

# Organ Transplantation

## COMAR 10.24.15

MHCC  
SHP Work Group Session  
April 29, 2015

# Agenda Overview

- ▶ **Need projection**
  - Current methodology
  - Concerns and possible revisions
  - Johns Hopkins presentation
- ▶ **Additional new policies and standards**
  - Support statements for other initiatives
  - Quality of care standard
  - Impact on existing health care system standard
  - Support services standard
  - Donor recruitment commitment
  - Disease prevention and patient advocacy policies

# Current Need Projection Methodology for Organ Transplant Services

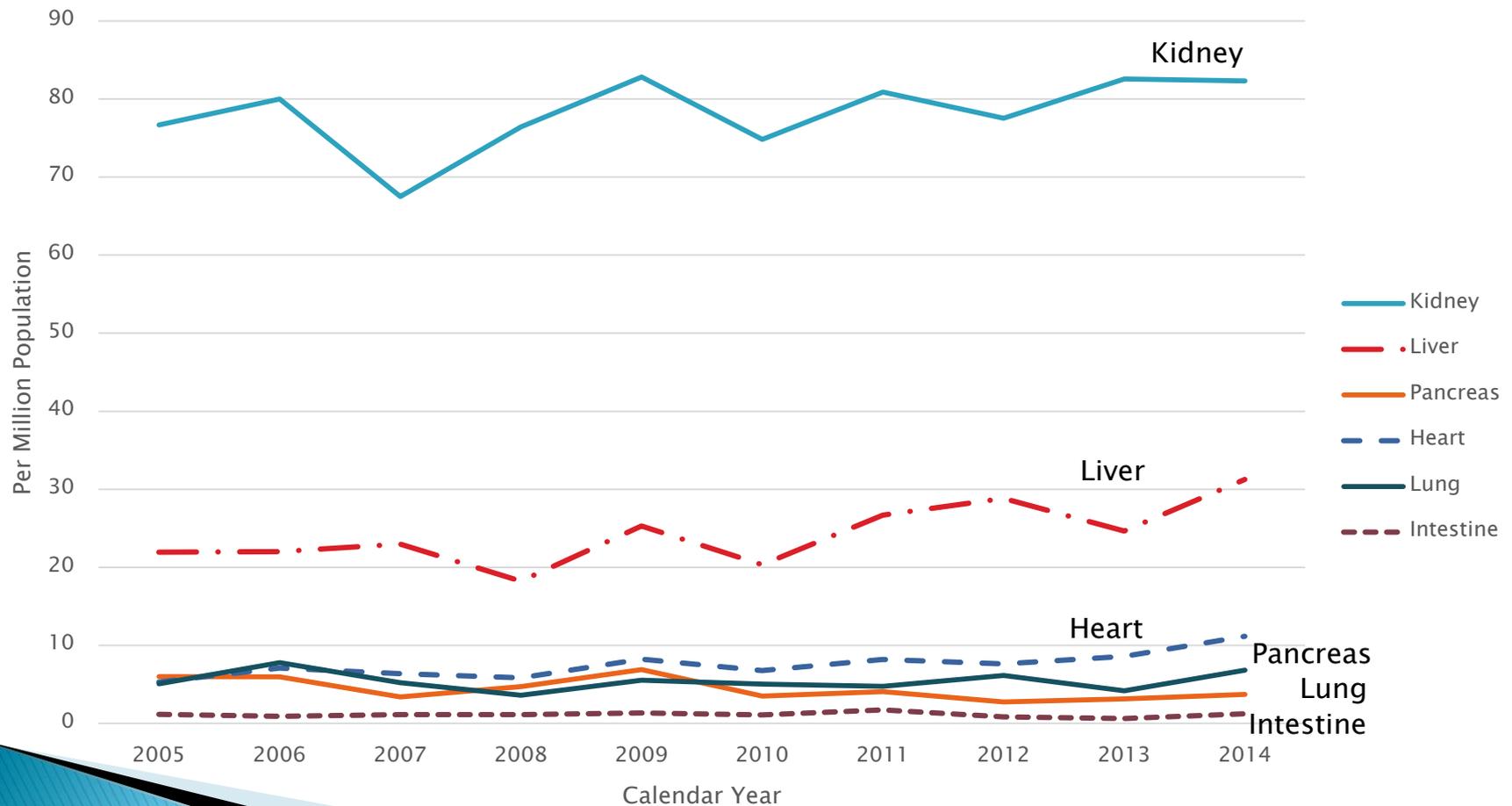
# Definitions and Sources in the Current Need Projection for Organ Transplantation Services

