

1. Name: Richard Pietroski, CEO
2. Organization: Gift of Life Michigan
3. Phone: 800.482.4881
4. Email: rpietroski@giftoflifemichigan.org
6. Testimony: Attached is written testimony regarding Pancreas and Heart/Lung and Liver Transplantation Standards for the public hearing May 1, 2012.

Content-Length: 130854



May 1, 2012

Heart/Lung and Liver (HLL) Transplantation Services:

Gift of Life Michigan supports the technical amendments to the HLL Services as provided by the department. We also anticipate a robust dialogue in 2015 regarding potential deregulation of these services and support the Commission's discussion to revisit these standards through a SAC or workgroup in the future.

Pancreas Transplantation Services:

Gift of Life Michigan supports the action taken to eliminate the certificate of need for Pancreas Transplantation Services. The duplication of a state level program is no longer cost effective nor can it provide the scope of oversight that is performed by the Organ Procurement and Transplantation Network (OPTN).

There is continued federal regulation of organ transplant centers by the Department of Health and Human Services through both the OPTN and the Centers for Medicare and Medicaid Services (CMS).* The national OPTN requires each approved program to meet rigid criteria for establishing a transplant program (OPTN Bylaws: Attachment I - Criteria for Transplant Program Designation), and ongoing requirements for timely patient-level data submission (OPTN Policy 7.0: Data Submission Requirements). Furthermore, each center undergoes a robust analysis for transplant and outcome data under the federal Scientific Registry for Transplant Recipients (<http://www.srtr.org/>). Center specific data are refreshed every six months, and statistically analyzed to identify underperforming programs which trigger a quality review by the OPTN.

Thank you for this opportunity to comment on the Pancreas and Heart/Lung and Liver Transplantation Services Review Standards.

A handwritten signature in black ink, appearing to read "Richard Pietroski".

Richard Pietroski
Chief Executive Officer

Contact: rpietroski@giftoflifemichigan.org, 800.482.4881

*References:

Policies and Bylaws. Department of Health and Human Services: Organ Procurement and Transplantation Network. <http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp>
<http://optn.transplant.hrsa.gov/policiesAndBylaws/bylaws.asp>

Federal Register. Department of Health and Human Services: Centers for Medicare & Medicaid Services. 42 CFR Parts 405, 482, 488, and 498: *Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants.*

<http://www.cms.hhs.gov/CFCsAndCoPs/downloads/trancenterreg2007.pdf>

1. Name: Dennis McCafferty
2. Organization: The Economic Alliance for Michigan
3. Phone: 248-596-1006
4. Email: DennisMcCafferty@Eaonline.org
6. Testimony: May 7, 2012

James Falahee, Chair
Certificate of Need Commission
C/O Michigan Department of Community Health Certificate of Need Policy Section Capital View Building,
201 Townsend Street Lansing, Michigan 48913

Dear Mr. Falahee,

The following is the public comment from the Economic Alliance for Michigan related to the proposed action taken by the Commission at its March 29, 2012 meeting.

Health/Lung and Liver Transplantation Services We would support the position taken by the Commission that only technical changes are required that would modify this Standard for consistency with other CON Standards. Other substantial changes are not needed at this time.

Hospital Beds

The proposed changes in the standards for determining which hospitals service which communities (hospital groups) and for projecting the future need of additional acute beds, in our opinion, were well thought out and reasonable. The proposed standards also include new provisions to reduce a portion of the excess licensed beds at low occupancy urban county hospitals when these hospitals need a new CON to replace or relocate their licensed acute-care beds or if the hospital is acquired. EAM believes that removing this excess licensed capacity from these urban county hospitals that consistently have low average annual occupancy rates will help improve hospital planning in the long run and, serves the best interest of the citizens of Michigan. We support these proposed changes to the standards and believe they are in the best interest of the citizens of Michigan.

