106TH CONGRESS 1ST SESSION

H. R. 2418

To amend the Public Health Service Act to revise and extend programs relating to organ procurement and transplantation.

IN THE HOUSE OF REPRESENTATIVES

July 1, 1999

Mr. Bilirakis (for himself, Mr. Green of Texas, and Mr. Pallone) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Public Health Service Act to revise and extend programs relating to organ procurement and transplantation.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Organ Procurement
- 5 and Transplantation Network Amendments of 1999".
- 6 SEC. 2. FINDINGS.
- 7 (a) IN GENERAL.—The Congress finds as follows:
- 8 (1) It is in the public interest to maintain and
- 9 improve a system for promoting and supporting a
- 10 central network in the private sector to assist organ

- procurement organizations and transplant centers in the distribution of organs among transplant patients and the provision of organ transplantation services, and to assure quality and facilitate collaboration among network members and individual medical practitioners participating in network activities.
 - (2) The Organ Procurement and Transplantation Network ("Network"), which is in the private sector, exists because of a partnership between public and private enterprise. A nonprofit private entity established the Network pursuant to a contract awarded by the Federal Government, and that same entity has operated the Network since the Network was established.
 - (3) It is desirable to continue this partnership, and the Federal Government should continue to provide Federal oversight of and financial assistance for the services performed by the Network.
 - (4) The responsibility for developing, establishing, and maintaining medical criteria and standards for organ procurement and transplantation belongs in the private sector and is a function of the Network.
 - (5) The Federal Government should cooperate with the Network to assist its efforts to serve pa-

1	tients and donor families in procuring and distrib-
2	uting organs.
3	(6) The Federal Government should carry out
4	programs to educate the public with respect to organ
5	donation, including the need to provide for an ade-
6	quate rate of such donations.
7	(b) Sense of Congress.—The Congress—
8	(1) recognizes the generous contribution made
9	by each living individual who has donated an organ
10	to save a life; and
11	(2) acknowledges the advances in medical tech-
12	nology that have enabled organ transplantation with
13	organs donated by living individuals to become a via-
14	ble treatment option for an increasing number of pa-
15	tients.
16	SEC. 3. ORGAN PROCUREMENT AND TRANSPLANTATION
17	NETWORK.
18	(a) In General.—Section 372 of the Public Health
19	Service Act (42 U.S.C. 274) is amended to read as follows:
20	"ORGAN PROCUREMENT AND TRANSPLANTATION
21	NETWORK
22	"Sec. 372. (a) In General.—The Secretary shall
23	by contract provide for the establishment and operation
24	of an Organ Procurement and Transplantation Network

- 1 (in this section referred to as the 'Network') that meets
 2 the following requirements:
 3 "(1) The Network shall be an independent,
- nonprofit private entity that has expertise and experience in organ procurement and transplantation.
 - "(2) The Network shall in accordance with criteria under subsection (b)(3) include as members qualified organ procurement organizations (as described in section 371(b)), transplant centers, and other entities that have a demonstrated interest in the fields of organ donation or transplantation.

 (Such members are in this section referred to as 'Network participants'.)
 - "(3) The Network shall have a board of directors (in this section referred to as the 'Board'). The Board shall, after consultation with Network participants, establish the policies for carrying out the functions described in this section for the Network.
 - "(4) The Board shall be in accordance with the following:
- 21 "(A) The Board shall include representa-22 tives of qualified organ procurement organiza-23 tions, transplant centers, voluntary health asso-24 ciations, and the general public, including a 25 reasonable proportion of the members of the

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Board who are patients awaiting a transplant or transplant recipients or individuals who have donated an organ or family members of patients, recipients or donors.

- "(B) The Board shall establish membership categories and qualifications with respect to serving on the Board, and shall have exclusive authority to admit individuals to membership on the Board. Transplant surgeons and transplant physicians shall comprise not less than 50 percent of the membership of the Board. The Board shall be limited to a total of 42 members.
- "(C) The Board shall have an executive committee, and such other committees as the Board determines to be appropriate.
- "(D) The chair of each such committee shall be selected so as to ensure the continuity of leadership for the Board.
- 20 "(b) General Functions.—The following applies 21 to the Network:
- "(1) The Network shall establish and operate a
 national system to match organs and individuals
 who need organ transplants, especially individuals

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- whose immune system makes it difficult for them to receive organs.
- "(2) The national system shall maintain one or more lists of individuals who need organ transplants, shall be operated in accordance with established medical criteria, shall be operated through the use of computers, and may function on a regionalized basis.
 - "(3) The Network shall establish criteria for being a Network participant, shall establish medical criteria for allocating organs, and shall provide to members of the public an opportunity to comment with respect to such criteria.
 - "(4) The Network shall maintain a twenty-fourhour telephone and computer service to facilitate matching organs with individuals included in the list.
 - "(5) The Network shall assist organ procurement organizations in the local, regional, and nation-wide distribution of organs. The distribution of organs shall be based on medical criteria established by the Network, and also shall be based on equity and ethics without regard to economic status of those awaiting organ transplants and without political control or influence.

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- "(6) The Network shall adopt and use standards of quality for the acquisition and transportation of donated organs, including standards regarding the transmission of infectious diseases.
 - "(7) The Network shall prepare and distribute, on a regionalized basis (and, to the extent practicable, among regions or on a national basis), samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the compatibility of such individuals with organ donors.
 - "(8) The Network shall coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers.
 - "(9) The Network shall work actively to increase the supply of donated organs.

18 "(c) Scientific Registry.—

"(1) IN GENERAL.—The Network shall maintain a scientific registry of patients awaiting organ transplantation, persons from whom organs are removed for transplantation, and organ transplant recipients for the ongoing evaluation of the scientific and clinical status of organ transplantation.

1	"(2) Reports.—The Network shall prepare for
2	inclusion in the report under section 375 an analysis
3	of scientifically and clinically valid information de-
4	rived from the scientific registry under paragraph
5	(1).
6	"(d) Information and Data.—
7	"(1) In general.—The Network shall—
8	"(A) provide information to physicians and
9	other health professionals regarding organ do-
10	nation and transplantation; and
11	"(B) collect, analyze, and publish data con-
12	cerning organ donation and transplantation.
13	"(2) Information for patients and gen-
14	ERAL PUBLIC.—The Network shall make available to
15	patients in need of organ transplants information in
16	accordance with the following:
17	"(A) The information shall be transplant-
18	related information specific to transplant cen-
19	ters that are Network participants, which infor-
20	mation has been determined by the Network to
21	be scientifically and clinically valid.
22	"(B) The information shall be designed to
23	assist patients and referring physicians in
24	choosing a transplant center, including informa-
25	tion on the supply of and demand for organs.

1	"(C) With respect to the patient involved,
2	the information shall (taking into account pa-
3	tients in similar medical circumstances) include
4	the following as applied to specific transplant
5	centers:
6	"(i) The probability of receiving an
7	organ transplant.
8	"(ii) The length of time that similarly
9	situated patients have waited historically to
10	receive a transplant.
11	"(iii) Medical outcomes for similarly
12	situated patients, which information shall
13	be adjusted to reflect the medical risk fac-
14	tors for such patients.
15	"(D) With respect to the patient involved,
16	the information shall include the information
17	described in subparagraph (C) as applied to the
18	service areas of specific qualified organ procure-
19	ment organizations (other than such areas in
20	which there is only one transplant center).
21	"(3) Annual Public Report.—The Network
22	shall annually make available to the public a report
23	on the overall status of organ procurement and
24	transplantation.

- 1 "(4) CONFIDENTIALITY.—Except for the re2 lease of information that is authorized under para3 graph (2) or (3) by the Network, neither the Net4 work nor the Secretary has authority to release the
 5 following information (unless authorized in writing
 6 by the patient or other entity with which the data
 7 is concerned):
 - "(A) Information that permits direct or indirect identification of any patient who is waiting for a transplant, or who is an organ transplant patient or recipient of an organ.
 - "(B) Information that permits direct or indirect identification of any potential or actual organ donors.
 - "(C) Information that permits direct or indirect identification of participants in Network deliberations or determinations related to practitioner or institutional qualifications, due process proceedings or peer review activities, except for information announcing final decisions of the Network.

This paragraph may not be construed as prohibiting the disclosure of information within the Network, including information disclosed in the course of interactive organ sharing operations within the Network.

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1 "(e) STUDIES.—
2 "(1) IN GE

"(1) IN GENERAL.—The Network shall carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation, including but not limited to projects to examine and attempt to increase transplantation among populations with special needs or limited access to transplantation.

"(2) CERTAIN TECHNOLOGIES.—The Network may study the impact of possible transplantation of animal organs (xenotransplantation) and other technologies to determine the impact upon, and prevent negative effects on, the fair and effective use of human allograft organs.

"(f) QUALITY ASSURANCE.—

"(1) IN GENERAL.—The Network shall develop a peer review system for assuring that members of the Network comply with criteria under subsection (b)(3).

"(2) Noncompliance.—

"(A) PAYMENT OF DAMAGES.—The Network shall require that, as a condition of being a Network participant, each such participant agree that the Network may, through a peer review proceeding under paragraph (1), require

the participant to pay damages for the failure of the participant to comply with criteria under subsection (b)(3). The Network shall establish procedures to ensure that such proceedings are conducted in an impartial manner, with adequate opportunity for the Network participant involved to receive a hearing. The Network shall identify various types of violations of such criteria and specify the maximum amount of damages that the Network may under this subparagraph require a Network participant to pay for the type of violation involved.

"(B) RESTRICTING ACCESS TO ALLOCATION SYSTEM.—If under subparagraph (A) it has been determined that a Network participant has engaged in substantial violations of criteria under subsection (b)(3), the Network may restrict the extent to which such participant is permitted to receive allocations of organs through the Network.

"(C) STATUS OF NETWORK PARTICIPANTS
WITH RESPECT TO VIOLATIONS.—Subject to
paragraph (3), the Network may take actions to
make the public aware of the extent to which a
Network participant has been required to pay

damages under subparagraph (A) or has been the subject of restrictions under subparagraph (B).

"(3) Confidentiality.—With respect to a peer review proceeding under paragraph (1), neither the Network nor the Secretary has authority to release data or information to the public relating to the proceedings without the written permission of all the parties involved, except that if damages under paragraph (2) are required to be paid, the requirement may be publicly announced after the conclusion of the proceeding.

"(g) Administrative Provisions.—

"(1) LIMITATION ON AMOUNT OF CONTRACT.—
The amount provided under a contract under subsection (a) in any fiscal year may not exceed \$6,000,000 for the operation of the Network, including the scientific registry under subsection (c). Such limitation does not apply to amounts provided under the contract for increasing organ donation and procurement.

"(2) Relationship between secretary and network.—The administrative and procedural functions described in this section for the Network shall be carried out in accordance with the mutual

agreement of the Secretary and the Network. For purposes of the preceding sentence, functions that are scientific, clinical, or medical in nature are not administrative or procedural functions and are within the sole discretion of the Network. With respect to the programs under titles XVIII and XIX of the Social Security Act, this section may not be construed as having any legal effect on such programs, except to the extent that section 1138 of such Act, or any other provision of such Act, provides otherwise.

"(3) Nonfederal assets of Network.—

"(A) In General.—No assets in the possession of the Network or revenues collected by the Network, other than amounts appropriated under section 378, shall be considered or be treated as Federal property, Federal revenues, or program funds pursuant to a Federal contract, nor shall such assets, revenues, or non-appropriated funds be subject to restriction or control by the Secretary, nor shall any member of the Network be required by the Secretary to pay any fees to the Network, nor shall the Secretary be authorized to collect or authorize collection of service fees with respect to the Network

work or the scientific registry under subsection (e).

"(B) GIFTS.—This section does not prohibit the Network from accepting gifts of money or services, including gifts to carry out activities to provide for an increase in the rate of organ donation.

"(4) Community endorsement of contract under subsection (a) that is awarded after the date of the enactment of the Organ Procurement and Transplantation Network Amendments of 1999, the Secretary shall select an applicant to receive the contract from among applicants that have the written endorsement of a majority of the combined total number of transplant centers and qualified organ procurement organizations that are Network participants (without regard to whether such centers or organizations endorse more than one applicant for the contract).