Data/Info Needed	Information Sources
Regional definitions*	Aligned with Donation Service Areas*
Population estimates and projections	MD – MD Dept. of Planning VA – Weldon Cooper Center DC – U.S. Census Bureau
Historic utilization data	UNOS – aggregated using regional definitions above

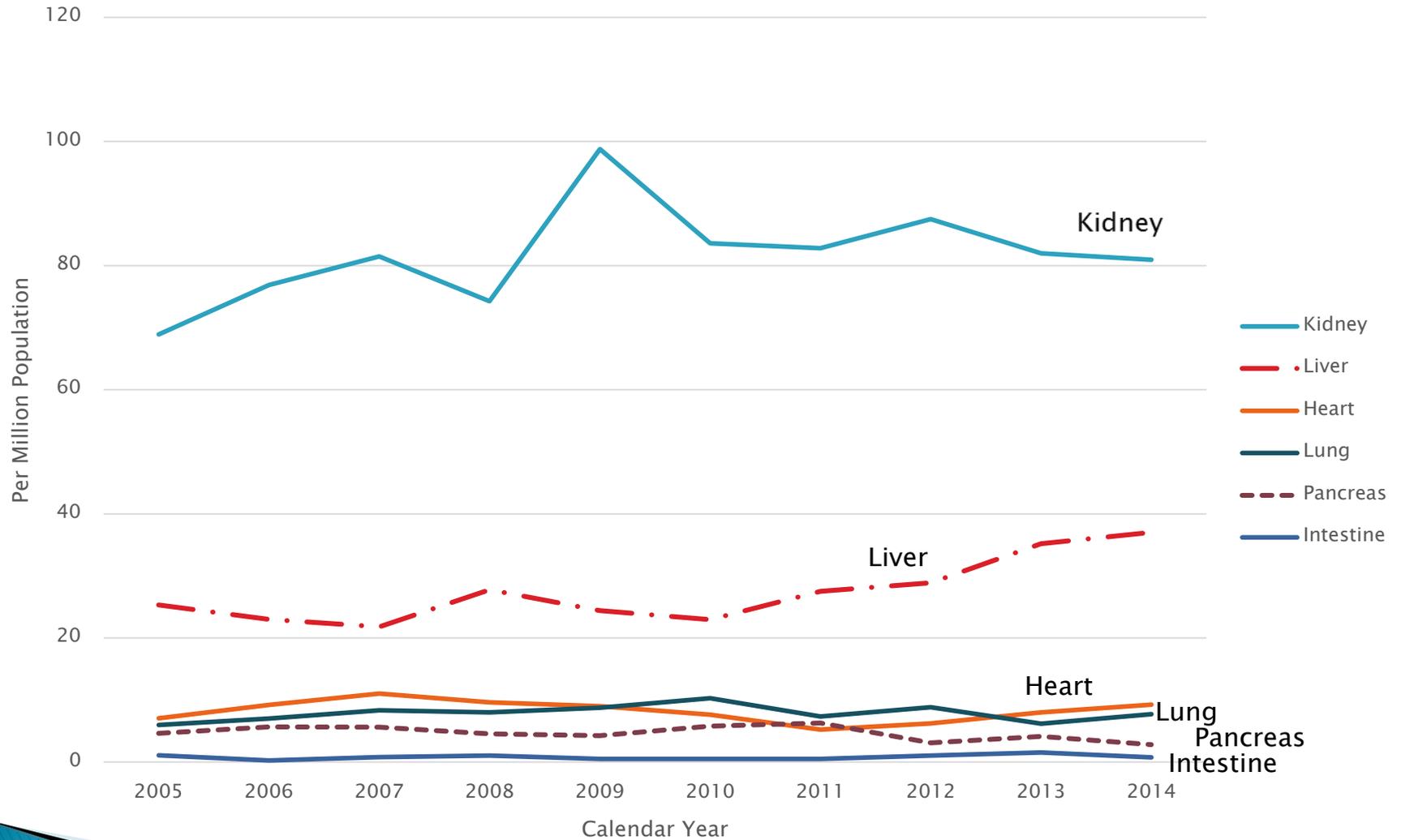
\*To be updated in SHP definition to reflect current DSAs

