

Regulations

Verbal Prescription Orders

UWMC Verbal Order Policy

A verbal prescription order is a medication order spoken by a qualified prescriber to a licensed nurse, pharmacist, or physician. Verbal orders shall only be issued in emergency or unusual circumstances. Verbal prescription orders will be immediately recorded in writing on the patient's medical record, consistent with normal operating procedures. Verbal prescription orders must be recorded legibly and completely. Verbal prescription orders must identify the provider giving the order and be signed by the registered recorder. The recorder will read back the verbal prescription order to the physician, ARNP, PA, or dentist for confirmation. The recorder will record the date and time of the order, clarify any questions, and will sign the order with an RBVO (Read Back Verbal Order) to denote that the verbal order was read back. Next to the RBVO the recorder will sign their name and the name of the prescribing physician, ARNP, PA, or dentist. Telephone orders for medications are considered an unusual circumstance since the physician, ARNP, or PA is not physically present. Telephone orders will be recorded as RBTO (Read Back Telephone Order). Next to the RBTO the recorder will sign their name and the name of the prescribing physician, ARNP, PA, or dentist. A registered recorder has the authority to not accept a verbal prescription order when, in his or her judgement, the order should be verified by the prescriber, or the patient should be seen by the prescriber before the prescription is carried out. Verbal prescription orders received and recorded in this manner are considered authenticated when communicated by a credentialed member of the medical staff to a duly authorized individual (as outlined above) and not countermanded by the prescriber within 24 hours. The following orders will not be accepted as a verbal prescription order:

1. Orders to give a medication except in an emergency or unusual circumstance as outlined above.
2. Orders to order Schedule II controlled substances for outpatients.
3. Orders to initiate chemotherapy agents.
4. Orders to initiate investigational agents.

HMC Verbal Order Policy

When an authorized practitioner receives a verbal prescription order, it is his/her responsibility to reduce this to writing in the patient order book as soon as possible. Practitioners authorized to receive verbal orders are identified in the HMC Medical Staff By-Laws. The pharmacist or other practitioner receiving a verbal order must verify the accuracy of the order by repeating the order back to the physician. The practitioner receiving the order must reduce the order to writing on a physician order sheet, and sign the order: v.o.r.v. Dr John Doe, Susan Smith, RPh. * v.o.r.v. stands for 'verbal order read-back and verified.' The verbal order is hand delivered to the charge RN or USC of the nursing unit for placement in the chart. Verbal orders shall NOT be sent via the pneumatic tube system. The pharmacist must use their professional judgement as to the need to telephone the nurse caring for the patient with the order change. Verbal orders are considered authenticated unless countermanded by the patient's primary team within 48 hours. The pharmacy may not dispense a medication from a second hand verbal order (i.e., verbal order from a nurse who received a verbal order from a physician).

of information which must be included on this form are the patient's name (this will take the place of the nursing unit), an indication that the dose was dispensed to a physician for administration to the patient, and the prescription number (the Rx number may be added after dispensing if necessary)

- c. The yellow copy of the order will be entered via the outpatient computer system, initialed and dated by the dispensing pharmacist.
4. The yellow copy will be sent to the Ambulatory Pharmacy to be filed.

Alternative HMC Dispensing Procedure – Urgent Care Clinic Administration

1. If the discharging physician is unable to follow primary dispensing procedures for methadone maintenance patients, (s)he must make arrangements in advance of discharge with the UCC Assistant Nurse Manager, ETC Nurse Manager, or the ETC Assistant Nurse Manager (Fridays only).
2. A specific appointment time must be arranged with the UCC and communicated in writing to the patient by the discharging physician. Patients must be instructed to register at the ETC triage desk prior to going to UCC.
3. The discharging physician must write Ambulatory Order Forms (**UH 0017**), ONE PER DOSE, and forward these to the UCC. UCC will obtain the methadone via standard narcotic dispensing policies and procedures. UCC will bring the yellow copies of the HAD Forms to the Inpatient Pharmacy for charging and filing.

UWMC Dispensing Procedure

1. Orders for methadone must be written by the physician on an Ambulatory Order form (**UH 0017**), one form per dose. Prescriptions written on regular prescription blanks are not valid.
2. The physician, in cooperation with the nursing staff, shall set up an administration site in an ambulatory care clinic, an inpatient ward, or in the Emergency Room.
3. The patient shall return to the designated site daily (for not more than three consecutive days) to receive the methadone dose.
4. The order form may be brought to the Outpatient Pharmacy (during weekday daytime hours) or the Inpatient Pharmacy (during off hours) by the physician, the nurse, or the patient. The dose may only be picked up by the physician or the nurse, AND only the physician may administer the dose to the patient.
5. The pharmacist shall dispense the methadone dose following standard controlled substance order procedures. The order form is to be numbered, initialed, and dated, with the white (chart) copy being returned to the nurse or physician to be placed in the chart. The yellow copy will be retained in the pharmacy C-II prescription file.

