Rules and Regulators

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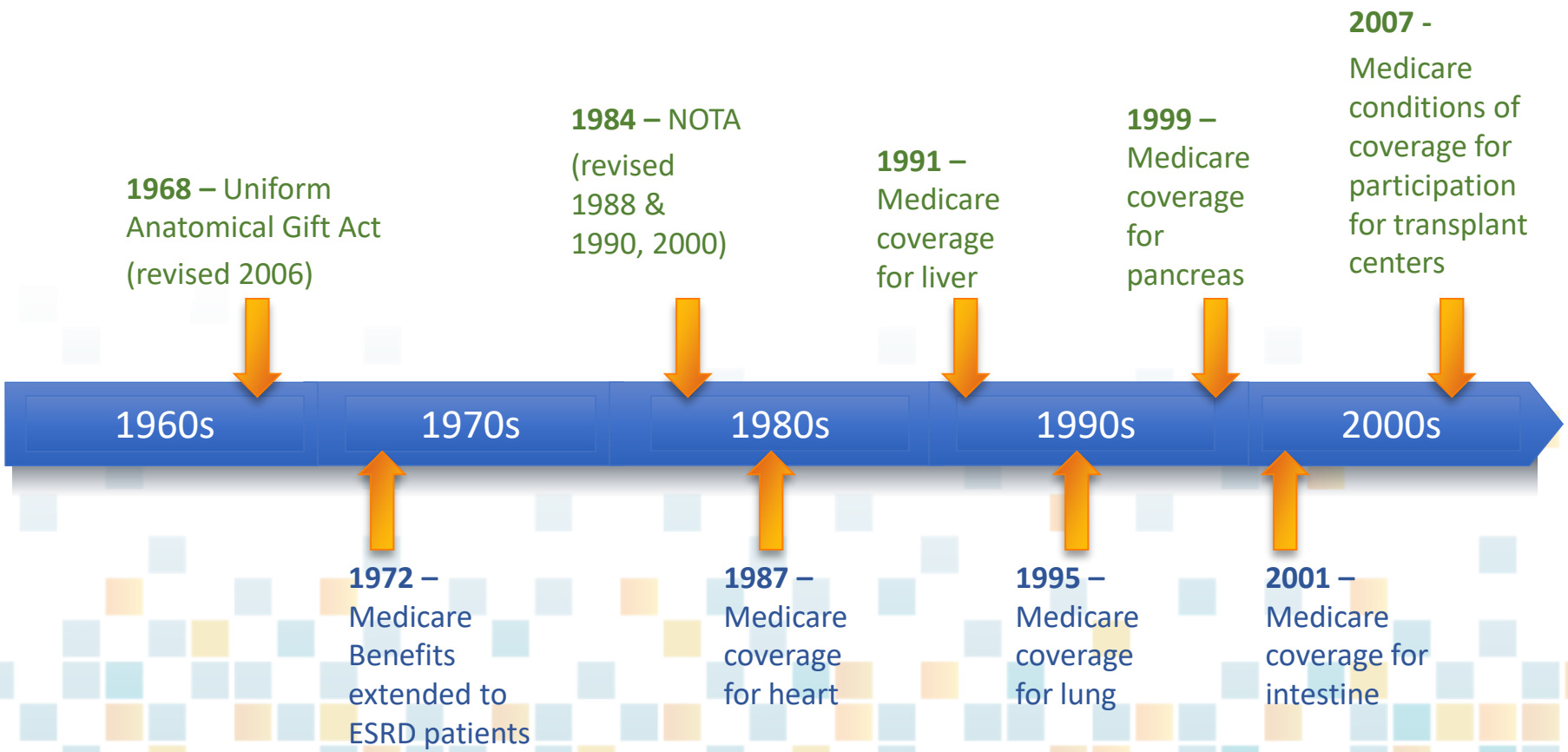
13th Annual Living Donation Conference
Presented by the American Foundation for Donation and Transplantation