"(5) Change in contract recipient.—With respect to the expiration of the period during which a contract under subsection (a) is in effect, if the Secretary makes a determination to award the contract to a different entity than the entity to which the previous contract under such subsection was

- 1 awarded, the Secretary shall publish in the Federal
- 2 Register a notice that such change in the adminis-
- 3 tration of the Network will take place, and the
- 4 change may not take effect any sooner than the ex-
- 5 piration of the six-month period beginning on the
- 6 date on which the notice is so published.
- 7 "(h) Additional Procedures Regarding Over-
- 8 SIGHT AND PUBLIC ACCOUNTABILITY.—For purposes of
- 9 providing oversight of and public accountability for the op-
- 10 eration of the Network, the Secretary shall establish pro-
- 11 cedures for—
- 12 "(1) conducting public hearings and receiving
- from interested persons comments regarding criteria
- of the Network and critical comments relating to the
- manner in which the Network is carrying out its du-
- ties under this section;
- 17 "(2) providing such comments to the Network
- and receiving responses from the Network; and
- 19 "(3) the consideration by the Secretary of such
- comments.
- 21 "(i) Evaluations by General Accounting Of-
- 22 FICE.—
- "(1) IN GENERAL.—The Comptroller General of
- the United States shall periodically conduct evalua-
- 25 tions of the Network, including the structure and

- function of the Network and the relationship be-tween the Secretary and the nonprofit private entity that under subsection (a) operates the Network. The first such evaluation shall be completed not later than one year after the date of the enactment of the Organ Procurement and Transplantation Network Amendments of 1999, and such an evaluation shall be completed not later than every third year there-after.
 - "(2) INPUT FROM FIELD.—In conducting evaluations under paragraph (1), the Comptroller General shall consult with experts in the field of organ transplantation, including organizations that represent transplant surgeons, transplant physicians, transplant centers, and qualified organ procurement organizations.
 - "(3) PROCEDURES OF NETWORK.—The Network shall establish procedures for coordinating with the Comptroller General for purposes of evaluations under paragraph (1).
 - "(4) Reports to congress.—The Comptroller General shall prepare reports describing the findings of evaluations under paragraph (1) and shall submit such reports to the Committee on Commerce of the House of Representatives and the Representatives and the Representative and the Representative

1	mittee on Health, Education, Labor, and Pensions
2	of the Senate.".
3	(b) Rule of Construction.—The amendments
4	made by this Act may not be construed as affecting the
5	duration of the contract under section 372 of the Public
6	Health Service Act that was in effect on the day before
7	the date of the enactment of this Act.
8	SEC. 4. ADDITIONAL AMENDMENTS.
9	(a) In General.—Part H of title III of the Public
10	Health Service Act (42 U.S.C. 273 et seq.) is amended—
11	(1) by striking section 373;
12	(2) in section 374—
13	(A) in subsection $(b)(1)$, by inserting after
14	"organization" the following: "and other orga-
15	nizations for the purpose of increasing the sup-
16	ply of transplantable organs";
17	(B) in subsection (c), by striking "or 373"
18	each place such term appears; and
19	(C) in subsection (d), by amending para-
20	graph (2) to read as follows:
21	"(2) The term "organ", with respect to trans-
22	plantation into humans, means the human or other
23	animal kidney, liver, heart, lung, pancreas, and any
24	other organ (other than human corneas and eyes)
25	specified by the Secretary by regulation. For pur-

1	poses of section 372(c), such term includes bone
2	marrow.";
3	(3) in section 375—
4	(A) in paragraph (1), by striking "this
5	part" and inserting "this section"; and
6	(B) in paragraph (4)—
7	(i) by redesignating clauses (i) and
8	(ii) as subparagraphs (A) and (B), respec-
9	tively; and
10	(ii) in subparagraph (B) (as so redes-
11	ignated), by striking "comparative costs
12	and patient outcomes" and inserting "com-
13	parative patient outcomes";
14	(4) in section 376—
15	(A) by striking "the Secretary" and insert-
16	ing "the Organ Procurement and Transplan-
17	tation Network under section 372"; and
18	(B) by striking "Committee on Energy and
19	Commerce" and inserting "Committee on Com-
20	merce''; and
21	(5) by striking section 377.
22	(b) Redesignations.—Part H of title III of the
23	Public Health Service Act, as amended by subsection (a)
24	of this section, is amended by redesignating sections 374
25	through 376 as sections 373 through 375, respectively.

1	(c) Prohibition Against Organ Purchases.—
2	Section 301(c)(2) of the National Organ Transplant Act
3	(42 U.S.C. 274e(c)(2)) is amended by inserting after
4	"does not include" the following: "a benefit, the exchange
5	of which is expressly contemplated by organ distribution
6	policies, demonstration projects, or programs duly estab-
7	lished or sanctioned by the board of directors of the Organ
8	Procurement and Transplantation Network under section
9	372 of the Public Health Service Act, or".
10	SEC. 5. PAYMENT OF TRAVEL AND SUBSISTENCE EXPENSES
11	INCURRED TOWARD LIVING ORGAN DONA-
12	TION.
13	Part H of title III of the Public Health Service Act,
14	as amended by section 4(b) of this Act, is amended by
15	inserting after section 375 the following section:
16	"PAYMENT OF TRAVEL AND SUBSISTENCE EXPENSES
17	INCURRED TOWARD LIVING ORGAN DONATION
18	"Sec. 376. (a) In General.—The Secretary may
19	make awards of grants or contracts to States, transplant
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	centers, qualified organ procurement organizations under
21	section 371, or other public or private entities for the pur-
21 22	
	section 371, or other public or private entities for the pur-
22	section 371, or other public or private entities for the purpose of—
22 23	section 371, or other public or private entities for the purpose of— "(1) providing for the payment of travel and

1	"(2) in addition, providing for the payment of
2	such incidental nonmedical expenses that are so in-
3	curred as the Secretary determines by regulation to
4	be appropriate.
5	"(b) Eligibility.—
6	"(1) In general.—Payments under subsection
7	(a) may be made for the qualifying expenses of a do-
8	nating individual only if—
9	"(A) the State in which the donating indi-
10	vidual resides is a different State than the
11	State in which the intended recipient of the
12	organ resides; and
13	"(B) the annual income of the intended re-
14	cipient of the organ does not exceed \$35,000
15	(as adjusted for fiscal year 2001 and subse-
16	quent fiscal years to offset the effects of infla-
17	tion occurring after the beginning of fiscal year
18	2000).
19	"(2) CERTAIN CIRCUMSTANCES.—Subject to
20	paragraph (1), the Secretary may in carrying out
21	subsection (a) provide as follows:
22	"(A) The Secretary may consider the term
23	'donating individuals' as including individuals
24	who in good faith incur qualifying expenses to-
25	ward the intended donation of an organ but

with respect to whom, for such reasons as the Secretary determines to be appropriate, no donation of the organ occurs.

"(B) The Secretary may consider the term 'qualifying expenses' as including the expenses of having one or more family members of donating individuals accompany the donating individuals for purposes of subsection (a) (subject to making payment for only such types of expenses as are paid for donating individuals).

"(c) Limitation on Amount of Payment.—

"(1) In General.—With respect to the geographic area to which a donating individual travels for purposes of subsection (a), if such area is other than the covered vicinity for the intended recipient of the organ, the amount of qualifying expenses for which payments under such subsection are made may not exceed the amount of such expenses for which payment would have been made if such area had been the covered vicinity for the intended recipient, taking into account the costs of travel and regional differences in the costs of living.

"(2) COVERED VICINITY.—For purposes of this section, the term 'covered vicinity', with respect to an intended recipient of an organ from a donating

1 individual, means the vicinity of the nearest trans-2 plant center to the residence of the intended recipi-3 ent that regularly performs transplants of that type 4 of organ. 5 "(d) Relationship to Payments Under Other Programs.—An award may be made under subsection (a) 6 only if the applicant involved agrees that the award will 8 not be expended to pay the qualifying expenses of a donating individual to the extent that payment has been made, or can reasonably be expected to be made, with respect 10 to such expenses— 11 "(1) under any State compensation program, 12 13 under an insurance policy, or under any Federal or 14 State health benefits program; or "(2) by an entity that provides health services 15 16 on a prepaid basis. 17 "(e) Definitions.—For purposes of this section: 18 "(1) The term 'covered vicinity' has the mean-19 ing given such term in subsection (c)(2). 20 "(2) The term 'donating individuals' has the meaning indicated for such term in subsection 21 22 (a)(1), subject to subsection (b)(2)(A). 23 "(3) The term 'qualifying expenses' means the 24 expenses authorized for purposes of subsection (a), 25 subject to subsection (b)(2)(B).

