Marilyn Moon, Ph.D.
CHAIR

STATE OF MARYLAND

Rex W. Cowdry, M.D.
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION
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MARYLAND HEALTH CARE COMMISSION
Thursday, December 16, 2010

Minutes

Chair Moon called the public meeting to order at 1:05 p.m.

Commissioners present: Conway, Falcone, and Krumm. Commissioners participating via teleconference: Fleig, Jefferson, Kan, McLean, Olsen, Petty, Weinstein, and Worthington.

ITEM 1.

Approval of the Minutes

Commissioner Kan made a motion to approve the minutes of the October 20, 2010 public meeting of the Commission, which was seconded by Commissioner Krumm and unanimously approved.

ITEM 2.

Update of Activities

Pam Barclay, Director of the Center for Hospital Services, introduced and welcomed Evanson Mukira to the Center for Hospital Services as the Hospital Associated Infectious Prevention Coordinator under the Commission's CDC grant. Ms. Barclay said Mr. Mukira has over 10 years in the health care field, with a background in Microbiology, Health Informatics and Infection Prevention.

ITEM 3.

ACTION: COMAR 31.11.06 – Comprehensive Standard Health Benefit Plan Regulations

Janet Ennis presented final regulations governing the Comprehensive Standard Health Benefit Plan. Ms. Ennis noted that the proposed and emergency regulations were approved at the August public meeting of the Commission, via teleconference, and published in the *Maryland Register*. She said the regulations are necessary to bring Maryland's small group regulations into conformance with the federally mandated provisions that became effective on September 23, 2010 under the Patient Protection and Affordable Care Act (PPACA). Ms. Ennis reviewed a summary of the changes. These

regulations will be implemented effective January 13, 2011. Commissioner Krumm made a motion to adopt the recommended regulations as final, which was seconded by Commissioner Conway, and unanimously approved.

ACTION: COMAR 31.11.06 – Comprehensive Standard Health Benefit Plan – ADOPTED as final regulations.

ITEM 4.

UPDATE: Annual Mandated Health Insurance Services Evaluation

After providing an update on the status of the mandated services report, Rex Cowdry, Executive Director, and Bruce Kozlowski, Director of the Center for Health Care Financing and Health Policy, discussed policy issues relating to mandate proposals in the coming session of the General Assembly. Mr. Kozlowski began the discussion by providing data on the full cost and the marginal cost of mandated services from Mercer's quadrennial report published in December 2007. Dr. Cowdry discussed provisions of the Affordable Care Act requiring HHS to establish an essential benefits package and requiring states to pay the cost of any state-mandated services that are not covered by the essential benefit package, if the coverage is purchased through an Exchange. The uncertainty about the exact provisions of the essential benefits package coupled with the possible state budget implications of state mandates raise the question of whether the Commission's position should be to oppose any additional mandates until the essential benefits package has been defined. After discussion, Chair Moon suggested that staff provide options for discussion at the January public meeting, including an option that the Commission would evaluate each proposed mandate to determine its likelihood of being included in the essential benefit package.

ITEM 5.

ACTION: Certificates of Need – Modifications

Govans Ecumenical Development Corporation (GEDCO) requested a modification to its previously approved Certificate of Need seeking a change in the financing mechanisms for this project. Susan Myers, Health Policy Analyst, presented the staff recommendation on the proposed modification. Ms. Myers said a combination of a mortgage loan and additional philanthropy are anticipated as funding sources for the project, replacing proceeds that GEDCO had hoped to obtain from the sale of New Market Tax Credits. She said a short term loan of $6.5 million will be used to cover construction costs until grants, including a $4.6 million State bond bill proceeds. Ms. Myers said that GEDCO estimated a lower total cost for the project since the last time the Commission considered the project's cost. Staff recommended that the Commission approve the modification to this Certificate of Need project as outlined in the Staff Report and Recommendation. Ms. Myers noted that the conditions of original CON remain in place for this modification. Commissioner Falcone made a motion to approve the staff recommendation, which was seconded by Commissioner Krumm and unanimously approved.

ACTION: Certificate of Need – Modification – Govans Ecumenical Development Corporation is hereby APPROVED.

