GIFT of LIFE
DONOR PROGRAM
THE REGION'S ORGAN & TISSUE TRANSPLANT NETWORK

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Pennsylvania House of Representatives
Judiciary Committee Hearing - House Bill 30
May 13, 2014

Good morning Chairman Cutler, Chairman White, and members of the Committee.

My name is Howard Nathan and I am the President and CEO of Gift of Life Donor Program. I am here today to tell you about the organ donation process in Pennsylvania and the United States, and to ask for your support in improving that process by passing House Bill 30. Thank you for providing me with this opportunity.

The urgent need for passage of House Bill 30 – Save a Life NOW PA

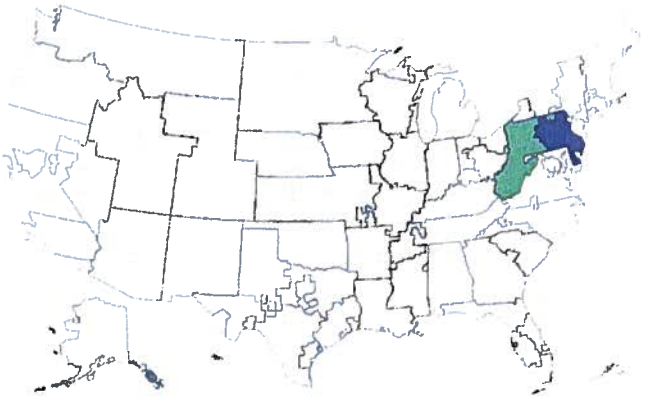
The shortage of organs available for transplantation is a public health crisis faced across the United States and the world. In the Commonwealth of Pennsylvania, more than 400 people die each year because an organ does not become available for transplant. But organ donation is only possible in 2% of all hospital deaths and so it is essential that, when possible, every effort is made to offer the donor option to families. The only way for Pennsylvania to save the lives of those awaiting transplant is to improve on its existing processes for coordinating donation in hospitals and educating the public about donation. House Bill 30 and its companion, Senate Bill 850, accomplish both of these goals. **That is why over 2,000 Pennsylvanians and every major healthcare system in Pennsylvania (including all 18 transplant hospitals) have signed a petition or indicated support of the Save a Life NOW PA Campaign (www.savealifenowpa.org) calling for enactment of this bill.**

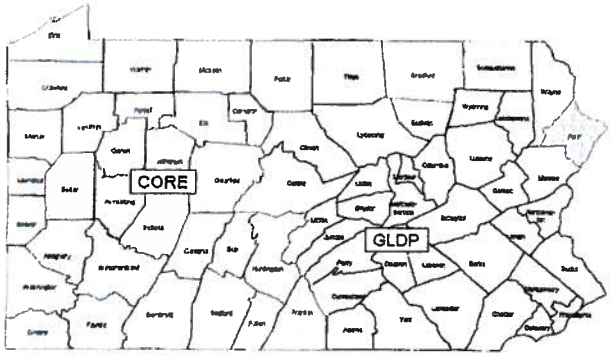
Pennsylvania is one of only four states not to have adopted the most recent version of the Uniform Anatomical Gift Act (UAGA). As a result, clinical provisions of Pennsylvania law are outdated. In June 2007, the Legislative Budget and Finance Committee (LBFC) released a report with numerous recommendations to support clinical best practices, improve public education about organ donation and to close loopholes in current law that allowed unregulated and unethical recovery of gifts for transplant. House Bill 30 (including the anticipated amendments) incorporates provisions of the updated UAGA, the recommendations of the LBFC, as well as input from stakeholders. Most importantly, House Bill 30 will save lives.

I. Organ Donation in the Commonwealth of Pennsylvania

The United States organ donation and transplantation system is primarily regulated by the federal government. Recognizing the increasing demand for the already limited supply of critical life-saving organs and the need to establish a framework for recovering and allocating this scarce resource, Congress enacted the National Organ Transplantation Act of 1984 and established the Organ Procurement Transplantation Network to oversee organ donation and transplant in this country. Organ procurement organizations (OPOs) are nonprofit, federally-designated organizations responsible for coordinating human organ transplants and educating the public about organ donation. The Federal Centers for Medicare and Medicaid Services has certified 58 OPOs to serve their specific areas of the country. The two OPOs that serve Pennsylvania are Gift of Life Donor Program (GLDP), which serves the eastern half of Pennsylvania, and the Center for Organ Recovery and Education (CORE), which serves the western half of Pennsylvania. These OPOs serve as the vital link between the donor and recipient and are responsible for collaborating with hospitals on the identification and medical suitability of potential donors, communications with families regarding the donor option and the retrieval, preservation, and transportation of organs for transplantation. Each OPO also provides public education to the community on the critical need for organ donation.

The service areas for GLDP and CORE are shown on the maps below. Together the two OPOs work with approximately 175 hospitals and 18 transplant hospitals in 66 of Pennsylvania's 67 counties.





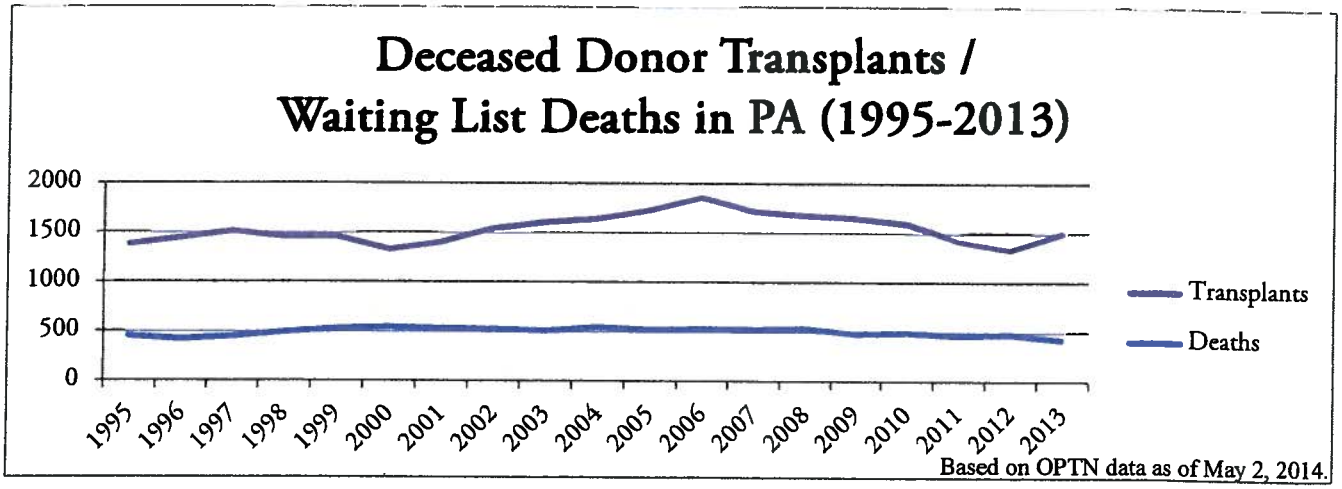
*Pike County is in the service area of the New York Organ Donor Network.

