

Testimony
Blue Cross Blue Shield of Michigan/Blue Care Network
Public Hearing
October 16, 2008

On behalf of Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network (BCN), I would like to thank the Commission for this opportunity to testify. BCBSM and BCN continue to support the Certificate of Need (CON) program, which is designed to ensure the delivery of cost-effective, high quality health care to Michigan residents.

Bone Marrow Transplant Services

Fro the reasons listed below, BCBSM/BCN believes that there is no need to formally address the Bone Marrow Transplant (BMT) Service standards at this time:

- An informal BMT work group, facilitated by CON Commissioner Dr. Michael Young, met multiple times during 2006. The workgroup was comprised of expert physicians, providers and purchasers. The majority of workgroup members requested that the Commission determine whether a standard advisory committee (SAC) should be appointed, however, a very vocal minority indicated there was no need. Ultimately the Commission did not appoint a SAC, as they didn't feel it was necessary at that time.
- Since the BMT work group was convened, public testimony has been given almost routinely at Commission meetings by providers interested in initiating new BMT programs. No compelling evidence, however, has been provided as to the need for additional programs; rather only anecdotal accounts have been described.
- While the geographic distribution of existing programs may not be perfectly distributed, the current programs appear sufficient to support current patient volumes.
- Annualized state-wide bone marrow transplant service trends indicate that the volume of these procedures has stabilized with some decreases in volumes observed. Due to low patient volumes, Oakwood Health Care voluntarily surrendered its BMT program CON.
- Opening up the standards for review could result in more programs, which could seriously deplete existing programs' patient volumes and staffing; reduce the quality of care and increase health care costs.
- The recent Commission action to modify the BMT standards allowed for an expedient technical solution. This action allowed the retention of a highly regarded BMT program with a long history of service to residents throughout the State of Michigan.



BCBSM/BCN, however, would consider supporting a review of the BMT standards if compelling evidence of community benefit, in terms of cost, quality and/or access concerns, were provided.

Heart/Lung and Liver Transplantation Services

A review of state-wide transplant services data for heart, lung and liver transplants shows stable individual program volumes. No evidence of a need for increased access exists. BCBSM/BCN, thus, sees no compelling need to review these standards.

MRI Services

BCSM/BCN has performed state-wide reviews of MRI access over the past few years and found no access to care issues. We are also not aware of any compelling new applications or scientific evidence that would merit a complete review of these standards.

Additionally, based on the Commission's ability to address issues on an ad hoc basis, a potential problem was addressed expeditiously that allows the use of intra-operative MRI units (IMRI) in the acute care setting. BCSM/BCN strongly supported the Commission's action that allowed for this new application of MRI technology. This quick action results in improved patient safety and quality of health care.

Pancreas Transplantation Services

A review of state-wide pancreas transplant data shows relatively consistent individual program volumes for these services. In fact, due to low patient volumes, Harper and St. John Hospitals voluntarily surrendered their CONs for this service. BCBSM/BCN is not aware of any access issues and, thus, sees no reason to review these standards.

Psychiatric Beds and Services

BCBSM/BCN commends the results of a Psychiatric Service work group (including staff from facilities, providers, care givers, and community agencies) facilitated by Commission Deremo last year. This work group's recommendations were supported and moved forward by the CON Commission and resulted in timely, well articulated modifications of the standards. Given this recent work, we see no need to address these standards at this time.

Conclusion

The majority of BCBSM/BCN testimony indicates no compelling need to address the standards. We do, however, want to go on record as supporting the process and if others feel that one or more standards should be reviewed, and the Commission concurs, then BCBSM /BCN will be an active participant.

Summation

BCBSM/BCN commends the CON Commissioners and MDCH staff for their work in maintaining CON as a strong, vibrant program that continues to help ensure the delivery of high quality, safe and effective care to patients across the state. We thank the Commission for their continued vigilance on these very important issues to the citizens of the state of Michigan.

**Certificate of Need for
Pancreas Transplantation in Michigan:
Volume Criterion of 12 Cases/Year**

Scott A. Gruber, M.D., Ph.D., MBA, FACS, FCP

President Elect, Gift of Life Michigan

Professor and Chief

Section of Transplant Surgery

Director, Organ Transplant Program

Wayne State University/Harper University Hospital

Rationale for CON

- **Belief that restricting the performance of a surgical procedure to certain institutions will:**
 - **Produce superior clinical outcomes based on increased volume**
 - **Be cost efficient and avoid unnecessary duplication of resources and expenditures**
 - **Benefit the patients in the state of Michigan**

Simultaneous Pancreas/Kidney Transplants: Patient Survival

Yearly Center Volume	1 Year (%) (Tx 2003-04)	3 Years (%) (Tx 2001-04)	5 Years (%) (Tx 1999-04)
0-3	93.2	89.9	84.3
4-6	96.3	90.3	83.4
7-9	96.4	92.7	89.0
10-16	94.2	91.0	87.6
17+	95.8	90.4	84.8

2006 OPTN/SRTR

www.ustransplant.org/annual_reports/current

Simultaneous Pancreas/Kidney Transplants: Pancreas Graft Survival

Yearly Center Volume	1 Year (%) (Tx 2003-04)	3 Years (%) (Tx 2001-04)	5 Years (%) (Tx 1999-04)
0-3	82.4	77.5	70.7
4-6	84.2	79.8	72.1
7-10	83.0	76.2	66.8
11-17	83.7	80.8	72.6
18+	87.1	79.3	71.2

2006 OPTN/SRTR

www.ustransplant.org/annual_reports/current

Conclusions

- **Across the nation, there is no correlation between the annual number of pancreas transplants performed by a transplant center and outcomes**
- **In the state of MI, the publically-available results (SRTR) of lower volume programs are at least as good as those of higher volume programs**

