Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. 2006N–0051]

Health Resources and Services Administration

42 CFR Part 121

Blood Vessels Recovered With Organs and Intended for Use in Organ Transplantation; Companion Document to Direct Final Rule

AGENCIES: Food and Drug Administration, Health Resources and Services Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Health Resources and Services Administration (HRSA) and the Food and Drug Administration (FDA) are proposing to amend their regulations to consider as part of an organ those blood vessels recovered with the organ that are intended for use in organ transplantation (HRSA regulation); and to exclude such blood vessels from the definition of human cells, tissues, and cellular and tissue-based products (HCT/Ps) (FDA regulation). We (HRSA and FDA) are taking this action to provide that blood vessels recovered with organs and intended for use in organ transplantation will be governed by the regulations pertaining to organs. The regulation of other recovered blood vessels would remain unchanged. We believe that this change will eliminate the unnecessary burden resulting from an organ procurement organization's efforts to comply with both FDA and HRSA rules with respect to blood vessels (FDA jurisdiction) and organs (HRSA jurisdiction). This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**. We are taking this action because the proposed changes are noncontroversial, and we do not anticipate any significant adverse comments. If we receive any significant adverse comments that warrant terminating the direct final rule, we will consider such comments on the proposed rule in developing the final rule.

DATES: Submit written or electronic comments on the proposed rule by July 26, 2006.

ADDRESSES: You may submit comments, identified by Docket No. 2006N–0051, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph. FDA will share all comments received with HRSA.

Instructions: All submissions received must include the agency name (FDA) and Docket No. 2006N–0051 for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments see the ''Comments'' heading in section IX of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

For information regarding FDA's rule: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

For information regarding HRSA's rule: Jim Burdick, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), 5600 Fishers Lane, rm. 12C–06, Rockville, MD 20857, 301–443–7577.

SUPPLEMENTARY INFORMATION:

I. Introduction

We propose to amend certain regulations to:

- Revise the definition of ''organ'' to include blood vessels (usually segments of iliac arteries and veins) recovered from an organ donor during the same recovery procedure of such organ(s) and intended for use in organ transplantation (hereinafter referred to as ''blood vessels intended for use in organ transplantation''); and
- Exclude blood vessels intended for use in organ transplantation from the definition of human cells, tissues, and cellular and tissue-based products (HCT/Ps).

By taking this action, blood vessels labeled and intended solely for use in organ transplantation would be subject to HRSA requirements in 42 CFR part 121 and any enforceable organ procurement and transplantation network (OPTN) policies established under 42 CFR part 121. This action would keep blood vessels intended for use in organ transplantation and organs under the same regulatory scheme, making blood vessels intended for use in organ transplantation readily available to meet organ transplant needs.

II. Background

HRSA oversees transplantation of organs through the OPTN, which sets policies related to the procurement, transplantation, and allocation of human organs. An ''organ'' is ordinarily defined as a bodily part that performs a function or cooperates in an activity.

Vascularized human organs for transplantation are under the purview of HRSA and are excluded from FDA's tissue regulations in §§ 1270.3(j)(4) and 1271.3(d)(1) (21 CFR 1270.3(j)(4) and 1271.3(d)(1)). Blood vessels are currently regulated by FDA. Blood vessels are included in the definition of ''human tissue'' under FDA regulations in § 1270.3(j) (applicable to tissue recovered before May 25, 2005), and in the definition of ''human cells, tissues, or cellular or tissue-based products (HCT/P's)'' in § 1271.3(d) (applicable to tissue recovered on or after May 25, 2005).

There is a routine practice of recovering blood vessels intended for use in organ transplantation during organ procurement and using such blood vessels to connect donor organ and recipient vessels. We propose to regulate such blood vessels intended for use in organ transplantation as part of the organ under 42 CFR part 121. Therefore, the applicable provisions of 42 CFR part 121 would apply. We propose that such blood vessels do not need to be attached to the organ(s), nor transplanted simultaneously with such organs to the same recipient, nor transplanted together with the organ(s) from the same donor. Occasionally, blood vessels not used immediately for the transplantation of a donated organ are stored for a number of days and subsequently used to modify the organ transplant in the same recipient or to accomplish transplantation in the recipient of an organ from a different donor.