Magnetic Resonance Imaging (MRI) Services and Positron Emission Tomography (PET) Scanner Services We would support the inclusion of MRI-Guided EPI definition within the MRI standards and the language restricting this technology to hospitals with existing MRI services that have been operational for at least 36 months and are meeting the minimum volume requirements for both MRI and OHS. We would also support the inclusion of the PET/MRI scanner hybrid to be used for stand-alone MRI procedures and the proposed changes in both the MRI and PET Standards.

Pancreas Transplantation Services

The deregulation of this Standard is being proposed. There are only a few providers for this service and there are not likely to be many others. The lack of suitable organs and the very limited time between the availability of an organ donor and the implantation to the recipient, limits the number of pancreas transplants that can be performed each year.

We would still recommend that a work group be asked to review this question of deregulation. Our members strongly supported the changes made in these Standards during the last review that limited this service to only the higher volume kidney transplant centers. In the absence of a CON Standard for Pancreas Transplantation, what reassurance does the public have that this service is only being provided by the most qualified providers? We would ask that this quality assurance issue be addressed by this work group that is considering the deregulation of this service.

Sincerely,

Dennis McCafferty
Vice President Health Policy
The Economic Alliance for Michigan

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THE ECONOMIC ALLIANCE FOR MICHIGAN

The Statewide Business-Labor Coalition

41650 Gardenbrook Road, Suite 175 • Novi, MI 48375-1320 • Phone (248)-596-1006 • Fax: (248) 596-1012
Website : www.eamonline.org • E-mail: EconomicAlliance@EAMonline.org

Co-Chairs:

Cindy Estrada,
Vice President
International Union, UAW

Sharon Miller
President
ITH Staffing

Jean Rose,
Executive Director, Global HR
Operations, General Motors

Karla Swift
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Trades Council

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Ford Motor Company

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President
Kushner & Company

Sergio Marchionne
CEO,
Chrysler Group LLC.

Daryl Newman
Secretary-Treasurer
Michigan State AFL-CIO

David Robinson
President, Michigan Teamsters
Joint Council No. 43

Diana D. Tremblay
Global Chief Manufacturing Officer,
General Motors Co.

Dennis E. Williams
Secretary-Treasurer
International Union, UAW

Secretary:

Ron Bieber
Michigan Director
Community Action Program
International Union, UAW

Treasurer:

Gary B. Kushner
President
Kushner & Company

Founding Co-Chairs:

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International Union, UAW
(1917-2007)

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Retired Exec. Vice President
Ford Motor Company

Co-Founders:

Douglas A. Fraser,
President Emeritus
International Union, UAW
(1916-2008)

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Former Chair & CEO
General Motors Corporation
(1906-2004)

President:

Bret Jackson

Vice-President:

Dennis McCafferty

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Sincerely,


Dennis McCafferty
Vice President Health Policy
The Economic Alliance for Michigan



HEALTH CARE

Philip A. Incarnati
President and CEO

TESTIMONY IN RESPONSE TO THE PROPOSED HOSPITAL BED STANDARDS

My name is Philip Incarnati President and CEO of McLaren Health Care. I would like to provide comment for public record on the proposed changes to the Certificate of Need (CON) Hospital Bed Standards.

As a matter of business, McLaren Health Care routinely addresses the issues of balancing access to high quality health care in a cost effective manner while remaining mindful of our responsibilities to the communities we serve. We are proud that we provide access for the physical health and well being of the people we care for; and we are a major contributor to the economic health of the community as well. We believe that as a good corporate citizen, we must develop and execute comprehensive plans that ensure that our services are the best they can be, that they reflect the needs of the community today, as well as into the future and contribute to the economic stability and growth of the community.

The health care environment changes every year. These changes come to us through advances in technology, medicine, the economy, reimbursement and regulation. Health care is something we all care about and providers like McLaren are looked to for answers. In addition we serve as a major employer (one of the top 10 largest in Michigan) and our resources are depended upon for the financial viability of the areas in which we serve our patients. McLaren understands this responsibility and our strategic plan includes economic investment in the regions where we provide care.