Excellent Outcomes at Low-Volume Programs

- Individual prior experience of the surgeons (eg. Harper):
 - Dr. Scott Gruber successfully started two other pancreas transplant programs from scratch and performed close to 80 cases
 - Dr. Miguel West had performed approximately 50 transplants
- Ongoing experience with renal transplants keeps the team “greased and ready” for the performance of the occasional pancreas transplant

Cost and Efficiency: Pancreas Program

- **No additional capital, equipment, or personnel expenditures beyond that required for renal transplantation alone**
- **Same pre- and post-transplant coordinators, social workers, nutritionist, pharmacist, financial coordinator, clinic staff, nurses, nephrologists, surgeons, OR teams, and instruments that are involved with the kidney transplant program**
- **No additional costs have been incurred**

Deleterious Effect on Patients

- **Low volume program may care for a uniquely challenging cadre of patients who, in many cases, have their dialysis access, prior general surgical, renal transplant and other medical care at the center and do not want to, cannot afford to, or do not have the insurance coverage to go elsewhere**

Conclusion

There is no rational basis for continuing the volume criterion as part of the CON for pancreas transplantation in the state of Michigan beyond that already stipulated on the federal level by the United Network for Organ Sharing



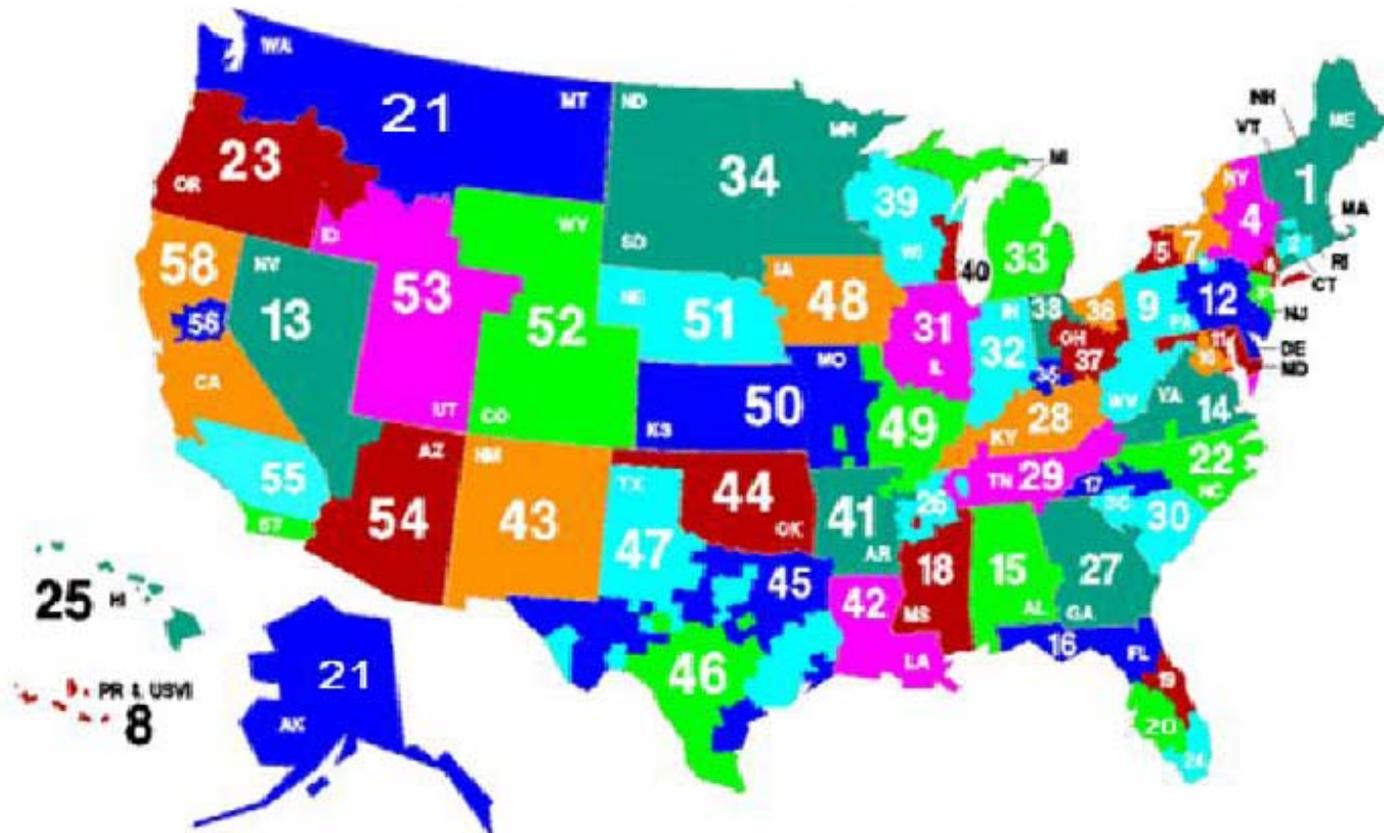
IMPACT OF PANCREAS CON ON GIFT OF LIFE MICHIGAN