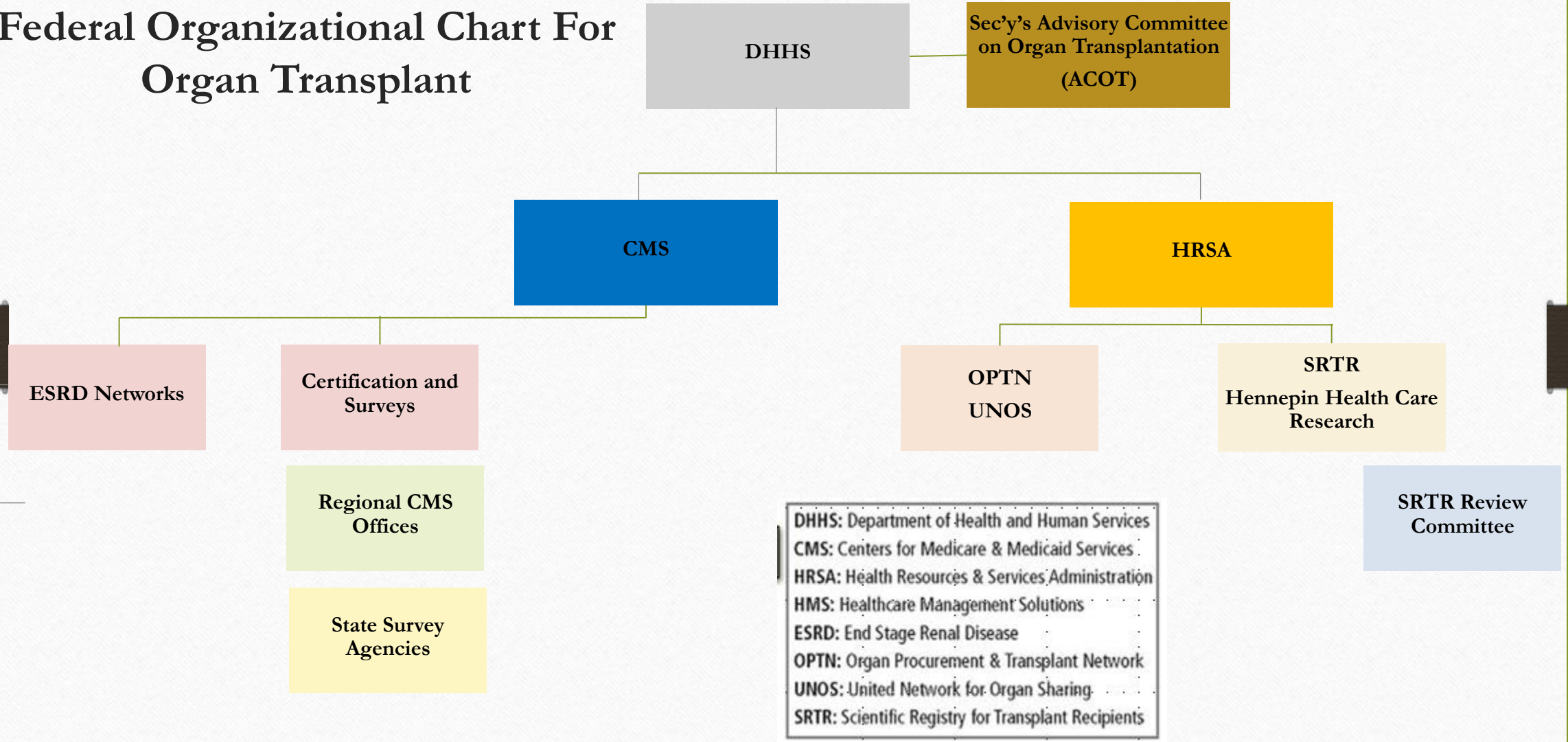
Objectives

- Discuss the history of organ transplant within the framework of regulation
- Describe the government regulatory agencies that govern organ transplant in the US
- Provide an overview of regulations, policies and by laws that impact living donation
- Describe consequences of non-compliance with the regulations

History of Transplant Related Legislation



Federal Organizational Chart For Organ Transplant



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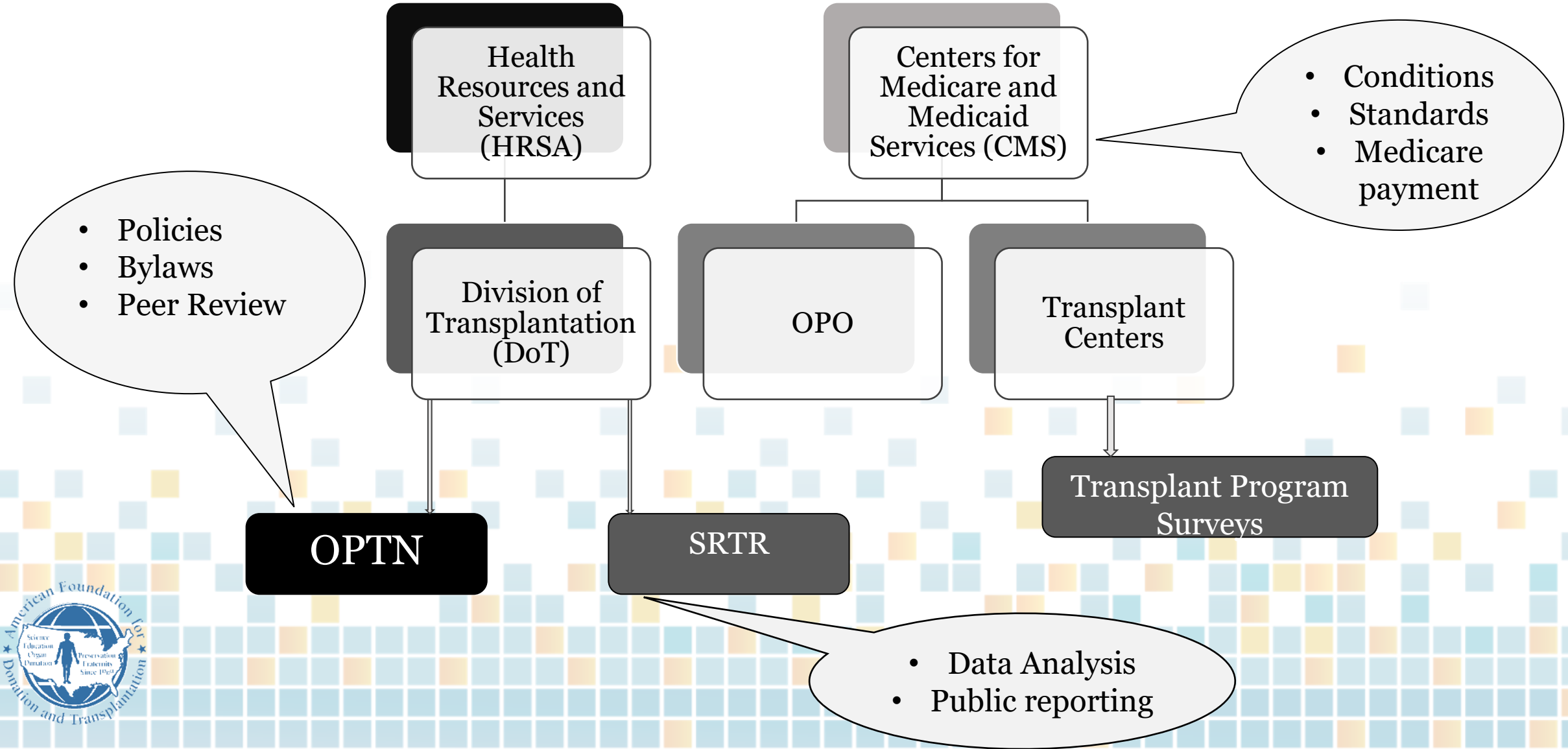

National Organ Transplant Act

- Unified transplant network
- Prohibited buying and selling organs
- Created the OPO system
- Established the OPTN
- Established the Scientific Registry of Transplant Recipients(SRTR)

OPTN

CMS

Regulator

Payer

Organ Donor Death Raises Questions About Living Donors

Four more transplant programs scrutinized

A national regulator finds problems at San Francisco, San Diego and two L.A. hospitals.

