this rule effective within less than 30 days.

List of Subjects in 14 CFR Part 91

Air traffic control, Aircraft, Airmen, Airports, Aviation safety.

The Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends Chapter I of Title 14, Code of Federal Regulations, as follows:

PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 1. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(g), 1155, 40103, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180).

■ 2. Amend Appendix D to Part 91 by revising section 1 introductory text to read as follows:

Appendix D to Part 91—Airports/ Locations: Special Operating Restrictions

Section 1. Locations at which the requirements of § 91.215(b)(2) and § 91.225(d)(2) apply. The requirements of §§ 91.215(b)(2) and 91.225(d)(2) apply below 10,000 feet MSL within a 30-nautical-mile radius of each location in the following list.

* * * * *

Issued in Washington, DC, on October 1, 2010.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

[FR Doc. 2010–25102 Filed 10–5–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1306

[Docket No. DEA–339S]

Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Statement of policy.

SUMMARY: The Drug Enforcement Administration (DEA) is issuing this statement of policy to provide guidance under 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.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152; telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Legal Authority

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. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical, scientific, research, and industrial purposes and to deter the diversion of controlled substances to illegal purposes. Controlled substances are drugs that have a potential for abuse and dependence; these include substances classified as opioids, stimulants, depressants, hallucinogens, anabolic steroids, and drugs that are immediate precursors of these classes of substances. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity.

Background

Under longstanding Federal law, controlled substances are strictly regulated to ensure a sufficient supply for legitimate medical, scientific, research, and industrial purposes and to deter diversion of controlled substances to illegal purposes. The substances are regulated because of their potential for abuse and likelihood to cause dependence when abused and because of their serious and potentially unsafe nature if not used under proper circumstances. To minimize the likelihood that pharmaceutical controlled substances would be diverted into illicit channels, Congress established under the CSA a closed system of drug distribution for legitimate handlers of controlled substances. The foundation of this system is the concept of registration. The only persons who may lawfully manufacture, distribute and dispense controlled substances under the CSA are those who have obtained a DEA registration authorizing them to do so. 21 U.S.C. 822. Thus, the prescribing of controlled substances may be carried out only by those practitioners who have obtained a DEA registration authorizing such activity.

To be eligible for a DEA registration as a practitioner under the CSA, one must be a physician, dentist, veterinarian, hospital, or other person licensed, registered, or otherwise permitted by the United States or the State 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 to do so. The term "individual practitioner" excludes institutions such as hospitals, which are themselves DEA registrants and are permitted to administer and dispense, but not prescribe, controlled substances under their registration. 21 CFR 1300.01(b)(17).

By longstanding statutory requirement, a valid prescription issued by a DEA-registered practitioner is required for dispensing a controlled substance. To be effective (*i.e.,* valid), a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. *United States* v. *Moore,* 423 U.S. 122 (1975); 21 CFR 1306.04(a). Thus, the practitioner must determine that a prescription for a controlled substance is for a legitimate medical purpose. While the core responsibilities pertaining to prescribing controlled substances may not be delegated to anyone else, an individual practitioner may authorize an agent to perform a limited role in communicating such prescriptions to a pharmacy in order to make the prescription process more efficient. Nonetheless, it is important to understand that any agency relationship must also preserve the requirement that medical determinations to prescribe controlled substances be made by a practitioner only, not by an agent. Accordingly, this statement of policy outlines DEA's existing statutory and regulatory requirements as to the proper role of duly authorized agents of individual practitioners. DEA anticipates the utilization of electronic prescribing by practitioners for

controlled substance prescriptions will reduce the role of agents over time.

Medical Determination of Need for a Controlled Substance Prescription Cannot Be Delegated

DEA regulations state: "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 CFR 1306.04(a). Accordingly, the practitioner must determine that a prescription for a controlled substance is for a legitimate medical purpose. This determination is the sole responsibility of the practitioner and may not be delegated.

Elements of a Valid Prescription Must be Specified by the Practitioner and Cannot be Delegated

Controlled substance prescriptions are orders for medication to be dispensed to an ultimate user and are required to contain specific information including: Patient name, address, drug name and strength, quantity prescribed, directions for use, and the name, address and DEA number of the issuing practitioner. 21 CFR 1306.05(a). All prescriptions for controlled substances must be dated as of, and signed on, the day when issued. Paper prescriptions must be manually signed by the issuing practitioner in the same manner that the practitioner would sign a check or other legal document (21 CFR 1306.05(d)); electronic prescriptions for controlled substances must be signed in accordance with DEA regulations (21 CFR 1306.05(e), 21 CFR 1311.140).