Federal law requires that all OPOs be recertified by CMS every four years. This process also involves continuous reporting of data on every patient death and the assessment of donor potential as well as on-site audits. Compliance is assessed with regard to comprehensive standards relating to (i) hospital relationships and referrals of deceased patients, (ii) donor screening and suitability determinations, (iii) donor family communications, including communications regarding donation authorization and ensuring sensitivity and discretion, (iv)

donation rates and outcomes, (v) staff training and quality monitoring, (vi) retrieval, processing, and preservation, (vii) confidentiality and information security, (vii) governance and management, (ix) fiscal stability and (x) donor management and clinical support. Failure to adhere to the standards may result in adverse action, up to and including decertification.

In addition to CMS oversight, OPOs are also required to be members of the Organ Procurement and Transplantation Network (OPTN)[1] and most (including GLDP & CORE) are accredited by the Association of Organ Procurement Organizations (AOPO). GLDP also coordinates tissue and cornea donation in Pennsylvania and as a result is regulated by the Federal Food and Drug Administration (FDA) and accredited by the American Association of Tissue Banks (AATB) and the Eye Bank Association of America (EBAA).

GLDP has served the eastern half of Pennsylvania continuously for 40 years and in that time has coordinated more than 36,000 organ transplants and more than 500,000 tissue transplants. One of the reasons for the successes in Pennsylvania has been its landmark legislation - Act 102 of 1994 - which will be discussed in greater detail later. The GLDP service area is consistently among the three most active in the country resulting in record numbers of transplants for our residents.[2] However, as of May 2, 2014 there are still 8,523 people waiting for an organ transplant in Pennsylvania. More than 200 of those waiting are children.[3] Each year more than 1,300 of those waiting will receive a transplant, but more than 400 will die waiting.[4] As the chart below shows, there has been no appreciable reduction in the number of waiting list deaths in the past 19 years.



While some of this may be attributed to the overall increase in the number of patients waiting, it also illustrates the importance of maximizing each donation opportunity.

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[1] 42 U.S.C. § 273(b)(1)(D); § 273(b)(3)(H).
[2] Organ Procurement and Transplantation Network, Data Reports (OPTN), Donation Year by Donation Service Area, Donors Recovered: January 1, 1988 - February 28, 2014, (based on OPTN data as of May 2, 2014).
[3] OPTN, Organ by Age, Current P.A. Waiting List, (based on OPTN data as of May 2, 2014).
[4] OPTN, Death Removals by Age by Year, (based on OPTN data as of May 2, 2014).

II. Anatomical Gift Legislation in Pennsylvania

Since 1968, the National Conference of Commissioners on Uniform State Laws (NCCUSL) has published the Uniform Anatomical Gift Act (UAGA). The goal of this model legislation is to improve the system for patients awaiting transplant and to provide for uniformity across state lines in order to ensure that organ donation can be successful nationally.

In 1994, under the leadership of Rep. Mark Cohen and Sen. Stewart Greenleaf, Pennsylvania passed its landmark anatomical gift law commonly referred to as Act 102.[5] While in part derived from the Uniform Anatomical Gift Act, Act 102 also advanced the field of organ donation immeasurably by addressing both routine hospital referrals and donor designation. Prior to Act 102, referral of hospital deaths to the designated OPO was requested but not required. Act 102 instituted routine referral, requiring hospitals to notify their OPO of every death to allow the OPO to evaluate the patient as a possible donor.[6] The immediate success of this change caused the federal government to make routine referral a national requirement as part of its Medicare and Medicaid provider regulations.[7] Act 102 also provided for a statewide Organ Donation Advisory Committee to develop initiatives that would encourage donor designation and a mechanism for recording those designations within the state driver's license and ID card system.

The UAGA was revised in 1987 and again in 2006 to incorporate clinical best practices as observed throughout the country and to address any inconsistencies between state practice and federal administration of organ procurement and transplantation in order to add to the efficiency of the current system. Since 2006, 46 states and the District of Columbia have adopted the most current version of the model act.[8] House Bill 30 would bring Pennsylvania law up-to-date with the UAGA and address inconsistencies with federal law.

In 2007, the Legislative Budget and Finance Committee (LBFC) conducted a performance evaluation of Pennsylvania's organ and tissue donation awareness programs. The report included numerous recommendations to improve public awareness programming designed to increase donor designation. As discussed below, many of the provisions of House Bill 30 are taken directly from these recommendations.

III. The Donate Life PA Act (House Bill 30)

As discussed above, House Bill 30 reflects recommendations regarding clinical practice and anatomical donation reflected in the 2006 UAGA and LBFC report as refined and adapted for Pennsylvania. Amendments offered to Senate Bill 850 (Printer's No. 1593) to address

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[5] Act of Dec. 1, 1994, P.L. 655, No. 102; 20 PA. CONS. STAT. § 86, et seq.
[6] PA. CONS. STAT. § 8617(a).
[7] 42 C.F.R. § 482.45 (a)(1).
[8] National Conference of Commissioners on Uniform State Laws, Enactment Status Map (http://www.nccusl.org/Act.aspx?title=Anatomical%20Gift%20Act%20(2006)).

stakeholder concerns and to add clarity are expected to be offered to House Bill 30. The following are some key provisions of the legislation and how those changes will help increase donation and save lives.

