I. Background

On June 11, 2003, the Commission held a hearing concerning its enforcement procedures. The Commission received comments from those in the regulated community, many of whom argued for increased transparency in Commission procedures and expanded opportunities to contest allegations. In response to issues raised at the hearing, the Commission has made a number of changes and clarifications. These changes and clarifications include allowing respondents to have access to their deposition transcripts, See Statement of Policy Regarding Deposition Transcripts in Nonpublic Investigations, 68 FR 50688 (August 22, 2003), and clarifying questions concerning treasurer liability for violations of the FECA, See Statement of Policy Regarding Treasurers Subject to Enforcement Proceedings, 70 FR 3 (January 3, 2005).

On December 8, 2006, the Commission published a proposal for a pilot program for probable cause hearings, and sought comments from the regulated community. See Proposed Policy Statement Establishing Pilot Program for Probable Cause Hearings, 71 FR 71088 (Dec. 8, 2006). The comment period on the proposed policy statement closed on January 5, 2007. The Commission received four comments, all of which endorsed the proposed pilot program for probable cause hearings. These comments are available at http://www.fec.gov/law/policy.shtml#proposed under the heading “Pilot Program for Probable Cause Hearings.”

On February 8, 2007, the Commission decided by a vote of 6–0 to institute the pilot program. The program went into effect on February 16, 2007. The pilot program was designed to remain in effect for at least eight months, after which time a vote would be scheduled on whether the program should continue. The Commission finds that the pilot program has been successful and hence, is issuing this notice to announce that the Commission has determined to make the program permanent.

II. Procedures for Probable Cause Hearings

A. Opportunity To Request a Hearing

A respondent may request a probable cause hearing when the enforcement process reaches the probable cause determination stage (see 11 CFR 111.16–111.17) and the respondent submits a probable cause response brief to the Office of General Counsel. The General Counsel will attach a cover letter to its probable cause brief to inform the respondent of the opportunity to request an oral hearing before the Commission. See 11 CFR 111.16(b). Hearings are voluntary and no adverse inference will be drawn by the Commission based on a respondent’s request for, or waiver of, such a hearing. The respondent must include a written request for a hearing as a part of the respondent’s filed reply brief under 11 CFR 111.16(c). Each request for a hearing must state with specificity why the hearing is being requested and what issues the respondent expects to address. Absent good cause, to be determined at the sole discretion of the Commission, late requests will not be accepted.

Respondents are responsible for ensuring that their requests are timely received. All requests for hearings, scheduling and format inquiries, document submissions, and any other inquiries related to the probable cause hearings should be directed to the Office of General Counsel.

The Commission will grant a request for an oral hearing if any two Commissioners agree that a hearing would help resolve significant or novel legal issues, or significant questions about the application of the law to the facts. The Commission will inform the respondent whether the Commission is granting the respondent’s request within 30 days of receiving the respondent’s brief.

B. Hearing Procedures

The purpose of the oral hearing is to provide a respondent an opportunity to present the respondent’s arguments in person to the Commissioners before the Commission makes a determination as to whether there is “probable cause to believe” that the respondent violated
the Act or Commission regulations. Consistent with current Commission regulations, a respondent may be represented by counsel, at the respondent’s own expense, or may appear pro se at a probable cause hearing. See 11 CFR 111.23.

Respondents (or their counsel) will have the opportunity to present their arguments, and Commissioners, the General Counsel, and the Staff Director will have the opportunity to pose questions to the respondent, or respondent’s counsel, if represented. At the hearing, respondents are expected to raise only issues that were identified in the respondent’s hearing request. Such issues must have been previously presented during the enforcement process, either in the response, during the investigation or pre-probable cause conciliation, or in the reply brief. Respondents may discuss any issues presented in the enforcement matter, including potential liability and calculation of a civil penalty, and should be prepared to address questions related to the complaint, their initial response, and any other material they have submitted to the Commission. The reply brief should include specific citations to any authorities (including prior Commission actions) on which the respondent is replying or intends to cite at the hearing. If respondents discover new information after submission of the reply brief, or need to raise new arguments for similarly extenuating circumstances, they should notify the Commission as soon as possible prior to the hearing. Commissioners may ask questions on any matter related to the enforcement proceedings and respondents are free to raise new issues germane to any response.