November 14, 2006 | Tracy Weber and Charles Ornstein | Times Staff Writers

Hospital's Kidney Transplant Death Rate Raises Concerns

December 17, 2005 | Charles Ornstein, Alan Zarembo and Tracy Weber | Times Staff Writers

U.S. Department of Health and Human Services

Office of Inspector General

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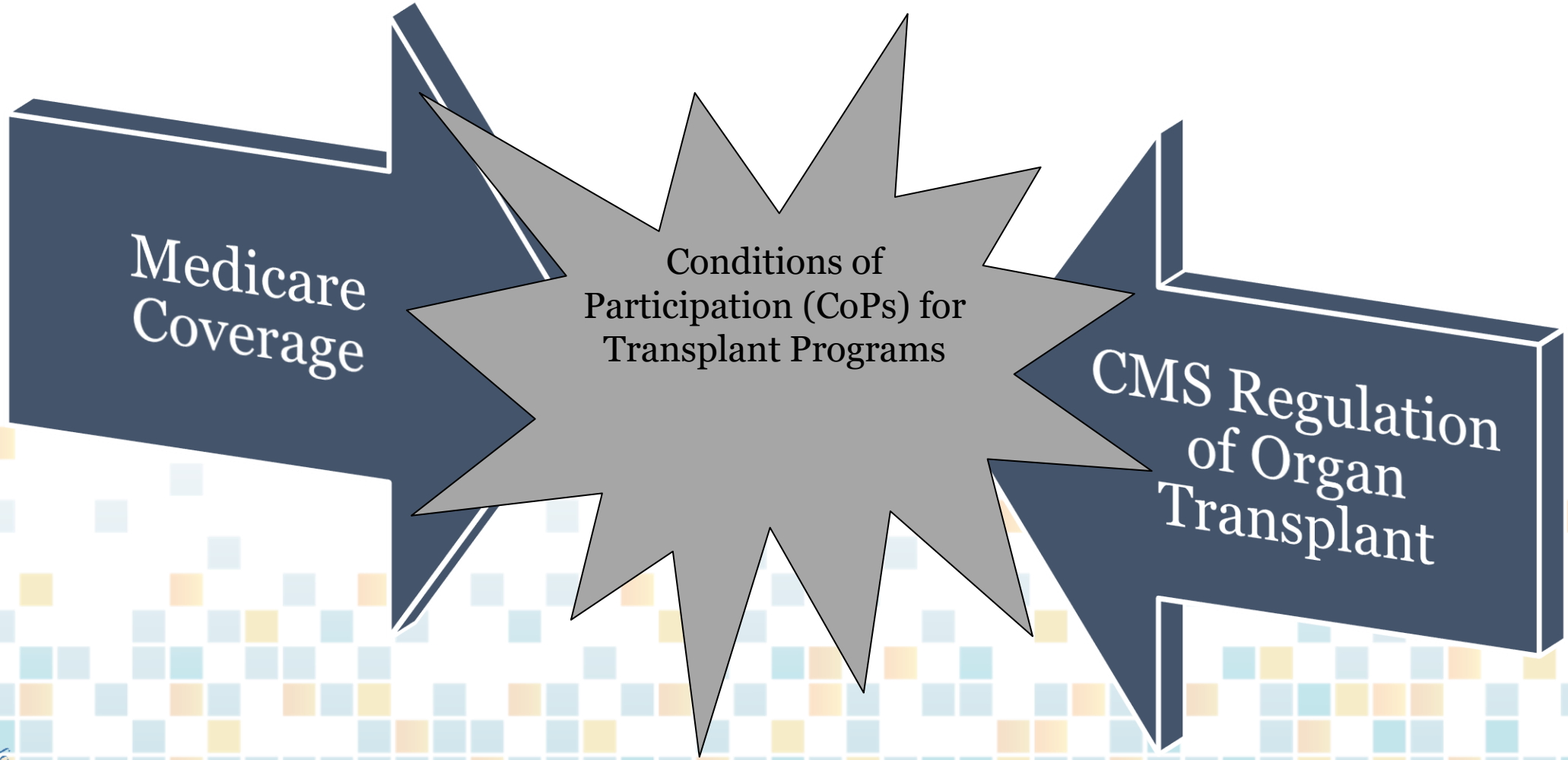
Organ Procurement and Transplantation Network

American Foundation for Donation and Transplantation

2007


Medicare Coverage
Conditions of Participation (CoPs) for Transplant Programs
CMS Regulation of Organ Transplant

Why so Much Regulation?

Demand is greater than supply

- Rationing of scare resource
- Benefit to individual may not benefit the whole

High Cost

- Billions per year

Donation is dependent of public trust

- Rules
- Transparency

Intense Media Focus

- Human interest stories
- Public concern

Centers for Medicare and Medicaid Services (CMS)

Establishment of minimal standards to protect patient health and safety

Implement oversight mechanism of transplant centers

- Conforming to minimal performance standards issues by government

Adapted several OPTN requirements as conditions

OPTN applies to all transplant programs – CMS CoPs only apply to programs seeking Medicare payment for transplant service

OPTN Primary Focus

- Equity of organ allocation
- Effective and efficient organ procurement and allocation
- Increase the supply of organs for transplantation
- Collect data
- Designate transplant programs

- Blood typing and verifications before listing and at time of transplant
- Notification to patients
- Allocation of organs
- Accurate waiting list
- Reporting deaths & graft failures
- Reporting f/u on transplant recipients for life
- Follow-up on living donors

Main Elements of COPs and OPTN regulations/policy/bylaws address:

- Structure
- Process
- Outcomes

These are also the main three components of quality in healthcare

QUALITY

Donabedian (2005)

Overview: Structure

CMS

- Located in Medicare participating hospital
- UNOS membership
- Sufficient resources such as medical specialists
- Availability of transplant physicians and surgeons
- Written agreement with Organ Procurement Organization (OPO)
- Provision of immunology and tissue typing services
- Availability of dialysis services

OPTN/UNOS

- Geographically contiguous
- Compliance with OPTN obligations
- Full approval by Medicare or VA or OPTN
- Sufficient resources such as operating rooms, ICUs, medical specialists, etc.
- Availability of transplant physicians and surgeons (Coverage Plan)
- Written agreement with Organ Procurement Organization (OPO)
- Provision of immunology and tissue typing services

Overview: Structure

CMS

- Patient medical records requirements
- Written Policies/Procedures/Protocols
- Multidisciplinary team with physician leadership
  - Social Worker
  - Dietitian
  - Pharmacist
  - Independent Living Donor Advocate
  - Transplant Coordinator
- QAPI structure with tie to hospital QAPI