Richard E. Pietroski

Gift of Life Michigan

Executive Director

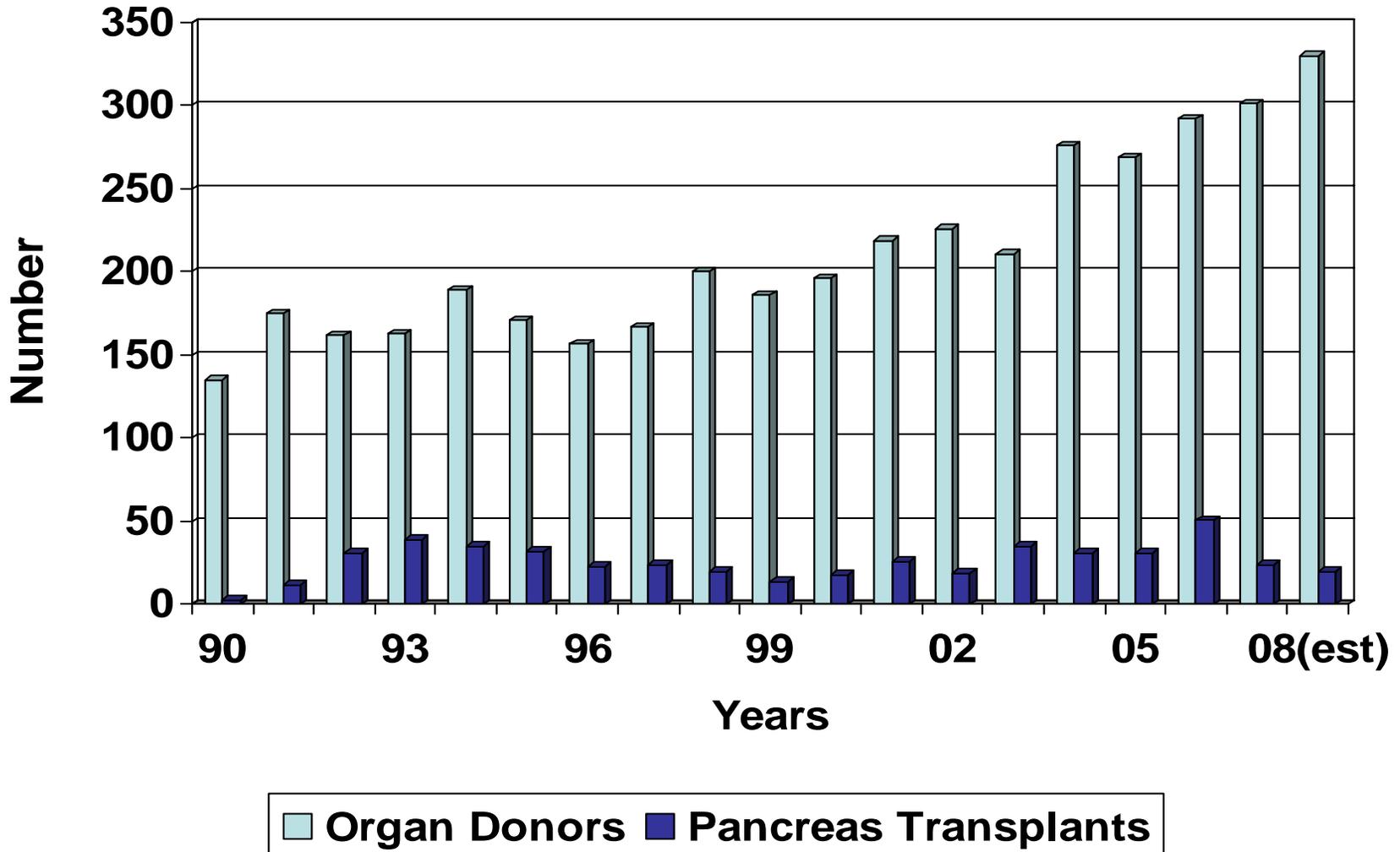
FEDERALLY DESIGNATED ORGAN PROCUREMENT ORGANIZATIONS



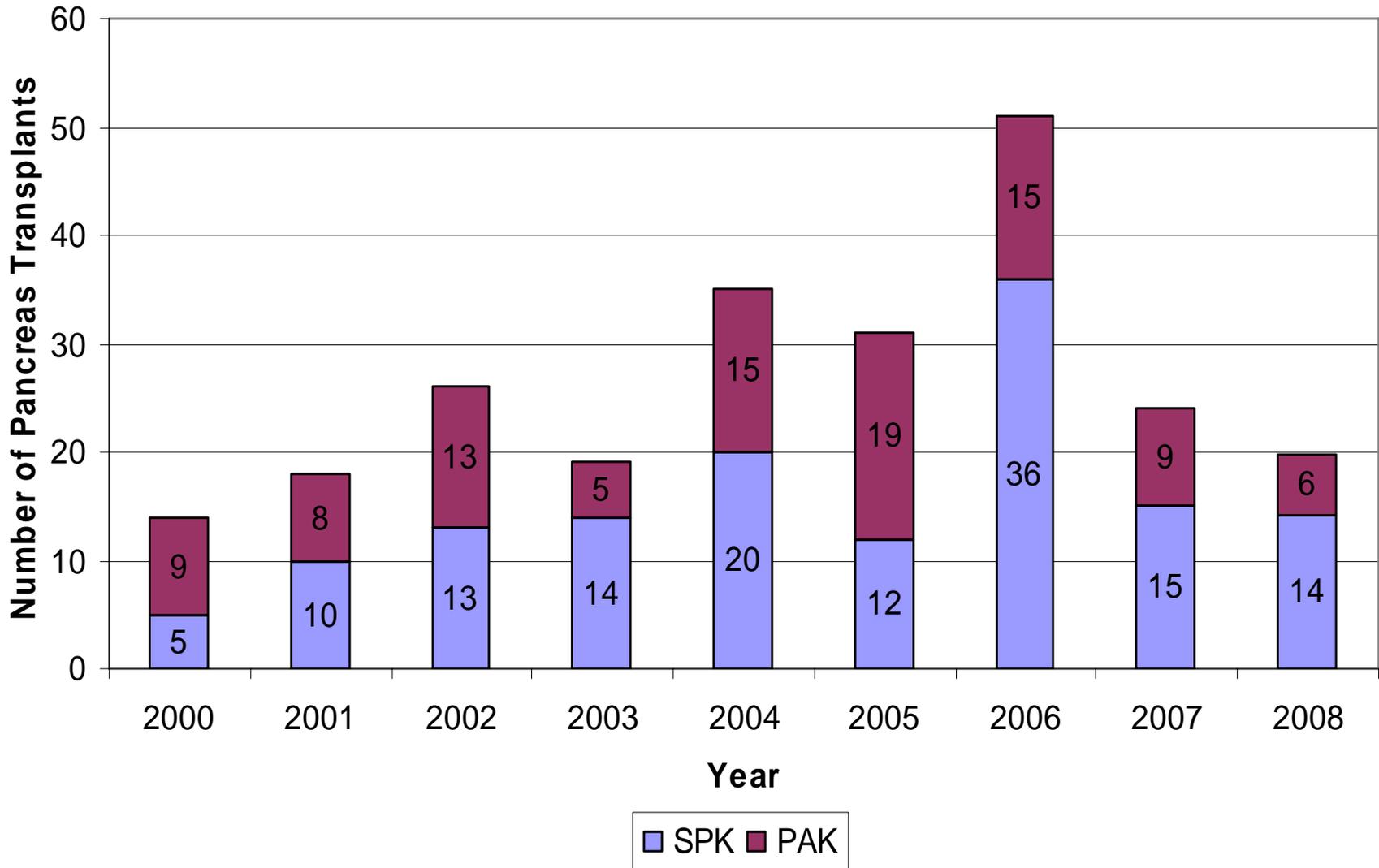
GIFT OF LIFE MICHIGAN BOARD OF DIRECTORS

