Appendix: Basic Commission Enforcement Procedure

The Commission's enforcement procedures are set forth at 11 CFR part 111. An enforcement matter may be initiated by a complaint or on the basis of information ascertained by the Commission in the normal course of carrying out its supervisory responsibilities. 11 CFR 111.3. If a complaint substantially complies with certain requirements set forth in 11 CFR 111.4, within five days of receipt the Office of General Counsel notifies each party determined to be a respondent that a complaint has been filed, provides a copy of the complaint, and advises each respondent of Commission compliance procedures. 11 CFR 111.5. A respondent then has 15 days from receipt of the notification from the Office of General Counsel to submit a letter or memorandum to the Commission setting forth reasons why the Commission should take no action on the basis of the complaint. 11 CFR 111.6.

Following receipt of such letter or memorandum, or expiration of the 15-day period, the Office of General Counsel may recommend to the Commission whether or not it should find ''reason to believe'' that a respondent has committed or is about to commit a violation of the Act or Commission regulations. 11 CFR 111.7(a).[4] With respect to internally-generated matters (*e.g.*, referrals from the Commission's Audit or Reports Analysis Divisions), the Office of General Counsel may recommend that the Commission find ''reason to believe'' that a respondent has committed or is about to commit a violation of the Act or Commission regulations on the basis of information ascertained by the Commission in the normal course of carrying out its supervisory responsibilities, or on the basis of a referral from an agency of the United States or any state. If the Commission determines by an affirmative vote of four members that it has ''reason to believe'' that a respondent violated the Act or Commission regulations, the respondent must be notified by letter of the Commission's finding(s). 11 CFR 111.9(a).[5] The Office of General Counsel will also provide the respondent with a Factual and Legal Analysis, which will set forth the bases for the Commission's finding of reason to believe.

After the Commission makes a ''reason to believe'' finding, an investigation is conducted by the Office of General Counsel, in which the Commission may undertake field investigations, audits, and other methods of information-gathering. 11 CFR 111.10. Additionally, the Commission may issue subpoenas to order any person to submit sworn written answers to written questions, to provide documents, or to appear for a deposition. 11 CFR 111.11–111.12. Any person who is subpoenaed may submit a motion to the Commission for it to be quashed or modified. 11 CFR 111.15.

Following a ''reason to believe'' finding, the Commission may attempt to reach a conciliation agreement with the respondent(s) prior to reaching the ''probable cause'' stage of enforcement (i.e., a pre-probable cause conciliation agreement). See 11 CFR 111.18(d). If the Commission is unable to reach a pre-probable cause conciliation agreement with the respondent, or determines that such a conciliation agreement would not be appropriate, upon completion of the investigation referenced in the preceding paragraph, the Office of General Counsel prepares a brief setting forth its position on the factual and legal issues of the matter and containing a recommendation on whether or not the Commission should find ''probable cause to believe'' that a violation has occurred or is about to occur. 11 CFR 111.16(a).

The Office of General Counsel notifies the respondent(s) of this recommendation and provides a copy of the probable cause brief. 11 CFR 111.16(b). The respondent(s) may file a written response to the probable cause brief within fifteen days of receiving said brief. 11 CFR 111.16(c). After reviewing this response, the Office of General Counsel shall advise the Commission in writing whether it intends to proceed with the recommendation or to withdraw the recommendation from Commission consideration. 11 CFR 111.16(d).

If the Commission determines by an affirmative vote of four members that there is ''probable cause to believe'' that a respondent has violated the Act or Commission regulations, the Commission authorizes the Office of General Counsel to notify the respondent by letter of this determination. 11 CFR 111.17(a). Upon a Commission finding of ''probable cause to believe,'' the Commission must attempt to reach a conciliation agreement with the respondent. 11 CFR 111.18(a). If no conciliation agreement is finalized within the time period specified in 11 CFR 111.18(c), the Office of General Counsel may recommend to the Commission that it authorize a civil action for relief in the appropriate court. 11 CFR 111.19(a). Commencement of such civil action requires an affirmative vote of four members of the Commission. 11 CFR 111.19(b). The Commission may enter into a conciliation agreement with respondent after authorizing a civil action. 11 CFR 111.19(c).

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[4] The Office of General Counsel may also recommend that the Commission find no ''reason to believe'' that a violation has been committed to is about to be committed, or that the Commission otherwise dismiss a complaint without regard to the provisions of 11 CFR 111.6(a). 11 CFR 111.7(b).

[5] If the Commission finds no ''reason to believe,'' or otherwise terminates its proceedings, the Office of General Counsel shall advise the complainant and respondent(s) by letter. 11 CFR 111.9(b).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1306

[Docket No. DEA–287F]

RIN 1117–AB01

Issuance of Multiple Prescriptions for Schedule II Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Department of Justice

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is finalizing a Notice of Proposed Rulemaking published on September 6, 2006 (71 FR 52724). In that document, DEA proposed to amend its regulations to allow practitioners to provide individual patients with multiple prescriptions, to be filled sequentially, for the same schedule II controlled substance, with such multiple prescriptions having the combined effect of allowing a patient to receive over time up to a 90-day supply of that controlled substance.

DATES: *Effective Date:* This rule is effective December 19, 2007.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Background

On September 6, 2006, the Drug Enforcement Administration (DEA) published in the **Federal Register** a Notice of Proposed Rulemaking (NPRM) (71 FR 52724) proposing to amend its regulations to allow practitioners to provide individual patients with multiple prescriptions, to be filled sequentially, for the same schedule II controlled substance, with such multiple prescriptions having the combined effect of allowing a patient to receive over time up to a 90-day supply of that controlled substance.

Comments Received

DEA received 264 comments regarding the NPRM. Two hundred thirty-one commenters supported the NPRM, 33 commenters opposed the rulemaking. Commenters supporting the NPRM included six physician associations, including those representing anesthesiologists, pediatricians, and psychiatrists, and three state level licensing organizations;

five nursing associations, including several nursing specialty associations; 3 pharmacy associations and 6 state boards of pharmacy; 17 organizations focusing on the treatment of pain and end of life issues; 8 other organizations; and individual commenters including 73 pain patients, 65 physicians or physicians' offices, 31 parents of children with attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD), 30 individual citizens, 16 pharmacists, 5 nurses, and 2 physician's assistants. Commenters opposing the NPRM included 1 organization focusing on the treatment of pain; 17 individual citizens; 8 physicians; 3 pharmacists or pharmacy workers; 2 parents of pain patients; 1 nurse; and 1 physician's assistant.