OPTN/UNOS

- Written Policies/Procedures/Protocols
- Multidisciplinary team
  - Approved primary physician and surgeon
  - Mental health
  - Dietitian
  - Pharmacist
  - Independent Living Donor Advocate
  - Transplant Coordinator
  - Financial Coordinator
- Separate pediatric criteria
- QAPI structure

Overview Process:

CMS

- Evaluation and listing
- Waitlist management
- Transplant event management
- **ABO validation**
- **Organ Recovery & Receipt**
- Discharge planning
- Informed consent
- **Living donor evaluation, event and discharge management**
- **Evidence of multidisciplinary care planning throughout transplant and living donor processes**

OPTN/UNOS

- Criteria for listing
- Waitlist management
- **ABO validation**
- **Organ Recovery and Receipt**
- Informed consent/patient notification
- **Living donor evaluation, informed consent**
- **Living donor exclusion criteria**
- **Reporting on Living Donor outcomes**

Overview Process:

CMS

- Initial education and continuing education for nurses and other staff
- Patient and dialysis unit notification
- Notification to CMS of key personnel or ~~outcome changes~~
- Communication with dialysis units
- Participation in ESRD Network

OPTN/UNOS

- Patient notification
- Notification to OPTN of key personnel changes

Overview: Outcomes

CMS

- Standard – Initial approval only
  - Volume (Adult Center): At least 10 per year for heart, intestine, liver, lung. 3 per year for kidney
- Standard:
  - 95% UNOS data submission rate
- Standard – Initial approval only
  - Outcomes*: One year patient and graft (transplant) thresholds:
    - Observed – expected > 3
    - Observed/expected ratio > 1.85 Standard >1.5
    - Observed vs. Expected one-sided p value <.05

OPTN/UNOS

- Functional inactivity
  - Kidney, heart, liver: At least one in three consecutive months
  - Lung: At least one in six consecutive months
  - Pediatric: At least one in 12 consecutive months
  - Pancreas: At least two in 12 months plus waiting time above 67th percentile or no candidates
- Outcomes – Bayesian HRs 1 year graft/pt
  - Probability is greater than 75% the HR is greater than 1.2
  - Probability is greater than 10% that the HR is greater than 2.5

What are the Rules that Apply to Living Donation?

- OPTN Policy 14.0 Living Donation
- CMS Standards

Addressed Elsewhere

- Informed Consent
- ILDA
- Psychosocial Evaluation
- Medical Evaluation

Medical Evaluation 14.4A

History — Donor history

- Donor history - emphasis on organ related
- Family history – emphasis on organ related

Psychosocial History — Donor Risk Assessment

- Psychiatric illness including suicide attempts and substance abuse

Transmissible Disease — Protocol for seasonal and geographically endemic

- If risk of TB, must include PPD or Interferon Gamma Release Assay (IGRA)

Viral Testing

CMV, EBV, Syphilis
HIV, HBV, HCV NAT and serology testing must be within 28 days of donation

Other

Blood specimen to be frozen for 10 years to test for transmissible disease
Patient must sign consent

Cancer Screening

- Protocol aligned with American Cancer Society or U.S Preventative Services Task Force
  - Cervical
  - Breast
  - Prostate
  - Colon
  - Lung

Recipient Outcomes

National 1 Yr patient and organ survival

- Provide recipient hospital data when donor and recipient hospital different

CMS/OPTN

- CMS – allow us to direct donors to SRTR site
- OPTN – we must provide the data to donors

LD Exclusion Criteria

- Is both less than 18 years old and mentally incapable of making an informed decision
- HIV, unless the requirements for a variance are met, according *to Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors*
- Active malignancy, or incompletely treated malignancy
- High suspicion of donor coercion
- High suspicion of illegal financial exchange between donor and recipient
- Evidence of acute symptomatic infection (until resolved)
- Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality

Kidney

- Uncontrolled hypertension
- Hx of Htn with end organ damage
- Diabetes (may change)

Liver

- HCV RNA positive
- HBsAg positive
- Donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes
- Expected donor remnant volume less than 30% of native liver volume
- Prior living liver donor

ABO Related

Policy & Procedure

- At least two
- All available ABO's prior to generating Donor ID
- Include subtyping in P&P if used for allocation
- Define procedures for resolving conflicting blood type (Policy 14.5A)

Define Qualified Health Care Professional

- Maintain documentation of education/competency

Pre Recovery Verification

Occur prior to induction of GA on day of LD recovery

- Does not need to be in the OR per OPTN but must be ‘after arrival in OR prior to induction’ per CMS
  - CMS also requires ‘immediately before organ removal’
- Recovery Surgeon and LHP

Documentation must include

- Donor and Recipient ID
- Organ and laterality (site marking per institutional policy)
- ABO and subtype
- Statement of compatibility or intended incompatibility
- Statement that donor identified for intended recipient

Organ Packing and Labeling Requirements

- OPTN Policy 14.8 and 16.1
- Defines documentation that must accompany the shipped organ
- Defines labeling and packing requirements

Other considerations NOT in the rules

- Not a Rule but consider…
  - What your center policy/practice would be if the intended recipient cannot be transplanted after LD organ is removed
    - Donor wishes documented pre surgery
    - Run center waitlist for next suitable recipient
    - Store/pump kidney until donor wakes up

OPTN Policy 14.8A Vessels

- Donor must consent to removal of extra vessels for transplant
- Consider adding language to Informed Consent or Surgical Consent
- Can only be used in the original intended organ recipient
- Extra vessels can be stored according to Policy 16.6.B

Discovery of Post Donation Infection, Disease or Malignancy

2 Years Post Donation

New Information indicating risk of disease or malignancy

Must do following

- Disclose to the donor required reporting to the OPTN
- Notify receiving center
- Report in the OPTN Patient Safety Portal within 7 days
- Contribute to any f/u requested by OPTN staff
- Provide additional information/specimens if requested

Living Donor Feedback

Prior to donation surgery

- Starts data collection process on Living Donors

Complete within 72 hrs. of donor organ recovery

- All donors who received anesthesia
  - Including LD whose organ was not transplanted

Living Donor Registration (LDR)