Lorien LifeCenter requested a modification to its previously approved Certificate of Need seeking a change in the financing mechanisms for this project. Ms. Myers presented the staff recommendation, noting that Lorien proposed to borrow $8.1 million through a bond financing program created through the American Reinvestment and Recovery Act, which would replace an anticipated borrowing of $5.1 million, at a substantially higher interest rate, a smaller, shorter-term loan, and equity contributions. Ms. Myers noted that there would be modest changes to the physical plant design including two more single rooms than the last design iteration. Staff recommended that the Commission approve the modification to this Certificate of Need project as outlined in the Staff Report and Recommendation. Ms. Myers noted that the same conditions in the original CON would apply. Commissioner Conway made a motion to approve the staff recommendation, which was seconded by Commissioner Krumm and unanimously approved.

ACTION: Certificate of Need – Modification – Lorien LifeCenter is hereby APPROVED.

ITEM 6.

ACTION: Extension of Two-Year Waiver Permitting Participation in C-PORT E Research Study of Non-Primary PCI Services without On-Site Cardiac Surgery

Chair Moon said that four hospitals that hold waivers allowing their participation in the C-PORT E research project studying whether non-primary PCI can be provided as safely in hospitals without on-site cardiac surgery services are seeking an extension of those waivers.

Dr. Cowdry provided a summary of the issues surrounding the waiver extension requests and provided policy questions that the Commission will need to consider in the upcoming months.

- **Anne Arundel Medical Center (Docket No. 08-02-0032 NPRW)**

Dolores Sands, Chief of Specialized Services Policy and Planning, presented the staff recommendation. Ms. Sands said that the research waiver issued to Anne Arundel Medical Center (AAMC) became effective on December 31, 2008, and is scheduled to expire on December 31, 2010. The Commission's regulations (COMAR 10.24.05) include the conditions for maintaining an approved waiver. On January 9, 2009, AAMC became the first hospital in Maryland to initiate patient enrollment in the C-PORT E study. Between mid-May and early November 2009, AAMC experienced problems with physician on-call coverage for its primary (emergency) PCI program; corrective actions taken by the hospital to assure consistent coverage have been successful since that time. AAMC exceeded the required minimum volume of procedures during the first and second years of its research waiver; the hospital has maintained a patient follow-up rate of at least 98 percent. Ms. Sands said, based on an analysis of available data and supporting documentation, AAMC is in compliance with the conditions for maintaining a waiver to provide non-primary PCI services as part of the C-PORT E study. She noted that the hospital's Institutional Review Board (IRB) has approved continuation of the C-PORT trial at AAMC. The Commission's staff recommended that the Commission issue an extension of AAMC's non-primary PCI waiver for one year from the second-year anniversary of the issuance of the waiver, or the date patient accrual into the C-PORT E study ends, whichever occurs first. Commissioner Krumm made a motion to issue the staff-recommended extension of the waiver

that permits Anne Arundel Medical Center to participate in the C-PORT E study of non-primary PCI services, which was seconded by Commissioner Conway and unanimously approved.

ACTION: Anne Arundel Medical Center's Request for an Extension of Two-Year Waiver Permitting Participation in C-PORT E Research Study of Non-Primary PCI Services without On-Site Cardiac Surgery is hereby APPROVED.

- **Saint Agnes Hospital (Docket No. 08-24-0028 NPRW)**

Ms. Sands presented the staff recommendation. She said that the two-year research waiver granted to Saint Agnes Hospital (SAH) is scheduled to expire on December 31, 2010. SAH initiated C-PORT E enrollment on January 13, 2009. As required by the conditions of its non-primary PCI waiver, the hospital has maintained compliance with the Commission's requirements for primary PCI programs. SAH exceeded the minimum PCI volumes by the first- and second-year anniversaries of its non-primary PCI waiver, and has maintained the required follow-up rate for patients enrolled in the C-PORT E study. Saint Agnes Hospital's IRB has approved continuation of the research study at the hospital. Ms. Sands said, based on the staff's analysis, SAH is currently in compliance with the conditions for maintaining its research waiver; the staff recommended that the Commission issue an extension of SAH's non-primary PCI waiver for one year from the second-year anniversary of the issuance of the waiver, or the date patient accrual into the C-PORT E study ends, whichever occurs first. Commissioner Krumm made a motion to issue an extension of the two-year waiver that permits Saint Agnes Hospital to participate in the C-PORT E research study, as recommended by the staff. Commissioner Conway seconded the motion, which was unanimously approved. Commissioner Falcone recused himself from this action.

