New Veterinary Guidance Regarding 503B Outsourcing Facility Products

When traditional pharmaceutical products don't meet the needs of your patients and you turn to compounded medications, it can be unclear about how and when the different types of compounded products can be dispensed.

A recent inquiry into the Ohio Board of Pharmacy regarding the legality of maintaining office stock and dispensing of 503B Outsourcing Facility products has resulted in new guidance issued from the board. As traditionally compounded medications (503A) and outsourcing facility products (503B) can sometimes be conflated, this new guidance makes it clear for veterinarians in Ohio that the 7-day supply limitation does **NOT apply** to compounded drugs purchased from an outsourcing facility.

The new guidance can be found on the <u>Veterinary Clinic – Inspection Guide pdf</u>, located on the Ohio Board of Pharmacy website. On page four, the document states (emphasis added): "Personally Furnishing Compounded Drugs Obtained from an Outsourcing Facility An outsourcing facility is permitted to provide non-patient specific compounded sterile drug products to healthcare professionals. These products are compounded under current good manufacturing practice (CGMP) requirements and the facilities are inspected by the FDA on a risk-based schedule. For more information on outsourcing facilities, including how to find those licensed by the Board of Pharmacy, visit: www.pharmacy.ohio.gov/outsourcing

The Board has confirmed with the FDA that non-patient specific drugs purchased directly from an outsourcing facility may be further prescribed and personally furnished to a patient. Please be advised that the 7-day supply limitation that applies to personally furnishing compounded drugs provided by a pharmacy (see 4729:7-2-05(E)) does not apply to compounded drugs purchased from an outsourcing facility."

So when looking for compounded medications, remember: 503A, or traditionally compounded products have specific limitations including a 7-day supply limit, while 503B, or outsourcing facility products, do not have the dispensing restrictions.