Prior to donation

Submit within 60 days of submitting the Living Donor Feedback Form

- Timely data is whichever is first: discharge or 42 days following donation date

Living Donor Follow-Up

Minimum of 2 years post donation

Forms due within 60 days of 6, 12, and 24 month anniversary

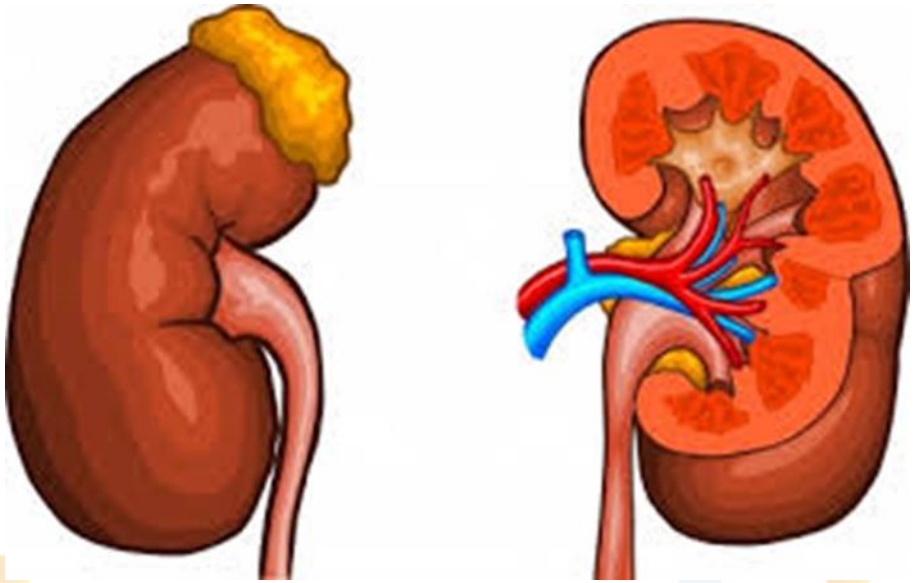
- Data may be collected 60 days before or after anniversary

100% of forms submitted

Compliance thresholds for

- Laboratory data
- Clinical data

Required elements stated in policy



Urine
Protein

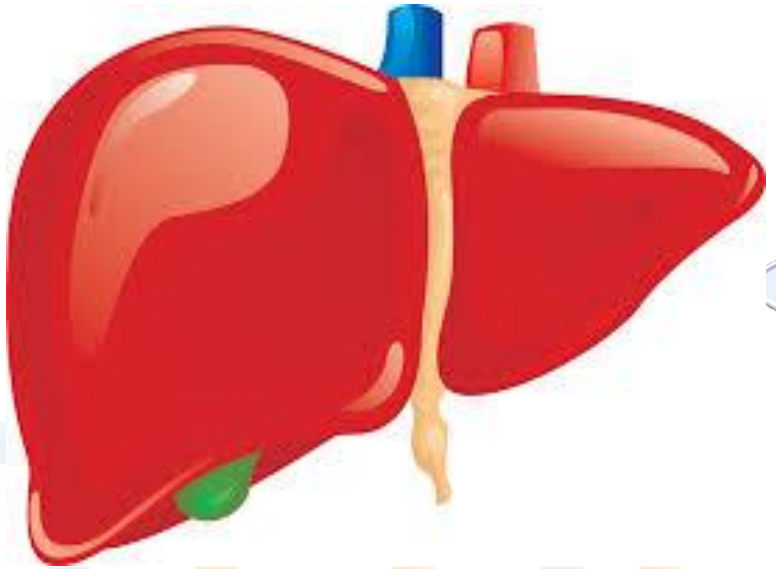
Serum
Creatinine

Lab data: 70% for donors
Clinical data: 80%

Donor Status & Clinical Information

- Patient status – if dead, cause of death
- Working for income, and if not working, reason for not working
- Loss of medical (health, life) insurance due to donation
- Has the donor been readmitted since last LDR or LDF form was submitted?
- Has the donor had: DM, HTN, dialysis, kidney complications?

Laboratory Data



- Alanine aminotransferase
- Alkaline phosphatase
- Platelet count
- Total bilirubin

75% of donors on 6 mos LDF
70% of donors on 12 mos. LDF
Clinical: 80%

Donor Status & Clinical Information

80% of donors

- Patient status
- Cause of death, if applicable and known
- Working for income, and if not working, reason for not working
- Loss of medical (health, life) insurance due to donation
- Hospital readmission or complications since last LDR or LDF was submitted

Donor Status & Clinical Information

Liver complications

- Abscess
- Bile leak
- Hepatic resection
- Incisional hernias due to donation surgery
- Liver failure
- Registered on the liver candidate waiting list

Adverse Event Reporting in Living Donors

- Death of living donor within 2 years of donation
- Failure of living donors remaining organ function within 2 years
- Organ recovered but not transplanted to intended recipient
- Organ recovered but not transplanted to any recipient
- Aborted organ recovery after general anesthesia commenced

Aborted after general anesthesia

- OPTN
- Patient Safety Portal
- Within 72 hrs. of aborted procedure

Organ recovered but not transplanted

- OPTN
- Patient Safety Portal
- Within 72 hrs. of organ recovery surgery

Recovered and transplanted into recipient other than intended

- Patient Safety Portal
- Within 72 hrs. of organ recovery surgery

Domino Donors and Non-Domino Therapeutic Donors

LD policies 14.9A to 14.9E Only

- Informed Consent
- Psychosocial Evaluation for Domino and NDTD
- Medical Evaluation

Recovery and transplant of organs can occur at a hospital that is an approved transplant program for that organ

- Hospital does not need to be an approved LD center for that organ

Data Submission

- Living Donor Feedback and Living Donor Registration (LDR) required

Policy notes

Evaluation

- Inclusive at a minimum of OPTN and CMS requirements
- Include duration that specific evaluation components are current

Psychosocial evaluation

- Who can perform, include all noted factors in OPTN and CMS regulations at a minimum

Donor Selection criteria

- Inclusive of OPTN requirements on exclusions
- Documentation as to suitability to donate or not

ABO related to include prior to registration, prior to anesthesia, and prior to donor organ removal

