

dispensed per day, the cost savings can be between \$1.00 and \$5.00 per prescription dispensed.

Executive Order 12866

The Deputy Assistant Administrator, Office of Diversion Control, further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). DEA has determined that this is not a significant regulatory action. Therefore, this action has not been reviewed by the Office of Management and Budget. As previously noted, this rule will provide a number of benefits to the regulated industry as efficiencies are gained in the processing of controlled substance prescriptions.

Executive Order 12988

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

Executive Order 13132

This rulemaking 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 \$100,000,000 or more 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.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. 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

21 CFR Part 1300

Definitions, Drug traffic control.

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1304

Drug traffic control, Reporting requirements.

21 CFR Part 1305

Drug traffic control, Reporting requirements.

21 CFR Part 1306

Drug traffic control, prescription drugs.

■ For the reasons set out above, title 21, Code of Federal Regulations, parts 1300, 1301, 1304, 1305, and 1306 are amended to read as follows:

PART 1300—[AMENDED]

■ 1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 871(b), 951, 958(f).

■ 2. Section 1300.01 is amended by adding a new paragraph (b)(43) to read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

(b) * * *

(43) The term *central fill pharmacy* means a pharmacy which is permitted by the state in which it is located to prepare controlled substances orders for dispensing pursuant to a valid prescription transmitted to it by a registered retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user. Such central fill pharmacy shall be deemed "authorized" to fill prescriptions on behalf of a retail pharmacy only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner.

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 1301.13 is amended by revising paragraph (e)(1)(iii) to read as follows:

§ 1301.13 Application for registration; time for application, expiration date, registration for independent activities; application forms, fees, contents and signature; coincident activities.

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(e) * * *

(1) * * *

(iii) Dispensing or Instructing (Includes Practitioner, Hospital/Clinic, Retail Pharmacy, Central Fill Pharmacy, Teaching Institution).	Schedules II–V	New—224 Renewal—224a	210 210	3	May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under state statute. A pharmacist may manufacture an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in Schedule II–V in a proportion not exceeding 20% of the complete solution, compound or mixture. A retail pharmacy may perform central fill pharmacy activities.
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■ 3. Section 1301.76 is amended by adding new paragraph (d) to read as follows:

§ 1301.76 Other security measures for practitioners.

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(d) Central fill pharmacies must comply with § 1301.74(e) when selecting private, common or contract carriers to transport filled prescriptions to a retail pharmacy for delivery to the ultimate user. When central fill pharmacies contract with private, common or contract carriers to transport filled prescriptions to a retail pharmacy,

the central fill pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106. Retail pharmacies must comply with § 1301.74(e) when selecting private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy. When retail pharmacies contract with private,