1. Incorporating Best Hospital Practices

Updates the hierarchy of who may make an anatomical gift

A change taken from the UAGA updates the hierarchy of who may make an anatomical gift in the absence of any decision by the decedent. Under current anatomical gift law, a healthcare agent or power-of-attorney designated by the decedent to make healthcare decisions may not be recognized as having the authority to make an anatomical gift. House Bill 30 corrects this by recognizing the priority of the decedent's appointed agent. The bill also expressly recognizes other relatives such as aunts, uncles, grandparents and grandchildren. It continues to recognize the caregiving or decisional role that non-family members may play in the life of a patient.[9]

Provides for timely determination of suitability

Time is of the essence in connection with organ and tissue donation. This is also true as it relates to determining whether a decedent's organs may be medically suitable for donation so that families can be presented with an understanding of what donor option (organ and tissue), if any, may be available. House Bill 30 expressly provides for blood testing for suitability following a patient's death that is referred to the OPO. It allows the hospital to facilitate a minimally invasive blood or tissue test necessary to determine the suitability of a donor, preventing families from being unnecessarily approached regarding donation where a gift cannot be transplanted. A recent guidance document from the federal Centers for Medicare and Medicaid Services provides that this modification be made to state law.[10]

Aligns state law with federal organ allocation requirements

Pennsylvania's current anatomical gift law is not in accord with the federal system of organ donation and allocation. All deceased donor organs are required to be allocated under the system established by the National Organ Transplant Act and subsequent regulations. House Bill 30 corrects this by updating Section 8612 with language from the UAGA that addresses the allocation process for organs donated for directed donation, transplantation generally, and for research and education.[11]

2. Improving Pennsylvania's Organ Donation Awareness Programs

Extends membership of the Organ & Tissue Donation Advisory Committee

As recommended by the LBFC, House Bill 30 expands membership of the PA Organ and Tissue Donation Advisory Committee. It provides for a member of a community health organization to serve on the board. It also directs that members be appointed in a manner reflecting geographic

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[9] House Bill 30, Session of 2013, Printer's No. 2125, at § 8611(b).
[10] Id. at § 8617(d).
[11] Id. at § 8612.

diversity with input sought from the Hospital and Healthcare Association of Pennsylvania and similar statewide groups.[12]

Expand educational programs to increase donor designation rates on driver's licenses and save lives

House Bill 30 also provides for increased education regarding donation as recommended by LBFC. It extends the educational initiatives regarding donation and transplantation in current law to include all high schools in the Commonwealth. States such as Iowa (67%) and Ohio (55%) that require some form of organ donation education in their high schools lead the nation in driver's license donor designation rates. Pennsylvania's designation rate currently stands just under 46%. Increasing the designation rate will increase the number of people who actually go on to become donors after their death. The bill also provides that nursing and medical schools in Pennsylvania include organ and tissue donation in their curriculum. This will assist healthcare practitioners in understanding best practices and regulatory requirements by incorporating this information into their training so there will be some baseline knowledge to prepare them for hospital practice. It also provides that state boards of medicine and nursing encourage physicians and nurses who have not yet received instruction regarding donation to do so.[13]

3. Providing for Collaboration between Organ Procurement Organizations and Coroners and Medical Examiners

Ensure the wishes of the donor and next-of-kin are carried out while supporting forensic investigations

Finally, a provision of House Bill 30 taken from the 2006 UAGA that has been the subject of considerable review by stakeholder groups in Pennsylvania is Section 8627, the provisions addressing Collaboration between OPOs and Coroners/Medical Examiners (ME). This section is significant in that it memorializes the best practices between OPOs and the Coroner/Medical Examiner's offices to ensure that anatomical donation goals and forensic investigation goals are both met. It accomplishes these goals first by requiring that the OPO provide to the Coroner or ME all medical records, photographs, specimens, laboratory and other test results that may assist in their investigation. The Coroner or ME frequently request additional testing be performed at the hospital including toxicology, skeletal series and CT scans, all of which would be made available upon request pursuant to the bill.

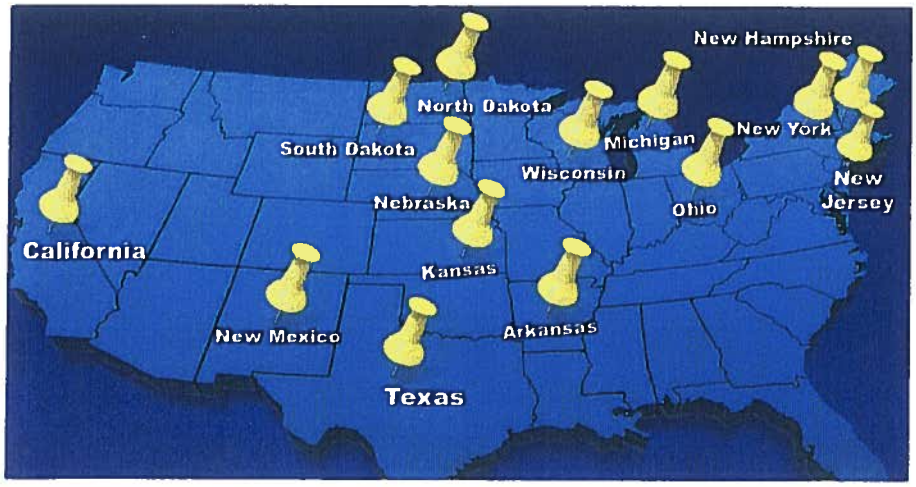
House Bill 30 also provides that if a Coroner or ME anticipates limiting or denying recovery of organs identified as suitable for transplant and where donation has been authorized by the decedent or family, then the Coroner or ME or designee must attend the scheduled recovery procedure (after notification) in order to observe whether any forensic issues exist that might require a limitation on the organ recovery. Note, this standard would apply only if the organ were considered suitable for transplant (typically an organ that is implicated in an investigation is not considered transplantable and no request would be made for the Coroner or ME or their designee

[12] Id. at § 8622(c).
[13] Id. at § 8629 - 8630.

to attend the recovery). If the Coroner or ME or their designee chooses to decline or restrict the organ donation, that decision is to be explained in writing. Any expenses associated with the attendance are to be reimbursed by the OPO. This is in contrast to current law whereby the decision to limit or deny recovery can be made without the Coroner or ME or their designee having ever viewed the body to determine whether there are forensic issues that would be affected by donation. Historically, this type of situation arises approximately 3-6 times per year in the Commonwealth. This is a very limited number of occasions that a Coroner/ME or designee might be asked to attend the recovery to weigh against the possibility of likely saving more than 10 additional lives each year (conservatively estimating 2-3 organs transplant per donor).[14] And in the case of a child awaiting transplant, given the even more limited donor pool, the failure to facilitate transplant from a deceased child may eliminate the only opportunity to receive the pediatric organ that will save their life.