The regulations provide that "[a] prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations." 21 CFR 1306.05(f). Accordingly, an authorized agent may prepare a controlled substance prescription only based on the instructions of the prescribing practitioner as to the required elements of a valid prescription and then provide the prescription to the practitioner to review. The authorized agent does not have the authority to make medical determinations. The practitioner must personally sign the prescription, whether manually or electronically. The prescribing practitioner cannot delegate his or her signature authority.

Role of Agent Under the CSA

As discussed above, the CSA does not permit a prescribing practitioner to delegate to an agent or any other person the practitioner's authority to issue a prescription for a controlled substance. A practitioner acting in the usual course of his or her professional practice must determine that there is a legitimate medical purpose for a controlled substance prescription; an agent may not make this determination. Even though the CSA established a closed system in which all persons in the distribution chain are required to be registered and are held accountable for every controlled substance transaction, Congress recognized a role for agents under the Act. The CSA exempts agents of registrants, including practitioners, from the requirement of registration. 21 U.S.C. 822(c)(1). 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. As explained below, 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.

Communication by Facsimile or Oral Communication of a Valid Prescription for a Schedule III, IV, or V Controlled Substance May be Delegated to an Authorized Agent

The CSA provides that a pharmacy may dispense Schedule III and IV controlled substances pursuant to a "written or oral prescription." 21 U.S.C. 829(b). DEA regulations further specify that a pharmacist may dispense a Schedule III, IV, or V controlled substance pursuant to "either a paper prescription signed by a practitioner [or] a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, * * *." 21 CFR 1306.21(a). Accordingly, an authorized agent may transmit such a practitioner-signed paper prescription via facsimile to the pharmacy on behalf of the practitioner.

Controlled substances in Schedules III, IV and V may also be dispensed by a pharmacy pursuant to "an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required [for a valid prescription], except for the signature of the practitioner." 21 CFR 1306.21(a). Under DEA regulations, an authorized agent may orally communicate such a prescription to a pharmacist. 21 CFR 1306.03(b). Where the pharmacist has reason to believe that a prescription has been communicated by an agent, the pharmacist, in accordance with his or her responsibility for proper dispensing of controlled substances, may have a duty to inquire into the legitimacy of the prescription. The particular circumstances will dictate the appropriate level of inquiry by the pharmacist. As noted above, the practitioner remains responsible for ensuring that the prescription conforms to the law and regulations, and the practitioner cannot delegate to an agent the authority to make a medical determination of need for a controlled substance prescription.

Generally, a Valid Schedule II Controlled Substance Prescription May Not be Communicated by Facsimile

Because Schedule II controlled substances have the highest potential for abuse and the greatest likelihood of dependence among the pharmaceutical controlled substances (those in Schedules II–V), the CSA controls on Schedule II drugs are the most restrictive. The CSA requires that a Schedule II controlled substance be dispensed by a pharmacy only pursuant to a written prescription, except in emergency situations, and prohibits Schedule II prescriptions from being refilled. 21 U.S.C. 829(a). Thus, in most cases, a pharmacist must receive the original, manually signed paper prescription or an electronic prescription prior to dispensing a Schedule II controlled substance. 21 CFR 1306.11(a).

A Valid Schedule II Controlled Substance Prescription For a Person in a Hospice or Long Term Care Facility (LTCF) May be Communicated by Facsimile and That Communication May be Delegated to an Authorized Agent

DEA regulations specify two exceptions whereby a Schedule II controlled substance prescription sent by facsimile may serve as the original written prescription. A practitioner or a practitioner's authorized agent may transmit a valid Schedule II controlled

substance prescription to a pharmacy via facsimile for: (1) Patients enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or hospice programs which are licensed by the State (21 CFR 1306.11(g)); and (2) residents of LTCFs (21 CFR 1306.11(f)). The facsimile serves as the original written prescription and must be maintained by the pharmacy as such. An authorized agent of the prescribing practitioner may transmit the practitioner-signed prescription by facsimile on behalf of the practitioner.

