

Legal Briefs

Drug Enforcement Administration mid-level practitioner regulation

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The U.S. federal Drug Enforcement Administration published a final regulation on June 1, 1993, regarding registration of so-called mid-level practitioners (MLPs). The regulation requires an MLP who "dispenses" controlled substances to register with the DEA unless the MLP is exempt as an agent or employee of a DEA registrant such as a hospital or physician.

In a June 18, 1993, meeting with AANA representatives, the DEA assured the AANA that most nurse anesthetists (CRNAs) would not have to register with the DEA as they would typically be considered agents or employees of DEA registrants.

On the other hand, CRNAs who practice in the handful of states (e.g. New Hampshire) in which CRNAs have authority to prescribe controlled substances must register with the DEA as an MLP in order to exercise that authority-

A [summary](#) of the AANA's June 18, 1993, meeting with the DEA is below. The DEA has reviewed the summary and acknowledged that it is an accurate description of our meeting.

The summary sets forth the DEA's views concerning the MLP regulation's effect concerning CRNAs.

July 1992 DEA proposed regulations

On July 29, 1992, the DEA proposed new regulations creating the classification of "Mid-Level Practitioner (MLP) " An MLP was defined to mean an individual practitioner "other than a physician, dentist ... veterinarian.... or podiatrist, who is licensed, registered, or otherwise permitted in the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice."

The proposed MLP regulations applied to more practitioners than just those who prescribe a controlled substance. A mid-level practitioner is one authorized to "dispense" controlled substances. In the introduction that preceded the proposed MLP regulation, the DEA stated that "dispense" included *either* "prescribing" or "administering." In a previous version of the DEA, regulation, the DEA had acknowledged that nurse anesthetists, in their traditional areas of practice, did not typically "prescribe" within the meaning of federal law. However, nurse anesthetists administer controlled substances every day.

DEA regulations exempt from registration those MLPs who administer and dispense (other than by issuance of prescription) controlled substances as the agent or employee of another practitioner, other than an MLP, registered to dispense controlled substances. If a CRNA were not covered by this exemption, the CRNA seemingly would have to register with the DEA even if the CRNA merely administered controlled substances and did not "prescribe."

The DEA included a paragraph in the introduction to the regulations that specifically addressed CRNAs:

"It should be noted that practitioners in institutional settings who issue orders for medications for direct administration to a patient, such as nurse anesthetists in the normal course of their practice, are not prescribing within the meaning [of 21 CFR 1306.02(f)],¹ and would be exempt from registration. In that context, DEA neither requires nor encourages registration for MLPs acting as agents of other registrants."

The DEA's comment was based in part on language that the AANA suggested for an earlier version of the DEA regulation which would have required practitioners who prescribed to register. The thrust of the DEA's regulations changed so radically, however, from registration based on prescribing to registration based on dispensing which included administration that the AANA did not believe that the comment adequately addressed the position of CRNAs. The exemption for CRNAs seemed to be based on "agency" rather than the DEA's previous acknowledgment that CRNAs do not prescribe within the meaning of federal law.

Consequently, on September 25, 1992, the AANA submitted comments regarding the proposed DEA regulation. The AANA pointed out that the DEA had never previously required registration of those who administered and suggested that the DEA exempt from registration those practitioners who administer but do not prescribe (within the meaning of CFR 1306.02(f)) controlled substances. Alternatively, if the DEA was not willing to provide that those who merely administer should be exempt, the AANA asked the DEA to

clarify its exemption for agents and employees. The AANA pointed out that there were more than 2,400 CRNAs who identified themselves as independent contractors and who were not employees of hospitals or physicians.

In addition, the AANA objected to other provisions in the proposed regulation. The AANA felt that the phrase "mid-level practitioner" implied that these practitioners provided a different and presumptively lesser level of care than practitioners who were previously entitled to DEA registration. The AANA objected to the DEAs proposed requirement that MLPs who registered maintain protocols, practice guidelines, agreements, and other documents required by the state describing the conditions and extent of authorization to "dispense" controlled substances. Most states do not require such documentation and practitioners could have difficulty convincing a DEA inspector that they had authority to engage in long-accepted practices for which there might be little documentation available.

June 1993 DEA final regulation and AANA meeting with the DEA

The DEA revised the MLP regulations that were proposed July 29, 1992, and issued a final regulation on June 1, 1993. While some of the AANA's minor comments were accepted, the language of the draft regulations requiring registration of those who administer, not just those who prescribe, remained unchanged.

Regarding the AANA's concern about the status of independent contractors, the introduction to the regulations stated that:

"DEA cannot provide a general response regarding circumstances involving the conditions of specific contracts. In cases other than those in which the contract specifies the individual will act as an agent of the registrant, the exemption from the registration requirement will depend upon the specific conditions under which the individual will handle controlled substances."

CRNAs who act as independent contractors will rarely, if ever, have contracts that provide that the CRNA is an agent of a DEA registrant. What circumstances was the DEA looking for to find that CRNAs who are independent contractors were exempt from registration? The AANA requested a meeting with the DEA to find out; the results are described in the [summary](#) of the meeting in this article.