INVESTMENT IN PONTIAC

McLaren Health Care believes a key element for success is our investment in the future of the communities we serve. This commitment allows our subsidiaries to grow and remain strong, thereby strengthening our entire organization. This is the primary reason that McLaren - Oakland (formerly POH Regional Medical Center) became a member of McLaren Health Care. Absent McLaren Health Care, the burden of uncompensated care in Pontiac would have become overwhelming for this facility and a valuable safety net asset of the community would likely have been lost.

As a result of the acquisition in 2007, McLaren has taken the following steps to reformat its pledge to Pontiac. Our commitment is based on providing the health care services that patients need and are essential to strengthen both McLaren - Oakland as a provider and McLaren Health Care as a system. There are three key components of our vision for the Pontiac community:

- I. Building a sustainable healthcare delivery model for the city of Pontiac
- II. Developing a platform for education, job training, housing, collateral development
- III. Strategically plan for the McLaren – Clarkston campus

I. BUILDING A SUSTAINABLE HEALTH CARE DELIVERY MODEL FOR THE CITY OF PONTIAC

Pontiac, along with other older industrial regions throughout Michigan, is faced with rapidly changing health and social services needs. These changes are due to advancements in medical technology, and constantly evolving public policy decisions combined with ongoing reductions in federal and state reimbursement for Medicare, Medicaid and Welfare programs. To further complicate matters, the decline in traditional manufacturing jobs has also contributed to significant economic challenges in Pontiac and the surrounding service area.

As part of an effort to respond proactively to this reality, and in keeping with our mission, vision and values, McLaren Health Care seeks to develop new models of healthcare delivery that build healthier neighborhoods, and find the right balance of services at each location to increase access to high quality, safe and affordable health care. The most successful communities will be those in which the stakeholders work collaboratively to define the blueprint for sustainable health and wellness services and the associated economic development those initiatives can bring to the community.

The Pontiac and Clarkston campuses of McLaren - Oakland are an example of this model for McLaren Health Care. McLaren will link its investments in a manner that will maintain high-paying health care jobs in downtown Pontiac. We will also create new jobs in health care delivery and health education through a partnership with local colleges, universities and school districts. McLaren Health Care has spent the last two years researching and studying this opportunity and is now in a position to implement a 3 point plan:

1. Population-based bed distribution

Dramatic shifts in population have occurred over the last three decades in the Pontiac and northern Oakland County market. Between 1970 and 2010, the City of Pontiac population decreased 30% from 85,279 to 59,515 (2010 U.S. Census). During this timeframe, the population of Independence Township has increased over 100%. Further, the growth of the seniors (65+) in the Clarkston service is expected to increase approximately 25%. A significant consideration as they consume health care resources at a much higher rate than all other population age segments.

These dramatic shifts in population demand a geographically appropriate, market based redistribution of licensed acute care beds. McLaren - Oakland maintains 308 licensed acute care hospital beds and 20 psychiatric beds at its downtown Pontiac site. The facility has recently received approval to add an additional 7 psych beds, bringing the total bed count to 335. This site typically maintains an average census of 97 admitted patients. McLaren proposes to retain 108 licensed acute care beds and the 27 psychiatric beds for a total of 135 beds at that location resulting in an average occupancy of 90%. Additionally the Pontiac hospital will continue inpatient and outpatient medical and surgical services, and remain a Level II trauma care provider.

As part of this restructuring, McLaren - Oakland will relocate 200 beds of the 335 beds to its Clarkston site. A 2011 Thompson Reuters bed-need study demonstrated that the Pontiac market will require 385 licensed beds to meet market demand in 2015. Currently there are 1,024 licensed beds serving the Pontiac market – an oversupply of 639. The same study also projected a need for 161 beds in the Clarkston market by 2015. McLaren - Oakland can

meet this demand and maintain at least 80% occupancy in Clarkston while doing its part to remove 200 beds from Pontiac. McLaren - Oakland can maximize efficiency, while not increasing the overall bed inventory in Oakland County.

2. Investment and Service Expansion in Pontiac

During 2012, McLaren - Oakland will make capital investments to support the growth and expansion of key health care services at the Pontiac Campus including, but not limited to, a nearly \$9,000,000 investment in program enhancement for Cardiovascular services, surgery, endoscopy, geriatric psychiatry, trauma, and infrastructure.

3. Primary Care Capacity Expansion

Access to basic primary care services is the cornerstone of a healthy community. McLaren - Oakland will continue to expand the primary care medicine base in the city of Pontiac by increasing the number of Family Practice physicians serving the market including increasing the size of the current Federally Qualified Health Center. McLaren - Oakland will be able to provide comprehensive services to both Pontiac and Clarkston by sharing system resources between the two campuses to benefit the patients served by both sites.

II. EDUCATION, JOB TRAINING, HOUSING, COLLATERAL DEVELOPMENT

McLaren, working in collaboration with local and regional business, education and political leaders, has invested considerable time and resources to identify and develop a realistic set of programs and initiatives designed to strengthen health care and educational resources available in and around Pontiac. These include:

- McLaren, in conjunction with a state university, will develop higher education programs and curriculum for students interested in careers in health care that will be housed in classroom space provided by McLaren at the Pontiac campus.
- McLaren will construct health care learning simulation labs dedicated for clinical learning for the health care education program.
- McLaren brokered a partnership arrangement for career ladders identified with area educational institutions including Oakland schools, Pontiac schools and a local community college.
- McLaren, through its partnerships with real estate firms, will develop student and workforce housing in downtown Pontiac. Also contemplated is recruitment of collateral retail tenants such as a cyber café, restaurant, grocery store, bookstore, fitness/wellness center, as well as a child care provider.
- The McLaren - Oakland Riley Foundation raised \$750,000 which will be designated for use as scholarships awarded to Pontiac children.
- McLaren will create educational programs for faculty development, advancement and patient teaching.

III. STRATEGIC PLAN FOR MCLAREN - CLARKSTON

McLaren - Clarkston is designed to deliver the full continuum of health care services using state of the art technologies to provide prevention, diagnosis, treatment and cure at one site. As the area's only comprehensive, one-stop health care destination, the McLaren – Clarkston campus is located on 80 acres at the corner of Sashabaw Road and Bow Pointe Drive in Clarkston. The \$500 million project is being built in two phases.

PHASE I (Completed 2009)

McLaren Health Care opened Phase I of McLaren – Clarkston in May of 2009 with an initial investment totaling \$100 million. Over 350 people are employed at this site with over 500 jobs created during the construction. The key components of Phase I are the 135,000 square foot Clarkston Medical Building and the 42,000 square foot McLaren Cancer Institute – Clarkston featuring a five acre garden of healing and renewal.

Located within the new Clarkston Medical Building is the Clarkston Medical Group (CMG). CMG is Clarkston's oldest and largest primary medicine group practice under the leadership of Dr. James O'Neill and Dr. Tim O'Neill. CMG employs 15 primary care physicians and over 125 support staff. The Clarkston Medical Building is also home to 64 physicians representing a wide range of specialty care services.

Other services in this building include a 24-hour urgent care center, a 17,000 square foot ambulatory surgery center with three operating rooms, a pharmacy, clinical laboratory services, home medical equipment, a breast care center featuring the area's only digital mammography unit, bariatric center, physical therapy, sports medicine, fitness center, diagnostic sleep clinic, wound care clinic in addition to a comprehensive diagnostic imaging center with CT, MRI and PET/CT modalities.

Also opened in May 2009 is the area's only dedicated, freestanding comprehensive cancer center. The McLaren Cancer Institute – Clarkston provides state of the art radiation therapy, advanced medical oncology, mobile PET/CT imaging, education programming, patient navigator and family support services.

The award winning five acre Garden of Healing and Renewal provides peaceful, soothing surroundings in which to focus healing energies, talk privately and build strength. The garden features an oasis of fountains and sculptures, sitting areas and beautiful paths to encourage exercise and curative reflection. The lush landscaped campus is open for the community to use and enjoy.