Emergency Oral Communication of a Valid Schedule II Controlled Substance Prescription May Not be Delegated to an Authorized Agent

The CSA contains an exception that allows a practitioner to issue oral prescriptions for Schedule II controlled substances in an emergency. 21 U.S.C. 829(a). An emergency for this purpose is defined by the Food and Drug Administration in 21 CFR 290.10. DEA regulations limit such an emergency oral prescription to the quantity necessary to treat the patient during the emergency period and require that it be followed up within 7 days by a practitioner-signed, written prescription to the dispensing pharmacy. 21 CFR 1306.11(d). Moreover, oral emergency prescriptions must immediately be reduced to writing by the pharmacist and must contain all the information ordinarily required in a prescription, except for the signature of the prescribing individual practitioner. If the prescribing individual practitioner is not known to the pharmacist, the pharmacist must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a call back to the prescribing individual practitioner and/or other good faith efforts to ensure the practitioner's identity. 21 CFR 1306.11(d). Because the more specific requirement that the emergency Schedule II oral authorization must be from a registered individual practitioner (21 CFR 1306.11(d)) supersedes the general rule that an employee or agent of the individual practitioner may communicate prescriptions to a pharmacist (21 CFR 1306.03(b)), the prescribing individual practitioner must personally communicate the emergency oral prescription to the pharmacist. An agent may not call in an oral prescription for a Schedule II controlled substance on behalf of a practitioner even in an emergency circumstance.

Pharmacist Dispensing a Controlled Substance Prescription Has a Duty To Fill Only Valid Prescriptions

Regardless of the method of transmission of a controlled substance prescription—by hand delivery, facsimile, phone call or electronically—DEA regulations make it clear that the legal responsibility for issuing a valid prescription that "conform[s] in all essential respects to the law and regulations" rests upon the prescribing practitioner. As noted, however, a pharmacist has a corresponding responsibility for the proper prescribing and dispensing of controlled substances. 21 CFR 1306.04(a). Further, "A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations." 21 CFR 1306.05(f). A pharmacist must carefully review all purported controlled substance prescriptions to ensure that the prescription meets all of the legal requirements for a valid prescription. The pharmacist has a duty to inquire further as to any question surrounding the satisfaction of any or all of the legal requirements for a valid prescription depending upon the particular circumstances, including the requirement that the prescription be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The pharmacist must be satisfied that the prescription is consistent with the CSA and DEA regulations before dispensing a controlled substance to the ultimate user.

Summary of the Acts That an Agent May Take in Connection With Controlled Substance Prescriptions

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.

Who Is an Agent of an Individual Practitioner for the Purpose of Communicating a Prescription for a Controlled Substance

The CSA 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). Under the CSA, the term "dispense" includes "prescribing." 21 U.S.C. 802(10). Establishment of an agency relationship, consistent with the CSA, is guided by general precepts of the common law of agency. For the purposes of explaining the law of agency as it relates to the CSA, it is appropriate to refer to and consider as generally applicable the Restatement of Agency (Restatement) which provides:

> Agency is the fiduciary relationship that arises when one person (a "principal") manifests assent to another person (an "agent") that the agent shall act on the principal's behalf and subject to the principal's control, and the agent manifests assent or otherwise consents so to act.
>
> Restatement (Third) of Agency § 1.01 (2006).

The Restatement is useful in evaluating whether, for CSA purposes, a valid agency relationship exists between a prescribing practitioner and another person for the purpose of communicating a prescription for a controlled substance to a pharmacy. The Restatement requires that the principal (in this context, the DEA-registered individual practitioner) "manifests assent" for a certain person to act on his or her behalf. This is consistent with the CSA and its registration-based system of accountability. Where non-DEA registrants communicate a prescription for a controlled substance on behalf of a registrant, it is important that such persons be clearly identified and their activities be subject to evaluation to ensure they do not exceed the bounds of the agency relationship and the legal limits of an agent's role under the CSA. Because the individual practitioner remains responsible for ensuring that all prescriptions issued pursuant to his or her DEA registration comply in all respects with the CSA and DEA regulations, it is important that the practitioner decide who may act as his

or her agent. This is also consistent with the CSA definition that an agent is "an authorized person who acts on behalf of or at the direction of" the prescribing individual practitioner. 21 U.S.C. 802(3).

