Proceedings, VIII: No. 2 Supplement 1, 133–138, 1976.

17. Sharkey, P. C., F. C. Usher, R. C. L. Robertson, and C. Pollard, "Lyophilized Human Dura Mater as a Dural Substitute," *Journal of Neurosurgery*, 15: 192–198, 1958.

List of Subjects in 21 CFR Part 882

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 882 be amended as follows:

PART 882—NEUROLOGICAL DEVICES

1. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c 360e, 360j, 371.

2. Section 882.1 is amended by adding paragraph (e) to read as follows:

§ 882.1 Scope.

* * * * *

- (e) Guidance documents in this part may be obtained on the Internet at http://www.fda.gov/cdrh/guidance.html.
- 3. Section 882.5975 is added to subpart F to read as follows:

§ 882.5975 Human dura mater.

- (a) *Identification*. Human dura mater is human pachymeninx tissue intended to repair defects in human dura mater.
- (b) Classification. Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Human Dura Mater; Guidance for Industry and FDA." (See § 882.1 for availability information for guidances.)

Dated: September 30, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.
[FR Doc. 02–26816 Filed 10–21–02; 8:45 am]
BILLING CODE 4160–01–8

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 20, 25, 31, 53, 54, 56, and 301

[REG-103735-00; REG-154117-02; REG-154116-02; REG-154115-02; REG-154429-02; REG-154423-02; REG-154426-02; REG-110311-98]

RIN 1545-AX81; RIN 1545-BB49; RIN 1545-BB50; RIN 1545-BB48; RIN 1545-BB53; RIN 1545-BB51; RIN 1545-BB52; RIN 1545-AW26

Tax Shelter Disclosure Statements

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations; notice of public hearing.

SUMMARY: These proposed rules provide the public with additional guidance needed to comply with the disclosure rules under section 6011(a). The rules also make conforming changes to the registration requirements under section 6111(d). The proposed rules affect taxpayers participating in certain reportable transactions. In the rules and regulations portion of this issue of the Federal Register, the IRS is issuing temporary regulations that modify the rules relating to the requirement that certain taxpayers file a statement with their Federal tax returns under section 6011(a) for certain transactions, including transactions involving Federal income, estate, gift, employment, and pension or exempt organizations excise taxes. The temporary regulations also make conforming changes to the rules relating to the registration of tax shelters under section 6111(d). The text of the temporary regulations also serves as the text of these proposed regulations.

DATES: Written or electronic comments and requests to speak and outlines of topics to be discussed at the public hearing scheduled for December 11, 2002, at 10 a.m., must be received by December 2, 2002.

ADDRESSES: Send submissions to: CC:ITA:RU (REG-103735-00; REG-154117-02; REG-154116-02; REG-154115-02; REG-154429-02; REG-154423-02; REG-154426-02; REG-110311-98), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:ITA:RU (REG-103735-00; REG-154117-02; REG-154116-02; REG-154115-02; REG-154429-02; REG-154423-02; REG-154426-02; REG-110311-98), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit electronic comments directly to the IRS Internet site at http://www.irs.gov/regs. The public hearing will be held in room 6718, Internal Revenue Building, 1111 Constitution Ave., NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tara P. Volungis, Danielle M. Grimm, or Charlotte Chyr, 202–622–3080 (not a toll-free number); concerning submissions, Sonya Cruse, 202–622–7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collections of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, W:CAR:MP:FP:S, Washington, DC 20224. Comments on the collection of information should be received by December 23, 2002. Comments are specifically requested concerning:

Whether the proposed collections of information are necessary for proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility:

The accuracy of the estimated burden associated with the proposed collections of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collections of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of service to provide information.

The collections of information in this proposed regulation are in § 1.6011–4T(a), (d), (e), (f), and (g), and in § 301.6111–2T(b), (e), and (f). This information is required to provide the IRS with notice of transactions that are potentially abusive. This information will be used to ensure compliance with the Federal tax laws. The collections of information are mandatory. The likely respondents and recordkeepers are individuals, business or other for-profit institutions, and small businesses or organizations.

The burden for the collection of information in § 1.6011–4T will be reflected on Form 8886, "Reportable Transaction Disclosure Statement". The burden for the collection of information in § 301.6111–2T is reflected on Form 8264, "Application for Registration of a Tax Shelter".

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

The temporary regulations amend the rules in 26 CFR parts 1, 20, 25, 31, 53, 54, and 56 regarding the filing and records requirements of certain taxpayers under section 6011. The temporary regulations also amend the rules in 26 CFR part 301 regarding the registration of confidential corporate tax shelters under section 6111. The text of the temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the regulations.

Special Analyses

It has been determined that these notices of proposed rulemaking are not significant regulatory actions as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. It is hereby certified that the collection of information in these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based upon the fact that the time required to prepare or retain the disclosure or registration is not lengthy and will not have a significant impact on those small entities that are required to provide disclosure or to register. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Internal Revenue Code, these notices of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (preferably a signed original and eight (8) copies) or electronically generated comments that are submitted timely to the IRS. The IRS and Treasury request comments on the clarity of the proposed rules and how they can be made easier to understand.

All comments will be available for public inspection and copying.

A public hearing has been scheduled for December 11, 2002, beginning at 10 a.m. in room 6718 of the Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the FOR FURTHER **INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 606.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit electronic or written comments and an outline of the topics to be discussed and the time to be devoted to each topic (signed original and eight (8) copies) by December 2, 2002. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal authors of these regulations are Tara P. Volungis, Danielle M. Grimm, and Charlotte Chyr, Office of the Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 20

Estate tax, Reporting and recordkeeping requirements.

26 CFR Part 25

Gift taxes, Reporting and recordkeeping requirements.