- **Marwan Abouljoud, MD**
Henry Ford Hospital
- **Denis Alix, MD** (retired)
- **Mark Boelkins, MD**
St. Mary Health Services
- **William Bouman, MD** (retired)
- **Bradley Eisenbrey, MD, PhD**
Henry Ford Hospital
- **Scott Gruber, MD, PhD**
Harper Hospital
- **John Konnak, MD** (retired)
- **Alan Leichtman, MD**
University of Michigan
- **Robert Merion, MD**
University of Michigan
- **Henry Oh, MD**
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- **J.C. Rosenberg, MD, PhD**
Gift of Life Michigan Laboratory
- **Stanley Sherman, MD**
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Genesys Health Park
- **Luis Toledo, MD, PhD**
Borgess Methodist Hospital
- **Jeremiah Turcotte, MD** (retired)
- **Henry Walters, MD**
Childrens Hospital
- **Atsushi Yoshida, MD**
Henry Ford Hospital

MICHIGAN ORGAN DONORS & PANCREAS TRANSPLANTS 1990 Thru 2008



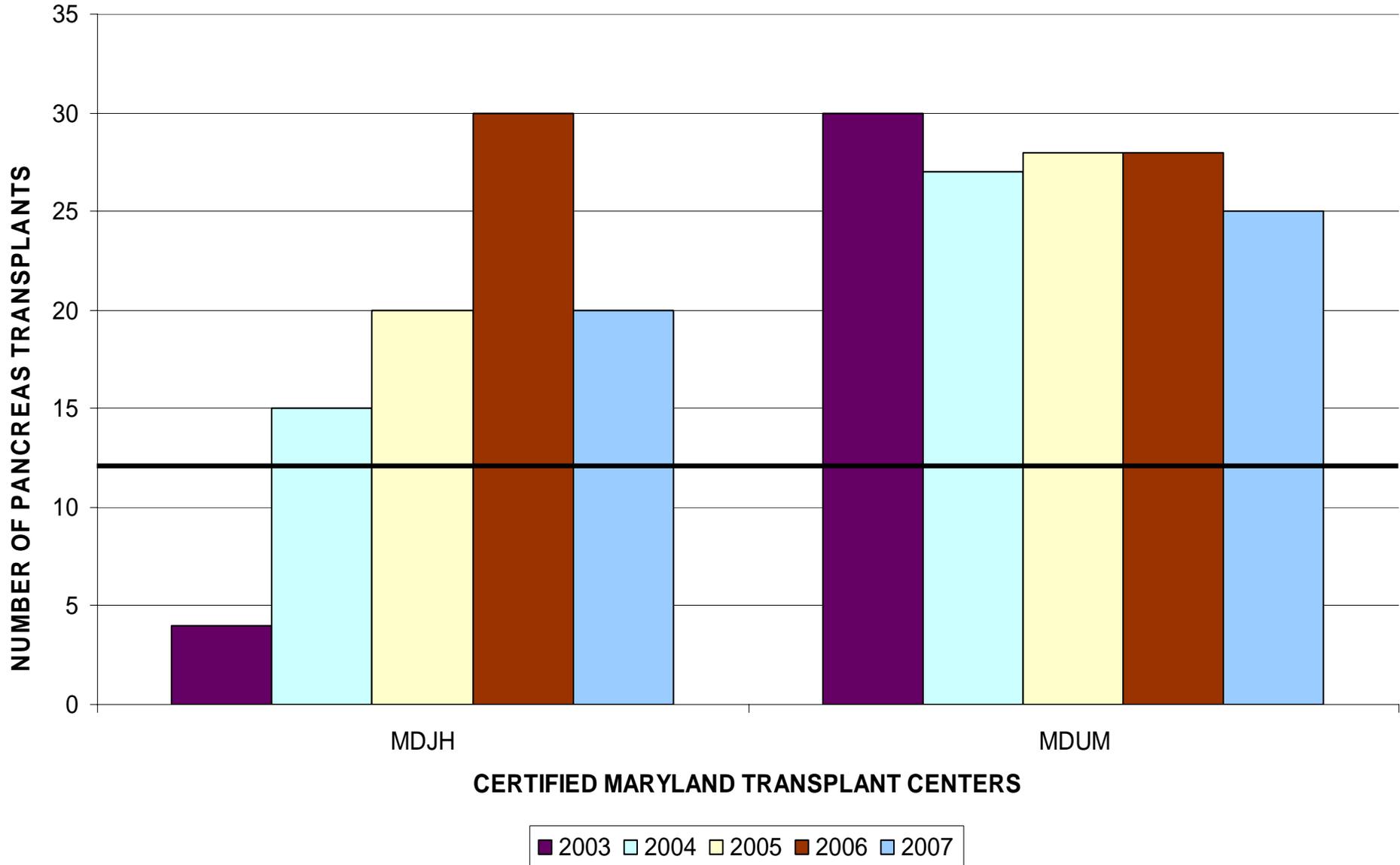
MICHIGAN PANCREAS AFTER KIDNEY (PAK) AND SIMULTANEOUS PANCREAS-KIDNEY (SPK) TRANSPLANTS 2000 THRU 2008 (est)



