Addressing Possible Shortages of Oseltamivir Products Used to Treat Influenza

Updated 2-6-2018

The Board has received several reports of possible shortages of oseltamivir oral powder for suspension (commonly known as TAMIFLU®). To address this issue, the Board has identified two options available to Ohio pharmacies:

1) Emergency Compounding of an Oral Suspension from Oseltamivir Capsules

Per FDA labeling and Ohio law and rules, pharmacies may compound patient-specific oral suspensions from Oseltamivir capsules.

Please be advised that compounding of an oral suspension from capsules is intended to be used only if the FDA-approved, commercially manufactured oral suspension is not readily available from wholesalers or the manufacturer.

Pharmacies engaged in compounding should comply with rule 4729-16-03 of the Ohio Administrative Code, including all applicable provisions of United States Pharmacopeia Chapter <797> and the manufacturer’s instructions.

2) Occasional Wholesale Sales by Ohio-Licensed Pharmacies

Rule 4729-9-10 of the Ohio Administrative Code permits Ohio-licensed pharmacies to conduct occasional wholesale sales of commercially manufactured dangerous drugs (i.e. prescription medications that are not compounded) to terminal distributors of dangerous drug or those locations exempted from licensure pursuant to section 4729.541 of the Ohio Revised Code.

Pharmacies may conduct such sales as long as the total value of all dangerous drugs sold by the pharmacy does not exceed five percent of the total value of dangerous drugs purchased by the pharmacy during the same calendar year.

Pharmacies selling to other terminal distributors must verify licensure using the Board’s online registry prior to sale or verify that the facility is exempted from licensure section 4729.541 of the Ohio Revised Code.