Currently, FDA's jurisdiction over blood vessels intended for use in organ transplantation overlaps with HRSA's oversight of the OPTN. OPTN's membership compliance review activities are required under 42 CFR 121.10(b)(1)(iii). In addition, under 42 CFR 121.10(c), the Secretary of Health and Human Services (the Secretary) may take actions against OPTN members (including, but not limited to termination of a transplant hospital's participation in or reimbursement under Medicare and Medicaid and removal of a transplant program's designation under 42 CFR 121.9) for noncompliance with 42 CFR part 121 or enforceable OPTN policies (those approved by the Secretary) and for actions that indicate a risk to the health of patients or to the public safety. Because blood vessels intended for use in organ transplantation are recovered by organ procurement organizations (OPOs) and stored temporarily at transplant centers, having two Federal inspectional programs for such facilities without a medical or public health need for such dual oversight would be inefficient and burdensome.

FDA requirements and recommendations for determining HCT/P donor eligibility are different than HRSA provisions for screening and testing organ donors. This is because of a different risk/benefit assessment for most HCT/P recipients than for vascularized human organ transplant recipients. HCT/Ps from a single donor can affect up to 100 recipients, they are often life extending, and alternative materials usually exist; whereas organs from a single donor go to fewer recipients, are almost always life saving, and are in short supply.

Therefore, in order to avoid duplication of efforts and reduce the burden on affected facilities, we are proposing to transfer jurisdiction over blood vessels intended for use in organ transplantation and labeled as such from FDA to HRSA. The proposed rule would not affect regulation of blood vessels intended for transplantation but not involving organ transplantation. Jurisdiction over such blood vessels would remain with FDA. Ordinarily, non-organ transplant uses will have a different risk/benefit assessment and the current FDA requirements are appropriate for these blood vessels.

III. Legal Authority

We are proposing to issue these regulations under the authority of the National Organ Transplant Act as amended (NOTA) and section 361 of the Public Health Service Act (the PHS Act). NOTA authorizes HRSA, by delegation from the Secretary, to issue regulations governing the operation of the OPTN. NOTA, as amended, also authorizes the Secretary to define human organs to be covered by the OPTN. Section 374 of the PHS Act specifically states, ''[t]he term 'organ' means the human kidney, liver, heart, lung, pancreas, and any other human organ (other than corneas and eyes) specified by the Secretary by regulation * * *'' (42 U.S.C. 274b(d)(2)) (emphasis supplied). Accordingly, HRSA is proposing to issue this regulation to modify the definition of ''organ,'' and to make blood vessels labeled and intended for use in the transplantation of organs subject to regulations governing the operation of the OPTN. Extending the definition of organs governed by HRSA in 42 CFR 121.2 to add blood vessels recovered with organs that are intended for use in organ transplantation, and labeled as such, furthers the Secretary's charge under NOTA.

Under the authority of section 361 of the PHS Act delegated to the Commissioner of FDA, the Department of Health and Human Services may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or from foreign countries into the States. This modification of FDA's existing regulation reflects FDA's re-evaluation of the level of regulation that is necessary to prevent disease transmission involving blood vessels intended for use in organ transplantation.

IV. Description of the Proposed Rule

To transfer from FDA to HRSA jurisdiction over blood vessels intended for use in organ transplantation, we propose the following revisions to 21 CFR 1271.3(d), 42 CFR 121.2, and 42 CFR 121.7.

A. 21 CFR 1271.3(d)

21 CFR 1271.3(d) defines HCT/Ps as ''articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.'' In the definition, we also identify articles not considered HCT/Ps. This proposed rule would add § 1271.3(d)(8), in order to exclude blood vessels intended for use in organ transplantation from the definition of HCT/Ps. The rule excludes such blood vessels intended for use in organ transplantation only when they are labeled as ''For use in organ transplantation only'' to distinguish such vessels from blood vessels not intended for use in organ transplantation. By labeling such blood vessels ''For use in organ transplantation only'' we expect that they would not be used for other purposes. Under the proposal, blood vessels intended for other uses would remain subject to 21 CFR part 1271 (or 21 CFR part 1270, for tissue recovered prior to May 25, 2005).