26 CFR Part 31

Employment taxes, Income taxes, Penalties, Pensions, Railroad retirement, Reporting and recordkeeping requirements, Social security, Unemployment compensation. 26 CFR Part 53

Excise taxes, Foundations, Investments, Lobbying, Reporting and recordkeeping requirements.

26 CFR Part 54

Excise taxes, Pensions, Reporting and recordkeeping requirements.

26 CFR Part 56

Excise taxes, Lobbying, Nonprofit organizations, Reporting and recordkeeping requirements.

26 CFR Part 301

Administrative practice and procedure, Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 301, which were proposed to be amended at 67 FR 41362 (June 18, 2002), are proposed to be further amended and 26 CFR parts 20, 25, 31, 53, 54, and 56 are proposed to be amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *

2. Section 1.6011–4, as proposed to be added at 66 FR 41169 (August 7, 2001) and amended at 67 FR 41362 (June 18, 2002), is revised to read as follows:

§ 1.6011–4 Requirement of statement disclosing participation in certain transactions by taxpayers.

[The text of the revision of this proposed section is the same as the text of the revision of § 1.6011–4T published elsewhere in this issue of the **Federal Register**.]

PART 20—ESTATE TAX; ESTATES OF DECEDENTS DYING AFTER AUGUST 16, 1954

3. The authority citation for part 20 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

4. Section 20.6011–4 is added to read as follows:

§ 20.6011–4 Requirement of statement disclosing participation in certain transactions by taxpayers.

[The text of this proposed section is the same as the text of § 20.6011–4T published elsewhere in this issue of the Federal Register.]

PART 25—GIFT TAX; GIFTS MADE AFTER DECEMBER 31, 1954

5. The authority citation for part 25 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

6. Section 25.6011–4 is added to read as follows:

§ 25.6011–4 Requirement of statement disclosing participation in certain transactions by taxpayers.

[The text of this proposed section is the same as the text of § 25.6011–4T published elsewhere in this issue of the Federal Register.]

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT SOURCE

7. The authority citation for part 31 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

8. Section 31.6011–4 is added to read as follows:

§ 31.6011–4 Requirement of statement disclosing participation in certain transactions by taxpayers.

[The text of this proposed section is the same as the text of § 31.6011–4T published elsewhere in this issue of the Federal Register.]

PART 53—FOUNDATION AND SIMILAR EXCISE TAXES

9. The authority citation for part 53 continues to read as follows:

Authority: 26 U.S.C. 7805.

10. Section 53.6011–4 is added to read as follows:

§ 53.6011–4 Requirement of statement disclosing participation in certain transactions by taxpayers.

[The text of this proposed section is the same as the text of § 53.6011–4T published elsewhere in this issue of the Federal Register.]

PART 54—PENSION EXCISE TAXES

11. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

12. Section 54.6011–4 is added to read as follows:

§ 54.6011–4 Requirement of statement disclosing participation in certain transactions by taxpayers.

[The text of this proposed section is the same as the text of § 54.6011–4T published elsewhere in this issue of the Federal Register.]

PART 56—PUBLIC CHARITY EXCISE TAXES

13. The authority citation for part 56 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

14. Section 56.6011–4 is added to read as follows:

§ 56.6011–4 Requirement of statement disclosing participation in certain transactions by taxpayers.

[The text of this proposed section is the same as the text of § 56.6011–4T published elsewhere in this issue of the Federal Register.]

PART 301—PROCEDURE AND ADMINISTRATION

15. The authority citation for part 301 is amended by adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 301.6111–2 also issued under 26 U.S.C. 6111. * * *

- 16. Section 301.6111–2, as proposed to be added at 66 FR 41169 (August 7, 2001) and amended at 67 FR 41363 (June 18, 2002), is amended as follows:
- 1. Paragraphs (a)(3) and (b)(3)(i) are revised.
- 2. Paragraph (c)(3) is amended by adding a sentence at the end of the paragraph.
- 3. Paragraph (h) is amended by revising the paragraph heading and removing the third sentence through the last sentence and adding two new sentences in their place.

The revisions and additions read as follows:

§ 301.6111–2 Confidential corporate tax shelters.

[The text of the amendments to this proposed section is the same as the text of the amendments to § 301.6111–2T published elsewhere in this issue of the Federal Register.]

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue. [FR Doc. 02–26725 Filed 10–17–02; 3:10 pm] BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG-103736-00]

RIN 1545-AX79

Requirement To Maintain a List of Investors in Potentially Abusive Tax Shelters

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations; notice of public hearing.

SUMMARY: These proposed rules relate to the preparation, maintenance, and furnishing of lists of persons in potentially abusive tax shelters under section 6112. These regulations apply to sellers and organizers, collectively known as material advisors, of potentially abusive tax shelters. In the rules and regulations portion of this issue of the Federal Register, the IRS is issuing temporary regulations modifying the rules relating to the list maintenance requirements under section 6112. The text of those temporary regulations also serves as the text of these proposed regulations.

DATES: Written or electronic comments and requests to speak and outlines of topics to be discussed at the public hearing scheduled for December 11, 2002, at 10 a.m., must be received by December 2, 2002.

ADDRESSES: Send submissions to: CC:ITA:RU (REG-103736-00), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:ITA:RU (REG-103736-00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit electronic comments directly to the IRS Internet site at www.irs.gov/regs. The public hearing will be held in room 6718, Internal Revenue Building, 1111 Constitution Ave., NW., Washington,

FOR FURTHER INFORMATION CONTACT:

Charlotte Chyr, Tara P. Volungis, or Danielle M. Grimm, 202–622–3080 (not a toll-free number); concerning submissions, Sonya Cruse, 202–622– 7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION: