

Craig P. Tanio, M.D.
CHAIR



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MARYLAND HEALTH CARE COMMISSION

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Tuesday, September 20, 2016

Minutes

Chairman Tanio called the meeting to order at 2:00 p.m.

Commissioners present: Carr-York, Fleig, Metz, Moffit, O'Connor, O'Grady, Phillips, Sergent, Thomas, Tomarchio, and Weinstein. Commissioner Metz participated via telephone.

ITEM 1.

Approval of the Minutes

Commissioner Fleig made a motion to approve the minutes of the July 21, 2016 meeting of the Commission, which was seconded by Commissioner Thomas and unanimously approved.

ITEM 2.

Update of Activities

Linda Cole, Chief of Long Term Care Policy and Planning, provided an update on the Home Health Agency Chapter of the State Health Plan. Ms. Cole said the Chapter was adopted and became effective in April of this year. She said that the Chapter focuses on a new approach based on the determination by the Commission that consumers need a choice of high quality HHA providers. Ms. Cole noted that, in accordance with the regulations, staff has posted for public comment draft quality measures and performance thresholds to be used in CON reviews. She also noted that a background paper has been posted and that public comments are due by September 22. Staff will review comments received and present analysis and recommendations to the Commission in October.

David Sharp, Director for the Center for Health Information Technology and Innovative Care Delivery, provided a brief overview of the report *Ensuring the Privacy and Security of Electronic Health Information – Keeping Pace with an Evolving HIE Landscape*. He mentioned that, over the last several years, a number of health care providers and commercial carriers have raised concerns about the narrow definition of an HIE in statute, at Md. Code Ann, Health-Gen. §4-301(h). Mr. Sharp stated that the revision to the definition that is recommended in the report would ensure enhanced privacy and security standards that would apply to all HIEs operating in Maryland.

ITEM 3.

ACTION: Certificate of Need – Sheppard Pratt at Elkridge (Docket No. 15-13-2367)

Sheppard Pratt Health System, Inc. applied for a Certificate of Need to replace and relocate its 78 bed inpatient psychiatric hospital from Ellicott City to Elkridge. Kevin McDonald, Chief of Certificate of Need, presented the staff recommendation. Mr. McDonald said that the replacement hospital will be approximately four miles from the existing facility and will have 85 beds in a three-level building of 155,707 gross square feet. He said that the total estimated project cost is \$96,532,906. Mr. McDonald said that Sheppard Pratt proposes to fund this project with \$14.86 million in cash, \$7.5 million in philanthropic gifts, \$66.7 million in debt, and \$7.5 million in the state grant funding. Mr. McDonald noted that the project, as described, was modified as a result of a status conference with Commission staff. The applicant agreed to reduce the bed capacity of the replacement hospital to 85 beds by eliminating approximately 16,000 gross square feet, which reduced the project cost estimate by approximately \$6 million. Staff recommended approval of this project. Commissioner Moffit made a motion to adopt staff's recommendation and issue the Certificate of Need, which was seconded by Commissioner O'Connor and unanimously approved.

ACTION: Sheppard Pratt at Elkridge's Certificate of Need is hereby APPROVED.

ITEM 4.

ACTION: Certificate of Need – Green Spring Station Surgery Center (Docket No. 15-03-2369)

Johns Hopkins Surgery Center Series applied for a Certificate of Need to establish an ambulatory surgical facility at Green Spring Station in Lutherville, Maryland. Mr. McDonald presented the staff recommendation. He said that the project will occupy 27,238 square feet of newly constructed medical office building space and will have five operating rooms and four non-sterile procedure rooms, as well as shell space for an additional operating room. He said that the total estimated project cost is \$16,340,840, funded with \$1,896,000 in cash, \$13,082,940 provided through loan agreements with Johns Hopkins Health System, and \$1,361,900 in "tenant allowances" from John Hopkins Suburban Health Center, LP. Staff recommended approval of this project. Commissioner Fleig made a motion to adopt staff's recommendation and issue the Certificate of Need, which was seconded by Commissioner O'Grady and unanimously approved. Chairman Tanio abstained from this action.

ACTION: Green Spring Station Surgery Center Certificate of Need is hereby APPROVED.

ITEM 5.

ACTION: Approval of Release of MCDB Data to University of Maryland, School of Public Health, Health Services Administration

Leslie LaBrecque, Chief of Database and Application Development, presented the staff recommendation regarding the the request of the University of Maryland, School of Public Health, Health Services Administration for access to the MCDB under the Commission's data release policy. Ms. LaBrecque said that the University's data request is for commercial data for calendar years 2010-2014. She noted that the "MCDB Standardized Research Identifiable" file to which access is requested contains eligibility records and claims files (professional services, institutional, and pharmacy), but had no direct identifiers in the data such as name, SSN, birthdate, address. Ms. LaBrecque provided an overview of University of Maryland, College Park's application, noting that its IRB is registered with the US Department of Health and Human Services and has an approved Federalwide Assurance for the Protection of Human Subjects,, which is a commitment to comply with the FWA Terms including the Federal Policy for Protection of Human Subjects ('Common Rule') and other relevant federal regulations. The University of Maryland, College Park's IRB determined that the project has minimal risk based on an appropriate risk/benefit ratio

and a project design wherein the risks have been minimized. Ms. LaBrecque said that staff will continue ongoing reviews for compliance under the data use agreement that requires oversight and protection of released data. Commissioner Fleig made a motion to recognize the University of Maryland, School of Public Health, Health Services Administration's IRB, which was seconded by Commissioner O'Connor and unanimously approved. Commissioner Metz made a motion to approve the release of the data to University of Maryland, School of Public Health, Health Services Administration, which was seconded by Commissioner Weinstein and unanimously approved.

