Pharmaceutical Procurement and Control Plan

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I. Introduction

This document outlines responsibilities, requirements, and guidelines for chemical procurement and control. Observing the requirements and guidelines in this document will promote a safe and healthful environment, and help to comply with federal, state, and local regulatory requirements.

II. References

- Controlled Substances Act (CSA) (21 USC 801-890)
- Drug Enforcement Administration (DEA) Regulations (21 CFR 1300-1316)
- Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR 1910.1450)
- SUNY WCC’s Hazard Communication Program
- SUNY WCC’s Laboratory Chemical Hygiene Plan
- Toxic Substances Control Act (TSCA)

III. Definitions

Chemical Inventory – The database used for retrieving information on chemicals/pharmaceuticals at SUNY WCC.

Material Safety Data Sheets (MSDSs) – Documents from chemical (incl. pharmaceutical) manufacturers, suppliers, and distributors that outline hazards, toxicological properties, and relevant control methods for chemicals.

New Pharmaceutical – A pharmaceutical chemical that is not currently listed on a department’s authorized list of pharmaceuticals (inventory), or has not been previously ordered by the college.
Pharmaceutical Approval Request Form – This form must be filled out by the requesting user department and submitted along with the product MSDS sheet to the EHS Manager for review and approval.

Existing Pharmaceutical – A pharmaceutical that is currently listed on a department’s authorized list of chemicals.

Toxic Substances Control Act (TSCA) - An Environmental Protection Agency regulation with objectives to regulate the manufacture, use, distribution in commerce, and disposal of chemical substances.

Practitioner- a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which (he) the individual practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

IV. Responsibilities

Practitioner – Responsible to ensure compliance with all relevant aspects of SUNY WCC’s Hazard Communication Program and/or Laboratory Chemical Hygiene Plan as they relate to the use of pharmaceuticals at WCC. This includes observing protocol for procurement, and implementing safe handling, use, storage, and disposal practices for pharmaceuticals.

- When a practitioner wants to order a new pharmaceutical that is not on the Department’s current chemical inventory and / or there is not an MSDS on file he or she is responsible for obtaining a copy of the manufacturer’s most current MSDS.
- The practitioner is then responsible for filling out the Pharmaceutical Approval Request Form (see attachment 1), attaching the MSDS to it, and submitting it to the EHS Manager for review.
- When the practitioner receives the approved Pharmaceutical Approval Request Form it should be attached to the purchasing requisition.
- The new pharmaceutical must be added to the User Department’s Chemical Inventory and the MSDS must be added to the files.
- The practitioner must ensure compliance with DEA recordkeeping requirements for practitioners as outlined in the CSA.

EH&S Manager – Reviews Pharmaceutical Approval Request Forms (see attachment 1) submitted by user departments and approves or disapproves new pharmaceutical requests. The EH&S Manager will endeavor to turn those requests over within as short a period of time as possible and keep a copy on file. The EHS Manager also specifies any special safe handling, use, storage, and disposal requirements for pharmaceuticals. The approved Pharmaceutical Request Form will be forwarded to the requestor and a copy will be sent to Purchasing.

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**Purchasing** – The Purchasing Department will only order a new pharmaceutical if the requisition is accompanied by a completed and approved Pharmaceutical Approval Request Form.

Additionally, whenever purchasing approved pharmaceuticals, the Purchasing Department will ensure the purchase order includes specific instructions for their delivery to WCC. These instructions will include specific date, time and signatory requirements for the delivery, so as to ensure an “in-person” delivery only to authorized personnel. The Purchasing Department will make it clear that, if an approved receiver (by name) is not present for the delivery, the delivery will not be made. All of this will require prior coordination with the practitioner to ensure availability to receive the delivery.

**V. Pharmaceutical Procurement**

Before any pharmaceutical is ordered, the practitioner should check the department’s existing chemical inventory. If the department is not authorized for the pharmaceutical of interest, the user should send information related to the pharmaceutical (i.e., pharmaceutical/chemical name, desired quantity, specific use, and a copy of the manufacturer’s most current MSDS) to the EH&S Manager. MSDS’s can be obtained from the supplier, or they are often times available on line.

The EH&S Manager will review requests for pharmaceuticals to assess potential hazards and determine whether or not regulatory restrictions apply. In rare instances where a specific pharmaceutical is, for example, extremely hazardous or not TSCA registered, the EH&S Manager will suggest that the user consider selecting another pharmaceutical. When a pharmaceutical is approved for use, the MSDS and other relevant information will be entered into the campus’s and department’s chemical inventory. Additionally, safe handling, storage, and disposal requirements might be specified to the user.

The user may order the pharmaceutical of interest after the pharmaceutical authorization review. Orders should be limited to quantities that are commensurate with current needs and in accordance with sound pharmaceutical management practices. After a pharmaceutical is received, the user should observe all safe handling, use, storage, and disposal requirements.

Existing pharmaceuticals do not require a pharmaceutical authorization review; therefore, these pharmaceutical can be ordered at the discretion of the user. In instances where large quantities are ordered or when certain control requirements apply (e.g., TSCA regulations or use restrictions), the user should contact the EH&S Manager before an existing pharmaceutical is ordered. The EH&S Manager will, thereafter, specify whether or not special ordering, handling, use, or disposal requirements are necessary.

**Note:** Free samples are not to be obtained from pharmaceutical manufacturers or distributors without approval from the EH&S Manager, and workers are not to...
VI. Pharmaceutical Authorization Review

The pharmaceutical authorization review is a process used by the EH&S Manager to evaluate certain pharmaceuticals prior to procurement. The objectives of the pharmaceutical authorization review are:
1) to evaluate the MSDS for hazardous characteristics; flammability, corrosiveness, toxicity, health hazards, and waste disposal requirements.
2) promote safe handling, use, storage, and disposal practices; and
3) ensure that regulatory requirements around storage, handling, and disposal are implemented.

While the pharmaceutical authorization review will require input from the practitioner, this review will not be used to restrict the user’s autonomy. However, if significant concerns with this pharmaceutical are identified during this review process they will be highlighted and the user department will be encouraged to seek alternative products. The pharmaceutical authorization review will generally be conducted in one week’s time or less. However, if the product is needed immediately the process can be expedited upon request to the EHS Manager.

VII. Pharmaceutical/Chemical Inventory Control

Practitioners must periodically review their department chemical inventory for accuracy. If a pharmaceutical is used, but not listed on the department chemical inventory, the user should contact the EH&S Office. The user should specify the pharmaceutical/chemical name, manufacturer and quantity when reporting unauthorized pharmaceuticals. Practitioners should also contact the EH&S Manager when a pharmaceutical is no longer used within a department. The department’s pharmaceutical authorization list will subsequently be updated and hazardous waste disposal arrangements will be made if required.
Attachment 1

WCC Pharmaceutical Approval Request Form
WCC Pharmaceutical Approval Request Form

Requesting Department: ______________________

Requestor’s Name: ______________________

Requestor’s Phone: ______________________

Date of request: ______________________

Pharmaceutical/Chemical Name: ______________________

CAS#: ______________________

Manufacturer: ______________________

Intended Use: ______________________

EHS Manager Review Date: ______________________

EHS Manager Review

Approval: ______________________

Disapproval: ______________________

Special Handling, Storage, or disposal Practices Required:

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