In addition to requiring that the principal (*i.e.,* individual prescribing practitioner) "manifests assent" to having a particular person act as his or her agent, and that the agent reciprocate by manifesting assent to serve as such, the Restatement also requires that the agent acts "subject to the principal's control." In an employment situation, an individual practitioner may establish the duties of his or her employees and is responsible for monitoring their activities. Absent an employer-employee relationship, a practitioner will generally have less control over other persons that he or she may designate as his or her agent(s). Prior to designating an agent, a practitioner may wish to consider the degree of control that the registrant may exercise over the proposed agent, the proposed agent's licensure, level of training and experience, and other such factors to determine whether the person would be an appropriate agent and to ensure that the agent will not engage in activities that exceed the scope of the agency relationship. Absent affirmative actions by the practitioner and the proposed agent, a valid agency relationship generally will not exist outside an employer-employee relationship.

By requiring that an agency relationship is created when (1) the principal manifests assent that a particular person 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 Restatement 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.

DEA notes that in a 2001 notice and solicitation of information on the potential use of automated dispensing systems to prevent the accumulation of surplus controlled substances at LTCFs, DEA briefly discussed the role of nurses in the narrow setting of LTCFs outside of an employer-employee relationship and where no affirmative actions established an agency relationship between the individual practitioner and the LTCF nurse. 66 FR 20833, 20834 (April 25, 2001). This incidental example and other informal discussions have resulted in the need for this published articulation of what existing law allows and what affirmative actions may be required to establish a valid agency relationship for purposes of an authorized agent to communicate controlled substance prescriptions to pharmacies, particularly in settings where there is no employer-employee relationship. DEA regulations on the role of authorized agents in communicating controlled substance prescriptions to pharmacies generally have not changed.

This policy statement outlines the proper role of agents in those situations where an individual practitioner and an individual agent (including but not limited to an LTCF nurse) have taken affirmative steps to establish a valid agency relationship for those aspects of the CSA that may be appropriately executed by an authorized agent under Federal law. As such, DEA is hereby outlining a suggested mechanism to establish a valid agency relationship as well as explaining the appropriate roles an authorized agent may play regardless of the setting. This statement of policy is intended to provide general guidance on establishment of a valid agency relationship between an individual practitioner and an identified individual. DEA wishes to emphasize that, regardless of the setting, it is the practitioner's sole decision as to whether or not to designate an agent to act on his or her behalf and subject to his or her control. To be consistent with the purpose of the CSA to implement a "closed system" of distribution and for DEA to enforce this framework, an agency relationship between a registered individual practitioner and an identified agent for the purposes of communicating controlled substance prescriptions must be explicit and transparent. DEA believes its existing regulations are adequate in addressing the role of an authorized agent but will analyze whether additional federal rulemaking or guidance is needed beyond this statement to establish the necessary explicit and transparent nature of an authorized agency relationship, particularly when outside an employer-employee relationship.

Written Authorization of an Agent Recommended—Sample Agency Agreement

Due to the legal responsibilities of practitioners and pharmacists under the CSA and the potential harm to the public from inappropriate and unlawful prescribing and dispensing of controlled substances, violations of the law are subject to criminal, civil, and administrative sanctions. DEA believes it is in the best interests of the practitioner, the agent, and the dispensing pharmacist that the designation of those persons authorized to act on behalf of the practitioner and the scope of any such authorization be reduced to writing.

DEA provides below an example of a written agreement that would properly confer authority to an agent to act on behalf of an individual practitioner with regard to controlled substance prescriptions. Individual practitioners may choose to designate and authorize one or more persons at one or more locations within or outside their practice to act as their agent. Likewise, an individual may act as an authorized agent for multiple individual practitioners depending upon the circumstances. A practitioner may or may not wish to delegate all of these types of authorized communications to a particular agent and may tailor the agreement accordingly. The agreement should be clear that the agent may not further delegate the outlined responsibilities.

Designating Agent of Practitioner For Communicating Controlled Substance Prescriptions to Pharmacies

_____

(Name of registered individual practitioner)

_____

(Address as it appears on certificate of registration) _____

_____

(DEA registration number)

I, _____ (name of registrant), the undersigned, who is authorized to dispense (including prescribe) controlled substances in Schedules II, III, IV, and V under the Controlled Substances Act, hereby authorize_____ (name of agent), to act as my agent only for the following limited purposes:

1. To prepare, for my signature, written prescriptions for controlled substances in those instances where I have expressly directed the agent to do so and where I have specified to the agent the required elements of the prescription (set forth in 21 CFR 1306.05).

2. To convey to a pharmacist by telephone oral prescriptions for controlled substances in Schedules III, IV, and V in those instances where I have expressly directed the agent to do so and where I have specified to the agent the required elements of the prescription (set forth in 21 CFR 1306.05).