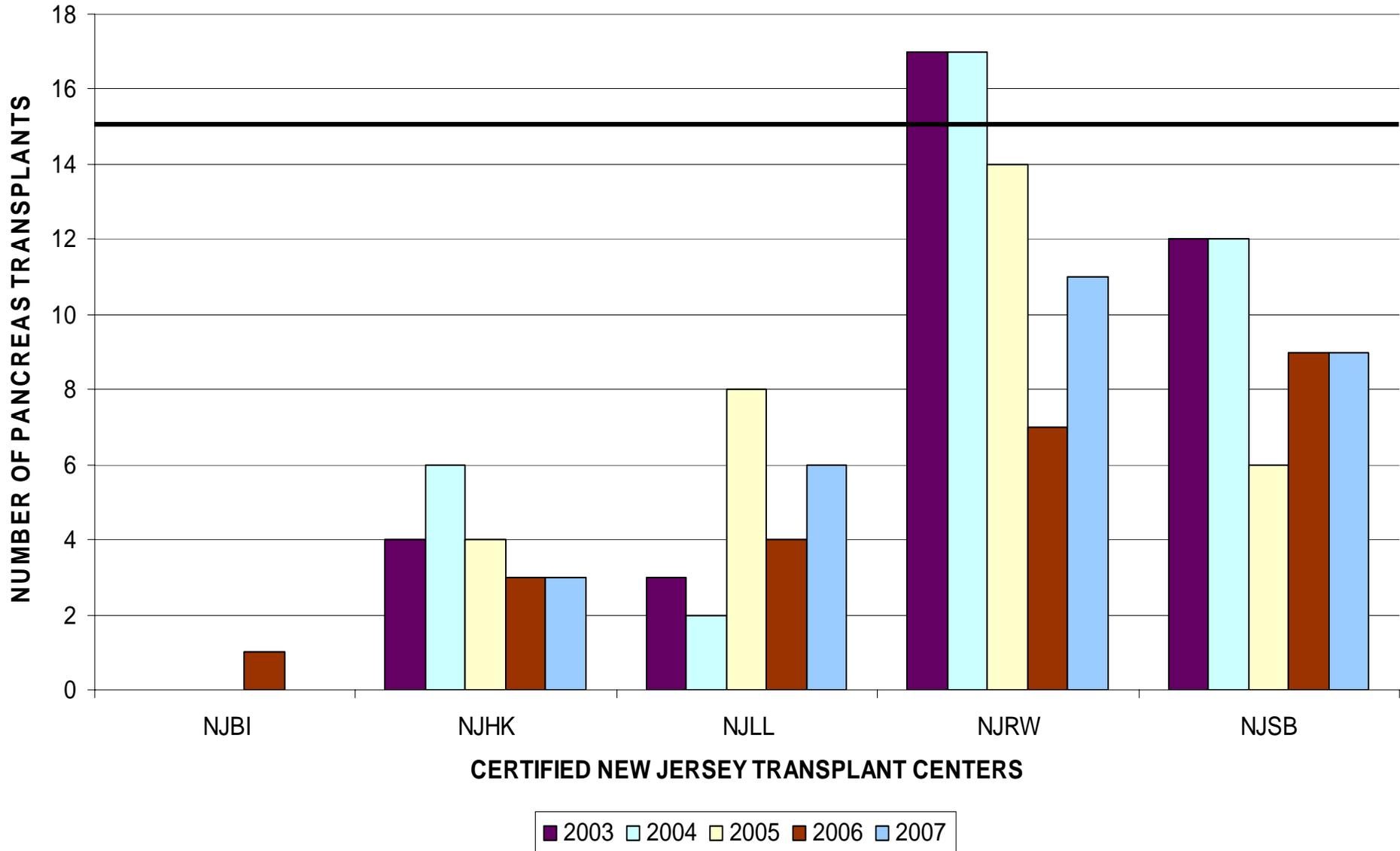
NATIONAL CON PROFILE:

- 5 states with CON for pancreas transplant
(CON#: MI:12, MD:12, NJ:15, NC:10, VA:12)
- 19 pancreas centers in CON states approved by the federal OPTN with data located at optn.org
(# Centers: MI:4, MD:2, NJ:5, NC:4, VA:4)
- 2003 thru 2007, show only 4 of 19 pancreas centers met their state CON requirement for all 5 years, and no state had all centers meet CON