# Fluctuations in Resident Utilization Rates and Trends for Transplantation, CY 2005 and CY 2013

Organ Transplants for Residents of DC DSA per Million Population, CY 2005–2014



## Organ Transplants for Residents of MD DSA per Million Population, CY 2005–2014



# Year-to-Year Volume Changes by Organ and Region

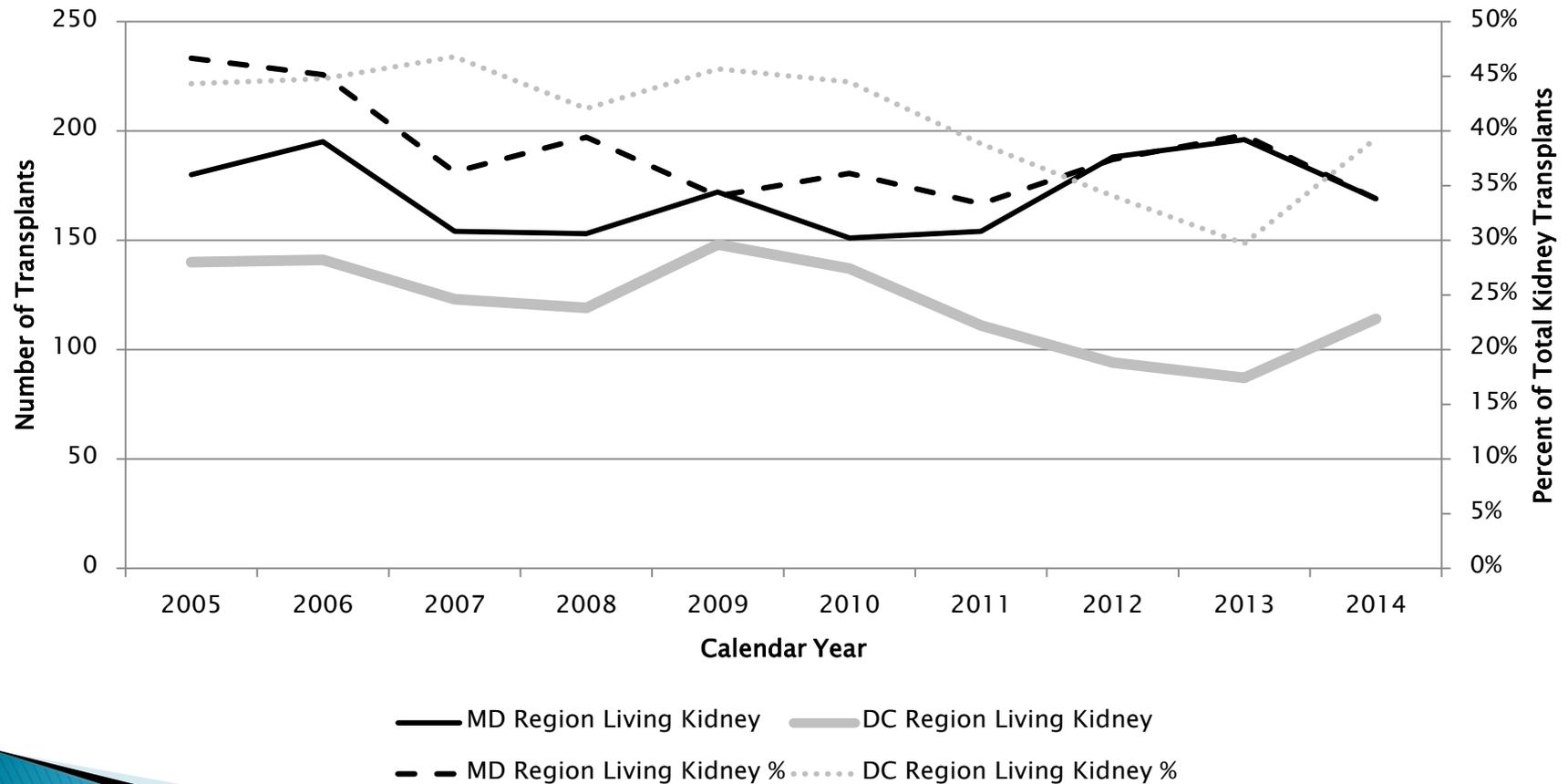
	05-06	06-07	07-08	08-09	09-10	10-11	11-12	12-13	13-14
<b>DC Region</b>									
Heart	6	3	-2	14	-11	13	-3	10	7
Lung	19	-13	-2	5	-2	-4	4	4	-1
Intestine	5	4	1	-3	-3	3	-1	-6	6
Kidney	3	-65	30	47	-27	-22	-11	17	2
Liver	20	-19	9	9	-11	16	16	-25	11
Pancreas	6	-8	8	6	-17	2	-5	2	6
<b>MD Region</b>									
Heart	12	12	-12	-7	0	-13	7	1	13
Lung	1	-1	-3	20	-4	-4	9	-5	-6
Kidney	62	-20	-44	116	-76	35	43	-12	-1
Liver	0	-6	12	-3	-18	20	20	38	29
Pancreas	10	-13	-23	2	8	-4	-6	6	-11