The vast majority of commenters supported the rulemaking as proposed, although some commenters suggested various changes or requested clarification of certain issues. DEA has carefully considered all comments received. An in-depth discussion of the issues raised by commenters and DEA's responses to those comments follows.

Discussion of Comments

Of the 264 comments DEA received, 166 expressed approval of the proposed rule without change. The remainder of the comments either objected to the proposed rule or suggested modifications thereto. The major issues raised by the commenters are addressed below.

Comments expressing approval of the proposed rule without change: Commenters who expressed support for this rule represented a broad variety of interest groups, medical professionals, pharmacists, and patients. General comments regarding the support for this rule and the benefits commenters believed it will have appear below.

Patients being treated for pain: Commenters who described themselves as patients who receive controlled substances for the treatment of pain were very supportive of implementation of the rule as proposed. These commenters noted that the allowance for multiple prescriptions would reduce the number of visits they would need to make to practitioners, which would be beneficial financially. Many of these patients indicated they are unemployed or underemployed due to their medical conditions, and each additional visit to practitioners for the purpose of receiving another prescription takes a financial toll on them.

Among the patients who commented in support of the rule were those who indicated that they live in rural areas. These commenters explained that, currently, they must either drive to their practitioners, which is difficult for them, or must find someone to drive them because they cannot drive themselves due to their condition. They noted that arranging rides is often difficult and that the drive to a practitioner may be several hours each way. Some also stated that the trip is expensive and that the length of the trip exacerbates their conditions. According to these commenters, implementation of the proposed rule would enable them to visit their prescribing practitioners less frequently, thereby lessening the foregoing difficulties.

Parents of children receiving controlled substances: Commenters who described themselves as parents of children with ADD or ADHD welcomed the proposed rule. In their view, if the proposed rule is implemented, they no longer will have to take their children to their prescribing practitioners every month. As a result, they indicated they will be able to take less time off from work and their children will have fewer absences from school. Many of these commenters also noted that having to make monthly visits to practitioners is especially burdensome to single parents. These commenters also identified reduced costs as a reason for their support of the proposed rule.

Prescribing practitioners: Commenters who identified themselves as practitioners who prescribe controlled substances were, for the most part, strongly supportive of the proposed rule. Many of these commenters expressed the view that allowing the issuance of multiple sequential prescriptions for schedule II controlled substances will drastically reduce the work of the practitioners' offices and free up valuable practitioner-patient time. Many also expressed the view that for some of their patients whom they characterized as ''stable'' (including certain patients with chronic pain and ADD or ADHD), they believe there is no medical need to see such patients every month. In such cases, some of these commenters added they believe having to make monthly visits to the practitioner is a hardship to patients who are already suffering. It should be noted that some commenters who identified themselves as practitioners expressed a sharply contrasting view, asserting that patients who receive schedule II controlled substances should be seen in person at least once a month to ensure proper medical supervision and to lessen the likelihood of drug addiction and abuse. This latter perspective of some commenting practitioners is addressed further below.

Pharmacists: Commenters who identified themselves as pharmacists were, for the most part, supportive of the proposed rule. These commenters stated that issuing multiple prescriptions for sequential filling for schedule II controlled substances would reduce the quantity of those controlled substances dispensed to a patient at any one time. They argued that this reduced quantity could reduce the potential for abuse or diversion of these controlled substances. Some pharmacists indicated they would be more comfortable dispensing these prescriptions because of the more limited quantities dispensed.

90-day supply at one time: Sixteen commenters who supported the NPRM, and six commenters who disagreed with the NPRM, believed that the entire 90-day supply of controlled substances was available at one time instead of in sequential prescriptions. Commenters who supported the rule but believed that DEA is advocating the dispensing of a 90-day supply of controlled substances at one time cited the ease of filling prescriptions and obtaining reimbursement as reasons for their support. Those who objected to the rule on this ground believed it would be more difficult to monitor patients.

DEA response: In view of these comments, DEA wishes to make clear that the NPRM did *not* advocate that physicians prescribe a 90-day supply of controlled substances with a single prescription. Rather, the NPRM stated that if a physician determines it is medically appropriate to issue multiple schedule II prescriptions, the physician may provide for up to a 90-day supply through the use of multiple schedule II prescriptions under the conditions specified in the proposed rule.

As to the comment that DEA should allow multiple schedule II prescriptions for unlimited days' worth of schedule II controlled substances, as DEA explained in the NPRM, for the proposed rule to be legally permissible, it must be consistent with the text, structure, and purposes of the Controlled Substances Act (CSA). In this regard, 21 U.S.C. 829(a) states: ''No prescription for a controlled substance in schedule II may be refilled.'' By comparison, subsection 829(b) states that, for a schedule III or IV controlled substance, a prescription may be refilled up to five times within six months after the date the prescription was issued. Thus, Congress clearly mandated greater prescription controls for schedule II substances than for schedule III and IV substances. For example, a physician may—consistent with the statute—issue a prescription for a schedule III or IV controlled

substance and indicate on the prescription a certain number of refills. In this manner, a physician may provide a patient with up to a six-month supply of a schedule III or IV controlled substance with a single prescription indicating five refills. The same cannot be done with a schedule II controlled substance since section 829(a) prohibits refills. The statute requires a separate prescription if the physician wishes to authorize a continuation of the patient's use of a schedule II drug beyond the amount specified on the first prescription. Thus, if DEA were to allow multiple prescriptions for an unlimited days' worth of schedule II controlled substances, the controls for prescribing schedule II controlled substances would be less stringent than for schedule III and IV controlled substances—a result that would conflict with the purpose and structure of the CSA. DEA believes that the 90-day limit, under the terms specified in the proposed rule, strikes a fair balance that takes into account the limitation imposed by Congress under section 829 as well as the general structure of the statute, which imposes greater controls for schedule II substances than those in lower schedules.

Sequential filling of prescriptions, ''refills'': One commenter opposed the NPRM because the commenter believed that sequential prescriptions were ''refills'' which are not permitted by law. Two commenters suggested writing all sequential prescriptions, which the commenters referred to as ''refills,'' on one prescription. They believed this would prevent the patient from changing the dates or using multiple pharmacies to fill the prescriptions. Commenters also believed this would eliminate the possibility of the patient claiming that the original prescription had been lost and requesting replacement prescriptions. Two commenters recommended allowing 90-day sequential prescriptions on one prescription blank, but allowing the practitioner to prescribe the intervals at which it would be filled, rather than only permitting 30-day interval sequential fillings.