Regulations

Physicians' identifying code numbers are required on all discharge prescriptions. Inclusion of physician pager numbers is critical to timely order processing. Additionally, DEA numbers are required to be included on discharge prescriptions for controlled substances. Other legal prescription requirements can be found diagramed inside the back cover of this formulary.

Medication Samples

Medication samples are not allowed at UWMC and HMC. Any clinic wishing to retain a specific medication for use as a sample must appeal to the Medical Director of their respective Medical Center. Authorization will be accompanied by a requirement that the clinic provide ongoing documentation demonstrating:

1. Compliance with all state and federal laws, JCAHO requirements, and institutional policies.
2. Appropriate sample medication use through an ongoing QA program.

Methadone Maintenance Prescriptions

The Narcotic Addiction Treatment Act of 1974, Section 21 CFR 1306.7, states: A physician may administer narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms (methadone maintenance) while arrangements are being made for referral for treatment. Not more than a one day supply may be administered to the person or provided for the person's use at any one time. Such emergency treatment may be carried out for not more than three days and may not be renewed. University of Washington and Harborview Medical Center Policies shall be consistent with the law.

HMC Dispensing Procedure

1. The requesting physician shall write orders for the daily methadone dose on an Ambulatory Order form (**UH 0017**). One form per dose. The yellow copy of the completed order form shall be delivered to the Inpatient Pharmacy. The white (original) copy of the order form shall be placed in the patient's chart.
2. The physician shall come to the Inpatient Pharmacy to obtain the daily dose. The physician shall physically administer the dose to the patient (see HMC-Dept/Anes-PRS-Manual of Information for Residents- "Dealing with the Opiate Dependent Patient at the Time of Discharge"). It is the physician's responsibility to set up administration logistics with the individual patient. If the physician is unavailable to administer the methadone, (s)he may set up alternative administration via the Urgent Care Clinic (see "Alternative HMC Dispensing Procedure – Urgent Care Clinic Administration," that follows).
3. The pharmacist shall dispense the methadone dose to the physician via narcotic policies and procedures.
 - a. The dose dispensed shall be recorded in the narcotic inventory book.
 - b. A narcotic requisition form shall be completed. Additional pieces

are being evaluated through carefully designed and controlled research protocols, others are used emergently through treatment INDs and compassionate use protocols to treat seriously ill patients who are refractory to available therapeutic alternatives. A previously approved drug may be considered investigational if it is being used for a new, unapproved indication, administered in a new dosage form or by a new route of administration, or if it is administered in a new combination product with another drug. Physicians wishing to use an investigational drug must first obtain approval from the University of Washington Human Subjects Review Committee (543-0098).

In addition, the Joint Commission for the Accreditation of Healthcare Organizations has recommended that investigational drugs be stored and dispensed from the hospital pharmacy. The Departments of Pharmacy at both the University of Washington and Harborview Medical Centers provide these services to investigators. Physicians wishing to use these services should contact the Investigational Drug Service at the appropriate institution's pharmacy before their plans for a clinical trial are finalized. The Investigational Drug Service is prepared to offer a wide range of services to facilitate research and/or the use of investigational drugs. For services at Harborview Medical Center call 731-5448; at the University of Washington Medical Center call 598-6054.

Personal Medication Supplies (Own Meds)

Medication supplies brought to the hospital by the patient will be administered only upon a signed physician's order. In addition, the medication must be verified by pharmacy, stored with other non-unit dose medications on the nursing unit, and administered and charted in accordance with standard hospital policy. Medications brought from home which will not be administered in the hospital will be processed as patient valuables or sent home with the patient's family.

Self-Administered Medications (SAM Program)

To develop self-reliance and increase the compliance of taking chronic medications, patients may be authorized to self-administer medications. The program is initiated, with an appropriately labeled seven-day supply of medication dispensed directly to the patient, pursuant to a signed physician's order (including drug name, dose, and sig) for the SAM medication(s) and after conferring with the nurse and/or pharmacist. Controlled substances are not eligible for administration as SAM medications.