ACTION: Saint Agnes Hospital's Request for an Extension of Two-Year Waiver Permitting Participation in C-PORT E Research Study of Non-Primary PCI Services without On-Site Cardiac Surgery is hereby APPROVED.

- **Shady Grove Adventist Hospital (Docket No. 08-15-0027 NPRW)**

Ms. Sands presented the staff recommendation. She said that, on January 16, 2009, Shady Grove Adventist Hospital (SGAH) became the third Maryland hospital to enroll patients in the C-PORT E study. The issuance of SGAH's approved research waiver became effective on December 31, 2008, with the two-year waiver expiring on December 31, 2010. SGAH has maintained compliance with the requirements for primary PCI programs, exceeded the minimum PCI volume by the first-year anniversary of its non-primary PCI waiver, and met the required follow-up rate of 98 percent for patients enrolled in the C-PORT E study. The hospital's IRB has approved continuation of the C-PORT E trial. Ms. Sands said, based on an analysis of data updated as of December 15, 2010, Shady Grove Adventist Hospital is expected to perform between 190 and 200 PCIs by December 31, 2010. The staff recommended that, if SGAH meets the second-year threshold of 200 PCIs, the Commission issue an extension of SGAH's non-primary PCI waiver for one year from the second-year anniversary of the issuance of the waiver, or the date patient accrual into the C-PORT E study ends, whichever occurs first. Further, the staff recommended that, if data show that the hospital did not meet the threshold of 200 PCIs by December 31st, the Commission's staff will monitor SGAH's volume data for the period from January 1 through March 31, 2011. If SGAH fails to perform at least 50 PCIs during that period,

the hospital shall, on written notice from the Commission, relinquish its waiver to perform non-primary PCI. Commissioner Krumm made a motion to accept the staff recommendation, which was seconded by Commissioner Conway and unanimously approved.

ACTION: Shady Grove Adventist Hospital's Request for an Extension of Two-Year Waiver Permitting Participation in C-PORT E Research Study of Non-Primary PCI Services without On-Site Cardiac Surgery is hereby APPROVED.

- **Southern Maryland Hospital Center (Docket No. 08-16-0031 NPRW)**

Ms. Sands presented the staff recommendation. She said that Southern Maryland Hospital Center (SMHC) began enrollment in the C-PORT E study on January 22, 2009; the hospital's research waiver is scheduled to expire on December 31, 2010. SMHC exceeded the first-year minimum PCI volume by the third quarter of 2009, and reached the second-year minimum before the end of that anniversary. The hospital is in compliance with the required follow-up rate. Southern Maryland Hospital Center's IRB has approved continuation of the non-primary PCI research study. The hospital has met the requirements for primary PCI programs, but at present does not appear to be on pace to reach the door-to-balloon threshold of 90 minutes or less for 75 percent of appropriate patients, effective January 1, 2010. A representative of the hospital described to the Commission the actions that the hospital has taken to improve the door-to-balloon times of primary PCI patients. SMHC is scheduled to file an application to renew its primary PCI waiver in March 2011. The Commission's staff recommended that the Commission issue an extension of SMHC's non-primary PCI waiver for one year from the second-year anniversary of the issuance of the waiver, or the date patient accrual into the C-PORT E study ends, whichever occurs first. Commissioner Falcone made a motion to issue an extension of the two-year waiver that permits Southern Maryland Hospital Center to participate in the C-PORT E study for one year from the second-year anniversary of the issuance of the waiver, or the date patient accrual into the C-PORT E study ends, whichever occurs first. The motion was seconded by Commissioner Krumm and unanimously approved.

ACTION: Southern Maryland Hospital Center's Request for an Extension of Two-Year Waiver Permitting Participation in C-PORT E Research Study of Non-Primary PCI Services without On-Site Cardiac Surgery is hereby APPROVED.

ITEM 7.

ADJOURNMENT

There being no further business, the meeting was adjourned at 2:30 p.m., upon motion of Commissioner Conway, which was seconded by Commissioner Krumm and unanimously approved.