# Program Volumes for Kidney and Liver Transplants, CY 2012–2014

Organ/Program Location	2012	2013	2014
<b>Kidney Transplant Programs</b>			
Johns Hopkins	214	241	259
University of Maryland	310	271	252
Georgetown University	64	77	98
George Washington (3 in '15)	–	–	–
Inova	111	100	102
Washington Hospital Center	73	90	69
<b>Liver Transplant Programs</b>			
Johns Hopkins	48	82	86
University of Maryland	86	90	115
Georgetown University	116	91	102

# Living Donation Trends

## Utilization of Living Kidney Transplants by DSA Listing Region, CY 2005–2014



# Methodological Steps for Organ Transplantation Need Projection

- ▶ Calculate the use rate for each region, for each of the last three years.
- ▶ Use the average annual percentage change in use rates and three-year aggregate utilization rate to project need for three years into the future.
- ▶ Includes migration trends for the aggregate time period.

# Methodological Steps for Organ Transplantation Need Projection

- ▶ Make projection for number of cases based on three years of data and migration trends.
- ▶ Subtract the most recent year's cases from the projected year's cases to determine net need for services.
- ▶ Allows for new programs to apply if there is projected net need above the program threshold.

# Concerns Regarding the Current Need Methodology

- ▶ Utilization of organ transplant services is largely driven by the supply of organs. Actual demand far exceeds the number of available organs.
- ▶ Volatility of projections: year-to-year changes result in projected volume trends that fluctuate widely in some cases.

