

PROVIDING FOR THE CONSIDERATION OF H.R. 2418, THE
ORGAN PROCUREMENT AND TRANSPLANTATION NET-
WORK AMENDMENTS OF 1999

APRIL 3, 2000.—Referred to the House Calendar and ordered to be printed

Mr. LINDER, from the Committee on Rules,
submitted the following

REPORT

[To accompany H. Res. 454]

The Committee on Rules, having had under consideration House Resolution 454, by a nonrecord vote, report the same to the House with the recommendation that the resolution be adopted.

SUMMARY OF PROVISIONS OF THE RESOLUTION

The resolution provides for the consideration of H.R. 2418, the Organ Procurement and Transplantation Network Amendments of 1999, under a structured rule. The rule provides one hour of general debate divided equally between the chairman and ranking minority member of the Committee on Commerce.

The rule makes in order the Committee on Commerce amendment in the nature of a substitute now printed in the bill as an original bill for the purpose of amendment. The rule also makes in order only those amendments printed in this report which may be offered only in the order printed in this report, may be offered only by a Member designated in this report, shall be considered as read, shall be debatable for the time specified in this report equally divided and controlled by the proponent and an opponent, shall not be subject to amendment, and shall not be subject to a demand for a division of the question in the House or in the Committee of the Whole.

The rule waives all points of order against the amendment printed in this report. The rule allows the Chairman of the Committee of the Whole to postpone votes during consideration of the bill, and reduce voting time to five minutes on a postponed question if the vote follows a fifteen minute vote. Finally, the rule provides one motion to recommit with or without instructions.

SUMMARY OF AMENDMENTS MADE IN ORDER UNDER THE RULE

DeGette: Provide a technical revision to language in the bill to ensure that our nation's organ transplantation system recognizes children's unique health care needs and provides for a study of immunosuppressive drug coverage for children, in follow-up to the congressionally mandated Institute of Medicine study on Medicare immunosuppressive drug coverage, and on children's unique growth and developmental health and organ transplant needs. 10 minutes.

Luther: Ensures that the policies of the Network could not be thwarted or preempted by state or local law. 10 minutes.

LaHood/Moakley/Rush/Peterson (PA): Provides that the policies and rules established by the Network shall be subject to review and approval by the Secretary of HHS; requires both HHS and its contractor to apply scientific principles to the development of organ allocation policies, and; ensures that data necessary to evaluate and improve the organ transplant system are provided to the public. 60 minutes.

Barrett (WI)/Kleccka: Provides a financial incentive for states to creatively tackle the challenges inherent in organ donation awareness and education; authorizes direct grants to states and allows partnerships with other public agencies or private sector institutions within states to mutually undertake organ donation activities. 20 minutes.

Scarborough/Thurman: Nullifies the final rule issued by the Secretary of HHS that gives HHS the sole authority to approve or disapprove organ allocation policies that are currently established by the private-sector transplant community. 30 minutes.

Text of amendments made in order under the rule:

1. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE DEGETTE OF COLORADO, OR A DESIGNEE, DEBATABLE FOR 10 MINUTES

Page 8, strike lines 11 through 14 and insert the following:

“(10) The Network shall recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children.

Page 29, line 18, redesignate section 8 as section 9 and insert after line 17 the following:

SEC. 7. STUDY REGARDING IMMUNOSUPPRESSIVE DRUGS.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall provide for a study to determine the costs of immunosuppressive drugs that are provided to children pursuant to organ transplants and to determine the extent to which health plans and health insurance cover such costs. The Secretary may carry out the study directly or through a grant to the Institute of Medicine (or other public or non-profit private entity).

(b) RECOMMENDATIONS REGARDING CERTAIN ISSUES.—The Secretary shall ensure that, in addition to making determinations under subsection (a), the study under such subsection makes recommendations regarding the following issues:

(1) The costs of immunosuppressive drugs that are provided to children pursuant to organ transplants and to determine the extent to which health plans, health insurance and government programs cover such costs.

(2) The extent of denial of organs to be released for transplant by coroners and medical examiners.

(3) The special growth and developmental issues that children have pre- and post-organ transplantation.

(4) Other issues that are particular to the special health and transplantation needs of children.

(c) REPORT.—The Secretary shall ensure that, not later than December 31, 2000, the study under subsection (a) is completed and a report describing the findings of the study is submitted to the Congress.

2. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE LUTHER OF MINNESOTA OR A DESIGNEE, DEBATABLE FOR 10 MINUTES

Page 8, after line 14, insert the following subsection (and redesignate subsequent subsections accordingly):

“(c) COMPLIANCE WITH ORGAN ALLOCATION POLICIES.—No State or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement that would restrict in any way the ability of any transplant hospital, organ procurement organization, or other party to comply with organ allocation policies of the Network.

3. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE LAHOOD OF ILLINOIS, OR REPRESENTATIVE MOAKLEY OF MASSACHUSETTS, OR A DESIGNEE, DEBATABLE FOR 60 MINUTES

Page 14, strike line 21 and all that follows through page 17, line 17, and insert the following:

“(h) CERTAIN SCIENTIFIC AND ADMINISTRATIVE PRINCIPLES.—

“(1) SCIENTIFIC PRINCIPLES.—Policies under subsection (b) for the allocation of organs—

“(A) shall be based on sound medical principles;

“(B) shall be based on valid scientific data;

“(C) shall be equitable and seek to achieve the best use of donated organs;

“(D) shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;

“(E) shall be specific for each organ type or combination of organ types;

“(F) shall, where appropriate for the specific organ, provide status categories that group transplant candidates from most to least medically urgent;

“(G) shall not use patient waiting time as a criterion unless medically appropriate; and

“(H) shall be designed to share organs over as broad a geographic area as feasible, consistent with subparagraphs (A) through (G).

“(2) PATIENT LISTING AND STATUS.—Policies under subsection (b) for listing patients shall address the suitability of patients for transplants, appropriate priority status of each candidate, and the situations for removing candidates from the waiting list. Such policies shall be uniform for each organ type, objective, and medically appropriate.

“(3) REVIEW AND APPROVAL OF POLICIES; CONSISTENCY WITH SCIENTIFIC PRINCIPLES.—The policies and rules established by the Network shall be subject to review and approval by the Secretary (after consultation with the advisory committee under paragraph (4)), and no policy or rule established under subsection (b) may be inconsistent with paragraph (1) or (2). The applicability of sanctions under subsection (g) to any Network participant is subject to review and approval by the Secretary.

“(4) INDEPENDENT SCIENTIFIC REVIEW.—The Secretary shall establish (consistent with the Federal Advisory Committee Act) an advisory committee to provide recommendations to the Secretary on the policies and rules of the Network, and on such other matters as the Secretary determines to be appropriate.

“(5) PATIENT LISTING AND OTHER FEES.—

“(A) AVAILABILITY; RESTRICTION.—Fees collected by the Network—

“(i) are available to the Network, without fiscal year limitation, for use in carrying out the functions of the Network under this section; and

“(ii) may not be used for any activity for which contract funds awarded under subsection (a) may not be used.

“(B) APPLICABILITY.—Subparagraph (A) applies only to patient listing fees of the Network and to fees imposed as a condition of being a Network participant, and such fees are subject to the approval of the Secretary. Such subparagraph does not prohibit the Network from collecting other fees and using such fees for purposes other than those specified in such subparagraph.

“(C) GIFTS.—This section does not prohibit the Network from accepting gifts of money or services, including for purposes other than those specified in subparagraph (A). The Network may accept gifts of money or services to carry out activities to provide for an increase in the rate of organ donation.

“(6) INFORMATION.—The Network shall provide to the Secretary such information and data regarding the Network and Network participants as the Secretary determines to be appropriate. The Network shall provide data in a timely manner, with suitable patient confidentiality protections, to independent investigators and scientific reviewers.

“(7) 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 limi-

tation does not apply to amounts provided under the contract for increasing organ donation and procurement.

4. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE BARRETT OF WISCONSIN, OR A DESIGNEE, DEBATABLE FOR 20 MINUTES

Page 28, after line 3, insert the following subsection (and redesignate subsequent subsections accordingly):

“(c) GRANTS TO STATES.—The Secretary may make grants to States for the purpose of assisting States in carrying out organ donor awareness, public education and outreach activities and programs designed to increase the number of organ donors within the State, including living donors. To be eligible, each State shall—

“(1) submit an application to the Department in the form prescribed;

“(2) establish yearly benchmarks for improvement in organ donation rates in the State;

“(3) develop, enhance or expand a State donor registry, which shall be available to hospitals, organ procurement organizations, and other States upon a search request; and

“(4) report to the Secretary on an annual basis a description and assessment of the State’s use of these grant funds, accompanied by an assessment of initiatives for potential replication in other States.

Funds may be used by the State or in partnership with other public agencies or private sector institutions for education and awareness efforts, information dissemination, activities pertaining to the State organ donor registry, and other innovative donation specific initiatives, including living donation.

Page 28, line 12, strike “\$10,000,000” and insert “\$15,000,000”.

5. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE SCARBOROUGH OF FLORIDA, OR REPRESENTATIVE THURMAN OF FLORIDA, OR A DESIGNEE, DEBATABLE FOR 20 MINUTES

Page 29, after line 17, insert the following:

SEC. 8. NULLIFICATION OF FINAL RULE RELATING TO ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.

Notwithstanding any other provision of law, the final rule relating to the Organ Procurement and Transplantation Network, promulgated by the Secretary of Health and Human Services and published in the Federal Register on April 2, 1998 (63 Fed. Reg. 16296 et seq. adding part 121 to title 42, Code of Federal Regulations) and amended on October 20, 1999 (64 Fed. Reg. 56649 et seq.), shall have no force or legal effect.

Page 29, line 18, redesignate section 8 as section 9.