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Issue Analysis

The Case for Compensating Live Organ Donors

By Jennifer Monti

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Executive Summary

Conflicting opinions on the ethics of organ donation have existed as long as organ transplantation has been medically feasible. Eligibility requirements, reason for transplant, and international organ tourism continuously resurface as difficult medical policy and ethics issues. One issue about which there is little dispute is demand for organs far exceeding the supply of donors. Demand for kidneys exceeds the current supply of deceased donor organs and altruistic donors. Approximately 73,000 people sit on the waiting list for a kidney—18 of them will die by tomorrow and 6,000 more patients join the list every year. By 2010, over 100,000 Americans will wait for a kidney donation. A kidney transplant in the United States generally requires a five-year wait.

The development of a transparent, regulated market for live organ donation is currently prohibited by the National Organ Transplant Act of 1984 (NOTA), which imposes criminal penalties of up to \$50,000 and five years in prison for any person who “knowingly acquire[s], receive[s], or otherwise transfer[s] any human organ for valuable consideration for use in human transplantation.”

The establishment of a transparent, public market to permit the sale of organs from live donors will transform organ procurement from a lengthy, stressful, medically damaging waiting game into a safer, more efficient, routine, life-saving process. Such a market would have both economic and moral merit; it would deliver more and better organs at less cost than alternative options, and will result in more lives saved.

A model of direct payment for organs is available in the experience of Iran, which has allowed compensation since the late 1980s. Singapore plans to introduce direct compensation in 2009. What can be learned from a study of this process and its potential role in the modern American medical landscape? The deliberate choice to rely on altruism has been unsuccessful and fails to reflect the advances that have been made in transplant techniques. Technology and success rates have improved; why has policy remained largely unchanged? The tide, however, is beginning to turn. Individual states are experimenting with indirect payment systems to increase the number of live donors.

Moral outrage ought to be directed not at the tension between markets and altruism, but at the needless loss of life as transplant waiting lists continue to grow. In that spirit, this paper offers two policy proposals to support the development of payment systems—both direct and indirect—for procurement of organs. The most expedient route to a transparent regulated market requires a repeal of Section 301 of the National Organ Transplant Act of 1984.

Introduction

Conflicting opinions on the ethics of organ donation have existed as long as organ transplantation has been medically feasible. Eligibility requirements, reason for transplant, and international organ tourism continuously resurface as difficult medical policy and ethics issues. One issue about which there is little dispute is demand for organs far exceeding the supply of donors.

As waiting lists continue to grow, policy makers discuss the organ donation problem in terms of supply and demand, but the potential solutions they consider rarely take these concepts into account. It is time to address this organ shortage by harnessing the power of the market to bring new donors by creating a win-win situation for both donor and recipient. In-demand organs could be donated by living donors at very low risk to the donor, but policies facilitating this option are rarely discussed. Instead, policy proposals to expand the donor pool usually include awareness campaigns or bone marrow drives to improve the rates of minority matching.

This problem has remained intractable because incentives for donors have been avoided out of fear that they would somehow demean life. Yet organs—or parts of organs—are not life. Life equals the sum of the parts, not the parts themselves. As such, incentives for organ donation that result in more donations, and thus more lives saved, honor life far more than does the fear of bringing the market into the organ donation process.

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This discussion centers on kidney and liver donation because they are the most common transplants from live donors, and because the risk to the donor is very low. The mortality risk to a donor of a kidney is 0.03 percent, and donors usually live a normal life span. Mortality for hepatic lobe transplants stands at 0.25 to 1 percent, and life span is not affected.² The liver will regenerate to its pre-transplant size within a month.

Such a market will prevent many unnecessary deaths, and the establishment of the payment system on which it would rely does not conflict with modern ethical concerns. Criticisms of a market can be deflected by the realities of modern medical decision making that values

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autonomy, as well as the relative safety of live organ donation procedures. Failure to establish such a market would actually kill people, something which should concern the market critics. Indeed, one country has established a market to good effect.

Outrage ought to be directed not at the tension between markets and altruism, but at the needless loss of life as transplant waiting lists continue to grow. In that spirit, this paper offers two policy proposals to support the development of payment systems for procurement of organs—both direct and indirect. The most expedient route to a regulated market requires a repeal of Section 301 of the National Organ Transplant Act of 1984 (NOTA).