3. To transmit by facsimile to a pharmacy prescriptions for controlled

substances in those instances where I have expressly directed the agent to do so and where I have specified to the agent the required elements of the prescription (set forth in 21 CFR 1306.05) and I have signed the prescription.

This authorization is not subject to further delegation to other persons. Both the undersigned DEA-registered individual practitioner and the undersigned agent understand and agree that the practitioner is solely responsible for making all medical determinations relating to prescriptions for controlled substances communicated by the agent pursuant to this agreement, and for ensuring that all such prescriptions conform in all other essential respects to the law and regulations.

The undersigned agent understands he or she does not have authority to make any medical determinations. The undersigned DEA-registered prescribing practitioner further understands that the prescribing practitioner must personally communicate all Schedule II emergency oral prescriptions to the pharmacist. Both the undersigned practitioner and agent understand that the agent may not call in an emergency oral prescription for a Schedule II controlled substance on behalf of the practitioner.

This agency agreement shall be terminated immediately if and when any of the following occur:

1. The undersigned practitioner no longer possesses the active DEA registration specified in this agreement.

2. The undersigned agent is no longer employed in the manner described in this agreement.

3. The practitioner or the agent revokes this agency agreement by completing the revocation section at the end of this document or by executing a written document that is substantially similar to the revocation section at the end of this document.

_____

(Signature of practitioner)

I, _____ (name of agent), hereby affirm that I am the person named herein as agent and that the signature affixed hereto is my signature. I further affirm that I am a _____ (title), licensed in the State of _____, (where applicable) and (if applicable) am employed by/under contract with _____ (name of employer or contracting entity). I agree to abide by all the terms of this agreement and to comply with all applicable laws and regulations relating to controlled substances.

_____

(Signature of agent)

_____

(State license number of agent where applicable)

_____

(Name of employer/contracting entity where applicable)

_____

(Address of employer/contracting entity where applicable)

Witnesses:

1._____

2._____

Signed and dated on the _____ day of _____ (month) _____, (year), at _____.

Revocation

The foregoing agency agreement is hereby revoked by the undersigned. The agent is no longer authorized to communicate Schedule II, III, IV and V controlled substance prescriptions to a pharmacy on my behalf. A copy of this revocation has been given to the agent this same day.

_____

(Signature of registered practitioner revoking power)

Witnesses:

1. _____

2. _____

Signed and dated on the _____day of _____(month)_____, (year), at _____.

DEA recommends that the original signed agency agreement be kept by the practitioner during the term of the agency relationship and for a reasonable period after termination or revocation. DEA requires that inventory and other records be kept for at least two years (21 U.S.C. 827(b), 21 U.S.C. 828(c), 21 CFR 1304.04). This is simply a suggested time period for retention of agency agreements and is not required by DEA. A signed copy should also be provided to the practitioner's designated agent, the agent's employer (if other than the practitioner), and any pharmacies that regularly receive communications from the agent pursuant to the agreement. Providing a copy to pharmacies likely to receive prescriptions from the agent on the practitioner's behalf may assist those pharmacies with their corresponding responsibility regarding the dispensing of controlled substances. It is important to reiterate that a pharmacist always has a corresponding responsibility to ensure that a controlled substance prescription conforms with the law and regulations, including the requirement that the prescription be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, and a corresponding liability if a prescription is not prepared or dispensed in a manner consistent with the CSA or DEA regulations. Even where the pharmacist has a copy of an agency agreement, the pharmacist may also have a duty to inquire further depending upon the particular circumstances. Because the agency agreement may be revoked at any time by the practitioner or by the agent, the party terminating the agreement should notify the other party immediately upon termination. The practitioner should notify those pharmacies that were originally made aware of the agency agreement of the termination of that agreement. In most circumstances where an agent changes employment, the agreement should be revoked.

Dated: October 1, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 2010–25136 Filed 10–5–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 323

[Docket ID DOD–2010–OS–0139]

Privacy Act of 1974; Implementation

AGENCY: Defense Logistics Agency; DoD.

ACTION: Final rule; request for comments.

SUMMARY: The Defense Logistics Agency is revising two exemption rules. The exemption rule for S100.10 entitled "Whistleblower Complaint and Investigative Files" is being deleted in its entirety and the exemption rule system identifier for the "Incident Investigation/Police Inquiry Files" system of records is being revised.

DATES: The rule will be effective on December 6, 2010, unless comments are received that would result in a contrary determination.

Comments will be accepted on or before December 6, 2010.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Room 3C843, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy