

# Legal Framework for Information Sharing in Organ Donation and Transplantation

Alexandra K. Glazier, Esq.  
VP & General Counsel  
New England Organ Bank

# HIPAA

## ■ True or False?

- HIPAA applies to all medical information
  - False
- HIPAA's privacy standards extend to deceased patient records
  - True — for 5 years
- HIPAA is the only legal standard for all medical privacy issues
  - False

# Legal principles

- HIPAA
- State laws
- Common sense

# HIPAA: Basic Principles

HIPAA governs the use and disclosure of PHI by Covered Entities

- ◉ Use and disclosure

- ◉ Authorization by patient or representative
- ◉ Regulatory exceptions

- ◉ Identifiable Personal Health Information (PHI)

- ◉ Medical info related to treatment or diagnosis that is identifiable
- ◉ Over 18 data elements to “de-identify”

- ◉ Covered Entities (CE)

- ◉ Health care providers

# Beyond HIPAA

- ◉ State law pre-emption
- ◉ More restrictive state laws remain in place
  - HIV
  - Alcohol & Drug Abuse
  - STDs

# Beyond HIPAA

## ◎ Common sense

- Keeping information confidential when there is an expectation of privacy.
- Most people expect disclosure and use of PHI in order to facilitate their medical care and treatment.
- A patient's general status is not confidential

# HIPAA: in the Donation and Transplantation Context

- ◉ Covered Entity
  - Transplant Centers are covered entities
  - OPOs are NOT
  
- ◉ Identifiable PHI includes
  - Name
  - UNOS ID
  - DOB
  - DOD

# HIPAA: in the Donation and Transplantation Context

- Use and Disclosure
  - Exception § 164.512(h)
  - Identifiable PHI may be used and disclosed by a CE to an OPO “engaged in the procurement ...of cadaveric organs...for purposes of facilitating organ, eye or tissue donation and transplantation” without authorization.
  - Only applies to deceased donation
    - No exception for living donation – HIPAA authorizations and release required for use and disclosure of donor and recipient PHI



# Information Sharing in Donation and Transplantation

## Deceased Donation Coordination

- Referral/screen/coordination of the donation required use and disclosure of donor's PHI
- Includes potential recipient PHI
- Exception applies –no authorization required for donor or potential recipient PHI to be used and disclosed as needed to coordinate the donation and transplant.
- Donor PHI should only be shared with persons for whom it is required to coordinate the donation and perform the transplant.

# Deceased Donor information shared with Recipients

- Transplant centers should only routinely provide minimal de-identified information about the donor to the recipient:
  - Age of donor by decade for adults
    - Child (12 – under)
    - Adolescent (13-19)
  - Donor's sex
- Informed consent for transplant may also require disclosure of the donor's general health or social information (de-identified) to the potential recipient.
- Reminder that donor's PHI is protected under HIPAA

# Information Sharing of Transplant Recipient outcomes

## Transplant recipient outcome info to OPO

- Identifiable PHI of transplant recipient
- Donation exception interpreted broadly should apply
- Basic outcome information may not be PHI
- Directory exception under HIPAA also supports disclosure of basic outcome info (in hospital? discharged home?) without authorization
- OPO should not disclose identifiable recipient information to donor family

# Information Shared Regarding Recipient Outcomes

## RECOMMENDED PRACTICE

- OPO should only disclose the following de-identified information about recipients back to donor families:
  - Age of recipient by decade for adults
    - Child (12 – under)
    - Adolescent (13-19)
  - General Status
    - hospitalized/ discharged home/ graft functioning
    - Immediate
    - 30 Days Post-Transplant
  - Recipient's sex

## Additional Recipient Information may be shared with permission

- Inquire what the transplant recipient/family would like to share:
  - Family Status
  - Geography by region (i.e. northwest, southeast, etc.)
  - Employment
  - Other information as desired
- Ideally determined at time of transplant consent.
- This information is shared only with permission.

# Recipient/Donor Information DO NOT DISCLOSE to donor families / recipients

- Religion
- Specific Diagnosis (recipient)
- Ethnicity and race
- Sexual Orientation
- Mechanism of injury or death (donor)

# Information Sharing policies and agreements

- HIPAA language should be incorporated in transplant center policy and staff should be trained on how HIPAA applies to deceased donation.
- Confidentiality requirements of OPO should be incorporated into the Agreement between the OPO and the transplant center.