The Reality of Supply and Demand

Demand for kidneys exceeds the current supply of deceased donor organs and altruistic donors. Approximately 73,000 people sit on the waiting list for a kidney—18 of them will die by tomorrow and 6,000 more patients join the list every year. By 2010, over 100,000 Americans will wait for a kidney donation. A kidney transplant in the United States generally requires a five-year wait.³

Waiting patients with liver failure have increasingly elevated levels of toxins in their blood. They will become confused, and bleed because their liver fails to make clotting proteins. Patients suffering from kidney failure can languish on dialysis—which is only partially effective at removing toxins from the body—and may die because of complications from it—including low blood pressure, cramps, nausea, vomiting, bleeding, and infection.⁴

Transplant patients enjoy better medical outcomes than dialysis patients. After five years, 65 percent of patients still on dialysis have died, compared with 25 percent of transplant patients. Organs fail more quickly in patients who wait three years for a transplant versus patients who receive one immediately.⁵ Furthermore, medical evidence demonstrates that organs from live donors perform better than deceased donor tissue. Live organ donations produce better results, including fewer complications and higher life expectancies, than cadaveric donations or hemodialysis.⁶

The wait for a liver is roughly 430 days. Demand is less because liver disease is less common and there is no treatment analogous to dialysis to support liver failure patients, so death comes more quickly to those in end-stage liver disease.

Legislation and the Rise of Illegal Organ Markets

Ethical and legal debates over paying live organ donors have raged as long as transplantation has existed. In the United States, the National Organ Transplant Act states:

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce...any person who violates...shall be fined not more than \$50,000 or imprisoned not more than 5 years, or both. (See Appendix.)

Thus, the organ donation system in the United States relies on organs being donated by family members or other altruistic individuals. If no live match emerges, organ procurement systems rely on cadaveric donations in the hopes that a random match can be found for the needy patient. Both of these non-remunerative methods could remain as options in a system that allowed for regulated payment to live organ donors.

The presence of NOTA in the United States, and similar legislation in other developed countries, has not prevented the development of a thriving black market for procurement of organs from live donors. In early 2008, Indian police, in an incursion into Nepal, arrested a physician in Chitwan, 100 miles south of Kathmandu, who had been buying kidneys from poor locals and transplanting them to wealthy Indians and Westerners.⁷ Little to no informed consent process accompanies these procedures, and there are reports of “donors” never receiving payment for their organs. Reports on black market surgeries detail operations taking place in outdated, dangerous facilities. Similar stories have been heard in villages near Chennai, India, and in refugee camps in Tamil Nadu.⁸ A transparent market could address these gross violations of medical ethics and safety controls.

A second type of market, known as a gray market or paired exchange, has emerged in the United States. Individual A may need a kidney but have no family member who matches, as may be the case for individual B. If a member of individual A’s clan matches with patient B, and a member of B’s clan matches with patient A, the families then strike a deal to undertake a kidney swap. Clearly the exchange involves more than just charity. NOTA was amended by Congress in December 2007 by

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the addition of the Charlie W. Norwood Living Donation Act. The addition of this act provides that criminal penalties do not apply to paired organ donation because the law was intended to prevent *commercialization* of organs not *commodification* of organs.⁹

However, this convenient interpretation of an inconvenient law has failed to increase the number of donors. In 2008, U.S. surgeons performed 251 paired exchanges.¹⁰ The low number of exchanges suggests the difficulty in utilizing paired exchange as a method to reduce, let alone eliminate, organ waiting lists. The need for an organ transplant is relatively rare, as is the likelihood of a good match between random people. Relying on paired exchange to solve this problem hinges on two families finding each other, family members willing to be tested and willing to donate to somebody they do not know, and the medical match being appropriate. Paired exchange is like a needle in the haystack—two patients in need of transplant may find each other, but most will be lost.