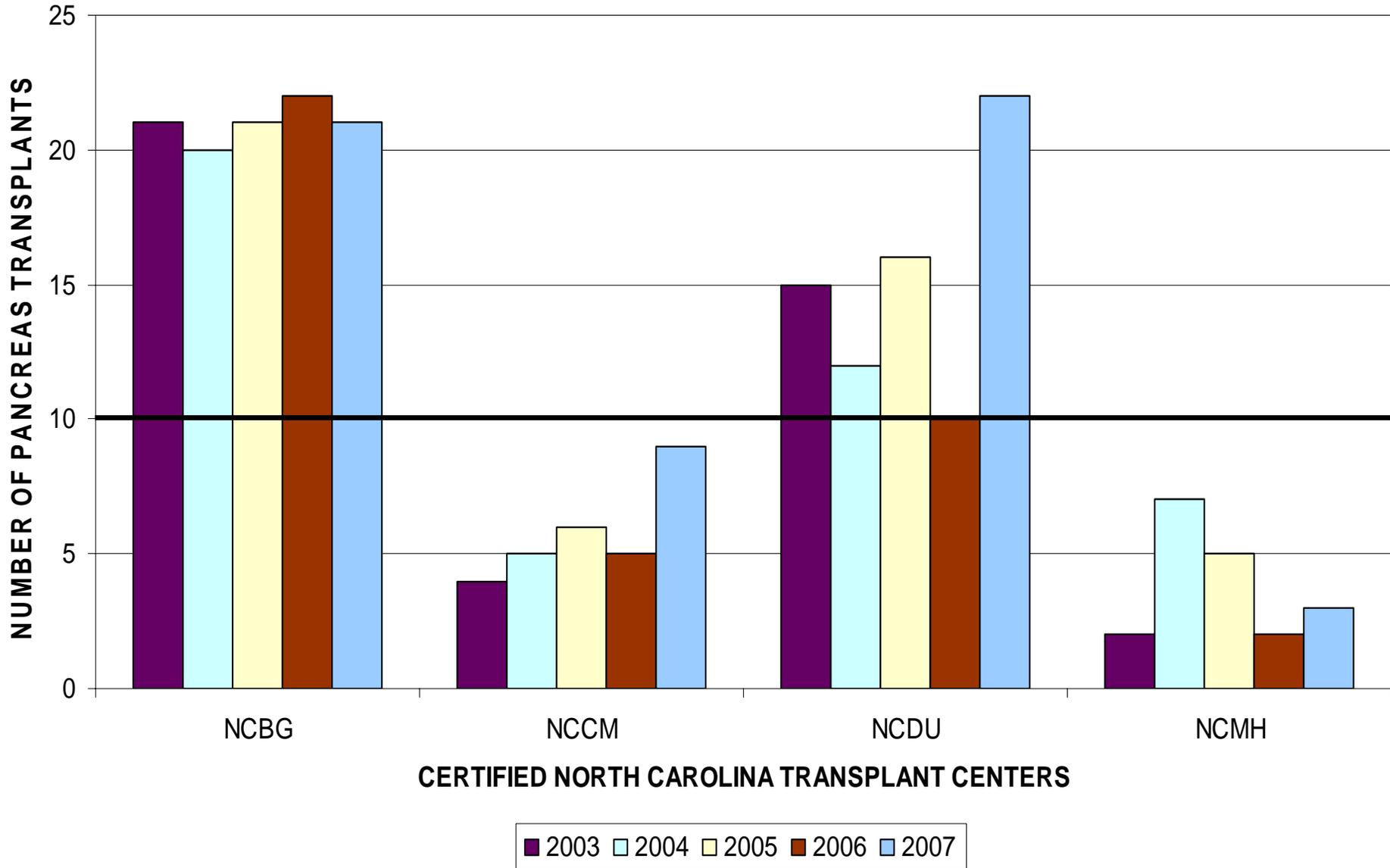
**MARYLAND TRANSPLANT CENTERS
NUMBER OF PANCREAS TRANSPLANTS 2003-2007
CERTIFICATE OF NEED STANDARD = 12 PER YEAR**



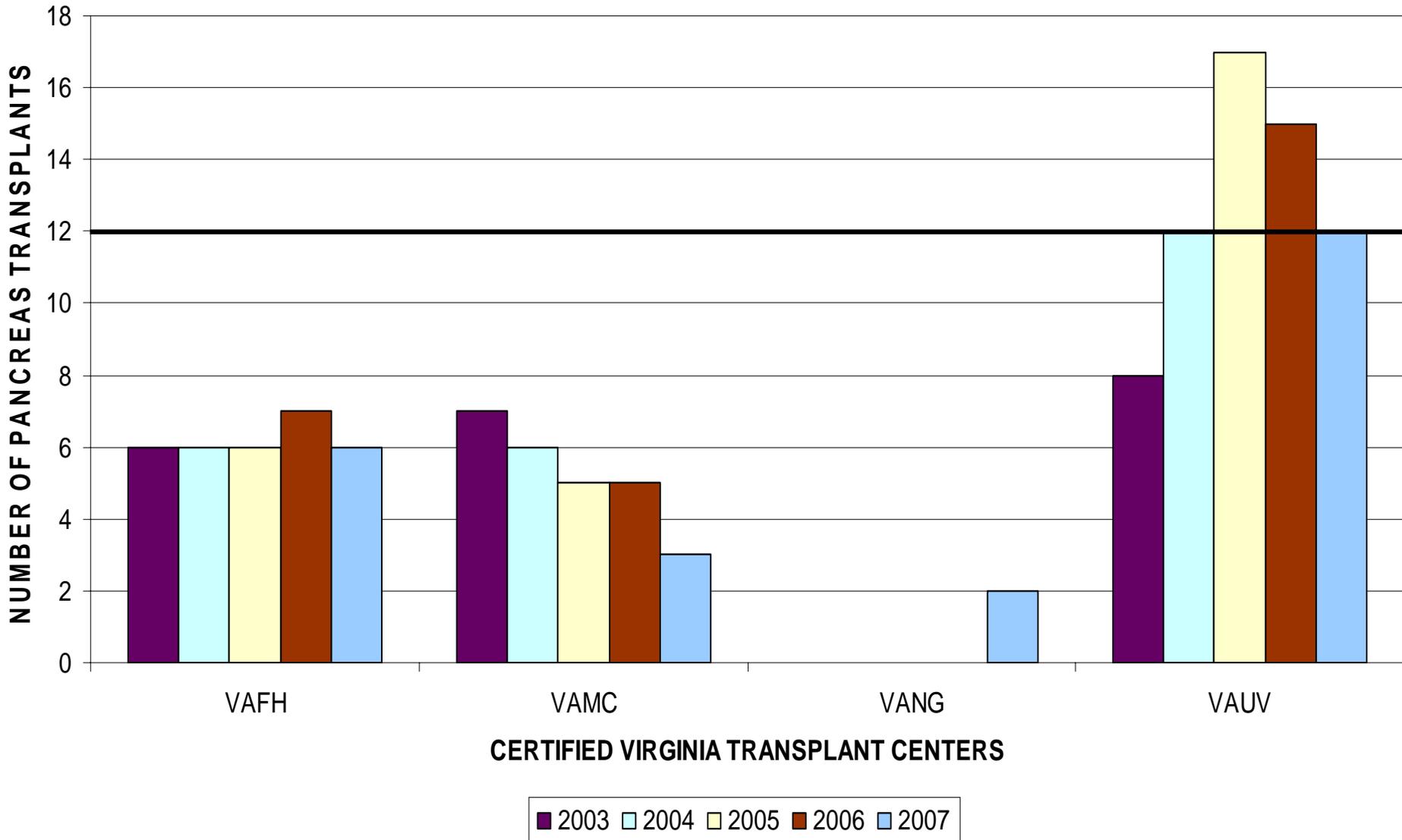
**NEW JERSEY TRANSPLANT CENTERS
NUMBER OF PANCREAS TRANSPLANTS 2003-2007
CERTIFICATE OF NEED STANDARD = 15 PER YEAR**



