DISPENSING LEGEND DRUG SAMPLES

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Under Kentucky law, an Advanced Practice Registered Nurse ("APRN") may order, administer, prescribe, and dispense noncontrolled legend drugs samples to a patient, provided that the APRN does so pursuant to applicable law, within his or her scope, and in a manner consistent with applicable practice standards. It is important to note that ordering, prescribing, administering, and dispensing are distinct concepts. A prescriber, such as an APRN with an active license, is a person with prescriptive authority as defined by KRS 314.011(8), KRS 314.042(8-10), KRS 217.015(35), and KRS 315.010(21). A prescriber may "order" the direct administration of a drug to a patient to address a legitimate medical need, provided that the order falls within the prescribing practitioner's scope of professional practice. See, KRS 314.011(8) and 315.010(24). "Administration" is defined as preparing, giving directly to the patient, and evaluating the effectiveness of prescription and non-prescription drugs. "Prescribing" is the act of providing written instructions to a pharmacist authorizing the dispensing of a prescription drug by a patient. "Dispensing" is the preparation, packaging, labeling, record keeping, and transfer of a prescription drug to a patient, or to an intermediary who is responsible for administration of the drug. Kentucky law expressly prohibits nurses from dispensing any and all controlled substances; however, dispensing noncontrolled legend drugs is permitted in the situations described below.

There are only two narrow situations in which nurses may dispense noncontrolled legend drugs in the Commonwealth. First, Kentucky APRNs may dispense noncontrolled legend drug samples from pharmaceutical manufacturers to a patient at no charge to the patient or any other party. See, 21 U.S.C. § 353 and KRS 314.011(17)(a). For ease of reference, drug samples that meet all of these requirements are referred to herein as "legend drug samples." Second, a Kentucky Registered Nurse ("RN") may dispense noncontrolled legend drugs from a local, district, and independent health department to a patient, subject to the direction of the appropriate governing board of the individual health department, pursuant to specific direction from a prescriber. See, KRS 314.011(6)(c)(1) and 314.011(17)(b). This article focuses on legend drug samples, and does not address the dispensing of noncontrolled legend drugs from a health department.

A legal opinion on the Board's website titled, Dispensing By Nurses, specifically addresses an APRN's ability to delegate aspects of task of dispensing legend drug samples. See, http://kbn.ky.gov/legalopinions, KRS 314.011(6)(d), KBN Advisory Opinion Statement #15 - Supervision and Delegation (Rev. 10/2014). It is not within the scope of RN or LPN practice to independently choose and/or order the administration of a drug, or prescribe a drug. This is true for either over the counter or prescription drugs. RNs and LPNs may implement an order, standing order, or protocol related to the administration or dispensing of a legend drug sample. When RNs and LPNs perform these

tasks, they should appropriately document their actions.

Governing laws and regulations are very specific with regard to what constitutes a legend drug sample. Legend drug samples must be either obtained by: (1) the prescriber from a pharmaceutical manufacturer or the manufacturer's authorized distributor, representative, or detailer; or (2) delivered directly from the manufacturer or the manufacturer's authorized distributor, representative, or detailer to the patient pursuant to a written request from the prescriber. See, 21 C.F.R. § 203.3(h) and 203.31. One notable exception to the foregoing rule allows charitable institutions to receive legend drug samples from a prescriber or another charitable institution. See, 21 C.F.R. § 203.39. Legend drug samples are required to be individually packaged, marked with lot numbers, and labeled as samples by the manufacturer. See, 21 C.F.R. § 203.38. Drug manufacturers and their agents must comply with detailed reporting and record-keeping requirements related to drug samples, as well as storage and handling requirements. See, 21 C.F.R. § 203.60 and 21 C.F.R. § 203.32. In summary, all aspects related to the manufacturing, packaging, and delivery of drug samples to prescribers or patients are heavily regulated by the U. S. Food and Drug Administration. See, 21 C.F.R. § 203.34.

APRNs may not purchase legend drugs in bulk from a manufacturer, wholesaler or retailer, repackage them in smaller quantities, call the repackaged drugs "samples," and then dispense them to patients free of charge. Federal laws, namely the Prescription Drug Marketing Act of 1987 and the Prescription Drug Amendments of 1992, narrowly define a legend drug sample as a drug that may not be sold, purchased, or traded. The legislative intent behind the federal provisions relating to drug samples was to allow drugs packaged and labeled as samples by a manufacturer to be given to patients for free to promote the sale of the drug. See, 21 U.S.C.A. § 353. The federal definition of a "sample unit" means a packet, card, blister pack, bottle, container, or other single package comprised of one or more dosage units of a prescription drug sample, intended by the manufacturer or distributor to be provided by a licensed practitioner to a patient in an unbroken or unopened condition. See, 21 C.F.R. § 203.3(i). Put simply, only a manufacturer or a manufacturer's authorized distributor, representative, or detailer may create a legend drug sample. A drug that was at any point sold, purchased, traded, broken, or opened cannot subsequently be a drug sample as referenced in KRS 314.011(17)(a). This is true in all practice settings, including free clinics, charitable settings, and places where medical care is provided to homeless persons.