The moralistic hubris in blocking the creation of a transparent market for live organ donation rests on the belief that life is invaluable, so to place a price tag on an organ, a slice of life, somehow cheapens its individual worth. As University of Chicago law professor Richard Epstein noted in *The Wall Street Journal* in 2006: “Only a bioethicist would prefer a world in which we have 1,000 altruists per annum and over 6,500 excess deaths over one in which we have no altruists and no excess deaths.”¹¹ The dissonance between such ethical self-righteousness and the reality on the ground comes into even sharper relief when one considers that prohibiting payment for organs sustains an international organ trafficking black market.¹² Observations by medical personnel and academic study groups, as well as data arising from black market transactions and the one legal market, suggest that permitting and regulating organ sales leads to more humane conditions than outlawing sales.¹³

Policy Proposals

A model of direct payment for organs is available in the experience of Iran, which has allowed compensation since the late 1980s. Singapore plans to introduce direct compensation in 2009. Indirect payment systems for organ donation currently exist in their infancy across the United States. A third option, an improved cadaveric donation system, is mentioned briefly to document the problems with previous attempts to improve the system through this method.

Direct Payment

The only country to have implemented a legal direct payment system for organs from live donors is Iran. Dialysis and Transplant Patient Association (DATPA)—a free-standing non-profit organization similar to the National Kidney Foundation in the U.S.—administers the market for live organ donation. Donors receive \$1,200 and one year of health care from the government, along with a payment from the organ recipient, generally ranging from \$2,300 to \$4,500. If the organ recipient does not have funds to offer, a charitable organization will provide such remuneration to the donor. The combination of charitable and governmental payments ensures that poor recipients are treated as well as wealthy ones. Financial exchanges take place above board, in terms that include government payment and rewards, in clean, modern operating rooms. There is no waiting list for a kidney in Iran.¹⁴

The historical development of the live organ donation program—known as a “white” market—in Iran sheds light on the financial consequences of America’s decision to forgo such a model. End-stage renal disease (ESRD) was untreatable until the development of widely available dialysis in the 1970s. Public enthusiasm for this scientific advance was extremely high, and Congress extended an invitation to its inventors to demonstrate the product in Washington, D.C. In 1971, National Association of Public Hospitals Vice President Shep Glazer, affected by kidney failure, testified before Congress while receiving dialysis.¹⁵ Not long after, dialysis became a fully funded Medicare benefit, regardless of patient age. In 2005, Medicare paid for dialysis for 341,000 Americans. This will increase to 400,000 patients by 2010, and to 525,000 to 700,000 patients by 2020.¹⁶ Dialysis treatment for ESRD patients cost Medicare \$21 billion in 2005. This total represents 6.5 percent of the Medicare budget being spent on 0.8 percent of beneficiaries.

In contrast, dialysis became widely available around the time Iran was emerging from the Iran-Iraq war, and there were insufficient resources to justify use of public funds for such expensive treatment. Patients were initially reimbursed to go abroad and get a transplant, until the live organ donation system came into existence in 1988. Since then, approximately 1,400 Iranians each year have donated kidneys. Kidneys from living unrelated donors constitute 80 percent of the supply of kidneys in Iran.¹⁷ Unfortunately, many donors from lower socioeconomic strata believe that selling a kidney will solve their financial problems. While such perceptions

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are undesirable, the presence of a regulated market has removed any illegal market from Iran, while extinguishing organ broker price mark-ups or transplants in dirty facilities with marginally skilled surgeons. Individuals without family or without a family match have better access to life-saving transplants.

Economists at the University of Chicago have estimated a kidney to be worth \$15,200. These estimates were compared to the average price agreed upon among 305 sellers in India in 2005 (\$1,177).¹⁸ This estimate corroborates very well with the underground kidney market in India. When adjusted for standards of living, the price paid in India for a kidney equals \$17,000. Similar modeling estimates a liver donation to be worth \$37,600 to the donor. Current costs of procuring an organ for transplant in the United States are over \$50,000. These estimates demonstrate that the cost of transplants would effectively go down in a well-supplied market system. Legislative action to legalize direct payment for organ donation would result in substantial cost savings to a government spending exorbitantly for dialysis treatments. Cost savings occurs if a recipient lives free of dialysis for more than 1.5 years; 95 percent of organ recipients would fall into this category.¹⁹

In the United States, a direct payment system for live organ donation could be regulated and managed by the United Network for Organ Sharing (UNOS), in a similar manner to the non-profit organization established in Iran. UNOS currently manages the waiting list for potential organ recipients. It has over 20 years of experience in managing the cadaveric donor pool and could easily extend its jurisdiction to include donation by living donors.²⁰ Even if a system of payment for organ donations were instituted in the United States, UNOS could continue to allocate organs to recipients on the basis of medical, not social or economic, criteria, in line with NOTA guidelines.

Indirect payment

Advocates of an incentivized organ donation program have seized on the vague term “valuable consideration” in NOTA in an effort to clarify and expand what states and other institutions can offer to potential donors without being in conflict with federal law. In 2007, Wisconsin enacted a law that gives living donors a tax deduction of up to \$10,000 for medical costs, travel, and lost wages.²¹ Recent changes to federal law suggest a growing recognition among policy makers of the need for incentivization. In 2004, the Organ Donation and Recovery Improvement Act authorized

the federal government to reimburse live-organ donors for costs incurred donating an organ.²² Policy makers claim that these programs do not pay people directly for donating an organ, but, rather, “keep them from losing money” (which is akin to companies offering benefits in lieu of pay raises).

In 2008, Sen. Arlen Specter (R-Penn.) tried to get support for a proposed Organ Donor Clarification Act, which would remove any legal concern states have expressed that their programs may run afoul of NOTA. This bill would allow non-cash incentives for organ donation, including tax breaks, health insurance, or funeral benefits. While the bill keeps the ban on organ *sales* intact, barring the explicit commercialization of organs, it does effectively allow organs to become commodities of value.

While indirect payments for donation are a promising step, a better proposal to increase the number of organ donors would be for Congress to repeal Section 301 of the National Organ Transplant Act. Section 301, entitled “Prohibition of Organ Purchases,” imposes criminal penalties of up to \$50,000 and five years in prison on any person who “knowingly acquire[s], receive[s], or otherwise transfer[s] any human organ for valuable consideration for use in human transplantation, if the transfer affects interstate commerce.”²³ This ought to be replaced with legislation that designates a non-profit organization like UNOS as a clearinghouse for organ brokerage arrangements.

UNOS is a natural partner; it administers the transplant network established by Congress via NOTA in 1984. Over the past 25 years, UNOS has received five contract renewals to collect and manage data on every transplant occurring in the United States and facilitate organ matching. While in the long run it would be desirable to open this contract to competitive bidding by other potential administrators, such a proposal is certain to meet significant resistance. Therefore, in the short term, repeal of Section 301 of NOTA followed by use of the UNOS system would have the most likely chance of gaining support.²⁴

An Opt-out System for Deceased “Donors”

Critics of payment systems who agree on the magnitude of the supply problem often suggest a third policy option to increase the donor pool. They seek to better incentivize organ donation from deceased donors, even though deceased donor organs are not as healthy as those from live donors. In these cases, remuneration for organ donation would pass to family members of the deceased instead of directly to the donor.

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A second suggestion is to develop an opt-out system, in which all organs from deceased persons are eligible for donation unless the donor or family has specifically stated otherwise. This solution has been adopted in some European countries, with varying degrees of success.²⁵ European physicians are reluctant to procure organs without asking the family. The system still relies on the physician introducing the topic of organ donation to a grieving family, which they often avoid doing because of the discomfort of the situation. Such an opt-out system contrasts starkly with the American body of law that emphasizes personal property and autonomy in decision-making. An opt-out system relies on the notion that, on someone's death, that person's assets become community property unless other arrangements have been made. The body no longer remains the most sacred private property. Previous efforts to increase the number of deceased donors have been marginally effective; incentives must be immediate and enjoyed by the actual donor to be effective.

Taking on the Critics

Critics of a regulated market system base their opposition on outdated precepts of bioethics and the potential for exploitation. This section addresses each of these concerns, in anecdotal order of their popularity in the anti-market literature.

Coercion of the Poor

Market critics fret that offering payment will be coercive to the poor, who need the money the most.²⁶ While it may be true that poorer people would be more likely to donate an organ in exchange for payment, it is also likely that poorer people are more likely to take any sort of job for payment. The poor are also more likely to take jobs that entail a higher risk of death, like coal mining or fishing—yet governments allow them to participate in these activities for money despite the higher risk. Is it coercive to offer a poor person any sort of job?

This “exploitation” criticism is paternalistically condescending. Is a poor individual unable to properly judge the risks and benefits of donating an organ under such a system? The organization responsible for regulating this market would administer informed consent procedures to ensure that every donor is fully informed, willing, and able to make such a decision.

Critics of payment for live organ donation go so far as to compare such transactions to prostitution.²⁷ This analogy muddles the distance between the physical and emotional investments inherent in prostitution

and the mundane relationship that most people have with a kidney or a liver lobe. In the United States, oocytes and sperm can be freely sold to assist people with infertility, and those payments seem, on their face, more emotionally invested than kidney or liver donation.

Perhaps it is the critics' concern that organs, rather than cells or tissues, are so valuable that any amount of money would not be enough. This begs the question: Enough money for whom?

The Business of the Body

In addition to egg and sperm cells, other parts of the living body are bought and sold every day by consenting American adults. Tens of thousands of Americans sell their blood plasma to companies that subsequently create intravenous immune globulin (IVIG) to treat myriad diseases from Kawasaki disease in children to autoimmune myopathies in adults.²⁸ Plasma donors earn \$40 per week for their trouble. Demand is expected to increase as the value of IVIG continues to be demonstrated in treating a variety of diseases.²⁹

Selling plasma to a private firm is legal, but selling whole blood is not. However, blood donation organizations are able to sell donor blood on the open market and use the funds to support other businesses. In 1989, nearly two-thirds of the Red Cross's \$2.1 billion in revenue came from the sale of blood and plasma products collected in donations.³⁰ Demand for plasma has skyrocketed since then, and the Red Cross relies on these sales to fund its operations. Why should the Red Cross make a profit from an individual's donation, but the individual is barred from doing so?³¹

Consider the flow of resources and rewards in organ transactions. The organ recipient will gain in quality of life and increased income from a greater ability to work. Hospitals and medical professionals also benefit. For hospitals, transplant is often a low-volume, high margin business for which there is competition. Hospitals charge \$400,000 to \$500,000 for a liver transplant. The University of Pittsburgh's transplant program produced \$130 million of revenue in its latest fiscal year.³² Concerns that payment stains the dignity of the donor ring hollow when everyone involved in the process enjoys material gain or prestige—except the donor.

A Breach of Medical Ethics?

Market critics express concern that such a system alters the medical equation for deciding when to intervene in the body. The fundamental ethic used to be "first, do no harm," but modern day ethics center on the

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autonomy of the patient. Medical decisions are made in consultation with a patient, and elective procedures are routine. Thus, if we accept the fact that “do no harm” does not consistently guide medical decision making in the modern era, and that patients have autonomy to decide whether to undergo the stated risks of donation, patients ought to have autonomy to decide whether to accept payment for offering their asset in service to another. Payment for organ donation might be the exact personal incentive the transplant system needs.

A Decline in Altruism?

Critics of payment for live organ donations fret that the number of altruistic donations will decline. The relevant question is not whether altruists disappear, but whether the number of available organs increases. The only evidence to evaluate this claim comes from Iran. Iran’s unpaid deceased donor program was started in 2000 (deceased donations were not really feasible in Iran before then). It has grown steadily *alongside* the number of live organ donations.³³ This suggests that allowing payment for organ donation does not discourage those who believe altruism is the only appropriate way to donate an organ. Donors could choose to donate their income to a charitable organization or refuse payment altogether.

Furthermore, critics who worry that the number of altruistic donors will decline ignore the complex dynamics that confront a matched, altruistic donor. Suppose a brother or cousin of a needy patient has matched, but the match is apprehensive to donate and would prefer not to donate one of his organs. Is it altruism if the donor is essentially forced by family pressure to donate an organ? Creating a market to increase the number of potential matches can free the potential altruist from the tyranny of being the match. The use of a third party broker to act as an intermediary between the organ donor and the patient creates space for the donor to exercise even greater free will over the choice to give, versus the constricted options of the altruistic donor who essentially must give an organ or a loved one will die. When acts of altruism are permitted but not required, choosing to act above and beyond adds moral dividends beyond that of simply meeting an obligation.³⁴

Conclusion

The debate over payment for live organ donation comes into sharpest focus when applied to real people in the medical office. By the time the sun sets today, 18 people will have died waiting for a kidney transplant

that never arrived. Several people with liver disease will turn a darker shade of yellow as bilirubin piles up in the blood. Medical science is ready and waiting to save these people's lives, but policy remains a roadblock. The development of a regulated market for payment to live organ donors will drastically reduce the waiting lists for organ transplants in the United States. How much is that worth? The smart money is on priceless.