One commenter suggested writing a single prescription with two ''refills'' with the annotation ''Do not fill more frequently than once a month.'' One commenter suggested permitting not more than two ''refills'' of a schedule II prescription, but requiring the use of triplicate prescription blanks with one copy being sent to the state and the second copy being sent to DEA. The commenter then suggested that if a practitioner chose not to agree to this system, then the practitioner would not be permitted to sequentially prescribe any schedule II prescription. The commenter believed that this system would prevent theft and loss.

DEA response: As discussed above, DEA believes that the proposed rule takes into account the CSA prohibition on refilling prescriptions for schedule II controlled substances in a manner consistent with the overall framework of the Act. The use of multiple prescriptions for the dispensing of schedule II controlled substances, under the conditions set forth in this Final Rule, ensures that the prescriptions are treated as separate dispensing documents, not refills of an original prescription. As this Final Rule indicates, each separate prescription must be written for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, and the practitioner must provide written instructions on each separate prescription regarding the filling of that prescription.

Regarding the comment that suggested allowing the writing of a single prescription with two ''refills'' with the annotation ''Do not fill more frequently than once a month,'' this would conflict with the CSA, which, as explained above, disallows the refilling of schedule II prescriptions. As indicated in this Final Rule, when issuing multiple prescriptions for a schedule II controlled substance, each of the prescriptions to be filled sequentially must be written on a separate prescription blank and must contain the information specified in this Final Rule.

As for the suggestion that DEA require the use of triplicate prescription blanks, DEA has never required triplicate prescription blanks for prescriptions and believes, at this time, that the requirements contained in this Final Rule provide adequate safeguards against diversion, which render unnecessary the use of triplicate prescription blanks. However, as with all newly promulgated regulations, DEA will continue to monitor the situation to determine whether additional modifications are needed to safeguard against diversion. DEA recognizes that some states require the use of triplicate prescriptions for some or all controlled substances. DEA supports the efforts of states to take the specific action they deem necessary to prevent the diversion of controlled substances within their jurisdictions. This Final Rule expressly requires practitioners to comply with all applicable provisions of state law when issuing multiple schedule II prescriptions.

Federal law and schedule II controlled substances: Five commenters requested written clarification that this rule is not intended to change existing Federal law which does not limit the length of time for which an individual prescription may be written or the total quantity, including the number of dosage units, that may be prescribed at one time. Further, two commenters suggested that DEA state, in the Final Rule, that federal law does not address how frequently a practitioner must see his patient, and that it remains within the practitioner's reasonable medical judgment as to how frequently the practitioner sees a patient.

Commenters requested that DEA clarify that the practitioner is not required to see the patient every 30 days or at the end of 90 days. One commenter requested that DEA clarify whether a practitioner is required to see a patient after 90 days. Alternatively, the commenter inquired as to whether the practitioner is permitted to write a new prescription with ''Do not fill until'' and mail it to the patient or have the patient pick it up if, in the prescribing practitioner's medical judgment, the patient does not need to see the practitioner. One commenter recommended DEA clarify whether it is DEA's intent to limit any schedule II controlled substance prescription to only a 90-day supply or, alternatively, to limit sequential schedule II prescriptions written on the same day to a 90-day supply. One commenter requested clarification as to whether the regulation limits the supply to 90 days when only a single schedule II controlled substance prescription is issued.

DEA response: As the NPRM made clear, the proposed rule in no way changes longstanding federal law governing the issuance of prescriptions for controlled substances. As stated in the NPRM: ''What is required, in each instance where a physician issues a prescription for any controlled substance, is that the physician properly determine there is a legitimate medical purpose for the patient to be prescribed that controlled substance and that the physician be acting in the usual course of professional practice.'' (71 FR 52725, September 6, 2006). Further, this Final Rule itself contains the following statement:

> Nothing in this subsection shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue

multiple prescriptions and how often to see their patients when doing so.

In addition, in the August 26, 2005, ''Clarification of Existing Requirements Under the Controlled Substances Act for Prescribing Controlled Substances'' (70 FR 50408), DEA stated the following:

> The CSA and DEA regulations contain no specific limit on the number of days worth of a schedule II controlled substance that a physician may authorize per prescription. Some states, however, do impose specific limits on the amount of a schedule II controlled substance that may be prescribed. Any limitations imposed by state law apply in addition to the corresponding requirements under Federal law, so long as the state requirements do not conflict with or contravene the Federal requirements. 21 U.S.C. 903. Again, the essential requirement under Federal law is that the prescription for a controlled substance be issued for a legitimate medical purpose in the usual course of professional practice. In addition, physicians and pharmacies have a duty as DEA registrants to ensure that their prescribing and dispensing of controlled substances occur in a manner consistent with effective controls against diversion and misuse, taking into account the nature of the drug being prescribed. 21 U.S.C. 823(f).

This Final Rule does not change any of the foregoing principles of the CSA and DEA regulations.

Effective date of prescription: Two commenters requested that DEA clarify the effective date of a sequential prescription for a schedule II controlled substance. Some commenters pointed out that some states stipulate ''effective dates'' for prescriptions, noting that these states have laws which require that, to be valid, prescriptions must be filled within a certain time after they are written, and that these time limits differ by state. Some commenters noted that if the time limit starts on the date all the sequential prescriptions are written, then it cannot be used in some states. If the effective date starts on the ''Do not fill until'' date on the second and third prescriptions, then it will be valid in many more states.

Three commenters requested clarification as to whether it is legally permissible for a practitioner to issue a *single* prescription with ''Do not fill before [date],'' in which the ''Do not fill'' date is, for example, 7–10 days in the future.

DEA response: Neither the CSA nor the DEA regulations use the term ''effective date'' for a prescription. The DEA regulations require that all prescriptions for controlled substances ''be dated as of, and signed on, the day when issued.'' 21 CFR 1306.05(a). This Final Rule does not amend the regulations regarding the date of issuance of a prescription.

