STATE OF MARYLAND

Andrew N. Pollak, M.D.
CHAIR

Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

Thursday, June 17, 2021

Minutes

Chairman Pollak called the meeting to order at 1:05 p.m.

Commissioners present via telephone: Akintade, Bhandari, Boyle, Brahmbhatt, Doordan, O'Connor, Rymer, Sergent, Thomas and Wang

AGENDA ITEM 1.

Approval of the Minutes

Commissioner O'Connor made a motion to approve the minutes of the May 20, 2021, public meeting by teleconference of the Commission. The motion was seconded by Commissioner Thomas and unanimously approved.

AGENDA ITEM 2.

Update of Activities

Ben Steffen, Executive Director, noted that on Tuesday, the Governor announced the end of the state of emergency. Some Executive Orders will end July 1st and almost all other Executive Orders will end on August 15th. Staff has concluded that the emergency Certificate of Need (CON) and other orders issued by the Maryland Health Care Commission (MHCC or Commission) are governed by the Executive Orders that end on August 15. Mr. Steffen noted that MHCC issued 41 E-CONs from March through January 2020. The bed and other capacity approved through those E-CONs continue for 30 days after the end of the state of emergency. The E-CONs may be extended beyond that date for good cause shown.

Next, Mr. Steffen reported that on March 31, 2020, MHCC announced that it would waive the following standards for Certificates of Ongoing Performance for cardiac surgery and percutaneous coronary intervention (PCI) services during the state of emergency: (1) excluding case volumes for programs and physicians; 2) compliance with door-to-balloon time requirements; and 3)

availability of primary PCI 24-7. The MHCC will issue guidance on both E-CONs and resumption of PCI program requirements in the coming months.

Lastly, Mr. Steffen stated that today is Kevin McDonald's, Chief, Certificate of Need (CON), final meeting with MHCC. Mr. McDonald joined MHCC in 2013. Over the past nine years Kevin directed the review of dozens of important projects, such as the relocation of the Washington Adventist HealthCare White Oak Medical Center, the relocation of Prince George's Hospital Center, and the award of a cardiac surgery program to Luminis. He restarted the review of the hospice projects and directed the review of at least half a dozen drug treatment projects. Mr. Steffen noted that many Commissioners worked with Mr. McDonald on contested cases and found him knowledgeable, well-prepared, and supportive of the role of Commissioners in CON reviews and that Mr. McDonald also spent considerable time developing the MHCC CON staff. Finally, Mr. Steffen stated that MHCC is in a far better place now than when Mr. McDonald arrived, and thanked him for his years of service.

Paul Parker, Director of the Center for Health Care Facilities Planning and Development, announced the employment of Wynee Hawk as the incoming Chief of the CON Division. Mr. Parker noted that Ms. Hawk most recently worked as the Manager of Policy and Legislation at the Maryland State Board of Physicians, and that her career has also included senior positions in government and community affairs in other Maryland State government posts and at a Maryland hospital. Ms. Hawk has a B.S. in Nursing from the University of Maryland at Baltimore and a J.D. from the University of Baltimore.

AGENDA ITEM 3.

ACTIONS: Certificates of Ongoing Performance – Percutaneous Coronary Intervention Services

Jessica Raisanen, Program Manager, Acute Care Policy and Planning, presented a slide with an overview of the standards for a Certificate of Ongoing Performance for percutaneous coronary intervention (PCI) services. She then presented the staff reports for the applications for Certificate of Ongoing Performance for PCI services submitted by the University of Pennsylvania Medical Center (UPMC) Western Maryland and Meritus Medical Center.

3A. UPMC Western Maryland (Docket # 19-01-CP024)

Ms. Raisanen reviewed UPMC Western Maryland's compliance with key standards included on three slides presented. Ms. Raisanen recommended that the Commission find all standards have been met and approve the Certificate of Ongoing Performance for UPMC Western Maryland to continue providing elective and primary PCI services for four years with the following conditions: UPMC Western Maryland shall hold meetings at least every other month for the purpose of conducting interventional case review that include physicians, technicians, and nurses who care for primary PCI patients, as required by COMAR 10.24.17.07D(5)(a), and shall submit to Commission staff attendance lists for each of these hospital staff meetings held between January and June by August 1 of each year, and attendance lists for meetings held between July and December by February 1 of each year until at least February 1, 2022. After this date, the Executive

Director may release UPMC Western Maryland from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition; and 2) UPMC Western Maryland holds monthly multiple care area group meetings and, as required in COMAR 10.24.17.07D(5)(b), and submits to Commission staff attendance lists for each of these meetings held between January and June by August 1 of each year, and attendance lists for meetings held between July and December by February 1 of each year until at least February 1, 2022. After this date, the Executive Director may release UPMC Western Maryland from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.

