



December 1, 2022

MEMORANDUM

TO: Hospital/Clinics
Local Health Departments
Long Term Care & Assisted Living
Physicians, Pediatricians, OB-GYN/Midwives/Doulas
Pharmacists/State Vaccination Providers
Health Care Coalition
Federal Qualified Healthcare Facilities
Emergency Response Coordinators
Regional Health Officers

FROM: Arti Barnes MD MPH.
Chief Medical Officer
IDPH/ Division of Medical Services

RE: **Illinois Department of Public Health Advisory on Oseltamivir Suspension Compounding from Commercially Available Oseltamivir Capsules**

Illinois pediatric providers have reported a shortage of commercially available oseltamivir suspension at their institution or in surrounding community pharmacies.

Illinois pharmacists have additionally expressed concern over the legality of compounding oseltamivir suspension (a commercially available product) from commercially available oseltamivir capsules to fulfill individual prescriptions.

IDPH acknowledges the importance of timely treatment with oseltamivir as an option in mitigating the current outbreak of influenza in pediatric patients. IDPH recognizes that commercially available oseltamivir suspension is currently unavailable or difficult to acquire by some pharmacies, though oseltamivir suspension is not yet listed in the Food and Drug Administration (FDA) Drug Shortages Database. When insufficient inventory and acquisition delays threaten the timely dispensing of commercially available oseltamivir suspension to fulfill a prescription, **IDPH supports Illinois pharmacists compounding an oseltamivir suspension product from commercially available oseltamivir capsules under the allowances of the Illinois Pharmacy Practice Act and Federal Food, Drug, and Cosmetic Act (FDCA).**

IDPH is releasing the following advisory:

1. The FDCA and the Illinois Pharmacy Practice Act permit the compounding of commercially available products such as oseltamivir suspension on a limited, prescription basis in this setting.
2. To facilitate this, prescribers should consider adding "**please compound if necessary**" language to their oseltamivir suspension prescriptions. Pharmacists should consider documenting the details of the experienced shortage on any prescription for which oseltamivir suspension is compounded.

3. Branded TAMIFLU (oseltamivir) package inserts include instructions for “*Emergency Compounding of an Oral Suspension from 75 mg TAMIFLU Capsules (Final Concentration 6 mg/mL)*” that are applicable to any commercially available, therapeutically equivalent 75 mg oseltamivir oral capsule.

Additional information and Resources:

The full scope of perceived barriers to oseltamivir suspension compounding by Illinois pharmacists is still being assessed, but initial concerns focused on the FDCA’s prohibition of compounding “copies of a commercially available drug product” ([FDCA Section 503A](#)).

Oseltamivir suspension is not listed in the FDA Drug Shortages Database.

Per FDA guidance on the compounding of copies of commercially available drug products ([January 2018 Guidance for Industry p5](#)), a drug product is not considered commercially available if it “appears on the FDA drug shortage list.” This would void concerns related to the FDCA described above. As of the publication date of this SIREN, oseltamivir suspension does not appear in the [FDA Drug Shortages Database](#). However...

The FDCA and the Illinois Pharmacy Practice Act permit the compounding of commercially available products on a limited, prescription basis in this setting.

The FDCA permits such compounding as long as it is not done “regularly or in inordinate amounts” ([FDCA Section 503A](#)). The [2018 FDA Guidance](#) defines this as “compounded more frequently than needed to address unanticipated, emergency circumstances, or in more than the small quantities needed to address unanticipated, emergency circumstances” (p10). [The Illinois Pharmacy Practice Act](#) states “Commercially available products may be compounded for dispensing to individual patients only if all of the following conditions are met: (i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet the patient's needs **and** (ii) the prescribing practitioner has requested that the drug be compounded” (emphasis added).

As such, IDPH supports Illinois pharmacists compounding an oseltamivir suspension product from commercially available oseltamivir capsules to ensure the timely filling of individual prescriptions at the pharmacist’s discretion per the real time unavailability of commercially available oseltamivir suspension and the needs of the individual patient.

In order to facilitate this in compliance with the conditions of the Illinois Pharmacy Practice Act, IDPH recommends that prescribers consider the addition of standard compounding request language to all oseltamivir suspension prescriptions such as, “***please compound if necessary.***” Pharmacists should consider documenting the details of the experienced shortage on any prescription for which oseltamivir suspension is compounded.

Branded TAMIFLU (oseltamivir) package inserts include instructions for “Emergency Compounding of an Oral Suspension from 75 mg TAMIFLU Capsules (Final Concentration 6 mg/mL)” that are applicable to any commercially available, therapeutically equivalent 75 mg oseltamivir oral capsule.

Resulting from similar supply and demand issues during the 2009-10 and 2012-13 influenza seasons, the package insert for branded TAMIFLU (oseltamivir) includes vetted instructions for compounding a 6 mg/ml oseltamivir suspension from 75 mg oseltamivir oral capsules. These instructions are applicable to any commercially available, therapeutically equivalent oseltamivir 75 mg capsule.

[Oseltamivir Suspension Compounding Instructions – TAMIFLU Package Insert Section 2.8](#)