# Illustration of Need Projection Volatility

Organ Type	DSA	Published Date		
		2011	2014	Preliminary, based on UNOS data thru 2013
		Projection Year		
		2013	2015	2016
Kidney	MD Region	Yes	No	No
	DC Region	No	No	No
Liver	MD Region	No	Yes	Yes
	DC Region	Yes	Yes	No
Lung	MD Region	Yes	No	No
	DC Region	No	No	No
Heart	MD Region	No	No	No
	DC Region	No	No	No
Pancreas	MD Region	No	No	No
	DC Region	No	No	No

# Historical Trending Versus Actual Utilization

Organ	Actual Transplants for Residents in 2014	3-year Projection for 2014 Using 2009-11 Data	% Difference	5-year Projection for 2014 Using 2005-09 data	% Difference
<b>DC Region</b>					
Kidney	398	373	-6%	409	3%
Liver	151	152	1%	129	-15%
Heart	54	44	-19%	60	11%
Lung	33	20	-39%	29	-12%
Pancreas	18	6	-67%	31	72%
Intestine	6	8	33%	7	17%
<b>MD Region</b>					
Kidney	315	233	-26%	546	73%
Liver	144	168	17%	95	-34%
Heart	36	12	-67%	52	44%
Lung	30	21	-30%	54	80%
Pancreas	11	31	182%	18	64%
Intestine	3	4	33%	2	-33%

# Possible Revisions

- ▶ Consider accepting applications based on existing programs' current volumes and thresholds, rather than a published need projection.
- ▶ Require a new program to demonstrate its ability to improve access to organ transplantation services\*, decrease disparities present in the current health care system, and address quality concerns\*\*, as well as how it will likely impact existing programs.
- ▶ Reduce the potential for establishment of unnecessary programs by allowing a new program three full years to become established before considering any additional programs in the same health planning region.

\*MHCC staff does not believe that residents obtaining transplants in a DSA other than where they reside should in and of itself be considered indicative of an access problem.

\*\* Definition to be developed

# Organ Transplantation Data Analysis Conducted by Staff at The Johns Hopkins Hospital

Brigitte Sullivan

# Additional Changes Proposed by MHCC Staff

# SHP Chapter Organization

- ▶ Introduction and Applicability
- ▶ Issues and Policies
- ▶ Standards
  - General Standards
  - Project Review Standards
- ▶ Methodological Approaches
- ▶ List of Definitions

# 10.24.15 Principles

- ▶ Chapter includes four general principles, unlike other recently updated SHP chapters.
- ▶ Content fits under the Introduction, Issue and Policies, and Standards sections.
- ▶ Elements include consideration of need, cost and effectiveness of alternatives, specialized services considerations, impact issues, and equity of access to quality and reasonably priced services

# 10.24.15 List of Policies

Current Location		Changes discussed	To be covered under:
Policy 1	Certificate of Need Coverage/Definition of Organ Transplants	Revised to include VCAs	Introduction and Applicability
Policy 2	Effective Dates for recognized providers	To be updated	Introduction and Applicability
Policy 3	Describes need for education, disease prevention, and health promotion	To be discussed	Issues and Policies Project Review Standards

# 10.24.15 List of Policies

Current Location		Changes discussed	To be covered under:
Policy 4	Minimum Volume	Pancreas changed to “TBD”	Project Review Standard: Minimum Volume
Policy 5	Threshold Volume	No specific change	Project Review Standard: Need/Impact
Policy 6	Preference for fewer services at higher volumes	No longer evidence-based	Not included in update

# 10.24.15 List of Policies

Current Location		Changes discussed	To be covered under:
Policy 7	Program must be in, or closely affiliated with, a teaching hospital	To be discussed	Discuss inclusion in Project Review Standards
Policy 8	Program should provide info on Medicaid, supplemental prescription drug coverage, and vocational rehab services	To be discussed	Discuss inclusion in Project Review Standards
Policy 9	Program should have ancillary and support services	To be discussed	Discuss inclusion in Project Review Standards and/or specific list of services