Hospital representatives Timothy Abrell, Dr. Christopher Haas, Jamie Karstetter, and Chrissy Lechliter also attended the meeting. The Commission approved staff's recommendation.

Commissioner Thomas made a motion to approve the Certificate of Ongoing Performance for UPMC Western Maryland, which was seconded by Commissioner O'Connor and unanimously approved.

ACTION: Certificate of Ongoing Performance – Percutaneous Coronary Intervention (PCI) Services – UPMC Western Maryland is hereby APPROVED.

3B. Meritus Medical Center (Docket#19-21-CP028)

Mary-Ann Dogo-Isonagie, Program Manager, Acute Care Policy and Planning, presented the staff report for the Certificate of Ongoing Performance application for PCI services by Meritus Medical Center. Ms. Dogo-Isonagie reviewed Meritus Medical Center's compliance with key standards included on three slides. She noted that case review meetings with nurses and technologists occurred infrequently between 2015 and 2019 and recommended that a condition be included on the Certificate of Ongoing Performance for the hospital with formal follow-up by the Commission. Ms. Dogo-Isonagie recommended that the Commission find all standards have been met by Meritus Medical Center and approve the Certificate of Ongoing Performance for Meritus Medical Center to continue providing primary PCI services for four years with the condition mentioned above.

Commissioner O'Conner inquired about the national benchmark for STEMI (ST-elevation myocardial infarction). Ms. Dogo-Isonagie responded that the national benchmarks vary each period. Executive director, Ben Steffen, added that the adjusted mortality rates and national benchmarks can be found on page 17 of the report.

The hospital representatives for Meritus Medical Center who attended the meeting were Angie Francart, Julie L. Miller, Jim Recabo, Dr. Robert Marshall, Tara Baker, Alex Sloan, Betty Myers, Melva Meminger.

Commissioner Boyle made a motion to approve the Certificate of Ongoing Performance for Meritus Medical Center, which was seconded by Commissioner Akintade and unanimously approved.

ACTION: Certificate of Ongoing Performance – Percutaneous Coronary Intervention (PCI) Services – Meritus Medical Center is hereby APPROVED.

AGENDA ITEM 4.

ACTION: Certificate of Need - Request for a Second Project Change After Certificate of Need Approval for Sheppard Pratt at Elkridge (Docket No. 15-13-2367)

Sheppard Pratt Health System filed a second request for a Project Change after Certificate of Need (CON) approval to authorize a $7.4 million increase to the Project Budget for its 85-bed replacement special psychiatric hospital in Elkridge, as well as a change in the funding sources for the project that shifted approximately $26 million that had been described as cash and philanthropy to debt in the form of a working capital loan. CON Chief, Kevin McDonald reported that both changes occurred during Sheppard Pratt's recent rate negotiations with the Health Services Cost Review Commission (HSCRC). The project cost increase resulted from the longer-than-expected construction period – partially exacerbated by the pandemic – and Sheppard Pratt had overlooked the resulting larger interest cost in its earlier modification request.

The changes in project funding resulted from what Sheppard Pratt described as a "reclassification." This occurred as a result of recent cash constraints, leading Sheppard Pratt to redirect $25 million of the proceeds of a bond issue meant to support other corporate-wide initiatives to the Elkridge project. In addition, Sheppard Pratt reduced the amount of philanthropy in the funding mix from $16.5 million to $5 million, based on its decision to use only those philanthropic funds specifically earmarked by donors for this project. Mr. McDonald stated that these changes would reduce the facility's projected profitability, but that it still projected a positive bottom line. In addition, HSCRC staff provided an opinion that Sheppard Pratt had the resources to support the project changes, and that it remained viable. Mr. McDonald noted that the Commission's earlier findings regarding the need for the project and its positive impact on the health system still be held, and that staff recommended approval of the project.

