number, with a unique suffix, of their collaborating physician. DEA has since determined that the procedure could not adequately address the unique practices of these health care professionals. The proposal was subsequently withdrawn on April 24, 1992 (57 FR 15037).

DEA now proposes to amend part 1304 to define MLP as an individual practitioner other than a physician, dentist, osteopath, veterinarian, ophthalmologist or podiatrist, who is licensed, registered or otherwise permitted in the United States or the jurisdiction in which he/she practices to dispense a controlled substance in the course of professional practice as a primary health care provider.

Based on the new definition, DEA will create a separate registration category for MLPs. The procedures used under this system will parallel those which have been used with traditional practitioner registrations. Upon application, each qualified MLP will be issued an individual DEA registration to dispense controlled substances to the extent that the registrant is authorized to dispense controlled substances by the state in which he/she will practice. The administrative structure of the number will identify the registrant as a MLP. Applicants will certify on their applications for registration and reregistration the controlled substances authority they have been granted by the state, the schedules of controlled substances they may handle, and any other controlled substance restrictions.

Part 1304 will also be amended to require that MLPs maintain a readily available copy of their practice agreement, guideline, protocol, or other documents which describe the conditions of their authorization to dispense controlled substances which are required by the state, and make such items available to DEA upon request for inspection and copying. This will provide DEA details regarding the specific circumstances under which a MLP practices without imposing a burdensome requirement that such documents be submitted with each application for registration or reregistration.

Section 1301.22(b)(6) will be amended to clarify when research is permitted as a coincident activity by registered MLPs, and §§ 1301.24 (b) and (c) will be amended to include MLPs in the registration exemption for practitioners in certain settings. It should be noted that practitioners in institutional settings who issue orders for medication for direct administration to a patient, such as nurse anesthetists in the normal course of their practice, are not prescribing within the meaning the § 1306.02(f), and would be exempt from registration. In that context, DEA neither requires nor encourages registration for MLPs acting as agents of other registrants.

The Deputy Assistant Administrator, Office of Diversion Control, hereby certifies that this proposed rulemaking will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* This proposed rule is not a major rule for the purposes of Executive Order (E.O.) 12291 of February 17, 1981.

Pursuant to sections 3(c)(3) and 3(e)(2)(c) of E.O. 12291, this proposed rule has been submitted to the Office of Management and Budget for review, and approval of that office has been requested pursuant to the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. *et seq.*

This proposed rule responds to the requirements of title 21, United States Code, section 823(f), that DEA registrations must be issued to those persons who are authorized by state authorities to dispense controlled substances, and is essential to the criminal law enforcement function of the United States. Further, Mid-Level Practitioners have expressed a strong interest in being registered by DEA. Accordingly, it is not subject to the moratorium on regulations ordered by the President of the United States.

This action has been analyzed in accordance with the principles and criteria in E.O. 12612, and it has been determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects

21 CFR Part 1301

Administrative practice and procedure, Drug Enforcement Administration, Drug Traffic Control, Security measures.

21 CFR Part 1304

Drug Enforcement Administration, Drug Traffic Control, Reporting requirements.

For reasons set out above, it is proposed that 21 CFR parts 1301 and 1304 be amended as follows:

PART 1301—[AMENDED]

1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

2. Section 1301.22 is proposed to be amended by revising paragraph (b)(6) as follows:

§ 1301.22 Separate registration for independent activities.

* * * * *

(b) * * *

(6) A person registered to dispense controlled substances in Schedules II through V shall be authorized to conduct research and to conduct instructional activities with those substances, except that a mid-level practitioner, as defined in § 1304.02(f), may conduct research coincident to his/her practitioner registration only to the extent expressly authorized by state statute.

* * * * *

3. Section 1301.24 is proposed to be amended by revising paragraphs (b) and (c) introductory text to read as follows:

§ 1301.24 Exemption of agents and employees; affiliated practitioners.

* * * * *

(b) An individual practitioner, as defined in § 1304.02 of this chapter (other than an intern, resident, foreign-trained physician, or physician on the staff of a Veterans Administration facility or physician who is an agent or employee of the Health Bureau of the Canal Zone Government), who is an agent or employee of another practitioner, other than a mid-level practitioner, registered to dispense controlled substances may, when acting in the usual course of his/her employment, administer and dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he/she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself. (For example, a staff physician employed by a hospital need not be registered individually to administer and dispense, other than by prescribing, controlled substances within the hospital.)

(c) An individual practitioner, as defined in § 1304.02 of this chapter, who is an intern, resident, mid-level practitioner, foreign-trained physician or physician on the staff of a Veterans Administration facility or physician who is an agent or employee of the Health Bureau of the Canal Zone Government, may dispense, administer and prescribe controlled substances under the registration of the hospital or other institution which is registered and by whom he/she is employed in lieu of