Discharge Prescriptions

To facilitate the discharge process, patient needs should be assessed (taking into account medication supplies that patients may already have at home). At HMC, refills are not permitted for discharge medications, but exceptions to the no refill policy may be made for psych meds when limited quantities are necessary for patient safety. At UWMC discharge medications are ordered on discharge prescription order form, for which the top copy can be given to the patient to take to the pharmacy of their choice (or tubed to the UWMC Outpatient Pharmacy for processing). To avoid interruption of needed drug therapy, when a delay in getting discharge prescriptions filled is anticipated, a limited (up to 3-day) supply of medications can be obtained for UWMC patients by sending the chart copy of the Discharge Prescription form to the pharmacy.

8 Regulations

UW Medicine Restricted Formulary Drugs (continued)

| Generic Name (Brand Name) | Restriction/Limit |
|---------------------------|--|
| Yellow Fever Vaccine | Restricted to those practitioners registered with the Washington State Department of Health. |
| Ziprasidone (Geodon) | Injectable formulations limited to use by Psychiatry Service. |

Non-Formulary Drugs

The use of non-formulary drugs within the institution is subject to the dispensing restrictions of the *Non-Formulary Drug Policy*. This policy was implemented to encourage the preferential consideration of formulary agents in an attempt to insure that only the most cost effective and efficacious of similar therapeutic agents are routinely used within the institution. The policy requires both the completion of the **Non-Formulary Drug Request Form** (available from the pharmacy) and verbal communication between the prescribing physician and the pharmacy to determine: 1) that the physician is aware of the non-formulary status of the item, 2) the reason that available formulary alternatives are not desirable, and 3) the estimated supply necessary for the hospital stay.

It should be anticipated that special acquisition procedures for non-formulary drugs may result in a delay of 24 hours in the delivery of the agent to the patient. In addition, it is also necessary for the pharmacy to charge the patient for the entire drug supply obtained regardless of the amount actually consumed by the patient. Upon discharge from the hospital and pursuant to the order of a valid prescription, unused supplies of a non-formulary agent may be dispensed to the patient, but additional quantities for home use cannot be provided.

Formulary Changes

Any request for changes to the drug formulary should be consistent with the mission to insure that only the most efficacious, cost-effective, and least toxic alternative medications are available for routine use within the institution. Requests for formulary changes must be submitted in writing to the secretary of the P & T Committee by an attending physician or member of the committee.

Additions to the formulary will be scheduled for consideration only upon the submission of a completed **Request For Addition To Formulary Form** (available from the Secretary of the Committee by calling 598-6052). The requester (or a designate) is required to be present at the P & T Committee meeting before any consideration will be given to requests for formulary additions. In addition, actions on all requests for drug formulary changes will be consistent with the mission of the P & T Committee to insure that only the most efficacious, cost-effective, and least toxic medications are available for routine use within the medical centers. P & T Committee activities, and summarization of all formal changes to the drug formulary, are published in the monthly *Drug Therapy Topics* newsletter. Formulary additions become effective on the first day of the month following the P & T Committee action.

Investigational Drugs

Investigational drugs are agents which have not yet been approved by the Food and Drug Administration for general use. While most of these new drugs

UW Medicine Restricted Formulary Drugs (continued)