Policy notes

Donor management

- From admission through to discharge

Social work

- Available – define this is your policy

Dietitian

- Available, define in your policy

Pharmacy

- Services provided by pharmacist or other qualifies person as defined in your policy

Resources

UAGA. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2001294/

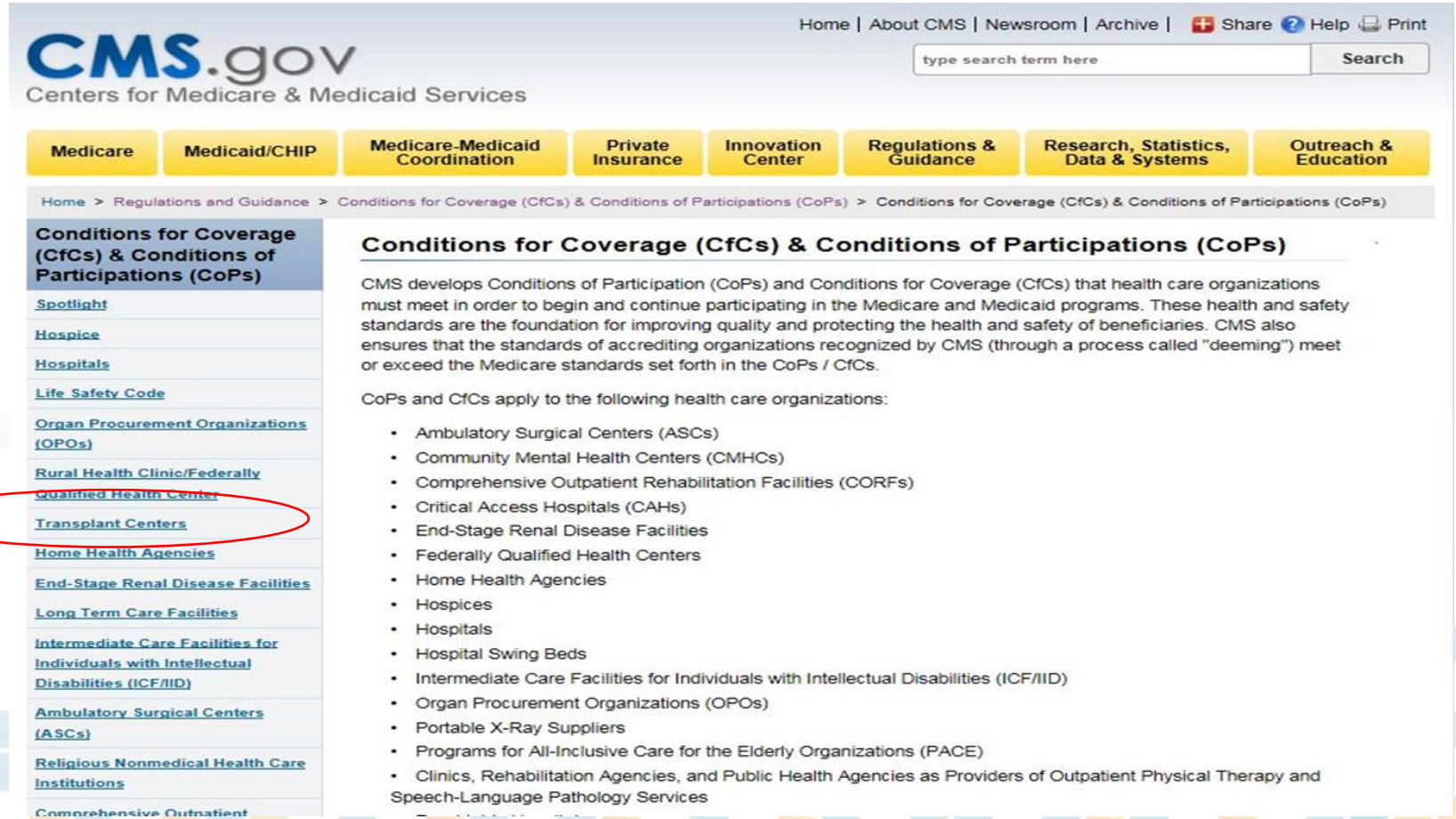
NOTA. http://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-2014-title42-section274&num=0#amendment-note

Final Rule. https://www.ecfr.gov/cgi-bin/text-idx?SID=bb60e0a7222f4086a88c31211cac77d1&mc=true&node=pt42.1.121&rgn=div5

OPTN Policy: https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

Gwen McNatt – gwen-mcnatt@uiowa.edu

Website Info



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Conditions for Coverage (CfCs) & Conditions of Participations (CoPs)

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- Organ Procurement Organizations (OPOs)
- Rural Health Clinic/Federally Qualified Health Center
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- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)
- Ambulatory Surgical Centers (ASCs)
- Religious Nonmedical Health Care Institutions
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)
- Clinics, Rehab Agencies, & Public Health Agencies as Providers of Outpatient PT and Speech Language
- Community Mental Health Centers

Organ Procurement Organizations (OPOs)

Publication date:

Final rule, CMS-3064-F, published May 31, 2006

Effective date:

Final rule effective July 31, 2006

CFR section numbers:

42 CFR §§486.301-348, et al. (final rule)

CFR section descriptions:

42 CFR Parts 413, 441, 486 and 498, Conditions for Coverage for Organ Procurement Organizations (OPOs); Final Rule

Brief description of document(s):

The final rule, CMS-3064-F, establishes new conditions for coverage, including new outcome and process performance measures, a new appeals process, and a new competition process.