Appendix

National Organ Transplantation Act

(As amended by the Charlie W. Norwood Living Organ Donation Act – January 2008)

Sec. 273. - Organ procurement organizations

(a) Grant authority of Secretary

- (1)** The Secretary may make grants for the planning of qualified organ procurement organizations described in subsection (b) of this section.
- (2)** The Secretary may make grants for the establishment, initial operation, consolidation, and expansion of qualified organ procurement organizations described in subsection (b) of this section.
- (3)** The Secretary may make grants to, and enter into contracts with, qualified organ procurement organizations described in subsection (b) of this section and other nonprofit private entities for the purpose of carrying out special projects designed to increase the number of organ donors.

(b) Qualified organizations

(1) A qualified organ procurement organization for which grants may be made under subsection (a) of this section is an organization which, as determined by the Secretary, will carry out the functions described in paragraph (2) and -

(A) is a nonprofit entity,

(B) has accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization,

(C) has an agreement with the Secretary to be reimbursed under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) for the procurement of kidneys,

(D) notwithstanding any other provision of law, has met the other requirements of this section and has been certified or recertified by the Secretary within the previous 4-year period as meeting the performance standards to be a qualified organ procurement organization through a process that either -

(i) granted certification or recertification within such 4-year period with such certification or recertification in effect as of January 1, 2000, and remaining in effect through the earlier of -

(I) January 1, 2002; or

(II) the completion of recertification under the requirements of clause (ii); or

(ii) is defined through regulations that are promulgated by the Secretary by not later than January 1, 2002, that -

(I) require recertifications of qualified organ procurement organizations not more frequently than once every 4 years;

(II) rely on outcome and process performance measures that are based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations;

(III) use multiple outcome measures as part of the certification process; and

(IV) provide for a qualified organ procurement organization to appeal a decertification to the Secretary on substantive and procedural grounds;

(E) has procedures to obtain payment for non-renal organs provided to transplant centers,

(F) has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs, and that either includes an entire metropolitan statistical area (as specified by the Director of the Office of Management and Budget) or does not include any part of the area,

(G) has a director and such other staff, including the organ donation coordinators and organ procurement specialists necessary to effectively obtain organs from donors in its service area, and

(H) has a board of directors or an advisory board which -

(i) is composed of -

(I) members who represent hospital administrators, intensive care or emergency room personnel, tissue banks, and voluntary health associations in its service area,

(II) members who represent the public residing in such area,

(III) a physician with knowledge, experience, or skill in the field of histocompatibility or an individual with a doctorate degree in a biological science with knowledge, experience, or skill in the field of histocompatibility, "histocompatibility".

(IV) physician with knowledge or skill in the field of neurology, and

(V) from each transplant center in its service area which has arrangements described in paragraph (2)(G) with the organization, a member who is a surgeon who has practicing privileges in such center and who performs organ transplant surgery,

(ii) has the authority to recommend policies for the procurement of organs and the other functions described in paragraph (2), and

(iii) has no authority over any other activity of the organization.

(2)

(A) Not later than 90 days after November 16, 1990, the Secretary shall publish in the Federal Register a notice of proposed rulemaking to establish criteria for determining whether an entity meets the requirement established in paragraph (1)(E).

(B) Not later than 1 year after November 16, 1990, the Secretary shall publish in the Federal Register a final rule to establish the criteria described in subparagraph (A).

(3) An organ procurement organization shall -

(A) have effective agreements, to identify potential organ donors, with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations,

(B) conduct and participate in systematic efforts, including professional education, to acquire all useable organs from potential donors,

(C) arrange for the acquisition and preservation of donated organs and provide quality standards for the acquisition of organs which are consistent with the standards adopted by the Organ Procurement and Transplantation Network under section 274(b)(2)(E) of this title, including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,

(D) arrange for the appropriate tissue typing of donated organs,

(E) have a system to allocate donated organs equitably among transplant patients according to established medical criteria,

(F) provide or arrange for the transportation of donated organs to transplant centers,

(G) have arrangements to coordinate its activities with transplant centers in its service area,

(H) participate in the Organ Procurement Transplantation Network established under section 274 of this title,

(I) have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors,

(J) evaluate annually the effectiveness of the organization in acquiring potentially available organs, and

(K) assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors

Sec. 274. - Organ procurement and transplantation network

(a) Contract authority of Secretary; limitation; available appropriations

The Secretary shall by contract provide for the establishment and operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b) of this section. The amount provided under such contract in any fiscal year may not exceed \$2,000,000. Funds for such contracts shall be made available from funds available to the Public Health Service from appropriations for fiscal years beginning after fiscal year 1984.