Hearings are confidential and not open to the public; generally only respondents and their counsel may attend. Attendance by any other parties must be approved by the Commission in advance. The Commission will determine the format and time allotted for each hearing at its discretion. Among the factors that the Commission may consider are agency time constraints, the complexity of the issues raised, the number of respondents involved, and the extent of Commission interest. The Commission will determine the amount of time allocated for each portion of the hearing, and each time limit may vary from hearing to hearing. The Commission anticipates that most hearings will begin with a brief opening statement by respondent or respondent’s counsel, followed by questioning from the Commissioners, General Counsel, and Staff Director. Hearings will normally conclude with the respondent or respondent’s counsel’s closing remarks.

Third party witnesses or other co-respondents may not be called to testify at a respondent’s oral hearing, nor may a respondent’s counsel call the respondent to testify. However, the Commission may request that the respondent submit supplementary information or briefing after the probable cause hearing. The Commission discourages voluminous submissions. Supplementary information may be submitted only upon Commission request and no more than ten days after such a request from the Commission, unless the Commission’s request for information imposes a different, Commission-approved deadline. Materials requested by the Commission, and materials considered by the Commission in making its “probable cause to believe” determination, may be made part of the public record pursuant to the Commission’s Statement of Policy Regarding Disclosure of Closed Enforcement and Related Files, 68 FR 70426 (Dec. 18, 2003).

The Commission will have transcripts made of the hearings. The transcripts will become a part of the record of the enforcement matter and may be relied upon for determinations made by the Commission. Respondent may be bound by any representations made by respondent or respondent’s counsel at a hearing. The Commission will make the transcripts available to the respondent as soon as practicable after the hearing, and the respondent may purchase copies of the transcript. Transcripts will be made public after the matter is closed in accordance with Commission policies on disclosure.

C. Cases Involving Multiple Respondents

In cases involving multiple respondents, the Commission will decide on a case-by-case basis whether to structure any hearings separately or as joint hearings for all respondents. Respondents are encouraged to advise the Commission of their preferences. Co-respondents may request joint hearings if each participating co-respondent provides an unconditional waiver of confidentiality with respect to other participating co-respondents and their counsel and a nondisclosure agreement. If separate hearings are held, each respondent will have access to the transcripts from the hearing of that respondent, but transcripts of other co-respondents’ hearings will not be made available unless co-respondents specifically provide written consent to the Commission granting access to such transcripts.

D. Scheduling of Hearings

The Commission will seek to hold the hearing in a timely manner after receiving respondents’ request for a hearing. The Commission will attempt to schedule the hearings at a mutually acceptable date and time. However, if a respondent is unable to accommodate the Commission’s schedule, the Commission may decline to hold a hearing. The Commission reserves the right to reschedule any hearing. Where necessary, the Commission reserves the right to request from a respondent an agreement tolling any upcoming deadline, including any statutory deadline or other deadline found in 11 CFR part 111.

E. Conclusion

Probable cause hearings are optional and no negative inference will be drawn if respondents do not request a hearing. Currently, the majority of the Commission’s cases are settled through pre-probable cause conciliation. Proceeding to probable cause briefing requires a substantial investment of the Commission’s limited resources. Consistent with the goal of expeditious resolution of enforcement matters, the Commission encourages pre-probable cause conciliation. The Commission has a practice in many cases of reducing the civil penalty it seeks through its opening settlement offer in pre-probable cause conciliation. However, once pre-probable cause conciliation has been terminated, this reduction (normally 25%) is no longer available and the civil penalty will generally increase.

This notice establishes rules of agency practice or procedure. This notice does not constitute an agency regulation requiring notice of proposed rulemaking, opportunities for public participation, prior publication, and delay effective under 5 U.S.C. 553 of the Administrative Procedures Act (‘‘APA’’). The provisions of the Regulatory Flexibility Act, 5 U.S.C. 605(b), which apply when notice and comment are required by the APA or another statute, are not applicable.


Robert D. Lenhard,
Chairman, Federal Election Commission.

Note: The following Appendix will not appear in the Code of Federal Regulations.
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 “reasonable cause” that a respondent has committed or is about to commit a violation of the Act or Commission regulations. 11 CFR 111.7(a). 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 “reasonable cause” 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 “reasonable cause” 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). 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 “reasonable cause” 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 “reasonable cause” 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 probable cause conciliation agreement). See 11 CFR 111.16(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(e).

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).

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.


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;