

DSCSA Exemptions



PRODUCTS EXPLICITLY EXEMPT FROM DSCSA

- Patient specific
- Radioactive/biological
- Compounded
- Medical gases
- Blood components for transfusion
- Intended for animal use
- Office use
- IV replenishment
- Samples
- Combination kits
- Dialysis & irrigation solutions
- Imaging
- Sterile water
- Intracompany transfers under common ownership.

The pharmacy has to use their knowledge of the product's characteristics and the following provisions in the DSCSA to make the determination if the drug is covered.[1]

- RX Only - DSCSA applies to prescription drugs – “in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution).”
- Animal Use – drugs specifically for animal use
- Drugs sold behind the counter – unless labeled RX Only (Sudafed D etc.)
- Over-The-Counter drugs
- Devices – even if they require a prescription.
- Combination Products (drug-device / biologic-device) – depending on the
- Primary Mode of Action (PMOA) If the PMOA is a drug the product is covered under DSCSA if it is a biologic then it is exempt.