(b) Functions

(1) The Organ Procurement and Transplantation Network shall carry out the functions described in paragraph (2) and shall -

(A) be a private nonprofit entity that has an expertise in organ procurement and transplantation, and

(B) have a board of directors -

(i) that includes representatives of organ procurement organizations (including organizations that have received grants under section 273 of this title), transplant centers, voluntary health associations, and the general public; and

(ii) that shall establish an executive committee and other committees, whose chairpersons shall be selected to ensure continuity of leadership for the board.

(2) The Organ Procurement and Transplantation Network shall -

(A) establish in one location or through regional centers -

(i) a national list of individuals who need organs, and

(ii) a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs,

- (B)** establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria,
- (C)** maintain a twenty-four-hour telephone service to facilitate matching organs with individuals included in the list,
- (D)** assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients,
- (E)** adopt and use standards of quality for the acquisition and transportation of donated organs, including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,
- (F)** 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,
- (G)** coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers,
- (H)** provide information to physicians and other health professionals regarding organ donation,
- (I)** collect, analyze, and publish data concerning organ donation and transplants,
- (J)** carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation,
- (K)** work actively to increase the supply of donated organs,
- (L)** submit to the Secretary an annual report containing information on the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network,
- (M)** 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,
- (N)** carry out studies and demonstration projects for the purpose of improving procedures for organ donation procurement and allocation, including but not limited to projects to examine and attempt to increase transplantation among populations with special needs, including children and individuals who are members of racial or ethnic minority groups, and among populations with limited access to transportation, and
- (O)** provide that for purposes of this paragraph, the term “children” refers to individuals who are under the age of 18.

(c) Consideration of critical comments

The Secretary shall establish procedures for -

- (1)** receiving from interested persons critical comments relating to the manner in which the Organ Procurement and Transplantation Network is carrying out the duties of the Network under subsection (b) of this section; and
- (2)** the consideration by the Secretary of such critical comments

Sec. 274a. - Scientific registry

The Secretary shall, by grant or contract, develop and maintain a scientific registry of the recipients of organ transplants. The registry shall include such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation. The Secretary shall prepare for inclusion in the report under section 274d of this title an analysis of information derived from the registry

Sec. 274b. - General provisions respecting grants and contracts

(a) Application requirement

No grant may be made under this part or contract entered into under section 274 or 274a of this title unless an application therefore has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall by regulation prescribe.

(b) Special considerations and priority; planning and establishment grants

(1) A grant for planning under section 273(a)(1) of this title may be made for one year with respect to any organ procurement organization and may not exceed \$100,000.

(2) Grants under section 273(a)(2) of this title may be made for two years. No such grant may exceed \$500,000 for any year and no organ procurement organization may receive more than \$800,000 for initial operation or expansion.

(3) Grants or contracts under section 273(a)(3) of this title may be made for not more than 3 years.

(c) Determination of grant amount; terms of payment; recordkeeping; access for purposes of audits and examination of records

(1) The Secretary shall determine the amount of a grant or contract made under section 273 or 274a of this title. Payments under such grants and contracts may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or

overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants and contracts.

(2)

(A) Each recipient of a grant or contract under section 273 or 274a of this title shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant or contract, the total cost of the undertaking in connection with which such grant or contract was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a grant or contract under section 273 or 274a of this title that are pertinent to such grant or contract.

(d) "Transplant center" and "organ" defined

For purposes of this part:

(1) The term "transplant center" means a health care facility in which transplants of organs are performed.

(2) The 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 and for purposes of section 274a of this title, such term includes bone marrow

Sec. 274c. - Administration

The Secretary shall designate and maintain an identifiable administrative unit in the Public Health Service to -

(1) administer this part and coordinate with the organ procurement activities under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.),

(2) conduct a program of public information to inform the public of the need for organ donations,

(3) provide technical assistance to organ procurement organizations, the Organ Procurement and Transplantation Network established under section 274 of this title, and other entities in the health care system involved in organ donations, procurement, and transplants, and

(4) provide information -

(i) to patients, their families, and their physicians about transplantation; and

(ii) to patients and their families about the resources available nationally and in each State, and the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network, in order to assist the patients and families with the costs associated with transplantation

Sec. 274d. - Report

Not later than February 10 of 1991 and of each second year thereafter, the Secretary shall publish, and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report on the scientific and clinical status of organ transplantation. The Secretary shall consult with the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report.