The Coroner/ME provision of House Bill 30 is critical to Pennsylvania because of the number of lives it will directly impact. In the past 10 years, there have been at least 24 instances where a Coroner denied organ donation in GLDP's service area (with at least as many in CORE's service area). Even a conservative estimate of 2 transplants per donor means that 48 potentially transplantable organs were buried needlessly. Moreover, 80 percent of these denials were in just four counties. This is in contrast to Philadelphia County, where the Office of the Medical Examiner has had zero organ donor declines in almost a decade.

Included in the UAGA as a recommended standard, the provision requiring a Coroner or ME or their designee to attend recovery prior to issuing a denial has been a part of New Jersey state law for 20 years.[15] Gift of Life is aware of only 1-2 occasions where the ME chose to attend the recovery and in each instance the ME elected to allow the organ donation after viewing the body. The map below shows all of the states that have a provision either requiring the Coroner or ME to attend recovery or prohibiting denials altogether.



[14] Scientific Registry of Transplant Recipients, Gift of Life Donor Program OPO-Specific Report, April 8, 2014.
[15] N.J. STAT. ANN. § 52:17B-88.8.

According to NCCUSL, this section was developed with medical professionals, and the National Association of Medical Examiners (NAME), and is in accord with the NAME policy guidelines.[16] The NAME position paper on the release of organs and tissues for transplantation is attached to this document as Appendix A and below are two brief excerpts from the document.

> Searches of the medical and legal literature have failed to find a single documented instance of organ procurement interfering with a criminal investigation, a prosecution, a defense, or the determination of cause and manner of death at autopsy.[17]
> ...
> Providing that appropriate protocols are followed, there is no reason that procurement of organs and tissues should not be able to occur, even in cases of suspected SIDS or child abuse. The proof of principle already exists in that release even in these types of cases is routine in many jurisdictions in the United States with no documented adverse outcomes.[18]

There has also been a great deal of confusion about what House Bill 30 changes with respect to current law. For clarification, listed below are some examples of changes the bill does not make.

- HB 30 does not allow others to supersede the rights of donors and families. Rights of donors, those they legally designate, and family members remain paramount.
- HB 30 is not a presumed consent bill. Individuals designated in the bill, starting with donors, their families, or other clearly designated individuals, must authorize donation before it can occur.
- HB 30 does not expand the OPO's communications with the family of a decedent. Federal and state laws already provide that OPOs communicate with families at the time of a patient's death in order for patients and families to have the donation option.
- HB 30 does not take away authority or jurisdiction away from Coroners. Coroners retain authority to deny organ recovery, as in current law.
- HB 30 does not permit the recovery of organs and tissue before a patient has died. This bill does not change current law about when recovery occurs.

IV. Amendments to Senate Bill 850

The companion to House Bill 30, Senate Bill 850, was amended to incorporate recommendations and requests of several stakeholder groups including the PA Catholic Conference, the PA District

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[16] National Conference of Commissioners on Uniform State Laws, Revised Uniform Anatomical Gift Act (2006), Aug. 26, 2009, at 59 (http://www.uniformlaws.org/shared/docs/anatomical_gift/uaga_final_aug09.pdf).
[17] J. Keith Pinckard, M.D., Ph.D., et al., Position Paper on the Medical Examiner Release of Organs and Tissues for Transplantation, National Association of Medical Examiners, Feb. 21, 2006, at 11.
[18] Id. at 18.

Attorneys Association, the PA Coalition Against Domestic Violence, the Office of the Victim Advocate, NCCUSL, and PennDOT. It is anticipated that a similar amendment addressing these and any other outstanding issues would be offered to House Bill 30. Below are some of the changes made in the amendment to SB 850.

- There is No Presumption of Consent. It has been suggested that Section 8611(b.1) relating to hospital administrators authorizing a gift created the appearance that this is presumed consent legislation. This was never the intent of the legislation, and as such this provision has been removed entirely.[19] Similar concern was expressed with Section 8626 relating to advance directives, which has also been removed in its entirety.[20]

- Hierarchy of Next of Kin/Decision makers. Stakeholders have suggested that the category of people who could authorize a gift under Section 8611(b)(7) is too broad. In response, that language was changed to reflect the language used in the 2006 UAGA model act.[21]

- Ensuring that Families are Approached with Sensitivity and Consideration to their Circumstances. A request was made to retain current PA statutory language relating to sensitivity in notifying families of the donor option and taking into account the deceased individual's religious beliefs. The language which is also in federal law has been reincorporated into Section 8617(c)(2) and provides for accountability.[22]

- Clarifying the Collaboration between OPOs and Coroner/Medical Examiners. The amendment also modifies Section 8627 relating to Coroners and Medical Examiners to make clear that those officials retain jurisdiction in all cases (**and retain the authority to deny donation**) and to provide for organ procurement organization collaboration with the Coroner/Medical Examiner. The changes also clarify that only in cases of organ donation for transplant are those officials or their designee to join recovery surgeons at the hospital before denying organ recovery.[23]

- PennDOT Modifications. Changes were made to clarify that no new donor registry is being created, including a modification of the definition of "Donate Life PA Registry" in Section 8601, along with other changes requested by PennDOT.[24]

- Technical changes. Other grammatical/technical changes were made, including a typographical error in Section 8615(e) of SB 850 where duplicative language from Section 8615(d) had been included rather than the correct language distinguishing between a "revocation" of a gift and a "refusal" to make a gift.[25]

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[19] Senate Bill 850, Session of 2013, Printer's Number 1593, at § 8611(b.1)
[20] Id. at § 86
[21] Id. at § 8611(b).
[22] Id. at § 8617(c)(2).
[23] Id. at § 8627.
[24] Id. at § 8601, § 8621(b).
[25] Id. at § 8615(e).