- 1 "(f) AUTHORIZATION OF APPROPRIATIONS.—For the
- 2 purpose of carrying out this section, there is authorized
- 3 to be appropriated \$5,000,000 for each of the fiscal years
- 4 2000 through 2005.".
- 5 SEC. 6. PUBLIC AWARENESS; STUDIES AND DEMONSTRA-
- 6 TIONS.
- 7 Part H of title III of the Public Health Service Act,
- 8 as amended by section 5 of this Act, is amended by insert-
- 9 ing after section 376 the following section:
- 10 "PUBLIC AWARENESS; STUDIES AND DEMONSTRATIONS
- 11 "Sec. 377. (a) Public Awareness.—The Secretary
- 12 shall (directly or through grants or contracts) carry out
- 13 a program to educate the public with respect to organ do-
- 14 nation, including the need to provide for an adequate rate
- 15 of such donations.
- 16 "(b) Studies and Demonstrations.—The Sec-
- 17 retary may make grants to public and nonprofit private
- 18 entities for the purpose of carrying out studies and dem-
- 19 onstration projects with respect to providing for an ade-
- 20 quate rate of organ donation. Such a grant may be made
- 21 to an entity only if the entity has a demonstrated history
- 22 and involvement in organ-donation activities.
- 23 "(c) Annual Report to Congress.—The Sec-
- 24 retary shall annually submit to the Congress a report on
- 25 the activities carried out under this section, including pro-

- 1 visions describing the extent to which the activities have
- 2 affected the rate of organ donation.
- 3 "(d) AUTHORIZATION OF APPROPRIATIONS.—
- 4 "(1) In general.—For the purpose of car-
- 5 rying out this section, there are authorized to be ap-
- 6 propriated \$10,000,000 for fiscal year 2000, and
- 7 such sums as may be necessary for each of the fiscal
- 8 years 2001 through 2005. Such authorization of ap-
- 9 propriations is in addition to any other authoriza-
- tions of appropriations that is available for such
- 11 purpose.
- 12 "(2) STUDIES AND DEMONSTRATIONS.—Of the
- amounts appropriated under paragraph (1) for a fis-
- cal year, the Secretary may not obligate more than
- \$2,000,000 for carrying out subsection (b).".
- 16 SEC. 7. AUTHORIZATION OF APPROPRIATIONS.
- 17 Section 378 of the Public Health Service Act (42
- 18 U.S.C. 274g) is amended to read as follows:
- 19 "AUTHORIZATION OF APPROPRIATIONS FOR ORGAN
- 20 PROCUREMENT AND TRANSPLANTATION NETWORK
- 21 "Sec. 378. (a) Operation of Network.—For the
- 22 purpose of providing for the Organ Procurement and
- 23 Transplantation Network under section 372, including the
- 24 scientific registry, there are authorized to be appropriated
- 25 \$6,000,000 for fiscal year 2000, and such sums as may

- 1 be necessary for each of the fiscal years 2001 through
- 2 2005.
- 3 "(b) Increasing Organ Donation and Procure-
- 4 MENT.—For the purpose of increasing organ donation and
- 5 procurement through the Organ Procurement and Trans-
- 6 plantation Network under section 372, there are author-
- 7 ized to be appropriated such sums as may be necessary
- 8 for each of the fiscal years 2000 through 2005. Such au-
- 9 thorization of appropriations is with respect to such pur-
- 10 pose in addition to the authorization of appropriations es-
- 11 tablished in subsection (a).".
- 12 SEC. 8. EFFECTIVE DATE.
- The amendments made by this Act take effect Octo-
- 14 ber 1, 1999, or upon the date of the enactment of this
- 15 Act, whichever occurs later.

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