# 10.24.15 List of Policies

Current Location		Changes discussed	To be covered under:
Policy 10	Compliance with all appropriate certification or accreditation (UNOS, FACT)	To be discussed	Project Review Standard
Policy 11	Programs should report survival rate statistics/program data for MHCC to conduct status reviews every 3 years	Incorporation of MHCC reviews of SRTR/UNOS reports	Issues and Policies
Policy 12	Services should be accessible within 3 hours one-way driving time for 95% of MD population	No change	Project Review Standard: Geographic Accessibility

# 10.24.15 List of Policies

Current Location		Changes discussed	To be covered under:
Policy 13	Support for MD's Organ & Tissue Donation Awareness Fund	To be discussed	Issues and Policies
Policy 14	MHCC will consider the expansion of existing program one development of new capacity to avoid duplication	Add provision to consider quality of existing programs and donation rates	Issues and Policies
Policy 15	MHCC will re-evaluate expected changes in supply and its effect on the need for new transplant programs every 3 years	To be discussed	Project Review Standard: Need

# 10.24.15 List of Policies

Current Location		Changes discussed	To be covered under:
Policy 16	A merged hospital system may not relocate any part of its existing organ transplant program to another hospital within its system without obtaining a CON		To be discussed/determined

# Support Services

Currently covered under existing policies 7–9:

A transplant program shall:

- ▶ Be located in, or closely affiliated with, a teaching hospital.
- ▶ Provide information on Medicaid eligibility, supplemental coverage for prescription drugs, and vocational rehab services for patients without adequate insurance coverage.
- ▶ Provide appropriate ancillary and support services (pathology, lab, radiology, rehab, social work, and mental health services).

# Policy 13

- ▶ Policy 13 supports the use of MVA's Organ and Tissue Donation Awareness Fund for broad-based public education to increase the supply of donated organs.

DHMH contracts with Donate Life Maryland to operate a donor registry and provide public education programs to increase public awareness about the Registry and organ and tissue donation.

Fiscal Year	Organ Donor Fund
FY 10	\$251,645
FY 11	\$217,482
FY 12	\$206,690
FY 13	\$309,784
FY 14	\$319,485

**What other initiatives should the SHP chapter include in a general support statement?**

# General Standards

- ▶ To be incorporated by reference to 10.24.12 (Acute Care General Hospitals)
  - Information Regarding Charges
  - Charity Care Policy
  - Quality of Care

# Additional Project Review Standards

- ▶ Impact to existing providers and health care system
- ▶ Commitment to donation
- ▶ Commitment to disease prevention

# Impact on Health Care System

## Impact Standards in Other SHP Chapters:

- ▶ 10.24.09 (Acute Rehab) – An approved program shall not have unwarranted adverse impact on the financial viability of an existing provider
- ▶ 10.24.10 (Acute General Hospitals) – “Unwarranted adverse impact” and considered under cost-effectiveness of alternatives.
- ▶ 10.24.12 (OB) – Approved only if the impact on volumes at existing facilities will not exceed 20% of current or projected volume, with consideration to changes in existing program’s payer mix and disproportionate indigent patients population and recent development at other existing programs and the projections upon which they relied.
- ▶ 10.24.13 (Hospice) – The application “shall address” the issue.
- ▶ 10.24.17 (Cardiac Surgery) – Shall not compromise the financial viability of cardiac services at an affected hospital or cause a hospital with 200 or more cardiac surgery cases and a STS rating of two stars or higher to drop below 200 cardiac surgery cases.

# Donor Recruitment and Disease Prevention

- ▶ Incorporate measures and metrics from OPOs' Hospital Strategy Plans, including documentation on:
  - Donor recruitment commitment
    - Established donation committee or council
    - Use of clinical triggers for referrals, or an established referral process
    - Policies and education for staff on donor preservation
    - Public outreach and education about donation, especially for underserved populations or innovative donor potential
  - Disease prevention programs
    - Special consideration for proven success

# Next Steps