V. Support for the Donate Life Pa Act

Thousands have recognized the need for action to support the more than 8,500 people awaiting a life-saving transplant in Pennsylvania. The Save a Life NOW PA website (www.savealifenowpa.org) includes their signatures along with the support of the healthcare community. The healthcare community has bonded in support of this bill and the realization that inaction in unacceptable when people are dying each day awaiting their life-saving transplant. Below is a list of just some of those organizations who have expressed their support.

- Abington Memorial Hospital
- Allegheny County Organ and Tissue Task Force
- Altoona Organ and Tissue Task Force
- American Liver Foundation – Allegheny Division
- Bedford County Organ and Tissue Donation Task Force
- Berks County Coalition for Organ & Tissue Donation
- Bradford Regional Medical Center
- Butler County Organ and Tissue Donation Task Force
- Capital Coalition for Organ & Tissue Donation
- Center for Organ Recovery & Education (CORE)
- Charles Cole Memorial Hospital
- Chester County Hospital
- Children's Hospital of Pittsburgh of UPMC
- Clarion Hospital Corry Memorial Hospital
- Crozer-Keystone Health System
- Delaware Valley Transplant Social Worker's Group
- Donors Are Heroes
- DuBois Regional Medical Center
- Einstein Healthcare Network
- Elk Regional Health Center
- Erie Organ and Tissue Task Force
- Family House of Pittsburgh
- Fayette County Organ and Tissue Task Force
- Gift of Life Donor Program
- Gift of Life Family House
- Hahnemann University Hospital
- Harrisburg Hospital
- Hospital of the University of Pennsylvania
- Johnstown Organ and Tissue Donation Task Force
- Lehigh Valley Coalition for Organ & Tissue Donation
- Lions Eye Bank of Delaware Valley
- Main Line Health System – Lankenau Medical Center, Bryn Mawr Hospital, Bryn Mawr Rehab Hospital, Riddle Hospital, Paoli Hospital, Mirmont Treatment Center
- National Kidney Foundation Serving the Delaware Valley
- NDRI – National Disease Research Interchange
- NE PA Coalition for Organ & Tissue Donation
- Penn Presbyterian Medical Center
- Pennsylvania Association of Community Health Centers
- Pennsylvania Hospital
- Pennsylvania Sports Medicine Association
- PinnacleHealth System
- The Children's Hospital of Philadelphia
- The Kidney Foundation of Central Pennsylvania
- The National Kidney Foundation Serving the Alleghenies
- TRIO – Transplant Recipients International Organization
- Uniontown Hospital
- University of Pennsylvania Health System
- UPMC Altoona, Bedford, Hamot, Health System, McKeesport, Mercy Hospital, Northwest, Passavant, Presbyterian Hospital, Shadyside Hospital, St. Margaret, Transplant Services
- Warren County Organ and Tissue Task Force
- Windber Medical Center

VI. Conclusion

Despite its place as a national and international leader in organ donation and transplantation, Pennsylvania still has much work to do. With more than 400 people dying in Pennsylvania each year, it is essential that we update our anatomical gift law to reflect best clinical practices and improve on our existing process. Gift of Life Donor Program emphatically supports the passage of House Bill 30 and encourages the members of this Committee to join us in supporting the thousands of Pennsylvanian's currently awaiting transplant.

Position Paper on the Medical Examiner Release of Organs and Tissues for Transplantation

J. Keith Pinckard, M.D., Ph.D., Charles V. Wetli, M.D., and Michael A. Graham, M.D.

Board of Directors Approved February 21, 2006 – Expires February 21, 2011

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ABSTRACT

The medical examiner community plays a key role in the organ and tissue procurement process for transplantation. Since many, if not most, potential organ or tissue donors fall under medicolegal jurisdiction, the medical examiner bears responsibility to authorize or deny the procurement of organs or tissues on a case-by-case basis. This responsibility engenders a basic dichotomy for the medical examiner's decision-making process. In cases falling under his/her jurisdiction, the medical examiner must balance the medicolegal responsibility centered on the decedent with the societal responsibility to respect the wishes of the decedent and/or next of kin in order to help living patients. Much has been written on this complex issue in both the forensic pathology and the transplantation literature. Several studies and surveys of medical examiner practices as well as suggested protocols for handling certain types of cases are available for reference when concerns arise that procurement may potentially hinder medicolegal death investigation. It is the position of the National Association of Medical Examiners (NAME) that the procurement of organs and/or tissues for transplantation can be accomplished in virtually all cases without detriment to evidence collection, postmortem examination, determination of cause and manner of death, or the conducting of criminal or civil legal proceedings. The purpose of this position paper is to review the available data, the arguments for and against medical examiner release, and to encourage the release of organs and tissues in all but the rarest of circumstances.

INTRODUCTION

The ability to transplant organs or tissues from one person to another is one of the greatest successes of modern medicine. However, the need for donor organs and tissues vastly outweighs the supply. As of this writing, greater than 90,000 people are on the United Organ Sharing (UNOS) Network waiting list for an organ transplant (1) and approximately 17 people on that list die each day while awaiting transplantation. It is estimated that less than 15% of the population has a signed organ donor card (2). The pediatric population is even more acutely affected by the shortage of organs and tissues, largely due to size constraint considerations. Approximately 30-50% of children less than 2 years of age will die waiting for an organ transplant (3).

The medical examiner is one of the most important components of organ and tissue procurement and thus the transplantation process because the majority of persons who are suitable donors fall under medical examiner jurisdiction. Indeed, it has been estimated that as many as 70% of potential donors may fall under medical examiner/coroner jurisdiction (4), and thus the medical examiner/coroner must give authorization before organ or tissue procurement may proceed in these cases.