B. 42 CFR 121.2

Under 42 CFR 121.2, ''Organ'' means a human kidney, liver, heart, lung, or pancreas. This proposed rule adds to that definition ''Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this Part if the vessels are intended for use in organ transplantation and labeled ''For use in organ transplantation only.'' Blood vessels intended for use in organ transplantation would be required to be in compliance with HRSA provisions for donor screening and testing. The labeling provision would be a distinct requirement in order for such blood

vessels to fall under the regulation governing the operation of the OPTN. Any OPTN labeling policies, whether voluntary or enforceable, would supplement this requirement.

C. 42 CFR 121.7

In 42 CFR 121.7, we are proposing to redesignate paragraph (e) as paragraph (f), and to add a new paragraph (e). Under proposed 42 CFR 121.7(e), a blood vessel intended for use in organ transplantation would be subject to the allocation requirements under 42 CFR part 121 and enforceable OPTN policies pertaining to the organ with which the blood vessel is procured. These provisions would apply until the transplant center receiving the organ determines that the blood vessel is not needed for the transplantation of that organ. This allocation priority will assure that vessels that may be necessary for the immediate transplantation of the organs with which they are recovered are made available for that use prior to being diverted to other organ transplant uses.

V. Analysis of Impacts

FDA and HRSA have examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA and HRSA believe that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the agencies do not expect that the transfer of jurisdiction over the blood vessels described in this rule from FDA to HRSA will result in substantial changes in the way transplant hospitals and OPOs procure, store, and transplant such blood vessels, FDA and HRSA certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA and HRSA do not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. The Paperwork Reduction Act of 1995

This proposed rule contains no collections of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

VII. Environmental Impact

FDA and HRSA have determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

FDA and HRSA have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA and HRSA have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, FDA and HRSA have concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

X. Proposed Effective Date

FDA and HRSA propose that any final rule that may issue based on this proposal become effective on the date of its publication in the **Federal Register**.

List of Subjects

21 CFR Part 1271

Biologics, Communicable diseases, Drugs, HIV/AIDS, Human cells, tissues, and cellular and tissue-based products, Medical Devices, Reporting and recordkeeping requirements.

42 CFR Part 121

Healthcare, Hospitals, Reporting and recordkeeping requirements.

Therefore, under the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs and to the Administrator, Health Resources and Services Administration it is proposed that 21 CFR part 1271 and 42 CFR part 121 be amended as follows:

21 CFR Chapter I

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

1. The authority citation for 21 CFR part 1271 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 263a, 264, 271.

2. Section 1271.3 is amended by adding paragraph (d)(8) to read as follows:

§ 1271.3 How does FDA define important terms in this part?

* * * * *

(d) * * *

(8) Blood vessels recovered with an organ, as defined in 42 CFR 121.2, that are intended for use in organ transplantation and labeled ''For use in organ transplantation only.''

* * * * *

42 CFR Chapter I

PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

3. The authority citation for 42 CFR 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); and sections 1102, 1106, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1320b–8 and 1395hh).

4. Section 121.2 is amended by adding a sentence at the end of the definition of ''Organ'' to read as follows:

§ 121.2 Definitions.

* * * * *

Organ *** Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels

are intended for use in organ transplantation and labeled ''For use in organ transplantation only.''

* * * * *

5. Section 121.7 is amended by redesignating paragraph (e) as paragraph (f) and by adding paragraph (e) to read as follows:

§ 121.7 Identification of organ recipient.

* * * * *

(e) *Blood vessels considered part of an organ.* A blood vessel that is considered part of an organ under this part shall be subject to the allocation requirements and policies pertaining to the organ with which the blood vessel is procured until and unless the transplant center receiving the organ determines that the blood vessel is not needed for the transplantation of that organ.

* * * * *

Dated: April 10, 2006.

Elizabeth M. Duke,

Administrator, Health Resources and Services and Administration.

Dated: February 8, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy, Food and Drug Administration.

[FR Doc. 06–4370 Filed 5–11–06; 8:45 am]

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DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 551

[BOP Docket No. 1140–P]

RIN 1120–AB42

Smoking/No Smoking Areas

AGENCY: Bureau of Prisons, Justice.

ACTION: Proposed rule.