PHASE II

The second phase of McLaren - Clarkston will include the development of a 200 bed hospital with all of the associated essential patient care services. McLaren conducted exhaustive research to arrive at the most appropriate and economically feasible development plans for all portions of the project. Phase I far exceeded expectations, making the Clarkston campus a health care destination for outpatient services in the planning area. Further, historical health utilization data shows an unmet need for continued development of the site to include inpatient services.

INPATIENT VOLUME GENERATED FROM CLARKSTON SERVICE AREA

According to data supplied by the Michigan Health and Hospital Association, the Clarkston service area generated 23,649 admissions to an acute care hospital during the 12-month period of July 2010 to June 2011. Assuming an average of 5 days length of stay per admission, a 200 bed acute care hospital located in Clarkston would need to capture only 37% of this volume in order to operate profitably at 60% occupancy. Even operating at 80% occupancy, the proposed facility would only need to capture 49% of this volume. Further, Thomson Reuters projects this annual volume to increase to over 30,000 admissions per year by 2025 based on continued growth in population and age-related increases in utilization.

CONSUMER SUPPORT FOR CLARKSTON PROJECT

A consumer survey of Clarkston area residents was performed by Intellitrends, a Clarkston based market research firm. When asked, "How important do you feel it is to have a full-service hospital in your community?" greater than 80% of responses rated this as "important".

ECONOMIC IMPACT

McLaren estimates that the Clarkston project, when complete will have created approximately 4,000 new jobs. Every 15 new jobs results in \$3 million dollars in economic impact (Oakland County and The Federal Reserve Board) to the area in the form of wages, state and local taxes in addition to the multiplier effect of these dollars moving through the local economy. Based on this estimate, these jobs will generate \$600 - \$800 million in annual economic impact.

CON RESTRAINTS

In spite of all of the positive outcomes listed above, the Hospital Bed Standard Advisory Committee (SAC) and ultimately the CON Commission produced a set of CON Review Standards for Hospital Beds that prohibit McLaren from reducing the number of beds in Pontiac, addressing the population growth in Clarkston, moving beyond the current 2 mile limit, creating 4,000 jobs, and investing an additional \$350 million dollars into the Michigan economy.

The bed need methodology recommended by the SAC and approved by the Commission has essentially preserved the status quo. The formula is based on patient days from existing facilities and is then compared to the total number of existing beds from those facilities. This methodology will always result in excess beds. It will never show a need for new beds in a given area. It fails to account for population shifts and makes capacity a proxy for access.

In addition to the limitations outlined above, the SAC set forth an arbitrary bed reduction requirement. The bed reduction language has no statistical basis and puts communities served by aging facilities, such as McLaren – Oakland in Pontiac, at a disadvantage. The language further complicates a potential bed move that would position Pontiac with the appropriate number of beds and allow the people of Clarkston and surrounding communities to be served by an acute care hospital.

The following proposal to regulate the structure for relocating existing hospital beds was submitted by McLaren at the November 16, 2011 Hospital Bed SAC.

The proposed methodology this committee is being asked to consider captures an historical picture of where hospital beds are in the State of Michigan and relies only on hindsight over foresight.

This methodology, like previous methodologies created by previous Standards Advisory Committees, groups and protects existing hospitals instead of projecting any future shifts in health care delivery needed to meet shifts in population. In fact, it creates a hospital grouping with a “bed surplus” that includes nearly 700 beds created by the legislature and or the courts.

This lack of foresight is further complicated by the proposals for bed reduction which discourage quality improvements to aging infrastructure and undermine a number of community hospitals.

Adopting the proposed language will continue to mean that the only new hospitals ever built in the State of Michigan will be approved by the Legislature or the courts and not the CON Commission. We can all look forward to more new, overbuilt towers at existing locations because that is the only permissible construction. And we can expect that certain communities will be abandoned entirely because the cost to maintain aging infrastructures with no ability to relocate far exceeds any benefit.

This committee has an opportunity to consider a simplified hospital bed regulatory framework that addresses community need and works toward developing the right-sized hospitals as opposed to maintaining the status quo.