Medical examiners are charged first and foremost with the responsibility of determining and certifying the cause and manner of death. To this end, they are given the legal authority and control over the body which generally begins when the person is pronounced dead and ends after the medical examiner has completed a medicolegal death investigation and in many cases, an autopsy examination. During this period of time the medical examiner must ensure that the integrity of the body is maintained such that the

cause and manner of death may be determined, that appropriate evidence may be collected, and that any injuries or natural disease may be documented.

Any decision to authorize or deny removal of organs/tissues for transplantation must consider and weigh the interests of the patients whose lives/health hang in the balance, the need to fulfill the statutory mandate to provide cause and manner of death opinions and the provision of a solid factual foundation or expert opinions. The medical examiner is the person best qualified to balance these sometimes competing interests of medicine and law and should not devolve the responsibility for deciding whether a body under medical examiner jurisdiction may be an organ/tissue donor to treating physicians, O/TPO (organ/tissue procurement organization) personnel, transplant surgeons, law enforcement personnel or prosecuting attorneys.

For the purposes of this discussion, the terms "deny" or "denial" refers to the blanket refusal of all organ or tissue procurement from a potential organ or tissue donor. It is recognized that not all cases are appropriate for full release of all organs and tissues. In some cases, it is appropriate for medical examiners to only allow procurement of some but not all organs or tissues (e.g., allowing procurement of internal organs but not skin in cases where many patterned injuries are present). These are not considered "denials" but rather "approvals with restrictions".

In some cases, medical examiners have denied organ or tissue procurement because of the well-intentioned but unfounded concern of compromising their ability to carry out their primary medicolegal responsibility.

Frequently, medical examiner denials for organ and/or tissue procurement involve cases of known or suspected child abuse or cases of possible Sudden Infant Death

Syndrome (SIDS). Unfortunately, these two categories make up a substantial portion of pediatric potential donors, and thus denials for procurement in these types of cases have a great impact on the availability of pediatric organs and tissues for transplantation.

NAME encourages the approval of organ and/or tissue procurement in virtually all cases. With rare exception, the procurement of organs or tissues can occur without jeopardizing the medical examiner's medicolegal responsibilities. As will be discussed further, arguments for denial in certain types of cases have no empiric or scientific evidence to support them. Indeed, many of the arguments against procurement in certain types of cases appear to be motivated not by such objective measures, but rather by fear of adversely affecting a future legal proceeding or from external political pressure from a funeral director or a prosecutor. Unfortunately, denials also occur because the procurement process might pose logistical problems for the medical examiner.

This manuscript deals with the philosophical principles regarding the release of organs and tissues for transplantation. This discussion is focused on the arguments for and against the medical examiner approval of procurement of organs/tissues for donation. A logistical analysis detailing specific procedures or comprehensive protocols of how to maximize medical examiner approvals is beyond the scope of this manuscript. Many medical examiners' offices have such protocols that outline the practical aspects of communicating and cooperating with organ/tissue procurement organizations (O/TPOs) and transplant teams to maximize the potential for medical examiner approval. It is recognized that there are logistical differences between considering the approval of organs and the approval of tissues for procurement. However, since this discussion is

primarily philosophical, the two topics are discussed together rather than separately since the philosophical issues are essentially the same.

DISCUSSION

The primary function of the medical examiner is to determine the cause and manner of death. Currently, all potential non-living organ donors will have some period of survival in the hospital. In many of these cases, the cause of death is already reasonably known from the investigation and clinical course at the hospital, especially if the patient has undergone adequate diagnostic evaluation. Practices vary from office to office; some medical examiners certify deaths without performing an autopsy in non-homicide cases where the cause of death is reasonably established and there are no other reasonably foreseen medicolegal issues (for example, a patient hospitalized for a drug overdose who died after being in a coma for several days), whereas others perform autopsies on all decedents with a non-natural manner of death. In cases in which the cause of death is not reasonably established or other medicolegal issues remain unresolved, an autopsy is usually performed.

Neither organ nor tissue procurement preclude the performance of a "complete autopsy". All components of examination may still be performed, although some may need to be performed in a different manner than usual. The first component of the autopsy is the external examination. Even though the medical examiner will be able to view the body following procurement, it is important to ensure that the medical examiner is able to view the appearance of the body before procurement. Ideally this may be accomplished by the medical examiner performing the external examination prior to

procurement, however this might be hindered or prohibited by various logistical constraints (e.g. staffing, time, travel distances, etc.). Medical examiners cannot necessarily depend on clinicians or procurement technicians to properly characterize injuries. This underscores the importance of complete photographic documentation of all body surfaces prior to procurement in order to ensure that the medical examiner will be able to view the external body surface in the unadulterated state. It is important to remember that organ procurement is performed via a single midline thoracoabdominal incision and sternotomy. The procurement of long bones from the extremities also involves isolated incisions. The entire skin surface remains in these cases such that an external examination should remain unhindered as long as steps are taken to preserve the integrity of defects (e.g. Gunshot or stab wounds) or, if the procurement incision must traverse a wound, to ensure the medical examiner is satisfied that the wound has been adequately examined and its features documented. In the case of skin tissue donation, this would not be the case, and any injuries involving a potential donor site that cannot be adequately examined or documented prior to procurement should be left intact or if numerous, the procurement of skin from the involved area should be denied.

The second component of the autopsy is the internal examination. Findings encountered upon opening the body, such as injured organs or blood within the body cavities, must be documented by the transplant surgeon to the satisfaction of the medical examiner. Procurement personnel, including the surgeon, must agree to return, if necessary, to the applicable jurisdiction at no expense to the taxpayers in order to testify as to their observations. Photographic and other imaging studies can further document the appearance of the body cavities and their contents. In some cases the medical

examiner may ask the O/TPO to conduct extra tests beyond those normally contemplated for organ screening (e.g., CT, angiography, full body radiography) when such tests are deemed necessary to adequately address foreseeable medicolegal issues. In general, an organ that appears unhealthy or that has sustained severe trauma will generally not be acceptable for donation and will not be removed from the body; the medical examiner will thus be able to directly examine the organ. In some instances, an organ may be sufficiently damaged to preclude successful transplantation but its procurement may be desirable for use in research. In such cases, these organs must not be removed prior to consultation with the medical examiner and without the explicit approval of the medical examiner. With minor trauma that would not medically prohibit transplantation (e.g., a small liver laceration that can be oversewn), the transplant surgeon must document his/her findings such that the medical examiner has access to this information. Although procured organs are not directly available to the medical examiner at autopsy, they can be photographed and even biopsied such that microscopic abnormalities may be detected. Directed biopsies may also be performed at the medical examiner's request. Furthermore, if the organ grafts successfully and functions properly in the transplant recipient, it is highly unlikely that it was associated with the cause of death of the donor. In fact, this "test" of donated organ function is unique to transplanted organs. Of course, the pathologist may attend the organ recovery surgery and personally view the organs if he/she feels that this is necessary.

