

August 4, 2005

John Stanley
Dane County Coroner
Public Safety Building
115 West Doty Street, Room 2144
Madison, WI 53703

Dear Mr. Stanley:

It has come to our attention that coroners and medical examiners throughout the State of Wisconsin, through written notice, intend to direct all tissue donations from counties they serve to the American Tissue Services Foundation (ATSF). Our understanding is that their intention is to take charge of bodies in all medical examiner cases so that tissue donation can be directed to ATSF, regardless of whether an autopsy is to be performed. In fact, it also has come to our attention that two donors from the University of Wisconsin Hospital, one tissue-only donor and one organ and tissue donor, were referred by your office to ATSF, despite the Hospital's contractual relationship with another tissue bank, Musculoskeletal Transplant Foundation (MTF) TransSource.

To involve a tissue recovery agency, other than the one with which a hospital has an agreement puts the hospital in a very precarious situation. Under Federal regulation at 42CFR §482.45(a)(1) and (a)(2), which supersedes State law, the hospital must "Incorporate an agreement with an OPO designated under part 486 of this chapter, under which **it must notify, in a timely manner, the OPO** or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital." In addition, the hospital must "Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement."

The regulation is explained within the CMS regulatory Interpretative Guidelines, which state: "The hospital **must have an agreement with at least one tissue bank and at least one eye bank. The OPO may serve as a 'gatekeeper'** receiving notification about every hospital death and should notify **the tissue bank or eye bank chosen by the hospital** about potential tissue and eye donors." (Emphasis added.) For the medical examiner or coroner to circumvent the hospital's arrangement with its designated tissue bank, risks putting the hospital out of compliance with Federal Regulation, as well as compromising the integrity and outcomes of the organ and tissue donation process.

We are not clear under what statutory or regulatory authority a medical examiner or coroner may circumvent Federal regulation and prevent a hospital from using its designated tissue bank. Based on Chapter 979.02 of Wisconsin Statute, "the coroner, medical examiner or district attorney may order the

conducting of an autopsy upon the body of a dead person any place within the state in which an inquest might be held, as provided in s. 979.04.” Section 979.04 states that “...the district attorney may order that an inquest be conducted for the purpose of inquiring how the person died.” However, it appears that physical custody of a deceased individual is being taken within the hospital for purposes beyond determination of the cause of death and/or the performance of an autopsy.

We would also note that section 301 of the National Organ Transplant Act (NOTA), 42 U.S.C. § 274e, prohibits organ purchases. For the purposes of the Act, a “human organ” is defined as the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin and any other human organ specified by the Secretary of Health and Human Services by regulation. NOTA 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” The penalty for violating this subsection of NOTA is a fine not to exceed \$50,000 or imprisonment not to exceed 5 years, or both.

We are concerned about the potential for problems for donor families and organ procurement organizations (OPOs), as well as hospitals, when a coroner or medical examiner interferes in the tissue donation process established by the hospital. Hospitals are required both by Federal statute and regulation to ensure that families of potential organ donors are informed of their options to donate organs, tissues, and eyes and to decline to donate. Further, hospitals must encourage discretion and sensitivity with respect to the circumstances, views and beliefs of potential donor families. (See §1138(A) of the Social Security Act and 42 CFR 482.45.)

If an OPO requests consent for tissue donation, it is obligated under its agreement with the hospital to request consent on behalf of the hospital’s designated tissue bank. However, if the medical examiner or coroner takes custody of the body after organ recovery so that ASTF can recover tissue, ASTF will have to re-approach the family and request consent for ASTF to recover the tissue. Even if the OPO requests consent only for organ donation, the family will have to be approached by ASTF for tissue donation. To have a second agency re-approach the family with a request for consent to donation is inappropriate and insensitive. To have a hospital work with a tissue recovery agency other than the one with which it has an agreement will confuse the hospital, its staff, and ultimately, the family.

We are also concerned about the potential for harming public attitudes toward donation when tissue banks compete for families’ consent to donation. The National Coalition on Donation has conducted extensive research into public perception surrounding donation. They have learned that to the public, “all donation is organ donation” which means that anything that casts tissue donation in a bad light also taints the public’s perception of organ donation.

We need to work together collaboratively and seamlessly so as to ensure optimal outcomes for donor families and transplant recipients. To that end, our office would strongly encourage you to work closely with the OPOs in your jurisdictional areas, the National Association of Medical Examiners (NAME), and all stakeholders in the donation and transplantation process. Our Office of the General Counsel (OGC) agrees that failure to do so could potentially result in litigation, legislation, and further regulation of the industry.

I hope this letter provides clarification which will assist you in your collaborative efforts. However, should you have any questions regarding this letter or need additional information, please feel free to contact Ruth Parker of my staff at 816-426-6459 or via e-mail at ruth.parker@cms.hhs.gov.

Sincerely yours,

Demetria Wills, Branch Manager
Division of Survey & Certification
Kansas City Regional Office

cc:

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Andy Olsen, Paul Rusk, Echnaton Vedder, Michael Hanson, Jack Martz

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Department of Justice (DoJ)

Food and Drug Administration (FDA)

Office of the Inspector General (OIG)

Centers for Disease Control and Prevention (CDC)

Centers for Medicare & Medicaid Services (CMS)

Wisconsin State Survey Agency

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