

Order & Receive Controlled Substances for Research Use

Ordering and receiving controlled substances requires strong internal controls as well as strict adherence to U-M, state, and federal policies. This procedure contains information about the controls required for the ordering and receiving process.

Ordering

Controlled substances are <u>restricted commodities</u> (see pharmaceuticals) per U-M Procurement policy. All orders must include the **DEA registrant's information** (i.e., name, address of the registered storage location, research registration number, expiration date).

There are two options for ordering controlled substances for research purposes:

Michigan Medicine B2 Pharmacy (preferred option)

a. Complete a Researcher Controlled
Substance Request Form

Note: Schedule II substances must be listed on a separate request form.

- b. Include a copy of the DEA registrant's current certification (225 form)
- c. For Schedule I-II substances, include a completed DEA 222 form.

2. Commercial Wholesalers/Vendors

- Contact <u>U-M Procurement Services</u> to establish a purchasing contract or to identify an existing contract to use with a commercial supplier.
- b. Orders must be submitted on an M-Pathways eProcurement (ePro) requisition. P-Cards cannot be used to order controlled substances.
- For Schedule I-II substances, verify 222 form requirements and process with U-M Procurement Services.

DEA 222 form (order form)

- For Schedule I-II substances only
- Numbered serially for tracking purposes
- **DEA registrant** must:
 - o Sign the order form
 - Lock forms in a secure location

Using the triplicate form:

 Mail/deliver copies 1 (brown) & 2 (green) attached together with carbons to the supplier

Each 222 form must be complete with no errors; otherwise the supplier may reject part or all of the order.

- Retain copy 3 (blue) and file with the controlled substance records.
- Order additional forms <u>online</u> from the DEA.

DEA procedures & more information:

<u>Title 21 CFR: Part 1305 - Orders</u> Form 222 - DEA FAQ

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Receiving

Vendors must ship orders within 60 days of the date on the DEA Form 222. Best practices for receiving a controlled substance order in your laboratory, regardless of substance Schedule, include:

- 1. Show your M-Card when picking up an order from the Michigan Medicine B2 Pharmacy.
- 2. Ensure invoice contains the following data:
 - a. Name, address, and DEA Registration number of registrant
 - b. Controlled substance name, concentration, dosage form, and quantity
 - c. Signature of authorized personnel who picked up or received the drug order
 - d. Date of pickup or receipt
- 3. Have the DEA registrant or an authorized agent receive, verify, log, and securely store the substances into the registered storage location. See Maintain Records for more information about inventories and usage logs.
- 4. Maintain invoices and packing slips with your controlled substance records, separated by schedule I-II, and schedule III-V.

Note: The completed *Researcher Controlled Substance Request Form* and/or a completed DEA 222 form copy 3 (blue) can act as an invoice.

Additional Process Information

Rejected Orders

A supplier may void all or any part of an order on a DEA Form 222, without an explanation other than "insufficient order." The supplier will return copies 1 and 2 to the DEA registrant (purchaser). The rejected DEA 222 form copies 1-3 must be kept on file and maintained for at least two years.

Lost/Delayed Order Forms

If a supplier does not receive a DEA 222 form for a particular order (i.e., lost) the DEA registrant, as the purchaser, must:

- 1. Submit in writing a notice to the supplier indicating the original DEA Form 222 serial number, the date on the form, and the controlled substances listed on the form.
- 2. Attach a copy of that written notice to copy 3 (blue) of the original DEA 222 form and maintain that as a record of a voided order.
- 3. Complete and send a new DEA 222 form to the supplier.
- 4. Report the voided form's serial number to the Detroit DEA field office.

If the vendor subsequently receives the original (i.e. voided) order form, the vendor will not accept the order and will return the form to the DEA registrant for their records.

If the lost DEA 222 form is found after notification to the Detroit DEA field office, re-notify the DEA of the discovery.

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