After reviewing the DEA's interpretation of its final MLP regulation, some might ask how an independent contractor can be an agent and therefore exempt from DEA registration for purposes of controlled substances utilization and yet still be an independent contractor for purposes of employment or negligence actions.

The answer is that a CRNA can be an "agent" for some purposes without being an "agent" for all purposes. As the summary of the AANA's meeting with the DEA indicates, if a CRNA who is otherwise an independent contractor is subject to whatever controls and procedures a DEA registrant² has adopted to guard against theft and diversion of controlled substances, the CRNA will be deemed an "agent" of the DEA registrant, avoiding the need to register as an MLP. However, just because the CRNA is subject to controls and procedures against theft of controlled substances and is deemed an "agent" by the DEA does not mean that the CRNA must be regarded as subject to the registrant's control concerning the administration of controlled substances for purposes of negligence law.

In most states, a person is liable for the negligence of another only if the person controlled the procedure that gave rise to the negligence. A hospital may require that anyone withdrawing drugs from the hospital pharmacy must follow certain procedures for signing out controlled substances, accounting for use, returning unused portions, and other matters relating to drug use. The hospital does not, however, have to control the manner in which a CRNA who is an independent contractor selects controlled substances, determines dosages, and physically administers them. Thus, the CRNA would be deemed an "agent" of a hospital for purposes of obtaining controlled substances but might not be the "agent" of the hospital in the area of malpractice liability.

At its June meeting with the AANA, the DEA was clear that very few CRNAs would have to register as MLPs. The AANA intends to continue its dialogue with the DEA to assure that the DEA's activities do not affect legitimate and well-accepted healthcare practices or unfairly restrict CRNA activities.

Complying with the DEA's new MLP regulation

Section 1301.24(b) of the DEA's regulations provides an exemption for:

"[A]n individual practitioner... who as an agent or employee of another practitioner (other than a mid-level practitioner) registered to dispense controlled substances may, when acting in the usual course of his/her employment, administer and dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he/she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself. (For example, a staff physician employed by a hospital need not be registered individually to administer and dispense, other than by prescribing, controlled substances within the hospital.)"

Consequently, if a CRNA does not prescribe, and if the CRNA is an agent or employee of a DEA registered practitioner (such as a hospital, an anesthesiologist or a surgeon) the CRNA does not have to register with the DEA as an MLP.

What about a CRNA who is an independent contractor and not an employee of a DEA registered practitioner? As long as the CRNA is subject to whatever controls and procedures a DEA registrant has adopted to guard against diversion of controlled substances, the CRNA will be deemed to be the agent of the DEA registrant and will be permitted to administer controlled substances without having to personally register. Because all DEA registrants are required by law to have such controls and procedures, the agency exemption

should apply to virtually all CRNA independent contractors. Both the AANA and the DEA believe that very few CRNAs will have to register with the DEA in order to continue practicing as they have been practicing.

For those CRNAs who either are not agents or employees of other DEA registrants, or have and utilize prescriptive authority for controlled substances under state law, registration will be required as an MLP. According to the DEA regulation, those MLPs who are now registered with the DEA will have their registrations converted to the MLP category by no later than December 31, 1993. The regulations provide that conversion will be accomplished by the assignment of a new registration number under the MLP format and the issuance of a new registration certificate. Upon receipt of their new certificates, MLPs will be required to return their old registration certificates to the DEA. The DEA has stated that it will give affected registrants advance notice of the conversion of their numbers. The authority of MLPs to handle controlled substances will not be affected by the conversion.

For those MLPs who register or whose registration is converted to MLP status, the new regulations require MLPs to:

"... maintain in a readily retrievable manner those documents required by the state in which he/she practices which describe the conditions and extent of his/her authorization to dispense controlled substances and shall make such documents available for inspection and copying by authorized employees of the [DEA]. Examples of such documentation include protocols, practice guidelines or practice agreements."

The DEA has not yet offered any advice on what documentation it expects regarding evidence of authority. When CRNAs are granted prescriptive authority in a state, the authority is likely to be clearly stated in the state's nurse practice act and/or board of nursing regulations. In a more traditional area of practice, such as administration of controlled substances, it is less clear what documentation would satisfy the DEA if a CRNA wanted to register with the DEA in connection with this activity alone. Some states merely recognize nurse anesthesia practice without specifically delineating CRNA scope of practice. The AANA is attempting to obtain clarification of this point from the DEA. However, if all a CRNA is doing is administering controlled substances, the lack of clarity in required documentation is one reason why it is hard to see any benefit in registration.

For those CRNAs who register, the registrant is required to provide effective controls and procedures to guard against theft and diversion of controlled substances. All controlled substances must be stored in a securely locked, substantially constructed cabinet, and no registrant may employ anyone who will have access to controlled substances if that person has had his or her application for registration denied or revoked. There are substantial reporting requirements. Biannual inventories must be taken, and extensive record keeping requirements exist for all controlled substances which are sorted or dispensed.