**NORTH CAROLINA TRANSPLANT CENTERS
NUMBER OF PANCREAS TRANSPLANTS 2003-2007
CERTIFICATE OF NEED STANDARD = 10 PER YEAR**



**VIRGINIA TRANSPLANT CENTERS
NUMBER OF PANCREAS TRANSPLANTS 2003-2007
CERTIFICATE OF NEED STANDARD = 12 PER YEAR**



OPO PERFORMANCE METRICS:

30982 Federal Register / Vol. 71, No. 104 / Wednesday,
May 31, 2006 / Rules and Regulations

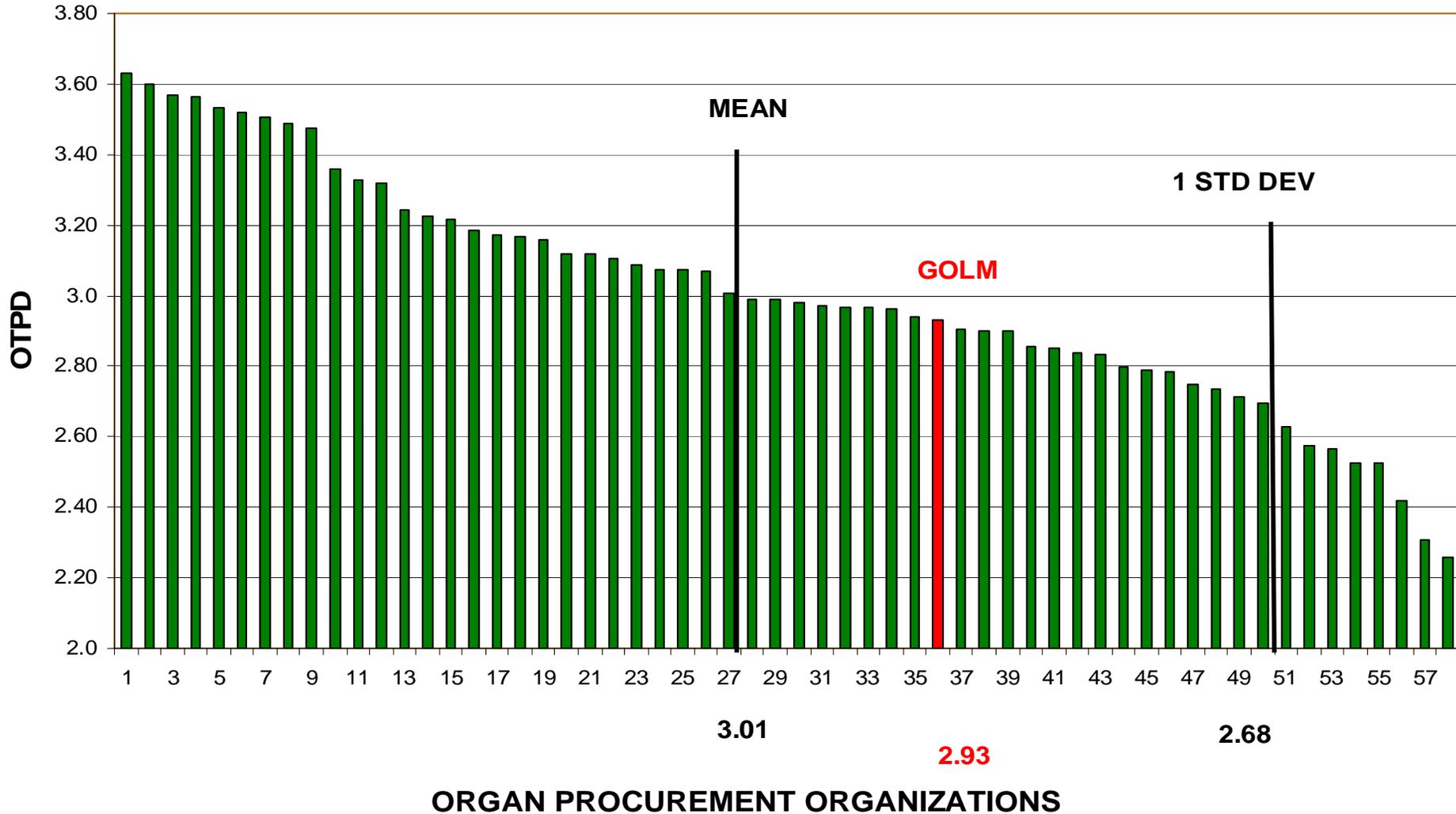
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

42 CFR Parts 413, 441, 486 and 498

Medicare and Medicaid Programs; Conditions for Coverage
for Organ Procurement Organizations (OPOs)

AGENCY: Centers for Medicare & Medicaid Services
(CMS), HHS. ACTION: Final rule.