| Generic Name (Brand Name) | Restriction/Limit |
|--|---|
| Celecoxib (Celebrex) | Limited to use in patients at high risk for an adverse GI event because of concurrent anticoagulation or <24 hours s/p invasive procedure with inherent bleeding risk. |
| Dalfoxipristin-quinupristin (Synercid) | The practice at HMC is to have the Infectious Disease Service or AARM team approve use. |
| Dornase Alfa (Pulmozyme) | Limited to use in patients with Cystic Fibrosis. |
| Eplerenone (Inspra) | Limited to use in spironolactone intolerant patients. |
| Epoprostenol (Flolan) | Restricted to use by Drs. Ralph, Clarke, and Hudson or their designees. Also requires approval from the Medical Director (or designee). Use as an alternative to INO in patients with pulmonary hypertension after cardiothoracic surgery is unrestricted. |
| Fluvoxamine (Luvox) | Limited to use by Psychiatry Service. |
| Fomepizole (Antizol) | Restricted to use by UW Medical Toxicology Service (Drs. Copass, Martin, and Robertson) or their designees (on call 24h/day via the WA Poison Center at 526-2121). |
| Interferon gamma 1b (Actimmune) | Restricted to use by Dr. Raghu or his designee. |
| Ketorolac ophthalmic (Acular) | Limited to use for post-phorefractive keratectomy (PRK) and post-phototherapeutic keratectomy (PTK). |
| Laronidase (Aldurazyme) | Prescriber must obtain prior authorization for patients from insurer before initiating therapy. |
| Lepirudin (Refludan) | Limited to use in patients with known or suspected heparin-induced thrombocytopenia and who have received a hematology consult. |
| Linezolid (Zyvox) | The practice at HMC is to have the Infectious Disease Service or AARM team approve use. |
| Mifepristone (Mifeprex) | Restricted to use by practitioners who are registered with the manufacturer and requires patient consent and education prior to dispensing. |
| Nalmefene (Revex) | Limited to use by Pain Service and UW Medical Toxicology Service. |
| Ramipril (Altace) | Limited to use in patients who meet HOPE trial criteria (i.e., 55 years of age or older with coronary or peripheral artery disease, stroke, or diabetes + one other CV risk factor (hypertension, elevated total cholesterol, low HDL, cigarette smoking, or microalbuminuria) and who are not known to have an ejection fraction <40% or to be s/p MI within the preceeding 4 weeks. |
| Succimer (Chemet) | Restricted to use by UW Medical Toxicology Service (Drs. Copass, Martin, and Robertson) or their designees (on call 24h/day via the WA Poison Center at 526-2121). |
| Teriparatide (Forteo) | Limited to use by Drs. Ott and Chesnut. |
| Thalidomide | Physician and patient registration is required by the manufacturer. Patients must receive education and consent to effective contraception and pregnancy testing. |

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Regulations

Traditionally the Pharmacy and Therapeutics Committee has helped to control drug costs through formulary management activities and educating practitioners about safe and rational drug prescribing. One measure of the success of these efforts is the relatively stable ambulatory costs per prescription at HMC since 1998.

Despite the excellent contributions from the P & T Committee, prescribers and pharmacists, drug costs are expected to continue to rise, necessitating heightened efforts to optimize drug utilization. In this regard, further cost savings can be realized by encouraging the preferential prescribing of agents that offer the highest degree of effectiveness at the lowest possible cost. Designating the most cost-effective agents via creation of a "UW Preferred Drug Formulary" (**UW - PDF**) stratifies key formulary options and creates a framework to guide rational drug selection by prescribers. Such a strategy also benefits prescribers and patients by aligning and simplifying choices with regard to 3rd party payor requirements and insuring that patients qualify for the lowest available co-pay. Finally such a strategy will benefit the institution by aligning with the CPOE (ORCA) initiative and allowing providers to view and evaluate formulary options at the point of prescribing. The UW-Preferred Drug Formulary List was adopted by the Pharmacy and Therapeutics Committee on December 16, 2003.

Restricted Formulary Drugs

Formulary drugs which are associated with a narrow therapeutic range, exceptional risk of toxicity, excessive cost or the potential for overuse may be assigned to "restricted" formulary status or otherwise have their use "limited" by the P & T Committee. Pharmacy dispensing of a restricted or "limited-use" formulary drug is in accordance with the guidelines specified by the P & T Committee. Restricted formulary agents used in clinical trials approved by the University of Washington Human Subjects Review Committee are exempt from the restricted formulary policy requirements when used for study subjects. The pharmacy will report restricted drug utilization data to the P & T Committee on a quarterly basis and the P & T Committee will review and renew the restricted status of formulary agents on an annual basis. The P & T Committee may restrict formulary drugs by requiring specialty service approval prior to pharmacy dispensing; by limiting them to use by one or more individual specialists, specialty services, or diagnoses; or by specifying the conditions under which the drugs may be ordered.

UW Medicine Restricted Formulary Drugs

| Generic Name (Brand Name) | Restriction/Limit |
|-----------------------------|---|
| Agalsidase beta (Fabrazyme) | Prescriber must obtain prior authorization for patients from insurer before initiating therapy. |
| Aprepitant (Emend) | Restricted to use with highly emetogenic chemotherapy regimens or in patients known to be refractory to other antiemetics |
| Butorphanol (Stadol NS) | Limited to use by Pain Service. |
| Calcipotriene (Dovonex) | Limited to use by Dermatology Service. |
| Cimetidine (Tagamet) | Limited to use as an immunomodulator in AIDS patients treated at the Madison Clinic. |

requested that the P & T Committee begin to consider evidence-based prescribing practices with a heightened sensitivity toward costs and to promote the fiscally responsible use of high-cost therapies. Initial steps toward achieving these goals were the revision of the criteria by which requests for formulary addition are evaluated and the streamlining Committee processes.