Under longstanding federal law and DEA regulations, there is no express requirement that a prescription be filled within a certain time after it was issued. The proposed rule likewise contained no such express requirement, as DEA believes that the requirements contained in the proposed rule provided adequate safeguards against diversion. At the same time, the proposed rule made clear that the issuance of multiple prescriptions is permissible only if ''the individual practitioner complies fully with all other applicable requirements under the [CSA] and [DEA] regulations as well as any additional requirements under state law.'' (71 FR 52726). To make this point unambiguous, the NPRM also stated that ''nothing in this proposed rule changes the requirement that physicians must also abide by the laws of the states in which they practice and any additional requirements imposed by their state medical boards with respect to proper prescribing practices and what constitutes a bona fide physician-patient relationship.'' (71 FR 52725).

The proposed rule did not address whether a *single* prescription with ''Do not fill before [date]'' instructions is permissible. Nor does any existing provision of the CSA or DEA regulations address this type of prescribing. Accordingly, there is no prohibition on doing so under the CSA or DEA regulations, provided the practitioner otherwise complies fully with all applicable requirements of federal and state law.

Insurance reimbursement considerations: Four commenters requested further relaxation of the regulations to allow a 90-day supply of schedule II controlled substances to be dispensed *at one time* because, these commenters asserted, this would significantly decrease the cost of the medications to the patients through their health insurance. One commenter also recommended permitting the pharmacy to dispense a 90-day supply on one prescription, making it available in 30-day intervals, but allowing the patient to pay for the entire supply at one time to save on the cost of the medication.

DEA response: It is beyond the scope of DEA's authority under the CSA to take regulatory action for the specific purpose of affecting the manner in which patients pay for the medications or the manner in which insurance providers reimburse patients for such costs. As mentioned previously, the CSA and DEA regulations contain no specific limit on the number of days' worth of a schedule II controlled substance that a practitioner may authorize per prescription.

Limitations regarding certain medications: Three commenters supported the use of sequential prescriptions specifically for schedule II controlled substances used to treat ADD or ADHD, but disagreed with the use of sequential prescriptions for schedule II controlled substances used in the treatment of pain. Commenters believed pain patients should be seen and evaluated every 30 days and have medications prescribed at that time. One commenter requested that DEA include explicit language indicating that this regulation is applicable to all patients being treated for ADHD with stimulant medications.

Conversely, one commenter supported the use of sequential prescriptions only for narcotic schedule II controlled substances, or pain medications.

Another commenter suggested rescheduling methylphenidate and amphetamines, except methamphetamine, to separate them from pain medications because the two populations for ADHD medications and pain medications are different.

DEA response: This rule pertains to all schedule II controlled substances, not just those substances intended or approved to treat certain conditions. As DEA stated in the September 6, 2006, Policy Statement published in conjunction with the Notice of Proposed Rulemaking (71 FR 52716), it is certainly appropriate for prescribing practitioners and medical oversight boards to explore questions regarding appropriate treatment regimens for particular categories of controlled substances. Moreover, it might indeed be beneficial toward preventing diversion and abuse of controlled substances for prescribing practitioners to see patients at regular intervals when prescribing certain controlled substances for certain medical conditions. However, as the Policy Statement made clear, DEA does not regulate the general practice of medicine and the agency lacks the authority to issue guidelines that constitute advice on the general practice of medicine. DEA wishes to reiterate the general principle that the prescribing practitioner must properly determine there is a legitimate medical purpose for the patient to be prescribed the controlled substance and must be acting in the usual course of professional practice. Similarly, a pharmacy has a corresponding responsibility in this regard.

Regarding the comment suggesting the rescheduling of certain schedule II

controlled substances based on the conditions and populations which they are intended to treat, DEA notes that scheduling of controlled substances is based on scientific determinations regarding the substance's potential for abuse, its potential for psychological and physical dependence, and whether the substance has a currently accepted medical use in treatment in the United States (21 U.S.C. 812(b)). DEA may not reschedule a substance merely based on the population it is intended or approved to treat.

Language on sequential prescriptions: Two commenters suggested not limiting the language on the prescription to ''Do not fill before [date].'' These commenters suggested other alternatives including ''Do not fill until xx/xx/xxxx,'' and ''Fill on xx/xx/xxxx.'' Five commenters requested that DEA provide examples of acceptable language in the Final Rule. One commenter suggested requiring a standardized method for dating prescriptions, and considering prescriptions void if that standard is not adhered to. Another commenter recommended that specific indication should be provided regarding sequential prescriptions by including ''1 of 3,'' ''2 of 3,'' and ''3 of 3'' on the prescriptions.

DEA response: The Final Rule states that the individual practitioner must ''[provide] written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription.'' The commenters have correctly observed that this provision does not mandate that the practitioner use any particular language in the instructions on the sequential prescriptions, so long as such instructions make clear what is the earliest date on which the pharmacy may fill each prescription. DEA believes this is a sufficiently clear rule that practitioners will be able to understand and carry it out and, therefore, it is unnecessary to insist on a particular scripted approach. Likewise, under this Final Rule, a practitioner may—but is not required to—do as the commenter suggested and write on the sequential prescriptions, ''1 of 3,'' ''2 of 3,'' and ''3 of 3'', so long as each prescription complies fully with all the requirements of this Final Rule, including that it contains specific instructions regarding the earliest date on which the sequential prescription may be filled.

One commenter recommended that the practitioner write in his/her own handwriting in blue ink ''Do not fill until [date].''

DEA response: DEA appreciates that the underlying intent of this comment is to ensure that the ''Do not fill until [date]'' instructions were actually written by the practitioner, as opposed to being the result of forgery. While DEA supports all efforts of practitioners to take steps to prevent forgery in the context of prescriptions, the agency believes it is unnecessary to adopt the particular added requirement suggested by this commenter.

One commenter recommended that certain diagnostic codes, known as ICD–9 codes, should be written by the practitioner in their own handwriting on the face of the prescription.

DEA response: DEA has not previously required that prescriptions contain such diagnostic information, and the agency does not believe that such requirement is necessary to prevent diversion and abuse of controlled substances when issuing multiple prescriptions in accordance with the rule being issued today.

Post-dating of prescriptions: One commenter recommended allowing *post-dated* prescriptions so the practitioner does not have to use space on the prescription blank for the phrase ''Do not fill before [date].''

DEA response: The DEA regulations have always required that all prescriptions for controlled substances ''be dated as of, and signed on, the day when issued.'' 21 CFR 1306.05(a). This requirement is essential to monitor compliance with all provisions of the CSA and DEA regulations relating to the prescribing and dispensing of controlled substances, including (but not limited to) the requirement that a controlled substance be dispensed, including prescribed, only for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. Accordingly, it would be inappropriate to allow post-dating of prescriptions under any circumstance, including when issuing multiple prescriptions under the Final Rule being issued today.