Downloads

Final Rule [PDF, 441KB]

Related Links

- The Health Resources and Services Administration's (HRSA's) Breakthrough Collaborative
- The Scientific Registry of Transplant Recipients
- United Network for Organ Sharing
- The Organ Procurement and Transplantation Network

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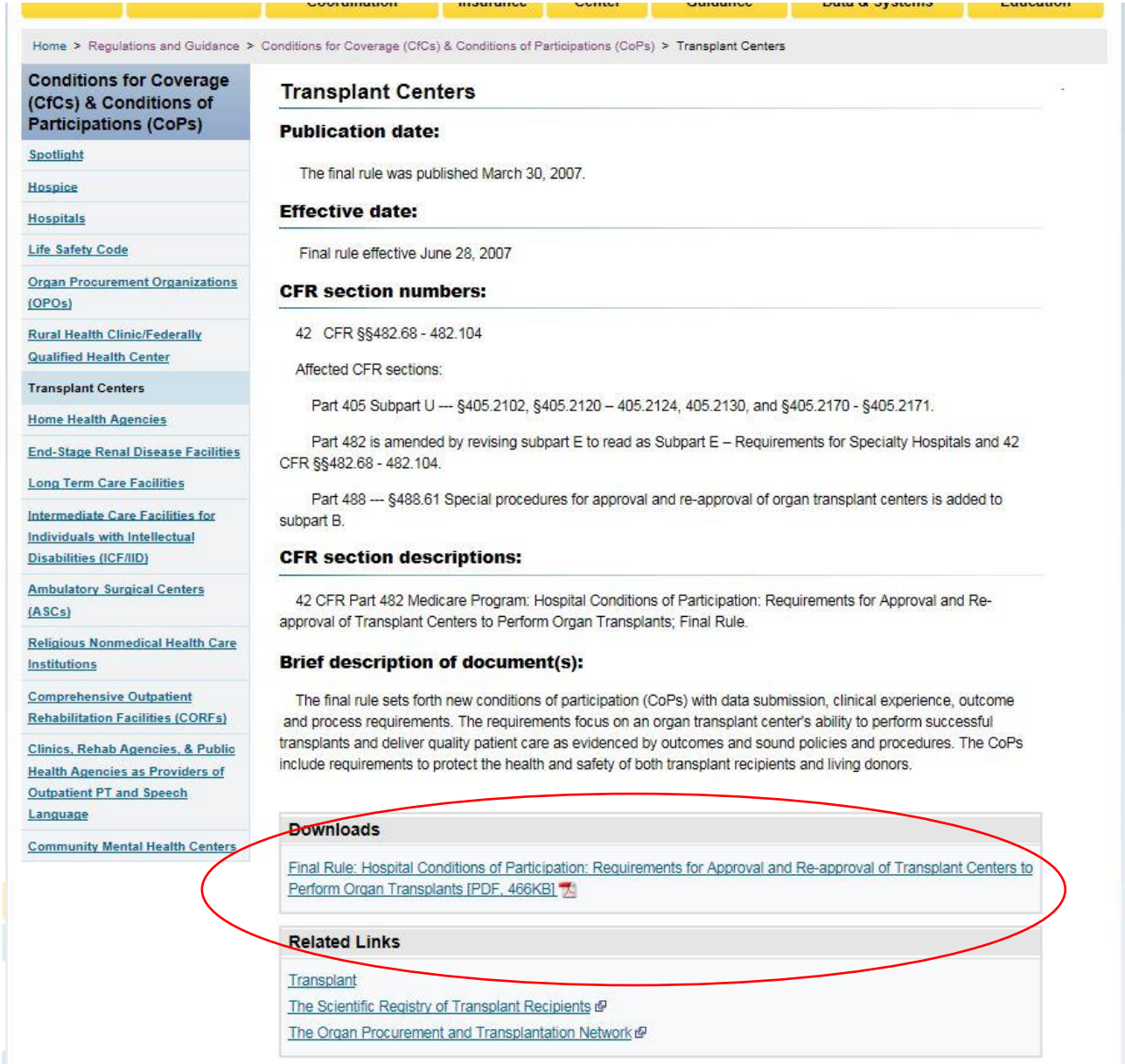

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Transplant Centers

Publication date:

The final rule was published March 30, 2007.

Effective date:

Final rule effective June 28, 2007

CFR section numbers:

42 CFR §§482.68 - 482.104

Affected CFR sections:

Part 405 Subpart U --- §405.2102, §405.2120 – 405.2124, 405.2130, and §405.2170 - §405.2171.

Part 482 is amended by revising subpart E to read as Subpart E – Requirements for Specialty Hospitals and 42 CFR §§482.68 - 482.104.

Part 488 --- §488.61 Special procedures for approval and re-approval of organ transplant centers is added to subpart B.

CFR section descriptions:

42 CFR Part 482 Medicare Program: Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants; Final Rule.

Brief description of document(s):

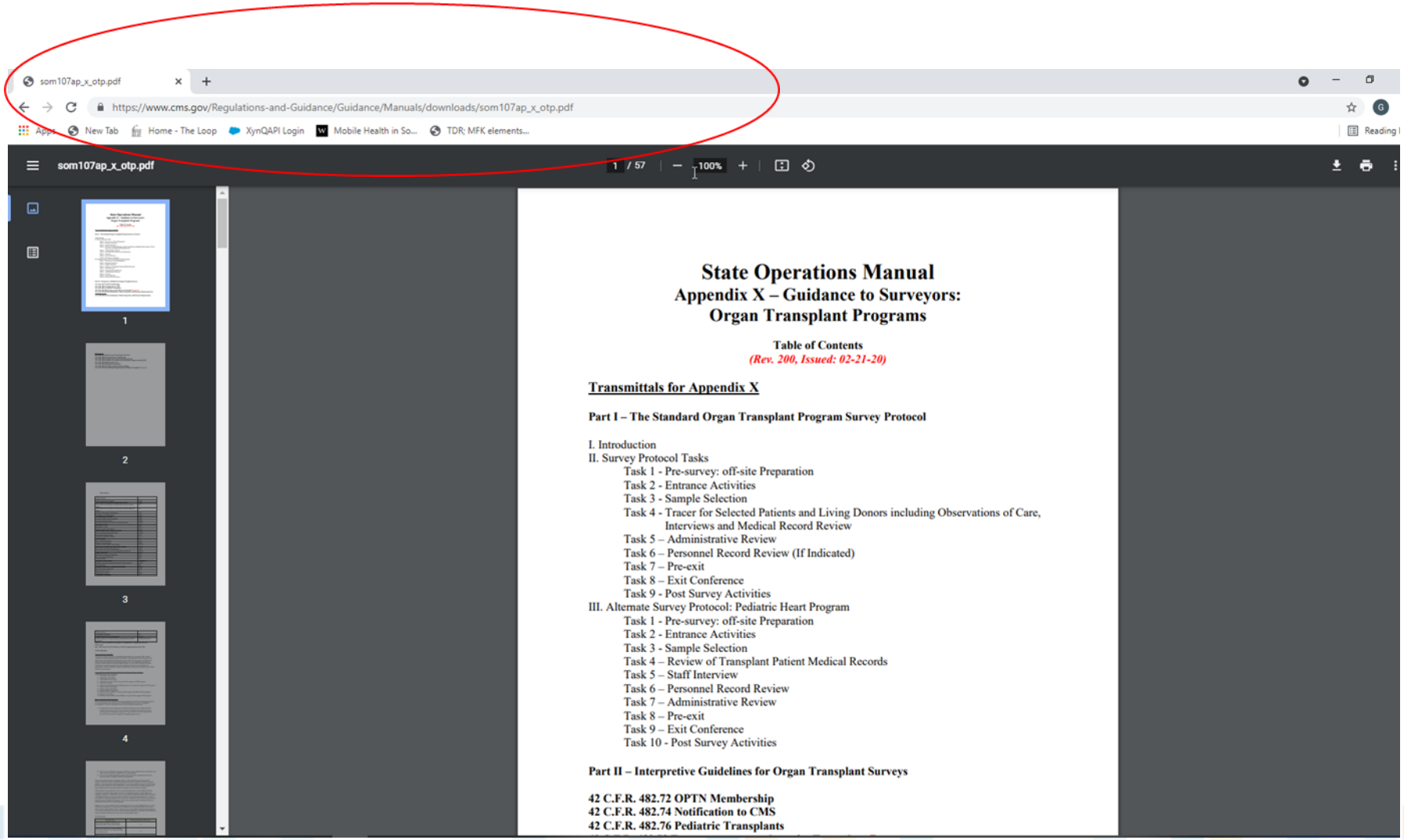
The final rule sets forth new conditions of participation (CoPs) with data submission, clinical experience, outcome and process requirements. The requirements focus on an organ transplant center's ability to perform successful transplants and deliver quality patient care as evidenced by outcomes and sound policies and procedures. The CoPs include requirements to protect the health and safety of both transplant recipients and living donors.

