

Coroner's, Medical Examiner's and Organ and Tissue Donation

Anthony M. D'Alessandro M.D.

Organ Procurement Organizations (OPO's)

- OPO's are responsible the recovery of heart, lungs, liver, kidney, pancreas and intestine for transplantation
- OPO's serve federally designated donation service areas(DSA) based upon counties
 - All hospitals within the designated group of counties are mandated to work with the assigned OPO
 - Two OPO's in the state UW OPO and Wisconsin Donor Network(WIDN)
- OPO's are regulated by the Center's of Medicare and Medicaid Services (CMS) and the United Network for Organ Sharing (UNOS)
- 1998 CMS conditions of participation requires all hospitals to work with the Federally designated OPO, select a tissue and eye bank to work with and refer all deaths and potential donors to the OPO

Tissue Banks

- Tissue Banks are responsible the recovery of bone, skin, tendons, and heart valves
- There are four tissue banks operating in Wisconsin
 - MTF Wisconsin Tissue Services, Wisconsin Tissue Bank, RTI Tissue Services (formerly Allograft Resources of Wisconsin), and American Tissue Services Foundation
- Tissue Banks are subject to the FDA's Good Tissue Practices Standards and may be certified by the American Association of Tissue Banks(AATB)
- Tissue Banks usually have three operations: Recovery, Processing and Distribution

Tissue Banks

- The Tissue Banks send the tissue recovered to be processed into usable "grafts"
- The business structures of tissue banks vary
 - some recovery operations of tissue banks are non-profit but send tissues to for-profit tissue processors others are affiliated with not-for-profit tissue processors
- Tissue processors then distribute the processed "grafts" to hospitals for surgical implantation or treatment of burn patients
- Tissue Banks contract with hospitals
 - the Medicare Conditions of Participation require that all hospitals have a relationship with a tissue and eye bank and develop criteria by which to select a tissue bank

Jurisdiction of Coroner's and Medical Examiner's vs. Federal Regulation

- Although Federal regulations require all hospitals to have an agreement with a tissue bank, some Wisconsin coroners and ME's believe their statutory authority allows them to refer to the tissue bank of their choice thereby disregarding the Federally mandated choice of the Hospital.
 - Some of the 30 coroner's and medical examiners who have sent letters notifying the OPO that **all** donors from their counties will be referred to the American Tissue Services Foundation are now redirecting tissue donors who die within the hospital, and that they take jurisdiction of, to American Tissue Services Foundation regardless of the hospital's contractual relationship with other tissue banks

Concerns with Re-direction of Hospital Tissue Donors by Coroner's and Medical Examiner's

- Hospitals have contractual relationships which require that all deaths within the hospital will be referred to the recovery agency with whom they contract
- Each hospital contracts with a tissue bank based upon criteria by which they have determined will best serve donor families within their organization
- Consent forms for tissue donation used within the hospital for tissue donation are specific to the tissue bank with whom the hospital contracts
 - When a coroner or medical examiner redirects a tissue donor the consent form used by the hospital may not reflect the business practices of the Coroner's or medical examiner's chosen tissue bank
- Tissue Banks require information from the patient's medical record for donation to proceed. If the hospital doesn't have a contractual relationship with the company that the coroner has chosen, then the hospital is not compliant with JCAHO, HIPAA and state statutes which require hospital's to have specific contractual language addressing confidentiality of released medical information.

What Does CMS Say about this Practice?

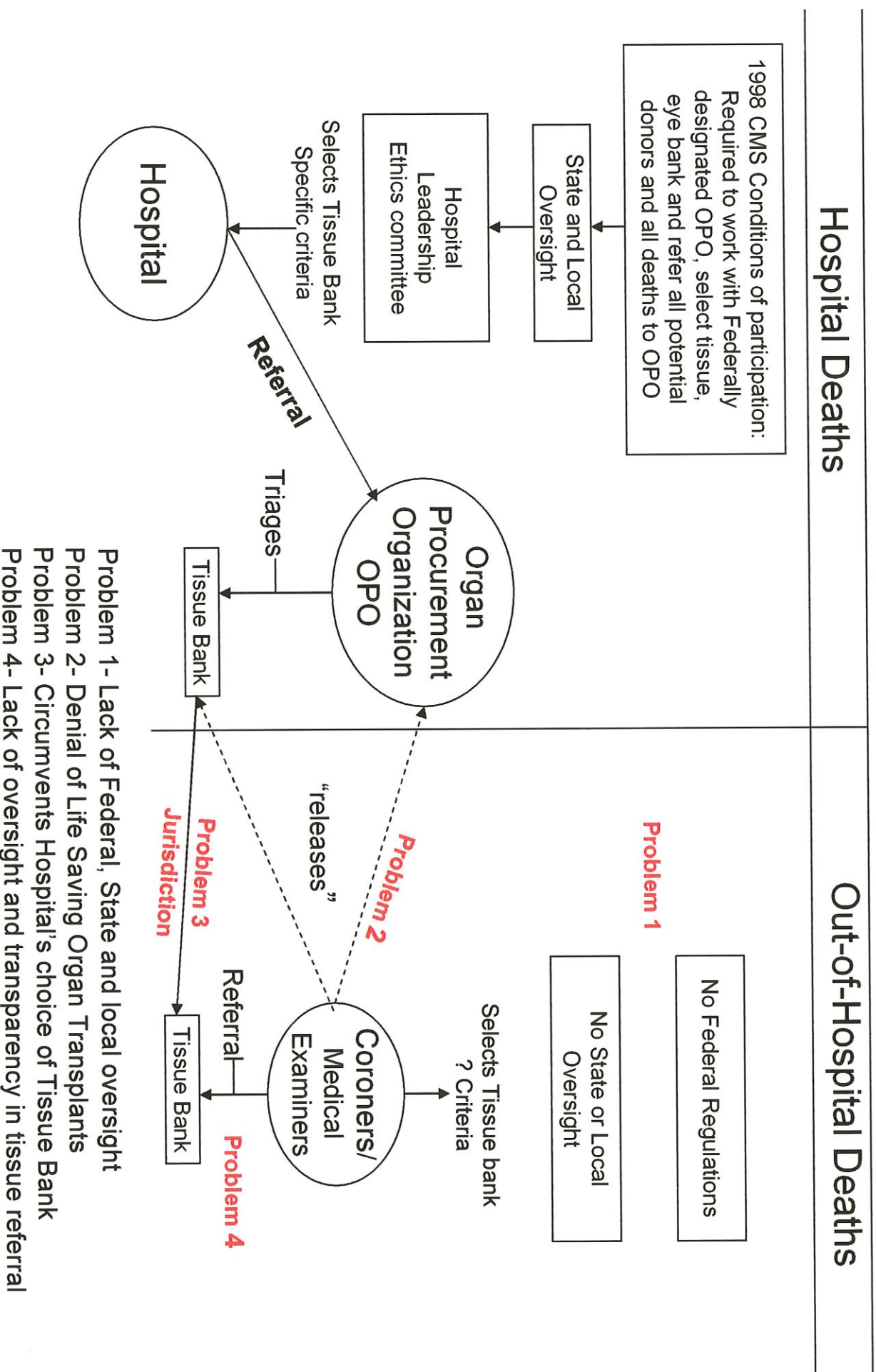
- In a letter dated August 4, 2005 to the Dane County Coroner:
 - ...The OPO may serve as gatekeeper receiving notification about every hospital death and should notify the tissue bank or eye bank **chosen by the hospital** about potential tissue and eye donors. For the medical examiner or coroner to 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...
 - ...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...

Lack of Oversight and Transparency for Out-of-Hospital Tissue Donor Referral

Since the majority of deaths occur out-of-hospital

- What are the selection criteria coroner's and me's use to exclusively work with one tissue bank for out-of-hospital deaths ?
- How many out-of-hospital deaths occur in a county?
- How many are referred for tissue donation?
- Which tissue bank received the referral for tissue recovery?

Organ and Tissue Donation



UWHC and WIDN OPO Donation Service Areas