SUMMARY: In this document, the Bureau of Prisons (Bureau) proposes to revise regulations pertaining to smoking/no smoking for inmates in Bureau facilities. The revised regulations indicate that smoking is generally prohibited in and on the grounds of Bureau institutions and offices, with the following two exceptions: Smoking is permitted as part of an authorized inmate religious activity; and, for Bureau staff and official visitors, smoking is permitted only in smoking areas designated by the Warden. This rule also clarifies that possession of smoking apparatus and tobacco in any form is prohibited for inmates, unless as part of an authorized inmate religious activity. Smoking is defined as inhaling the smoke of any substance through the use of smoking apparatus including, but not limited to, cigars, cigarettes, or pipes. We intend this amendment to promote a clean air environment and to protect the health and safety of staff and inmates.

DATES: Comments due by July 11, 2006.

ADDRESSES: Our e-mail address is *BOPRULES@BOP.GOV.* Comments should be submitted to the Rules Unit, Office of General Counsel, Bureau of Prisons, 320 First Street, NW., Washington, DC 20534. You may view an electronic version of this rule at www.regulations.gov. You may also comment via the Internet to BOP at *BOPRULES@BOP.GOV* or by using the *http://www.regulations.gov* comment form for this regulation. When submitting comments electronically you must include the BOP Docket No. in the subject box.

FOR FURTHER INFORMATION CONTACT: Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307–2105.

SUPPLEMENTARY INFORMATION: In this document, the Bureau proposes to revise regulations pertaining to smoking/no smoking for inmates in Bureau facilities. The revised regulations indicate that smoking is generally prohibited in and on the grounds of Bureau institutions and offices, with the following two exceptions: Smoking is permitted as part of an authorized inmate religious activity; and, for Bureau staff and official visitors, smoking is permitted only in smoking areas designated by the Warden. This rule also clarifies that possession of smoking apparatus and tobacco in any form is prohibited for inmates, unless as part of an authorized inmate religious activity. Smoking is defined as inhaling the smoke of any substance through the use of smoking apparatus including, but not limited to, cigars, cigarettes, or pipes. We intend this amendment to promote a clean air environment and to protect the health and safety of staff and inmates.

A final rule was published on this subject on March 24, 2004 (69 FR 13735), after publication of a proposed rule on November 25, 1998 (63 FR 65502), and a modification on May 6, 1999 (64 FR 24468). The 2004 final rule prohibited indoor smoking areas for general inmate use, but allowed Wardens to designate outdoor smoking areas for general inmate use.

Several comments to the proposed rule and modification objected to allowing even outdoor smoking areas for inmates. These commenters instead proposed a total ban on the possession and use of lighted tobacco products for all prisoners. The commenters expressed dissatisfaction with the enforcement of the then-current smoking policy. Also, commenters expressed a general belief that prohibiting indoor smoking within Bureau facilities would have little impact on reducing smoking and improving the air quality. Two commenters on the original proposed rule also suggested that all tobacco products be banned and no tobacco products be sold in federal prisons.

As stated in the 2004 final rule document, the Bureau does not believe that removing tobacco products from the institution's commissary will have a significant economic impact as defined by the controlling statutes noted below. While there may be some impact on commissary profits, the Bureau believes that the health benefits outweigh any potential drop in such profits.

Also, when the 2004 regulations were implemented, Bureau policy mandated smoking cessation programs for inmates at all institutions to help ease inmate concerns about the possibility of no smoking areas. Nicotine patches are now available at the inmate's expense through commissary purchase.

In consideration of the concerns raised by these commenters and to further strengthen the Bureau's intention to protect the health and safety of both staff and inmates, we propose to revise the Bureau's smoking regulations to indicate that smoking is generally prohibited in and on the grounds of Bureau institutions and offices, with the following two exceptions: Smoking is permitted as part of an authorized inmate religious activity; and, for Bureau staff and official visitors, smoking is permitted only in smoking areas designated by the Warden.

Also in consideration of the commenters' concerns, this rule will prohibit inmate possession of smoking apparatus and tobacco in any form, unless as part of an authorized inmate religious activity.

The hazards associated with tobacco smoke and second-hand inhalation of smoke by nonsmokers is well documented and the known health risks associated with smoking support implementation of stricter smoking/no smoking rules. The Bureau believes that prohibiting smoking, including inmate possession of smoking apparatus and tobacco in any form, with only limited exceptions for authorized inmate religious activity and for Bureau staff and official visitors, designated smoking areas is the most practicable step toward promoting a clean air environment and protecting the health and safety of staff and inmates.