycline\*
- Ticarcillin/Clavulanate
- Vancomycin Oral
- Voriconazole Intravenous and Oral

## Others:

- Alefacept\*
- Aprepitant\*
- Celecoxib\*
- Dofetilide\*
- Drotrecogin alfa activated\*
- Fosphenytoin
- Lansoprazole Intravenous\*
- Omalizumab\*
- Ondansetron (>4mg IV or >8 mg PO outside Oncology)
- Oxandrolone\*
- Paclitaxel Protein-bound Particles for Injection (Abraxane®)\*
- Recombinant Factor VIIa (NovoSeven®)\*
- Sodium Chloride 7.5%\*

\*These drugs may not be dispensed by Pharmacy until the protocol form is completed.

**The criteria for use of each of these drugs can be found in the drug monograph section of the on-line Formulary as well as on each specific Protocol Drug Order Form.**

## How to Order a Protocol Drug

To obtain a protocol drug, prescribers are required to forward a completed Protocol Drug Order Form that designates the indication for use to Pharmacy along with the usual A-1a Doctors' Order Form. The Protocol Drug Order Forms may be obtained on each patient care unit, from the pharmacy satellite, or through the on-line Formulary. **The completed Protocol Drug Order Form should be sent to pharmacy in conjunction with the written order. In the case of Abraxane®, alefacept, aprepitant, cidofovir, celecoxib, dofetilide, drotrecogin alfa activated, IV lansoprazole, omalizumab, oxandrolone, or recombinant factor VIIa, NO drug will be dispensed until the Protocol Drug Order Form has been received by Pharmacy. Use of the protocol drugs outside the criteria listed on the form requires that the indication for use be clearly stated on the form next to "other indication" and that the form be signed by the patient's attending physician.**

The protocol drug process is necessary in order to collect accurate information regarding the use of high cost, high risk, and high use drugs. This allows the P&T Subcommittee to evaluate usage patterns of these specific agents in order to meet its charge in assuring the safe and cost-effective use of drug products within UIHC.