DRUG ENFORCEMENT ADMINISTRATION (DEA) PRESCRIPTION ORDER FREQUENTLY ASKED QUESTIONS

Q.) What is the legal authority of the Drug Enforcement Administration (DEA)?

A.) The DEA is part of the U.S. Department of Justice. The DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 801-971), as amended. DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 through 1321.

Q.) Where can I find the DEA's statement of policy that provides guidance under the existing law, regarding the proper role of a duly-authorized agent of a DEA-registered individual practitioner, in connection with the communication of a controlled substance prescription to a pharmacy?

A.) You can find the information contained within the Federal Register: October 6, 2010 (Volume 75, Number 193)] [Rules and Regulations] [Page 61613-61617] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr06oc10-10]. The title of this register entry is: Role of Authorized Agents in Communicating Controlled Substances Prescriptions to Pharmacies – Agency.

Q.) What was the purpose of the DEA's Oct. 6, 2010 statement of policy?

A.) To provide guidance under the existing law regarding the proper role of a duly authorized agent of a DEA-registered individual practitioner, in connection with the communication of a controlled substance prescription to a pharmacy.

Q.) Who is eligible for the DEA registration as a practitioner?

A.) Under the Control Substance Act (CSA), a practitioner must be a physician, dentist, veterinarian, hospital or other person licensed, registered, or otherwise permitted by the United States or the sate in which he or she practices to dispense controlled substances in the course of professional practice – 21 U.S.C. 802 (21), 823 (f). Thus, state licensure to prescribe controlled substances is generally a prerequisite to obtaining a DEA registration.

Q.) Who is an agent of an individual practitioner, and what is their role for the purpose of communicating a prescription for a controlled substance under the CSA?

A.) The statute defines an "agent" as "an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser." 21 U.S.C. 802(3). Likewise, DEA regulations implementing the CSA specifically permit a practitioner to use an authorized

agent to perform certain ministerial acts in connection with communicating prescription information to a pharmacy. The common means to communicate a prescription to a pharmacy include hand delivery, facsimile, phone call, or an electronic transmission. The proper role of an agent depends upon the schedule of the controlled substance prescribed, the circumstances of the ultimate user, and the method of communication.

Q.) How does a nurse become an authorized agent?

A.) The DEA requires each individual nurse and practitioner, who chooses to participate, to sign a written agency agreement that would properly confer authority to the agent on behalf of the individual practitioner. An agency relationship is created when (1) the principal (practitioner) manifests assent that a particular person (the authorized agent) shall act (i) on his or her behalf and (ii) subject to his or her control, and (2) the agent manifests assent so to act, the definition of "agency" is consistent with the CSA's definition of "agent" as "an authorized person who acts on behalf of or at the direction of" the prescribing practitioner. 21 U.S.C. 802(3). An agent may not legally perform duties that must be personally performed by the individual practitioner. The practitioner may assign only those duties which may be carried out by an agent.

The DEA has provided a sample template of a written agency agreement that would properly confer authority to an agent to act on behalf of an individual practitioner with regard to controlled substance prescriptions contained within the policy statement. For more information, see: Federal Register: October 6, 2010 (Volume 75, Number 193)] [Rules and Regulations] [Page 61613-61617].

Q.) How may an authorized agent communicate a practitioner's valid prescription for a schedule III, IV, or V controlled substance?

A.) 1. An authorized agent of an individual practitioner may prepare a written prescription for the signature of the practitioner, provided that the practitioner, in the usual course of professional practice, has determined that there is a legitimate medical purpose for the prescription and has specified to the agent the required elements of the prescription. 21 CFR 1306.04(a); 1306.05(a), (f).

2. Where a DEA-registered individual practitioner has made a valid oral prescription for a controlled substance in Schedules III-V by conveying all the required prescription information to the practitioner's authorized agent, that agent may telephone the pharmacy and convey that prescription information to the pharmacist. 21 CFR 1306.03(b), 1306.21(a).

3. In those situations in which an individual practitioner has issued a valid written prescription for a controlled substance, and the regulations permit the prescription to be transmitted by facsimile to a pharmacy (as set forth in 21 CFR 1306.11(a), 1306.11(f), 1306.11(g), and 1306.21(a)), the practitioner's agent may transmit the practitioner-signed prescription to the pharmacy by facsimile.

Resources:
The Office of Diversion Control under the U.S. Department of Justice Drug Enforcement Administration: 202-307-7297.
U.S. Department of Justice Drug Enforcement Administration Office of Diversion Control: http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr1006.htm

GuideOne Risk Resources for Health Care
1111 Ashworth Road
West Des Moines, Iowa 50265
1-800-688-3628