Return of unfilled prescriptions: One commenter suggested that a patient return to the practitioner unfilled prescriptions (if issued for sequential dispensing) if the practitioner changes the medication and before the patient can receive a new prescription, as compared with simply destroying the previous prescriptions. The commenter asserted this would help to ensure that the previously-issued prescriptions will not be filled and diverted.

DEA response: Neither the CSA nor the DEA regulations address what a patient should do with an unfilled prescription for a controlled substance. Thus, regardless of whether the practitioner writes a single prescription or issues multiple prescriptions at the same time under the Final Rule being issued today, there is no mandatory procedure for handling unfilled prescriptions. In all situations, however, practitioners should use common sense in determining what steps are appropriate to prevent diversion in view of the particular patient's circumstances. While not required under the CSA or DEA regulations, it would be acceptable—and may even be the preferred practice—for a practitioner to ask the patient to return unfilled prescriptions for controlled substances, or for a patient to voluntarily do so.

Pharmacies and dispensing of sequential prescriptions: One commenter recommended that DEA clarify what a pharmacy is permitted to do if a prescription is written for 30 days and the month has 31 days (e.g., a prescription for 30 days with ''Do not fill'' before dates of 10/18/yy, 11/18/yy, 12/18/yy, but October has 31 days). The commenter also asked whether a pharmacist who fills a sequential prescription a day before the date stated because the pharmacy will be closed on the date the sequential prescription may be filled (e.g., Sunday) would be violating the regulation. Other commenters asked similar questions as to whether a pharmacist may fill sequential prescriptions earlier than the date specified by the prescribing practitioner. One commenter requested that DEA allow some language for a pharmacist's ''good judgment'' rather than having as an absolute that sequential prescriptions cannot be filled before the ''Do not fill'' date. At the very least, the commenter recommended that DEA include a statement of its intent to use enforcement discretion in these cases. Two commenters recommended that DEA clarify whether pharmacists can fill a sequential prescription before the ''Do not fill'' date (1) if the practitioner has not been contacted and (2) if the practitioner has been contacted. Three commenters requested that DEA clarify whether pharmacies are held accountable for filling the sequential prescriptions before the indicated date. Two commenters suggested that the Final Rule clarify any implications or responsibilities for the dispensing pharmacy.

DEA response: As explained in the NPRM, the requirements contained in the proposed rule were included to ensure that the rule can be reconciled with the text, purpose, and structure of the CSA. This includes, but is not limited to, adherence to the principles of requiring a written prescription for a schedule II controlled substance,

maintaining clear accountability by practitioners when prescribing controlled substances, and ensuring adequate safeguards to prevent diversion and abuse. The Final Rule being issued today states expressly that, where a practitioner has issued multiple prescriptions in accordance with the rule, no pharmacist may fill any prescription before the date specified by the practitioner. The rule contains no exceptions to this requirement. In addition, because the CSA states that prescriptions for schedule II controlled substances must be written (21 U.S.C. 829(a)), the essential elements of the prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed, and—in the case of multiple prescriptions under this Final Rule—the earliest date on which the prescription may be filled) may not be modified orally.

Changes to Regulatory Text

Section 1306.12: Some commenters suggested revising the proposed rule to state that multiple prescriptions do not constitute refills.

DEA response: DEA believes such a revision is unnecessary as it is clear from the text of the rule that it is permissible to issue multiple prescriptions in the manner specified in the rule.

Use of the term ''properly'': Section 1306.12(b)(1)(i) of the proposed rule read: ''The individual practitioner properly determines there is a legitimate medical purpose for the patient to be prescribed that controlled substance and the individual practitioner is acting in the usual course of professional practice.'' Several commenters suggested removing the word ''properly'' here, asserting that the use of the word ''properly'' in this context is unclear or modifies the meaning of the longstanding requirement that a controlled substance be dispensed for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

DEA response: Although the language of the proposed rule was meant simply to reiterate (and not modify) the meaning of the longstanding requirement that a controlled substance be dispensed for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, DEA has decided to revise section 1306.12(b)(1)(i) in view of the comments. Specifically, DEA has revised this paragraph to more closely track the pertinent language contained in the longstanding regulation 21 CFR 1306.04(a). The paragraph being finalized today reads: ''Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.''

Section 1306.12(b)(1)(iii): Section 1306.12(b)(1)(iii) of the proposed rule stated: ''The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.'' Several commenters objected to this provision, asserting that its meaning is unclear or that it imposes an undue burden on practitioners to prevent diversion and abuse. One commenter requested that DEA state whether this imposes a new standard on practitioners.

Eleven commenters recommended deleting the paragraph in its entirety. Commenters believed that the practitioner cannot account for all possible scenarios in making this conclusion. Commenters stated that the potential liability problem for practitioners is that their conclusions and prescribing actions could come into question any time a patient was implicated in abuse or diversion. Commenters believed that practitioners will waste valuable patient time documenting why issuing sequential prescriptions does not cause undue risk. Commenters believed it could also cause the unintended consequences of practitioners avoiding prescribing a medication the patient needs for fear of liability in court. Commenters argued that sequential prescriptions, in limiting the quantity of controlled substances prescribed at one time, supposedly decrease the potential for abuse/diversion.

DEA response: Since the inception of the CSA, it has always been a requirement that all DEA registrants (manufacturers, distributors, practitioners, pharmacies, researchers, importers and exporters) take reasonable steps to prevent their DEA registrations from being used in a manner that results in an undue risk of diversion. This requirement is inherent in the CSA registration provisions (21 U.S.C. 823) as well as the DEA regulations. For example, 21 CFR 1301.71 states: ''All * * * registrants shall provide effective controls to guard against theft and diversion of controlled substances.'' It bears emphasis that the Final Rule being issued today in no way changes this requirement. Under this Final Rule, practitioners who prescribe controlled substances are subject to the same standard in preventing diversion as they always have been under the CSA and DEA regulations. Section 1306.12(b)(1)(iii) of this Final Rule is intended to make clear that a practitioner may not simply comply with the other requirements of this Final Rule while turning a blind eye to circumstances that might be indicative of diversion. Thus, section 1306.12(b)(1)(iii) merely underscores that the longstanding requirement of providing effective controls against diversion remains in effect when issuing multiple schedule II prescriptions in accordance with this Final Rule.