UW Medicine Preferred Drug Formulary (uw-PDF)

All providers should prescribe the UW preferred formulary agents (uw-PDF) unless there is a compelling medical reason to do otherwise. Our goal of 75% utilization of preferred drugs will save over \$1 million. Thank you!

| Condition &/or Therapeutic Drug Group | Formulary Drugs | Patient Cost per 30-Days Supply# |
|---------------------------------------|----------------------|---|
| ACE Inhibitors | uw-PDF | Enalapril \$7 – 12 |
| | | Lisinopril \$10 – 15 |
| | | Ramipril \$18 – 33 |
| Allergy: Non-sedating antihistamines | uw-PDF | Loratadine \$16 |
| | | Fexofenadine \$75 |
| | | Cetirizine \$67 |
| Anti-Inflammatory Agents | uw-PDF | Ibuprofen \$7 – 9 |
| | | Naproxen \$12 – 18 |
| | | Nabumetone \$13 – 21 |
| | | Salsalate \$12 – 15 |
| | | Rofecoxib \$94 |
| | Celecoxib \$75 – 145 | |
| Calcium Channel Blockers | uw-PDF | Nifedipine ER (preferred for hypertension &/or angina without CHF or LVD) \$22 – 35 |
| | | Amlodipine \$50 – 76 |
| Chronic Pain: Long-Acting Opioids | uw-PDF | Methadone \$10 – 16 |
| | | MS SR (generic) \$40 – 250 |
| | | OxyContinR \$83 – 492 |
| | | Fentanyl Patches \$123 – 326 |
| Depression/Anxiety: SSRI's | uw-PDF | Fluoxetine \$9 – 14 |
| | | Paroxetine^ \$35 |
| | | Citalopram \$78 |
| | | Sertraline \$81 |
| Proton Pump Inhibitors (PPIs) | uw-PDF | Lansoprazole \$11 |
| | | Pantoprazole \$9 |
| Statins | uw-PDF | Atorvastatin (for LDL reduction >40%) \$74 |
| | | Lovastatin (for LDL reduction <40%) \$21 |
| | | Simvastatin (for LDL reduction >40%) \$97 – 102 |
| | | Pravastatin \$70 |

Based on HMC/UWMC outpatient costs as of November 2003 and not reflective of SCCA or Hall Health costs.

REGULATIONS GOVERNING DISTRIBUTION OF DRUGS

Prescribing Medications

The Department of Pharmacy Services dispenses drug products for UW Medicine patients only upon receipt of a properly completed and signed prescription order (see example diagramed inside back cover), standing order, or approved protocol. To be valid, all medication orders must be written in ink on pre-approved order forms which transmit a direct copy to the pharmacy. Verbal orders must be reduced to writing and authenticated as per each institution's policy.

Formulary System Rationale

With each change in the drug marketplace comes the responsibility of the institution to arrive at a consensus regarding the potential impact on UW Medicine patients and the appropriateness for incorporation of the change into the drug formulary. Hand-in-hand with this responsibility comes the moral, legal, and professional obligation of insuring the safe and rational use of drug products.

The multiplicity of drug products available and the complexities surrounding their safe and effective use make it increasingly necessary for the UW Medical Centers to have a sound, organized program for the determination of products to be routinely available from the pharmacy. The Pharmacy and Therapeutics (P & T) Committee, with responsibility for maintaining the drug formulary, is the organizational cornerstone of this program for UW Medicine.

Due to perpetual changes occurring in the marketplace, the joint HMC-MMC-SCCA committee meets a minimum of 10 times per year and the evaluation of products for inclusion in the hospital formulary dominates the committee's agenda. Committee decisions to add products to the formulary are based on an objective evaluation of the relative therapeutic merits, advantages, disadvantages, safety, and cost. In this manner, products "on formulary" reflect the collective clinical judgement of the medical staff and present only those products thought to be of the most value in routine patient care. From an organizational standpoint, the decisions of the Pharmacy and Therapeutics Committee, through the development and maintenance of the formulary system, form the first step in assuring that the highest possible quality of patient care is maintained.

Formulary Drugs

A formulary drug is defined as a therapeutic agent which has been approved by the P & T Committee for routine dispensing by pharmacy. These agents have a well established place in therapy and are considered necessary for optimal patient care within the institution.

"Preferred" Formulary Drugs (*UW - PDF*)

In October 2001 the Medical Directors gave the Pharmacy and Therapeutics Committee the charge of assisting UW Medicine in its mission to bolster patient access to essential medicines in the face of rising drug costs. Specifically they