Downloads

Final Rule: Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants [PDF, 466KB]

Related Links

Transplant
The Scientific Registry of Transplant Recipients
The Organ Procurement and Transplantation Network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State Operations Manual
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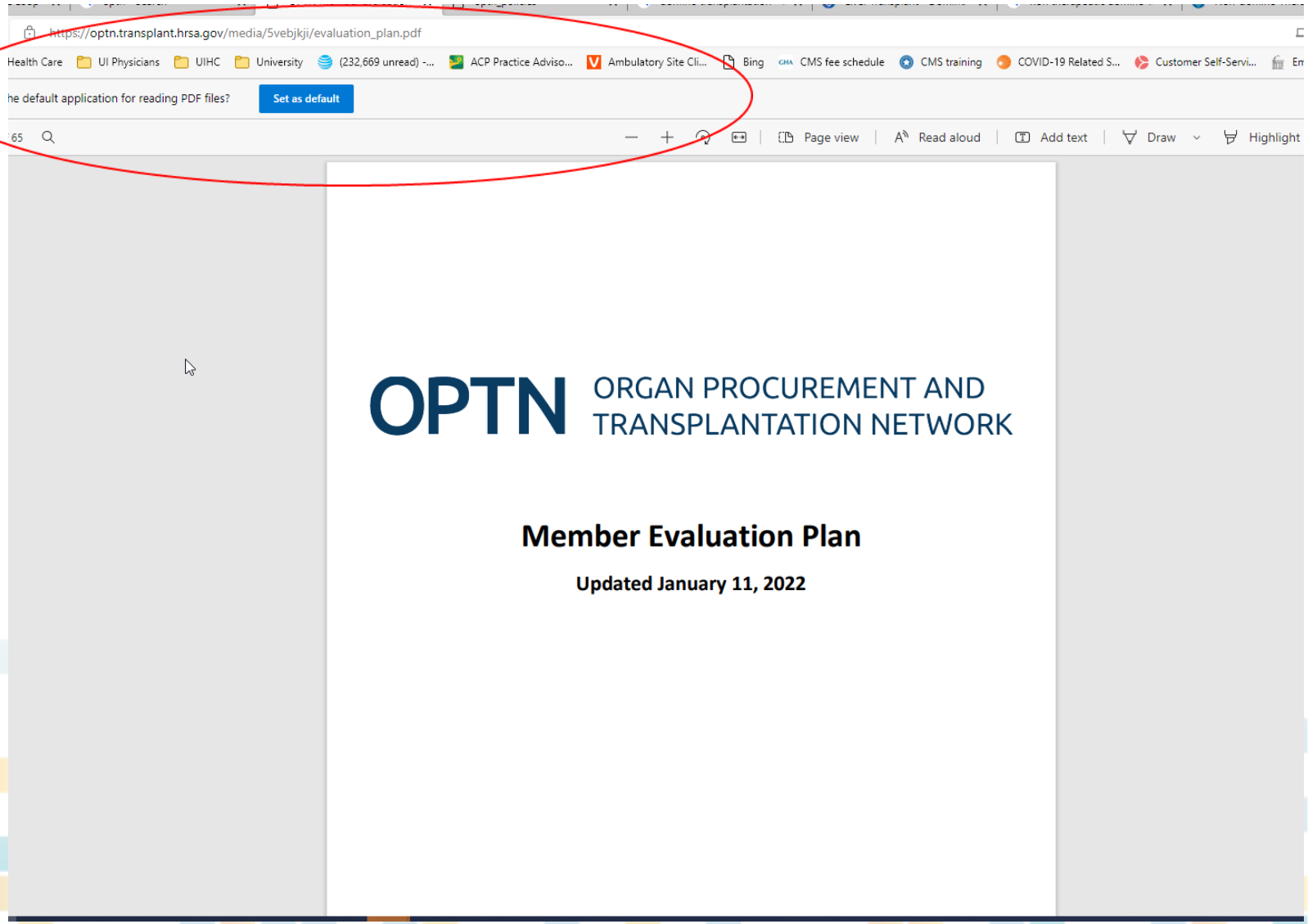
Part II – Interpretive Guidelines for Organ Transplant Surveys
42 C.F.R. 482.72 OPTN Membership
42 C.F.R. 482.74 Notification to CMS
42 C.F.R. 482.76 Pediatric Transplants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