Further, as DEA stated in the Policy Statement (71 FR 52716), published alongside the NPRM, ''one cannot provide an exhaustive and foolproof list of 'dos and don'ts' when it comes to prescribing controlled substances for pain or any other medical purpose.'' Just as DEA cannot provide an exhaustive list of ''dos and don'ts'' to elaborate on the phrase ''legitimate medical purpose in the usual course of professional practice,'' the agency cannot expand upon the general requirement that practitioners take reasonable steps to prevent diversion by setting forth a list of every hypothetical scenario a practitioner might encounter along with specific instructions on how the practitioner should handle the situation. DEA has an obligation to carry out all regulatory requirements in a reasonable manner, consistent with the governing statutes enacted by Congress, and to take into account all circumstances of the particular case at issue. The agency will do so with regard to all aspects of this Final Rule, including *section 1306.12(b)(1)(iii).*

Section 1306.12(b)(2): Section 1306.12(b)(2) of the proposed rule contained the statement:

> Nothing in this paragraph (b) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

In this context, two commenters suggested deleting the words ''in accordance with established medical standards.'' The commenters indicated they were not aware of any standards that a practitioner could use to determine whether it is appropriate to issue multiple prescriptions.

DEA response: The requirement that a prescription for a controlled substance be issued in accordance with established medical standards has been an integral part of federal law for decades and has been upheld by the

United States Supreme Court.[1] This requirement applies to all controlled substances and applies regardless of whether a practitioner issues a single prescription or multiple prescriptions in accordance with this Final Rule.

Pharmacies and dispensing of sequential prescriptions: In section 1306.14, Labeling of substances and filling of prescriptions, DEA proposed the following new paragraph (e): ''Where a prescription that has been prepared in accordance with section 1306.12(b) contains instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the prescription before that date.''

One commenter suggested the following additional language to section 1306.14(e): ''No pharmacist or pharmacy including mail order operations may auto-fill any additional prescriptions for schedule II drugs before verifying that the patient is still in need of each prescription refill.''

DEA response: It has always been the case under the CSA and DEA regulations that a pharmacist who fills a prescription for a controlled substance has a corresponding responsibility to ensure that the prescription was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. This requirement, which is set forth in 21 CFR 1306.04(a), is one of the primary legal bases upon which pharmacists are held accountable under the CSA. DEA believes it is not necessary to modify or expand upon this longstanding requirement in the context of multiple schedule II prescriptions, so long as the prescribing and filling of such prescriptions takes place in accordance with all the provisions of this Final Rule.

Other Issues

Electronically transmitted prescriptions: Four commenters recommended DEA allow electronically transmitted prescriptions for controlled substances.

DEA response: DEA notes that the electronic prescribing of controlled substances is outside the scope of this rulemaking. DEA intends to address electronic prescribing of controlled substances in a separate future rulemaking.

Authorization to use sequential prescriptions prior to publication of Final Rule: Two commenters requested that DEA allow practitioners to begin issuing multiple schedule II prescriptions based on the issuance of the NPRM (without waiting for a Final Rule to be published and to take effect).

DEA response: Under the Administrative Procedure Act (APA), when an agency seeks to impose a new substantive rule that modifies legal obligations of members of the public, the agency must first engage in notice-and-comment rulemaking (5 U.S.C. 553(b)). The APA further provides that substantive rules may not take effect until at least 30 days after publication of the final rule (5 U.S.C. 553(d)). Exceptions to these procedural requirements can be made only ''when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest'' (5 U.S.C. 553(b)(B)). DEA has not found that there is such a legal justification to exempt this Final Rule from the basic procedural requirements of the APA. Accordingly, this Final Rule does not take effect until the effective date indicated herein (December 19, 2007).

Long Term Care Facilities: One commenter asked if this rule will apply to patients in long term care facilities.

DEA response: The DEA regulations contain a variety of provisions relating to the dispensing of controlled substances at long term care facilities. These provisions are unaltered by this Final Rule. This Final Rule may be utilized in the context of a long term care facility, provided such activity complies with any other applicable provisions of the DEA regulations.

Miscellaneous: One commenter recommended that DEA make one federal rule regarding prescriptions to supersede the many different state laws.

DEA response: Under the CSA, Congress envisioned that the Federal and State Governments would work in tandem to regulate activities relating to controlled substances. This is reflected in 21 U.S.C. 903, which indicates that Congress did not intend to preempt state controlled substance laws, so long as such state laws do not conflict with federal law. Thus, each state may enact controlled substance laws that go beyond the requirements of the CSA, provided such laws do not conflict with the CSA. Given this aspect of the CSA, it would not be appropriate for DEA to seek to preempt or supersede state laws relating to the prescribing of controlled substances, provided such laws do not conflict with the CSA or DEA regulations.

One commenter suggested DEA work with other federal agencies and national professional medical societies to be certain doctors are screening for alcoholism and drug addiction in their private medical practices as they are prescribing schedule II controlled substances in the treatment of legitimate medical illnesses.

DEA response: DEA firmly supports all efforts of practitioners to screen for factors that might be indicative of whether the patient may be likely to seek controlled substances for purposes of abuse or to satisfy an addiction. However, such a consideration is beyond the scope of this Final Rule. Persons interested in such considerations might wish to review the Policy Statement, which was published in the **Federal Register** alongside the NPRM (71 FR 52716).

Three commenters recommended that DEA explain existing law and the impact of the new rule to health care professionals, state attorneys general, drug control officials, and professional licensing and regulatory boards.

DEA response: DEA works cooperatively with a wide variety of organizations who have an interest in the CSA and DEA regulations and policies, including, but not limited to: State Boards of Medicine and Boards of Pharmacy; law enforcement; regulatory and professional licensing authorities and agencies; the pharmaceutical industry; and professional organizations representing prescribing and dispensing practitioners. DEA meets regularly with these organizations to discuss matters of mutual concern. Included in these meetings are discussions of DEA legal and regulatory activities.

One commenter suggested allowing partial filling of schedule II prescriptions so as not to constitute a refill.

DEA response: The DEA regulations delineate the circumstances under which the partial filling of a prescription for a controlled substance in schedule II is permissible (21 CFR 1306.13). Adherence to this aspect of the DEA regulations serves a critical function in preventing diversion of schedule II controlled substances. Accordingly, this Final Rule does not modify the requirements of the DEA regulations relating to the partial filling of prescriptions.