As a result, we support simplifying the Hospital Bed Standards to include the following provisions:

Regulatory structure for relocating existing hospital beds:

- Reduce restrictions on CON for relocating hospital beds to a new site
 - If a hospital elects to relocate beds to a new site it must demonstrate:
 - ◆ Financial viability with regard to the entire project
 - ◆ Conclusive positive community need assessment for both the proposed hospital site that is receiving the beds and the hospital giving up the beds
 - Significant community benefit with a financially viable plan for reuse of existing facility
 - Existing facilities cannot close to move to a new facility
 - ◆ No additional beds in Michigan
 - ◆ Maintain existing payer contracts for at least five years
 - ◆ Delicense at least 10% of existing facility’s beds

- ◆ Proposed new hospital sites may not be approved within five miles of existing acute care hospitals, nor within the same county as single community providers

The SAC was scheduled to meet until December 20 but decided to end deliberation on the Hospital Bed Standards early and make November 16 their final meeting. There would have been an additional 30 days to fully consider the proposal. The main criticism from opponents of the proposal was that it would increase healthcare costs. As noted by Robert Cimasi in his paper, **Duped by Cries of Duplication**, “There has been no significant or empirical data that establishes that healthcare facilities or items of medical equipment actually, in and of themselves, raise either utilization or overall healthcare costs.”¹ In addition, in the report prepared for Michigan Department of Community Health by Conover and Sloan, the authors conclude that “With its roots in the rapidly disappearing cost based, third party reimbursement mechanisms of the past, CON is becoming clearly less relevant as a cost containment mechanism. Primary justification for CON, therefore, must rest on its ability to improve or maintain quality and/or access to care.”² The McLaren proposal will indeed improve quality and, most importantly, improve access to care through improved distribution of existing hospital beds.

It is no coincidence that, in the face of all the negative aspects of the proposed standards, the most outspoken opponents of hospital bed reform are hospitals themselves. The SAC-proposed Hospital Bed Standards, if enacted, will continue to protect existing franchises and allow for monopolistic control of hospital beds in a given area, continue to assure that the only new hospitals built in Michigan will be by Legislative or court action, encourage excess spending on overbuilt patient towers at existing locations, and subject aging urban communities to a separate standard of care. We can expect that certain communities will be abandoned entirely because the cost to maintain aging infrastructures instead of relocating them will far exceed any benefit. The implication further exists that restricting the growth of new facilities could become a burden on healthcare reform itself by exacerbating the growing access problem driven by the demand generated by the newly insured.

¹ Cimasi, Robert James (April 2002). Duped by Cries of Duplication: The Failure of Certificate of Need Regulations. Health Capital Consultants, 4.

² Conover, Christopher J., Sloan, Frank A. (May 2003). Evaluation of Certificate of Need in Michigan. Volume I: Final Report. Center for Health Policy, Law and Management. Terry Sanford Institute of Public Policy. Duke University, vi.

Thank you for this opportunity to submit comments regarding the proposed revisions to the Certificate of Need Standards for Magnetic Resonance Imaging (MRI) services. My comments relate to the changes associated with PET/MRI hybrid units. The Department has recommended adding the following language to the definition of "MRI procedure":

"THE TERM INCLUDES FDA-APPROVED POSITRON 110 EMISSION TOMOGRAPHY (PET)/MRI SCANNER HYBRIDS IF USED FOR MRI ONLY PROCEDURES."

I would like to suggest that this language would be more appropriately added to the definition of "MRI unit" rather than "MRI procedure". This would be consistent with how the similar provisions for PET/CT hybrids are handled in the CON Standards for CT Services.

I appreciate you taking the time to consider this suggestion. Please do not hesitate to contact me with any questions.

Melissa D. Cupp

Wiener Associates

721 N. Capitol Ave., Suite 1

Lansing, MI 48906

(517)374-2703 x 1010

(517)374-3877 Direct

(517)749-9503 Cell

(517)487-0372 Fax

www.wienerassociates.com