CRNAs who are merely engaging in traditional activities such as administration of controlled substances would not benefit from registering with the DEA. Registration would merely impose upon such CRNAs the obligation to maintain documentation and other requirements that the DEA is imposing on MLP registrants. In addition, CRNAs must understand that DEA registration does not confer upon the registrant authority beyond that granted by state law. For example, suppose a CRNA practices in a state that allows CRNAs to administer controlled substances but does not grant CRNAs prescriptive authority. While such a CRNA could register with the DEA, registration would not allow the CRNA to prescribe.

On the other hand, a CRNA who practices in a state that gives CRNAs authority to prescribe controlled substances (e.g., Alaska, New, Hampshire, and Montana) must register with the DEA to exercise that authority.

Footnotes

1. 21 CFR 1306.02(f) defines the term "prescription" as follows: "The term 'prescription' means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate use[r] (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription)"

2. A DEA registrant is not necessarily an individual. Hospitals and ambulatory surgery centers, for example, are typically DEA registrants. A nurse anesthetist in a hospital, therefore, would typically be acting as the hospital's agent regarding handling of controlled substances, rather than an individual physician.

Summary of Drug Enforcement Administration Mid-Level Practitioner Regulations

On June 18, 1993, representatives of the American Association of Nurse Anesthetists (AANA) met with the Drug Enforcement Administration (DEA) in Washington, DC and were assured that most Certified Registered Nurse Anesthetists (CRNAs) would be exempt from registration under the DEA's newly issued regulations concerning mid-level practitioners a (MLPs).

On June 1, 1993, the DEA published regulations in the *Federal Register* defining mid-level practitioners as "an individual practitioner other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice."

The DEA is defining "dispense" to include "administration," "prescribing" or both. Because almost every nurse anesthetist administers controlled substances, nurse anesthetists, even those who have no prescriptive authority, would be "mid-level practitioners" as that term is defined by the DEA. On the basis of past meetings with the DEA, the AANA believed that most nurse anesthetists would be exempt from registration because they were "agents" or "employees" of DEA registrants. However, the AANA was concerned about the status of CRNAs who are not employees of physicians or hospitals but act as "independent contractors," including those who work as *locum tenens* or moonlight. On June 18, 1993, AANA representatives met with the DEA in Washington, DC and were assured that most CRNAs would be exempt from the registration requirement as "agents" of DEA registrants even if their employment status was best described as being "independent contractors."

At the meeting, the DEA explained that the DEA's main responsibility in this area is to safeguard against the diversion of controlled substances. The DEA will treat CRNAs as "agents" of DEA registrants if the CRNAs are subject to whatever controls and procedures the particular DEA registrant has adopted to guard against diversion of controlled substances. Under existing DEA regulations, all DEA registrants are obligated to adopt these controls and procedures. The requirement can be found in 21 *CFR* 1301.71. DEA will not require additional controls or procedures for CRNAs to be considered agents of DEA registrants. Moreover, it will not be necessary for CRNAs to actually have contracts or particular terms in contracts to be considered agents and, therefore, exempt.

DEA has provided the following three examples illustrating whether or not CRNAs would be entitled to the exemption for employees and agents:

1. A CRNA is employed by a registrant, either a practitioner or a hospital/clinic, and in the normal course of employment, administers or dispenses controlled substances from the registrant's supplies. As an employee of a registrant acting in the normal course of employment, the CRNA would be exempt from the registration requirement.
2. A CRNA, other than as an employee of a registrant, is allowed by a registrant to administer or dispense controlled substances in the normal course of practice from the registrant's supplies. The CRNA is, for purposes of the regulations, an agent of the registrant and is not subject to the registration requirement.
3. A CRNA must individually obtain a personal supply of controlled substances from which he or she administers or dispenses. In this case, DEA registration is required because the individual is administering or dispensing controlled substances from personal supplies rather than from the supplies of another registrant.

The DEA stated that it did not intend to affect CRNA practice settings and that it expected very few CRNAs to have to register in order to continue practicing as they have been practicing. This interpretation is important because after July 1, 1993, practitioners who administer controlled substances (whether or not they have prescriptive authority) must be DEA registered unless they are exempt.

The new regulation also provides that the exemption for registration for employees or agents of DEA registrants would not be available for employees and agents of mid-level practitioners. The DEA confirmed that this regulation would not, for example, affect nurse anesthetists who write medication orders for hospital- or physician-employed nurses to administer. In these circumstances, the nurse administering the medication will continue to operate as the agent or employee of the DEA-registered hospital or physician not the CRNA. Thus, the adoption of the new regulation should not affect the ability of nurse anesthetists to continue to write orders for drugs to be administered by other nurses.

This summary of the meeting of June 18, 1993, has been reviewed by the representatives of the Drug Enforcement Administration with whom the AANA met, who have authorized the AANA to state that it constitutes a correct summary of our meeting and of the views of the staff of the Drug Enforcement Administration. July 1, 1993.

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