ACTION: Request to Recognize the IRB of University of Maryland College Park is hereby APPROVED

ACTION: Request by University of Maryland, School of Public Health, Health Services Administration for Release of MCDB Data is hereby APPROVED.

ITEM 6.

ACTION: COMAR 10.24.15 – State Health Plan for Facilities and Services: Organ Transplant Services Chapter – Proposed Regulations

Eileen Fleck, Chief of Acute Care Policy and Planning, discussed the draft regulations. She noted that a draft Organ Transplant Services Chapter was posted for informal public comment in May 2016 and two organizations commented on the draft Chapter. Staff provided analysis and recommendations regarding the comments received at the July public meeting, and were asked by the Commission to reconvene the Organ Transplant Workgroup to discuss issues raised. Those issues included: whether the draft Chapter could be revised further to address the disparity between the demand and supply of organs; whether the docketing rules potentially shut out programs that could reduce the disparity between the demand and supply of organs; and whether the draft docketing rule's threshold volume are appropriate for determining whether to allow consideration of applications for new transplant programs. Ms. Fleck said that the Workgroup was reconvened and was attended by Commissioner O'Grady. Ms. Fleck said that, with regard to the disparity between supply and demand, the Workgroup concluded that organ procurement organizations and the United Network for Organ Sharing (UNOS) can better address the issue. She noted that one Workgroup member described a national initiative that may increase the number of kidney transplants through reducing the number of kidneys discarded. Ms. Fleck said that work group members, including those who do not represent an existing transplant program, concluded that the draft docketing rules were acceptable and did not believe that the draft docketing rules would negatively affect patients' access to transplant services. For these reasons, the Workgroup did not recommend changes to the draft docketing rules. Commissioner Carr-York made a motion to approve the proposed permanent regulations, which was seconded by Commissioner Thomas. After a lengthy discussion, a motion to amend the pending motion was made and adopted. Commissioner Moffit made a motion to approve the proposed regulation striking Regulation .04, which was seconded by Commissioner Metz and unanimously approved.¹

ACTION: COMAR 10.24.15 – State Health Plan for Facilities and Services: Organ Transplant Services Chapter – Proposed Permanent Regulations were adopted.²

¹ Note that, subsequent to the September 20, 2016 meeting, Chairman Tanio decided that, because incidental changes to another regulation in the Chapter would be necessary, the Commission should again consider the adoption of COMAR 10.24.15 as proposed permanent regulations at the next Commission meeting.

² See footnote 1.

ITEM 7.

ACTION: Rural Health Workgroup Status and Membership Update

Erin Dorrien, Chief of Government and Public Affairs, discussed the status of the Rural Health Workgroup and presented an update to the Workgroup's membership that was recommended by its Chairs. Ms. Dorrien noted that the Memorandum of Understanding (MOU) with the University of Maryland School of Public Health (UMSPH) and the Walsh Center for Rural Health Analysis was executed. She said that the Workgroup held a Rural Health Summit on August 31, 2016 at Chesapeake College in Wye Mills, Maryland. The Workgroup discussed establishing advisory groups and decided that the following advisory groups would be helpful: Workforce Development; Transportation/Access to Care; Economic Development/Economic Impact of Health Facilities Changes; and Vulnerable populations/Health Disparities. Ms. Dorrien said that the leaders of the advisory groups were chosen by the Chairs of the Workgroup and it is expected that the groups will meet in October. She noted that staff is working with the advisory group leaders to develop the agendas. Ms. Dorrien stated that the Rural Health Workgroup will meet on November 1 in Cambridge, Maryland. At that November 1 meeting, the UMSPH and the Walsh Center will present their study plan, and five county region health systems will present. The Workgroup will also report on its progress. Ms. Dorrien provided the list of proposed new members requested by the Chairs of the workgroup: Anna Sierra, Dorchester County Department of Emergency Services; Frieda Wadley, Talbot County Health Department; Roger Harrell, Dorchester County Department of Health; and Doris Mason, Upper Shore Regional Council. Following discussion, Commissioner Metz made a motion to approve the new membership, which was seconded by Commissioner Fleig and approved by ten Commissioners. Commissioner O'Connor opposed the motion, and Commissioner Thomas abstained.

ITEM 8.

Overview of Upcoming Initiatives

Mr. Steffen said that the October meeting would include a presentation on Preauthorization Benchmark Attainment; recommendations for proposed permanent regulations regarding State-Regulated Electronic Health Record incentives; a presentation on the findings on the annual hospital health IT report; consideration of the adoption of the proposed Freestanding Medical Facility Chapter as final regulations; consideration of approval of quality measures and performance thresholds for use in the review of home health agency Certificate of Need applications.

ITEM 9.

ADJOURNMENT

There being no further business, the meeting was adjourned at 3:40 p.m. upon motion of Commissioner Fleig, which was seconded by Commissioner O'Connor and unanimously approved.