Some medical examiners have expressed concerns regarding the fact that they would be relying on the surgeon to accurately document his/her findings and to be willing to testify to them in court. The documentation of findings is something that must be

insisted upon when protocols for medical examiner cases are being formulated. The surgeon would not be interpreting or characterizing findings; only documenting them for the medical examiner to do so. Testimony by the transplant surgeon should rarely be required in person, but if so, the surgeon should fulfill any legal obligation to comply with a subpoena. However, with rare exception, there is no reason that medical examiners could not testify to the surgeon's documented observations. Medical examiners routinely testify to findings documented in hospital charts; testifying to the procurement surgeon's observations would be no different.

The discussion up to this point has addressed issues and concerns related to potential detrimental effects of organ and/or tissue procurement on the postmortem examination. Of equal importance, however, is the correlation of the postmortem examination with the scene and investigative findings. Indeed, many of the concerns about allowing procurement are ultimately focused on determining the manner of death rather than the cause. The investigation of the circumstances surrounding the death has a substantial bearing on the medical examiner's opinion regarding the manner of death, and the procurement of organs and or tissues obviously does not interfere with this investigatory component.

The collection, preservation, and documentation of evidence are also the medical examiner's responsibility. Potential organ donors almost always have some survival interval in the hospital, which implies that they have been undressed, possibly washed, and have undergone diagnostic and therapeutic procedures. If any evidence were on the body, it would likely have been lost well before procurement took place or the body taken to the morgue. If the investigation by law enforcement has suggested that a crime has

occurred, appropriate evidence collection (e.g., trace evidence, gunshot residue collection, sexual assault kits, etc) should have already been performed at the hospital. If procurement is to take place, the hands may be bagged to protect any further trace evidence that may remain or evidence may be collected from the surface prior to procurement. Regardless of whether procurement takes place, appropriate steps for the collection of evidence should already be in place, for example, retention of the clothing. In the case of tissue donors, the external examination and autopsy can be performed prior to procurement. In those cases where this is not possible, the clothing can be retained and the hands bagged by the procurement team.

Ensuring the ability to collect evidence, document the presence or absence and extent of disease and/or injury, and determine cause and manner of death enables the medical examiner to ensure that the procurement of organs or tissues does not interfere with adequately addressing medicolegal issues in future legal proceedings, either civil or criminal. Defendants in murder trials have, however, claimed that extubation and removal of organs for transplantation was the cause of death, rather than the proximate action that caused the brain-death of the patient (5, 6). However, none has been successful since the guilt of the accused is based upon his/her proximate action (7) and the organ/tissue procurement only occurs after death has occurred, regardless of what criteria are used to establish death. Searches of the medical and legal literature (8) have failed to find a single documented instance of organ procurement interfering with a criminal investigation, a prosecution, a defense, or the determination of cause and manner of death at autopsy. While this could be interpreted to mean that the proper subset of

cases had been appropriately denied for procurement, there are many medical examiners' offices with zero denials and without future problems with legal proceedings.

Over the last decade, medical examiner/coroner policies, practices and denials related to organ/tissue donation have been studied (4, 9, 11-16). The medical examiner denial rates overall have generally been between 6 and 10%. The incidence of medical examiner denials has decreased during the past two to three years following NAME's endorsement of the "Zero Denial" concept. It is clear that cases involving suspected child abuse or the possibility of SIDS are the most common types of cases in which medical examiners categorically deny the procurement of pediatric organs or tissues.

One nationwide survey of every organ procurement organization (OPO) queried the number and nature of organ denials from 1990-1992 (10). The respondents of that survey represented 71% of the OPOs and 77% of the donor population in the United States. Of all potential organ donors reported, 62.1% fell under medical examiner jurisdiction. 7.2%, 9.6%, and 11.4% of cases were denied in 1990, 1991 and 1992, respectively. Although this means that approximately 90% or more of cases were approved, the number of denials in this 3-year period was 561. Since multiple organs (usually three or more) can be procured from a single donor, this represents the potential for well over a thousand missed opportunities for transplantation from the OPOs that responded to the survey. In 1992, 29.3% of denials were in cases of suspected child abuse and 22.8% represented a single gunshot wound of the head. Approximately half of cases of suspected SIDS were denied for organ procurement.

In the same study, however, 10 OPO areas in the country reported no medical examiner organ denials and 5 others with only one denial. A similarly performed follow-

up study covering the years 2000-2001 generated an 83% response rate, representing 86% of the donor population respectively (16). The denial rates were 6.8% and 6.7% for 2000 and 2001, totaling 353 denied cases. Similar to the first survey, approximately one-third of suspected cases of child abuse and approximately one-half of suspected SIDS cases were denied. No organ denials were reported in ten cities and in four states. It is possible, however, that some OPOs did not ask for approval because of prior experience with denials from a particular medical examiner. Some OPOs may not have asked for approval in certain types of cases given that denial may have been the expected outcome. This selection bias would therefore falsely decrease the denial rate.

A survey of 64 medical examiner offices generated a response rate representing 29% of the U. S. population (17). The denial rate in that survey was 7%, similar to that found in other studies. This survey also discovered differing practices among the various medical examiner offices. In cases of suspected SIDS, 60% of offices reported that they always denied procurement, whereas 15% stated that they always approved these cases. Similarly, 40% stated they always denied cases of suspected child abuse, whereas 15% always approve. Homicides related to child abuse have the potential for much controversy due to their inflammatory nature and scientific controversies over the etiology of abusive head trauma. However, some medical examiner's offices routinely release organs for transplantation in cases of either known or suspected child abuse (4, 10, 16).