Objections to Notice of Proposed Rulemaking

Treatment of Pain Patients: Nineteen commenters opposed the NPRM because they believed that, for a patient who is receiving controlled substances for the treatment of pain, the practitioner should see the patient more than once every 90 days to properly monitor the

[1] *United States* v. *Moore*, 423 U.S. 122, 139–142 (1975).

patient's condition and whether that patient is responding well to the medication. These commenters asserted that such a patient should see the practitioner every 30 days because treatment for pain does not consist of medication alone.

One commenter stated that he had a family member who became addicted to schedule II controlled substances that were prescribed for pain and whose quality of life diminished significantly as a result. This commenter therefore objected to ''slackening the restrictions on these highly addictive and destructive drugs.''

DEA response: DEA recognizes, as these comments reflect, that some practitioners believe that seeing a patient who is receiving controlled substances only once every 90 days is inadequate. However, the CSA does not expressly address how frequently a practitioner must see a patient when prescribing controlled substances. At the same time, practitioners who prescribe controlled substances must see their patients in an appropriate time and manner so as to meet their obligation to prescribe only for a legitimate medical purpose in the usual course of professional practice and to thereby minimize the likelihood that patients will abuse, or become addicted to, the controlled substances. In this regard, section 1306.12(b)(2) of this Final Rule states:

> Nothing in this section shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

Diversion: One commenter opposed the NPRM, asserting that a practitioner cannot always tell whether he or she is ''getting scammed'' by a patient seeking drugs for abuse. This commenter suggested that, if a practitioner is being deceived by such a patient, the harm will be less if the prescription is only for a 30-day supply of a controlled substance (rather than a 90-day supply). Another commenter opposed the NPRM because the commenter believed that drug abusers will change the dates on the multiple prescriptions and have all the multiple prescriptions filled at once by different pharmacies. Another commenter, who indicated she worked in a pharmacy, expressed the view that drug addicts will see multiple practitioners in a 90-day period to obtain overlapping 90-day supplies of schedule II controlled substances.

DEA response: It is true that, other factors being equal, the diversion of a 90-day supply of controlled substances causes greater harm than the diversion of a 30-day supply. Likewise, the adverse effects of any improper conduct on the part of a drug-seeking patient (such as ''doctor shopping'' or seeing multiple prescribing practitioners) will be magnified if the patient is receiving a 90-day supply of a schedule II controlled substance as opposed to a 30-day supply. However, for the reasons provided in responding to the preceding comments, DEA believes it is appropriate to allow for up to a 90-day supply of schedule II controlled substances under the conditions set forth in this Final Rule—with the understanding that 90 days is the upper limit and by no means mandatory. To the contrary, as this Final Rule indicates, the practitioner must determine on his/her own, on a case-by-case basis, based on sound medical judgment, and in accordance with established medical standards, the appropriate amounts of schedule II controlled substances to prescribe.

Possibility of increased pressure on prescribing practitioners: Some commenters expressed the view that implementation of the proposed rule will result in practitioners receiving an increased number of ''demands'' by patients to receive a 90-day supply of controlled substances. As a result, these commenters asserted practitioners might feel undue pressure to prescribe a 90-day supply of controlled substances at each office visit.

DEA response: Given this important concern, DEA repeats for emphasis the following statement in this Final Rule:

> Nothing in this [Final Rule] shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

It is indeed essential that practitioners adhere to the above-quoted provision and not simply—based on pressure from patients or any other improper reason—feel obligated to provide multiple prescriptions totaling a 90-day supply of schedule II controlled substances. Toward this end, practitioners may wish to refer their patients to the above-quoted provision if they believe doing so will be beneficial.

Appropriateness of this rule in view of the extent of prescription controlled substance abuse in the United States: Among those commenters who objected to the proposed rule, many pointed to the alarming increase in prescription controlled substance abuse in the United States and resulting deaths and harm to the public welfare. Such commenters expressed the view that the proposed rule—or any other lessening of drug controls—will exacerbate the problem.

DEA response: DEA shares the concerns of those who are deeply troubled by the increasing levels of prescription controlled substance abuse in the United States and the resulting detriment to the public health and welfare of the American people. DEA addressed these concerns in depth in the September 6, 2006, Policy Statement that was published in conjunction with the proposed rule, and the agency encourages those interested in this topic to review that document. To minimize the likelihood that this Final Rule will exacerbate the extensive problem of prescription controlled substance abuse in the United States, DEA has reiterated in the text of the regulation several important and longstanding legal principles. Among these are the requirements that ''Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice'' and that ''The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.'' In addition, as stated repeatedly above, nothing in this Final Rule shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing schedule II controlled substances; rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so. It is with the understanding that adherence to all of these principles is essential that DEA has concluded that implementation of this Final Rule is consistent with the overall structure of the CSA and DEA's mission.

Methadone: Among the commenters who objected to the proposed rule, several mentioned the prescribing of methadone in particular and the significant number of deaths that have resulted from methadone abuse. These

commenters expressed concern that the proposed rule would lead to even more deaths from methadone abuse.

DEA response: DEA shares the concerns of those commenters who pointed to the unique and significant problems associated with methadone abuse. In view of these concerns, DEA repeats the following statement from the September 6, 2006, Policy Statement that was published in conjunction with the proposed rule:

> Methadone, a schedule II controlled substance, has been approved by the [Food and Drug Administration (FDA)] as an analgesic. While a physician must have a separate DEA registration to dispense methadone for maintenance or detoxification, no separate registration is required to prescribe methadone for pain. However, in a document entitled ''Methadone-Associated Mortality: Report of a National Assessment,'' [The Department of Health and Human Services, Substance Abuse and Mental Health Services Administration] recently recommended that ''physicians need to understand methadone's pharmacology and appropriate use, as well as specific indications and cautions to consider when deciding whether to use this medication in the treatment of pain.'' [2] This recommendation was made in light of mortality rates associated with methadone.

Since 2003, the FDA has issued revised labeling for methadone analgesic products, and physician education and training curricula have been developed for methadone treatment.[3] In 2007, SAMHSA convened an expert panel to consider the implications of methadone mortality.

Conclusion

As DEA discussed at the beginning of this document, the vast majority of comments received regarding this rulemaking were supportive of its adoption. Two hundred thirty-one of the 264 comments received supported this action. As DEA noted previously, this rulemaking was supported by a wide variety of individuals and organizations—medical professionals, patient advocacy organizations, and patients themselves. To reiterate, the majority of commenters believed this Final Rule would be beneficial from both physical and financial perspectives, citing the time and money saved due to less frequent visits to prescribing practitioners, and the reduced physical toll resulting from the reduced visits. While many commenters sought clarification regarding various aspects of this rulemaking, it is important to reiterate the overwhelmingly positive reaction this rule generated.

