# Kentucky Board of Pharmacy: Frequently Asked Questions on Medical Device Permit Requirements

## Helpful Definitions to Navigate KYBOP Permits:

Question 1: What is the applicable statutory definition of "drug" used by KYBOP?
A: Under KRS 315.010, a drug means any of the following:

- (a) Articles recognized as drugs are drug products in any official compendium or supplement thereto. This includes prescription and legend drugs;
- (b) Articles, other than food, intended to affect the structure or function of the body of man or other animals;
- (c) Articles, including radioactive substances, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals;
- or (d) Articles intended for use as a component of any articles specified in paragraphs (a) to (c) of this subsection.

Question 2: How is "device" defined?
A: KRS 315.400 adopts the definition found under Section 201(h) of the Federal Food, Drug, and Cosmetic Act. A device is defined as:

> An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar related article, including any component, part, or accessory, which is -- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Question 3: What is a drug product?
A: Under 21 C.F.R. § 210.3, A drug product is defined as: a finished dosage form, for example a tablet, capsule or solution that contains an active pharmaceutical ingredient, generally, but not necessarily, in association with inactive ingredients.

Question 4: How can I distinguish a device from a product?
A: A product is considered anything with a finished dosage form, inherently drugs achieve their ultimate purpose *through* chemical action. Conversely, devices impact the structure or function of the body *without* the chemical reaction.

Question 5: What is a combination product, and do they require a permit with KYBOP?
A: The full definition of combination product can be found under 21 CFR 3.2(e). Simply put, combination products are therapeutic and diagnostic products that combine a prescription drug or prescription biologic product with a device . These products are regulated by KYBOP and require a permit based on their drug properties.

A few helpful examples of combination products are: prefilled syringes like insulin auto-injectors,; metered dose inhalers, andtransdermal patches.

Question 6: KYBOP regulates drug-related products and devices, what is considered drug-related?
A: The object itself must contain a drug, or a drug must be distributed *with* the product or device to be drug-related. You are not required to get a pharmacy permit for a product or device that can be used to administer a drug so long as you are not distributing the accompanying drug with the product or device.

## Frequently Asked Questions:

Question 7: If you are distributing a medical device in Kentucky, do you need a Kentucky Board of Pharmacy permit?
A: The KYBOP regulates drug-related products and combination products composed of a device or biological product and a drug.

Question 8: If you have a product with a drug component, are you required to be permitted by the Board?
A: Yes. Remember that for Board purposes, it is less to do with classifying your item as a device or product and more about determining if there is a drug contained in the object or that will be distributed with that object. See the first question with the definition of drug.

Question 9: How does the KYBOP determine if a permit is required?
A: It is critical to note that a permit is issued based upon the items that the entity plans to distribute. This means that the facility could primarily distribute medical devices with no drug component and have a single product that can be considered "drug-related," and a permit will be required. Permits are not based on the facility; the analysis requires a product-by-product consideration.

Question 10: If the FDA classifies a product as a medical device, does that also mean the KYBOP will classify it as such, and not require a permit?
A: No. The classification assigned by the FDA is based on how the manufacturer applies for their FDA permit. Two products with the same composition can have different classifications with the FDA based on their listed primary intended purpose. KYBOP does not assume the FDA's classifications for purposes of regulation status.

It's also important to note that if the FDA classifies the product as a "device" then it will be a device even if it also meets their operational definition for "drug." This leads to the incorrect assumption that the drug component of the product no longer matters for purposes of classification. In other words, under the FDA, the device definition can consume the drug definition if the product can be defined as an FDA device. KYBOP takes the opposite approach in that if a product contains a prescription drug, the drug cannot be ignored, and it must be regulated.

Question 11: What is an example of a product that has a pure device FDA classification but will be regulated by KYBOP?
A: Heparin flushes, while they are used to flush out tubing and not as a blood thinner, they are classified as a drug-related device by KYBOP, requiring a permit. Because this product has a dose of a drug as defined by KRS 315.010, it must be regulated. The subpotent, small quantity does not place this product beyond Board regulation. However, given the small dosage and the way the FDA defines a drug, this would not be drug-related under the FDA classifications.

Question 12: If a device requires a prescription, does that impact the way the device is classified with KYBOP?
A: The device's requirement for a prescription does not factor into the permit analysis because there are devices that require a medical order that are not regulated by the Board of Pharmacy. To accurately determine if you need a Board permit, you must always focus on the product itself and whether it contains a prescription drug.

# Medical Device Permitting at Glance: A Step-by-Step Analysis: