Legal Briefs

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Federal drug laws and CRNAs

CRNAs are increasingly becoming involved in revisions to laws governing the prescription of drugs and controlled substances. In some instances, it is CRNAs seeking changes because their ability to administer anesthetics has been challenged. In other instances, amendments to these laws are sought by other nursing groups in efforts to expand or solidify their areas of practice. Laws controlling prescription drugs are complex and easily misunderstood. This column will, from time to time over the next few months, attempt to explore existing laws regulating prescriptive authority as well as some of the proposed changes to some of these laws. This month we will begin with federal laws governing prescriptive authority. Federal drug laws are, of course, applicable to all CRNAs. In addition, the federal Controlled Substances Act has served as a model for many state acts.

There are two principal federal acts applicable to the administration of drugs of the types routinely administered by CRNAs: the Food, Drug, and Cosmetics Act and the Controlled Substances Act.

The Food, Drug, and Cosmetics Act

The Food, Drug, and Cosmetics Act (21 U.S.C. 301) prohibits the introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded. Manufacturers, packers or distributors are required to maintain and transmit to "any practitioner licensed by applicable law to administer such drug" certain information known as "labeling" for any prescription drug distributed or offered for sale in interstate commerce. A prescription is required for drugs which are habit forming, not safe for use except under the supervision of a practitioner licensed by law to administer the drug, and for "new drugs" being introduced.

If drugs are dispensed without a prescription, the drug will become misbranded, which triggers enforcement provisions under the Act. The Food, Drug, and Cosmetics Act has not been enforced so as to require a prescription when drugs are administered in surgical settings. The legislative history of the provisions on prescriptive drugs, adopted in 1951, makes clear that the purpose of the amendment was to protect the public from abuses in the sale of prescription drugs and not to create unnecessary administrative work.

The Controlled Substances Act

The second major act which applies to the administration of drugs, is the Controlled Substances Act (21 U.S.C. 801). The purpose of the Controlled Substances Act is to establish a convention which would reduce the danger of illegal distribution and use of "psychotropic substances." A provision of the Act expressly provides that the convention is not intended to interfere with ethical medical practices.

The Act is a comprehensive effort to limit and monitor persons whose access to controlled sub-

stances could result in the introduction of controlled substances in black markets and other illegal channels. "Practitioners" who "dispense" controlled substances are required to register with the Drug Enforcement Agency of the United States Attorney General's Office. The Act imposes an obligation on persons who are registered under the Act to provide effective controls and procedures to guard against theft and diversion of controlled substances. There are substantial recordkeeping requirements.

Although the Act requires that controlled substances may not be dispensed without a written prescription, no prescription is required for medication which is dispensed for immediate administration to an ultimate user (21 U.S.C. Section 829(a)). Consequently, the Controlled Substances Act does not require CRNAs who immediately administer drugs or "dispense directly" to obtain a prescription. This exemption is consistent with the purposes of the Act. The Act was designed to prevent controlled substances from passing from legal distribution methods into the black market. Drugs which are dispensed within a hospital or other institution are not likely to be siphoned off into the black market. Various other regulations issued pursuant to the Act also exempt individual practitioners from the prescription requirements for drugs which are administered or dispensed directly in the course of their professional practices.

CRNAs often obtain controlled substances from hospital pharmacies either for direct application to the patient or to be placed on a cart for subsequent application to the patient. Is medication placed on a cart exempt from the requirement of a prescription because it is "for immediate administration to an ultimate user"? The Act and the regulations contain no definition of "immediate administration," and there have been no decided cases which deal with the issue. The question of whether a drug is intended for "immediate administration" will be decided in reference to the purposes of the Act. The purpose of the Act is to reduce the danger of illegal distribution of controlled substances, not to interfere with ethical medical practices. Few drugs are administered without first being stored, even for brief periods of time, on a cart or otherwise. Given the purposes of the Act previously discussed, it seems clear that routine stocking of an anesthesia cart is an ethical medical practice which would be considered an "immediate administration" that does not require a prescription.

It is our analysis that neither of the federal acts requires CRNAs to obtain a prescription for drugs administered in a hospital setting. This conclusion is certainly not startling, but it is surprising how much confusion and misinformation exists. In the coming months, we look forward to exploring federal and state drug laws in more detail.