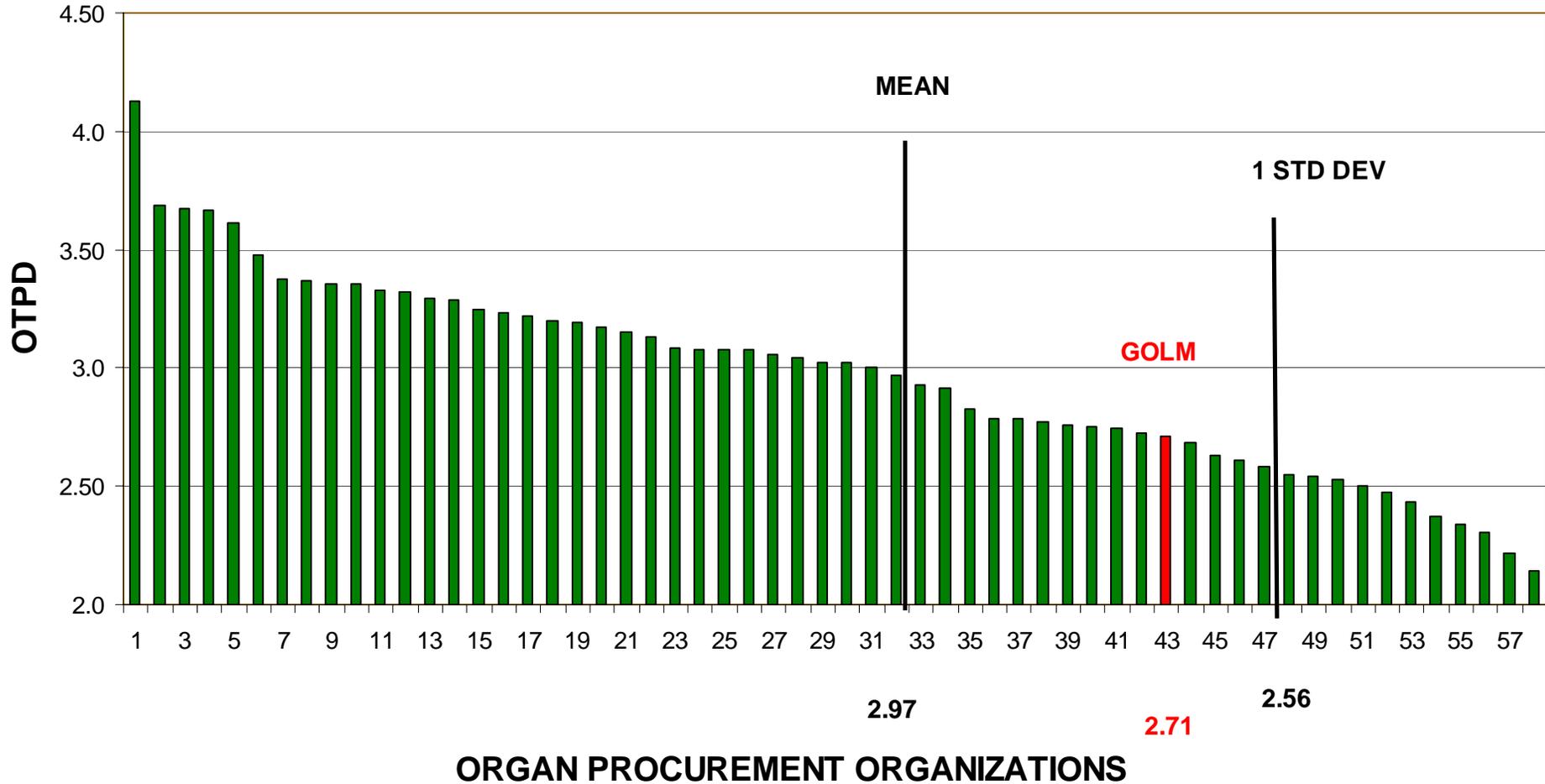
ORGANS TRANSPLANTED PER DONOR (OTPD) FOR ALL OPOs FOR ALL OF 2007 FOR ALL DONORS



ORGANS TRANSPLANTED PER DONOR (OTPD)

Gift of Life Michigan vs ALL OPOs January - April 2008

FOR ALL DONORS



CON PANCREAS REQUIREMENT PROPOSAL:

- A hospital will qualify to provide pancreas transplant services through the establishment of an on-site renal transplant service that has performed a minimum of 80 kidney transplants in any 24 consecutive months in the most recent three years for which data are available.
- A hospital will be considered to be active by performing at least one pancreas transplant in a six month period, otherwise the center must submit any required federal OPTN center status review documents for examination and center certificate disposition by the CON Commission.
- A hospital that has met the requirements for the above two criteria, and who voluntarily surrendered its pancreas certificate, may have its pancreas transplant program reinstated by means of submitting a formal application to the CON Commission.

OPTN PROGRAM ACTIVITY SURVEY:

- 14-Page Survey
- 70-Plus Questions
- Blind review by OPTN Membership and Professional Standards Committee