Certifying deaths of children and infants can be challenging; deaths in this population exclusive of known natural disease or accidental trauma are generally unexpected. SIDS is by definition a diagnosis of exclusion. A common argument against

procurement in cases consistent with this diagnosis is that procurement would interfere with the performance of a complete autopsy, thus prohibiting the exclusion of other potential causes of death. As discussed previously, procurement does not prevent the performance of a complete autopsy. One of the differential diagnoses of suspected SIDS cases is homicide; the concerns regarding denying procurement in such cases have been previously discussed.

The vast majority of cases that would potentially be certified as SIDS are pronounced dead at the scene or after transport to a hospital. These cases are therefore candidates only for tissue donation. The only tissues generally requested from non-beating heart infant or child cases are bone and heart valves.

Human valve tissue is far superior to prosthetic valves, primarily because they have far fewer thromboembolic complications and do not run the risk of mechanical failure. A large study of pediatric medical examiner cases concluded that the only significant cardiac abnormalities in this population that would likely be overlooked if heart valves were procured were conduction system defects, which are quite rare without a clinical history consistent with such a disorder (18). Furthermore, the heart may be examined in a sterile fashion prior to procurement of valve tissue (19). Similarly, since the heart is examined by a pathologist contracted by the TPO after valve procurement occurs, there is no reason to deny valve procurement in adults, even if a cardiac cause of death is suspected. A similar procedure has been developed for pediatric hearts (Wendy Gunther, in press).

Given the importance of organ and tissue donation, numerous advocacy groups and political lobbies are working for this cause. The response to the perceived lack of

cooperation and the categorical denials of organ/tissue procurement by medical examiners by such interested parties has resulted in legislation forcing the medical examiner release of organs and tissues in several states. New York and Tennessee passed legislation requiring the release of organs and tissues in 1991 and 1993, respectively (20, 21). Laws requiring the presence of the medical examiner or coroner at the procurement procedure if denial is anticipated were passed in New Jersey, Texas, and California in 1993, 1995, and 2003, respectively (22-24). If the medical examiner or coroner still insists on denying the removal of an organ for transplantation after viewing the procurement procedure, he/she must provide written documentation explaining the reasons for the denial.

We believe that the medical examiner/coroner and the transplant communities should cooperate rather than legislate and establish procedures and protocols to satisfy the needs of all parties, maintaining flexibility and causing the least disruption or inconvenience as have been accomplished in several jurisdictions.

CONCLUSION

Medical examiners play a key role in the transplantation process. Our primary responsibility is to speak for the dead, and to ensure that medicolegal issues pertinent to their deaths are appropriately addressed. The responsibility to ensure that all necessary documentation of findings and that appropriate collection of evidence take place rests with the medical examiner. As physicians and citizens, medical examiners also have a societal responsibility to enhance the health of citizens.

The procurement of organs will certainly increase in the future. The donor population is expected to markedly increase with the advent of donation after cardiac death, especially since the majority of potential donors are not brain dead but instead could become "non-beating heart donors". Because of donation after cardiac death, certain legal issues regarding medical examiner jurisdiction will have to be revisited due to the very limited time frame in which action must be taken. More types of tissues may also become available in the future, and obviously each would have to be evaluated with respect to medicolegal concerns.

Denial rates of 6-10% mean that medical examiners generally approve procurement in over 90% of cases. This is an excellent figure, but it is the remaining cases that are the concern of this manuscript. To someone waiting on a transplant list, every single donor potentially makes an enormous difference. Furthermore, the different practices at different offices with respect to categorical approvals or denials lead to the appearance of arbitrariness.

Legislation in five states has by definition reduced the number of medical examiner denials and conversely, increased the number of organs and tissues for transplantation. However, it is our opinion that coercive legislation imposed by outside groups is counterproductive to effective communication between medical examiners and O/TPOs. The fact that legislation dictates the course of action may actually lessen the communication between all involved parties, which may be detrimental to the death investigation of the decedents and to the public we are trying to serve. Further, legislation imposed due to our perceived lack of cooperation with O/TPOs is likely to result in far greater problems in carrying out our medicolegal responsibilities than if

medical examiners and O/TPOs work together to come to mutually beneficial understanding of one another's needs to generate appropriate protocols for dealing with these cases.

It is possible for medical examiners to allow procurement to occur and still fulfill their medicolegal responsibilities. That being said, it remains of critical importance that O/TPOs as well as the organ procurement surgeons provide the medical examiner with everything that is requested, every time. Each situation is different; every medical examiner's office and their O/TPO(s) need to come to a mutual understanding of what the medical examiner requires. Some denials do occur because the medical examiner may not have gotten everything he/she needed in past cases.

Other denials by medical examiners seem to be motivated by fear. Some are hesitant because they feel that they must see everything with their own eyes, prior to any procurement. Other medical examiners have concerns about a future adverse outcome such as being "blamed" if the prosecuting attorney does not secure a conviction. There are anecdotal reports that some prosecutors have allegedly dropped cases or reduced the charges because of the fear that the organ/tissue procurement process has somehow rendered the autopsy findings diminished or destroyed. Medical examiners have the responsibility to defend what is an appropriate, defensible position; that the procurement of organs and tissue is compatible with successfully fulfilling all of our medicolegal responsibilities. This may also involve educating attorneys about the organ/tissue procurement processes to assure them that a complete and accurate examination has been performed and that all the appropriate evidence has been collected.

Providing that appropriate protocols are followed, there is no reason that procurement of organs and tissues should not be able to occur, even in cases of suspected SIDS or child abuse. The proof of principle already exists in that release even in these types of cases is routine in many jurisdictions in the United States with no documented adverse outcomes. The only general restrictions that appear valid are the restriction of corneas or bones in cases of suspected child abuse, or the restriction of skin tissue procurement in any case if the disruption of a patterned injury could not be avoided and the injury could not be adequately documented prior to procurement. Good working relationships with the O/TPO and the transplant team are of the utmost importance to ensure that all of the necessary steps are taken in order to perform our medicolegal duties. Although our primary function is to investigate death, enabling transplantation is one of the few opportunities we have to directly save and improve lives.

This manuscript has been reviewed and endorsed by the following organizations:

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