Sec. 274e. - Prohibition of organ purchases

(a) Prohibition

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. The preceding sentence does not apply with respect to human organ paired donation.

(b) Penalties

Any person who violates subsection (a) of this section shall be fined not more than \$50,000 or imprisoned not more than five years, or both.

(c) Definitions

For purposes of subsection (a) of this section:

- (1)** The term “human organ” means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.
- (2)** The term “valuable consideration” does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.
- (3)** The term “interstate commerce” has the meaning prescribed for it by section 321(b) of title 21

(4) The term “human organ paired donation” means the donation and receipt of human organs under the following circumstances:

(A) An individual (referred to in this paragraph as the “first donor”) desires to make a living donation of a human organ specifically to a particular patient (referred to in this paragraph as the “first patient”), but such donor is biologically incompatible as a donor for such patient.

(B) A second individual (referred to in this paragraph as the “second donor”) desires to make a living donation of a human organ specifically to a second particular patient (referred to in this paragraph as the “second patient”), but such donor is biologically incompatible as a donor for such patient.

(C) Subject to subparagraph (D), the first donor is biologically compatible as a donor of a human organ for the second patient, and the second donor is biologically compatible as a donor of a human organ for the first patient.

(D) If there is any additional donor-patient pair as described in subparagraph (A) or (B), each donor in the group of donor-patient pairs is biologically compatible as a donor of a human organ for a patient in such group.

(E) All donors and patients in the group of donor-patient pairs (whether 2 pairs or more than 2 pairs) enter into a single agreement to donate and receive such human organs, respectively, according to such biological compatibility in the group.

(F) Other than as described in subparagraph (E), no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the human organs referred to in such subparagraph.

Sec. 274f. - Study by General Accounting Office

(a) In general

The Comptroller General of the United States shall conduct a study for the purpose of determining -

(1) the extent to which the procurement and allocation of organs have been equitable, efficient, and effective;

(2) the problems encountered in the procurement and allocation; and

(3) the effect of State required-request laws.

(b) Report

Not later than January 7, 1992, the Comptroller General of the United States shall complete the study required in subsection (a) of this section and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings made as a result of the study

Sec. 274g. - Authorization of appropriations

For the purpose of carrying out this part, there are authorized to be appropriated \$8,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993

Notes

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- 24 New legislation could also require a "cooling off" period to allow potential kidney donors to assess the opportunity and protect vulnerable people from exploitation. Children and mentally disabled adults would be excluded from the donor population. Legislation may have to consider whether a person who has previously donated and subsequently needs an organ ought to be able to enter the market at a reduced rate. Such special arrangements ought to be avoided to prevent the accumulation of exceptions to what ought to be a basic, predictable market. A second question emerges for liver donors. The liver can regenerate to normal size after a portion is removed for donation. Should liver donors be eligible to donate time and time again, provided the tissue continues to regenerate? Such decisions ought to be left to the discretion of the medical providers and the potential donor.
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Jennifer Monti is a fourth-year medical student at Case Western Reserve University in Cleveland, Ohio. Her policy interests include the application of public-private entrepreneurship to issues of medical and public health importance. Her research contributions have addressed inflammation and infection, as well as public investment in population health. Her research work has been published in academic journals, and her other writings have received recognition from *The New York Times* and the American Association of Medical Colleges. She has worked with the Cleveland Clinic in evaluating emerging technologies and has directed several teams of researchers and entrepreneurs in strategies to move promising technologies from clinical development to market viability.

Ms. Monti previously worked at the Health Technology Center in San Francisco on the assessment of emerging technologies and their impact on the capital investments of large health care organizations. She is currently a deputy to the Baltimore City Commissioner of Health, in which position she leads research efforts on a public strategy for reducing the obesity epidemic and on projects to increase healthy food access in urban neighborhoods that are underserved by traditional supermarket retailers. Ms. Monti will receive M.D. and master's in public health (MPH) degrees in Spring 2010 and will enter residency training in internal medicine.

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