DEA, state authorities, practitioners, and pharmacists all share a common interest in ensuring that controlled substances are prescribed for legitimate medical purposes by prescribing practitioners acting in the usual course of professional practice. As discussed throughout this document, DEA, through its enforcement of the CSA and its implementing regulations, must prevent the diversion and abuse of controlled substances while ensuring that there is an adequate supply for legitimate medical purposes. DEA supports the intent of this Final Rule to address patients' needs for schedule II controlled substances while preventing the diversion of those substances. DEA believes that this Final Rule provides an option for practitioners to treat their patients, which is legally permissible and consistent with the text, structure, and purposes of the CSA.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. This rule provides an additional option that practitioners may utilize when prescribing schedule II controlled substances under certain circumstances. The rule will not mandate any new procedures. Therefore, a regulatory flexibility analysis is not required for this rule.

Executive Order 12866

The Deputy Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866, Regulatory Planning and Review, Section 1(b). This rule has been deemed a ''significant regulatory action.'' Accordingly, this rule has been reviewed by the Office of Management and Budget.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rule does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1306

Drug traffic control, Prescription drugs.

■ Pursuant to the authority vested in the Attorney General under sections 201, 202, and 501(b) of the CSA (21 U.S.C. 811, 812, and 871(b)), delegated to the Deputy Administrator pursuant to section 501(a) (21 U.S.C. 871(a)) and as specified in 28 CFR 0.100 and 0.104, Appendix to Subpart R, the Deputy Administrator hereby orders that Title 21 of the Code of Federal Regulations, Part 1306, be amended as follows:

PART 1306—PRESCRIPTIONS

■ 1. The authority citation for part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 829, 871(b), unless otherwise noted.

■ 2. Section 1306.12 is revised to read as follows:

§ 1306.12 Refilling prescriptions; issuance of multiple prescriptions.

(a) The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

[2] CSAT Publication No. 28–03. Available at *http://dpt.samhsa.gov/medications/methreports.aspx*.

[3] The FDA health advisory can be found at *http://www.fda.gov/cder/drug/advisory/methadone.htm* and the package insert can be found at *http://www.fda.gov/cder/foi/label/2006/006134s028lbl.pdf*.

(b)(1) An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:

(i) Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;

(ii) The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription;

(iii) The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;

(iv) The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and

(v) The individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.

(2) Nothing in this paragraph (b) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

■ 3. Section 1306.14 is amended by adding a new paragraph (e) to read as follows:

§ 1306.14 Labeling of substances and filling of prescriptions.

* * * * *

(e) Where a prescription that has been prepared in accordance with section 1306.12(b) contains instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the prescription before that date.

Dated: November 7, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7–22558 Filed 11–16–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF STATE

22 CFR Part 51

[Public Notice: 5991]

RIN 1400–AC28

Passports

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule reorganizes, restructures, and updates passport regulations in order to make them easier for users to access information, to better reflect current practice and changes in statutory authority, and to remove outdated provisions. In general, the revisions do not mark a departure from current policy. Rather, the Department's intent is to bring greater clarity to current passport policy and practice and to present it in a less cumbersome way.

DATES: This rule becomes effective February 1, 2008.

FOR FURTHER INFORMATION CONTACT: Consuelo Pachon, Office of Passport Policy, (202) 663–2662. Hearing- or speech-impaired persons may use the Telecommunications Devices for the Deaf (TDD) by contacting the Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The Department published a proposed rule, with a request for comments, amending and updating numerous sections of Part 51 of Title 22 of the Code of Federal Regulations. The rule was discussed in detail in Public Notice 5712, as were the Department's reasons for changes in the regulation (**Federal Register**, March 7, 2007, 72 FR 10095). The comment period closed on May 7, 2007. The Department of State is now promulgating its final rule. Some of the more notable changes in the regulations include: Changes regarding minors, extending the two-parent consent and personal appearance requirements to minors under the age of 16; changes regarding Passport Agents and Passport Acceptance Agents, codifying the definitions and clarifying their qualifications and responsibilities, including the requirement that they be U.S. citizens or U.S. nationals respectively; changes on denial, revocation and restriction of passports to permit the Department to deny a passport, for example, to applicants who are the subject of an outstanding State, local, or foreign warrant of arrest for a felony, intended to enhance U.S. law enforcement and cooperation; and changes regarding change of names on passports, intended to clarify what is required of an applicant whose name has changed and to reflect more accurately Department practice in this regard.

Subpart F remains under review and may be addressed in a future rulemaking. Public Notice 5712 further advised that a separate rulemaking was underway to amend Part 51 to introduce the passport card and that comments regarding the passport card would be considered in that separate rulemaking, which is ongoing. The final rule for the passport card will include any necessary renumbering of its sections for compatibility with the numbering of this overall revision, as well as language modifications to take into account the changes made in this Final Rule.

Analysis of Comments: The Department received four (4) comments. One comment expressed support of the change to increase the maximum age requiring two-parent consent for minors from under 14 to under 16. A second comment, addressed in detail below, underscored the importance of competent adjudicators, recommended the Department always require applicants to appear in person (rather than permit mail-in procedures), and suggested passport fees should be considerably increased. The two remaining comments concerned passport fees and the proposed passport card. Because issues regarding passport fees and the passport card are addressed in a separate rulemaking, the Department will respond to these comments at a later time.

One comment suggested that the Department should always require that a passport application be executed personally rather than allowing renewals by mail. The comment also seemed to misunderstand the role of the U.S. Postal Service and clerks of court, who act as passport acceptance agents but do not have the ability to adjudicate and issue passports. The commenter also opined that the passport application process should be made more difficult because passports are ''as easy to get as turning on a water faucet.''

The passport application process for first time passport applicants is designed to verify the citizenship and identity of the applicant. A U.S. passport is, by definition, a citizenship and identity document. U.S. citizens may apply for subsequent passports by mail within certain parameters described in the regulations. This is an acceptable practice because the Department has previously thoroughly reviewed and verified the applicant's citizenship and ensured that the applicant's identity is genuine. Furthermore, fraud prevention measures allow the Department to instantly