

DEPARTMENT OF HEALTH AND HUMAN SERVICES**42 CFR Part 121****Organ Procurement and Transplantation Network; Final Rule Amendment, Stay of Final Rule, and Additional Comment Period**

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final Rule Amendment, Stay of Final Rule, and Additional Comment Period.

SUMMARY: Section 413 of the Ticket to Work and Work Incentives Improvement Act of 1999, signed into law by the President on December 17, 1999, provides that the Organ Procurement and Transplantation Network (OPTN) Final Rule published on April 2, 1998, together with the amendments published on October 20, 1999, shall not become effective before March 16, 2000. This document announces a stay of the final rule, consistent with section 413, announces that the public may submit comments on the final rule, as amended, for a 60-day period, and amends a compliance deadline in the final rule, as amended.

DATES: Under Section 413 of the Ticket to Work and Work Incentives Improvement Act of 1999 (H.R. 1180, signed into law by the President on December 17, 1999 published on April 2, 1998 (63 FR 16296), as amended by the final rule published on October 20, 1999 (64 FR 56650), is stayed effective December 17, 1999 through March 15, 2000. The amendment to 42 CFR 121.8 is effective on March 16, 2000. To ensure consideration, comments on the final rule as amended must be received by February 22, 2000.

ADDRESSES: Written comments should be submitted to Lynn Rothberg Wegman, Acting Director, Division of Transplantation, Office of Special Programs, HRSA, 5600 Fishers Lane, Room 7C-22, Rockville, Maryland 20857. The comments submitted will be available for public inspection and copying at the address listed above.

FOR FURTHER INFORMATION CONTACT: Lynn Rothberg Wegman, at the address listed above, telephone 301-443-7577.

SUPPLEMENTARY INFORMATION: On April 2, 1998 (63 FR 16296), the Secretary of Health and Human Services published in the **Federal Register** as 42 CFR part 121 a final rule governing the operation of the Organ Procurement and Transplantation Network.

As a result of the enactment of section 4002 of the Fiscal Year 1998 Supplemental Appropriations Act, Public Law 105-174, the comment period was extended until August 31, 1998, and the final rule was not to become effective before October 1, 1998. On July 1, 1998, the Department published a document in the **Federal Register** announcing the extension of the comment period and the delay until October 1, 1998, of the effective date of the final rule. (63 FR 35847.) In addition, several of the dates contained in provisions of the final rule were also amended in the July 1, 1998, document.

On October 21, 1998, Public Law 105-277, the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, became effective. Section 101(f) of Division A of the public law enacted the Department of Labor, Health and Human Services, Education, and Related Agencies Appropriations Act for Fiscal Year 1999. Section 213 of that Act provided that the final rule at 42 CFR part 121 was not to become effective before the expiration of the 1-year period beginning on the date of enactment of that Act. Section 213 also called for the Institute of Medicine to study several aspects of the final rule and of the organ transplant system generally and encouraged the Department to meet with representatives of the OPTN. The Institute's report, issued in July 1999, the public comments received on the April 2, 1998, rule, and extensive consultation with representatives of the OPTN. The Institute's report, issued in July 1999, the public comments received on the April 2, 1998, rule, and extensive consultation with representatives of the OPTN informed the Department's deliberations on possible revisions to the rule. The result was the Department's issuance on October 20, 1999 (64 FR 56650), of amendment to the final rule, with an effective date for

the rule as amended of November 19, 1999.

It is this amended rule that is subject to the provisions of section 413 of the Ticket to Work and Work Incentives Improvement Act of 1999. The rule is not to become effective before March 16, 2000. As provided in section 413(b)W, comments may be submitted for a period ending on February 22, 2000. The Department will consider any revisions that may be appropriate based on our review of the comments.

Section 121.8(e)(2) within part 121, as amended on October 20, 1999, established a compliance deadline of February 15, 2000, for the OPTN to transmit to the Secretary revised policies and supporting documentation for liver allocation. Because we do not seek to have the deadline occur during the period when the regulation is stayed, we have decided to extend the deadline to March 16, 2000.

List of Subjects in 42 CFR Part 121

Health care, Hospitals, Organ transplantation, Reporting and recordkeeping requirements.

Dated: December 16, 1999.

Claude Earl Fox,

Administrator, Health Resources and Services Administration.

Approved: December 17, 1999.

Donna E. Shalala,

Secretary.

Accordingly, 42 CFR Part 121 is amended as follows:

PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

1. The authority citation for part 121 continues to read as follows:

Authority: Sections 215, 371-376 of the Public Health Service Act (42 U.S.C. 216, 273-274d); sections 1102, 1106, 1138 and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1320b-8 and 1395hh).

§ 121.8 [Amended]

2. Effective March 16, 2000, in § 121.8, paragraph (e)(2) is amended by revising the words "February 15, 2000" to read "March 16, 2000".

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