Commissioner Doordan made a motion to approve the request for a second project change after the CON approval for Sheppard Pratt at Elkridge, which was seconded by Commissioner O'Connor and unanimously approved.

ACTION: Certificate of Need Application - Request for a Second Project Change After Certificate of Need Approval for Sheppard Pratt at Elkridge is hereby APPROVED.

AGENDA ITEM 5.

ACTION: COMAR 10.25.05: Data Release – Proposed Permanent Regulations – to replace existing COMAR 10.25.05: Small Group Market Data Collection

Ms. Mahlet ("Mahi") Nigatu, Chief of APCD Public Reporting and Data Release, presented as proposed permanent regulations, Code of Maryland Regulations, Title 10, Subtitle 25, Chapter 05 (COMAR 10.25.05) governing the release of data collected and maintained by MHCC.

Ms. Nigatu stated that the existing regulations in COMAR 10.25.05, entitled, "*Small Group Market Data Collection* are no longer being administered by the Commission because of the enactment of the Affordable Care Act and the establishment of the Maryland Health Benefit Exchange, which now regulates the small group insurance market. The impetus for the new data release regulations is to expand the permissible uses and recipients of data. The new data release regulations permit a broader range of uses of data beyond traditional research purposes, diversifies the types of data sets that can be provided, allows the establishment of a data fee structure, and streamlines the review standards for release of Medicaid data that is housed in the Maryland Medical Care Data Base (MCDB). Overall, the new regulations increase the transparency and efficiency of the data application review process.

Ms. Nigatu reviewed some sections of the new COMAR 10.25.05 data release regulations. She stated that Regulation .03 of COMAR 10.25.05 covers the type of data set that will be made available, namely, deidentified, limited and custom:

- De-identified does not include direct or indirect identifier.
- Limited data set includes indirect identifier mean a data element that can be used to identify an individual when combined with other information or data.
- Custom data file as the name suggests is a custom data set created based on the criteria provided by an applicant and is the minimum amount necessary.

Ms. Nigatu summarized the requirements of Regulation. 04 governing requests for Medicaid data housed in the MCDB. Medicaid data will be sent to Medicaid for review after an application is deemed complete by MHCC staff. Medicaid is then required to respond to MHCC within 15 days on Medicaid's decision to either conduct an independent application review and approval process or inform MHCC staff that the application should go through MHCC's review and approval process in accordance with COMAR 10.25.05.

Ms. Nigatu explained that Regulations .08 and .09 of COMAR 10.25.05 allow the establishment of a Data Release Advisory Committee (DRAC) that will perform the function of a privacy board. The DRAC members will represent various stakeholders, such as academic research organizations, consumer advocacy organizations, employers, health care providers, health maintenance organizations, insurers, and nonprofit health service plans. Ms. Nigatu offered that a more detailed list of criteria can be found in the Regulation .09 of COMAR 10.25.05. She noted that the final task of the DRAC, after reviewing the application, is to prepare a written report and recommendation for the Executive Director.

Ms. Nigatu next explained the difference between a government and non-government application. First, a request from a governmental entity, which is defined in the regulations as any State of Maryland or federal governmental body. A governmental entity is required to submit a written request that includes information on whether the data will be linked with other data sources and a data management plan. The Commission's Executive Director can approve or disapprove the data request or decide not to make a decision on the data request and refer it to the DRAC for review and recommendation, to a panel of three Commission members, or to the full Commission for review and a final decision. A non-governmental entity must submit a written application for data and pay a non-refundable $200 application fee. Once staff deems an application complete, the regulations require the application be referred to the DRAC for review and a written

recommendation. Unlike a data request received from a government entity, the Executive Director cannot make a final decision on a non-governmental application; the regulations require that the application be referred to the DRAC for review and a written recommendation.

Ms. Nigatu noted that the Regulation. 07 requires that all completed applications (without any sensitive information removed) be published on the Commission's website and that the public is permitted to submit written comment on completed applications. Staff will refer all public comments received on an application together with the application to the DRAC for review.

Lastly, Ms. Nigatu pointed out that Regulation .14 includes compliance and enforcement provisions that authorize the Commission to take appropriate administrative and judicial enforcement actions if a data recipient does not comply with the terms and conditions of a data use agreement or if it becomes known that a data recipient provided false information during the application process. In addition, the Commission may notify the appropriate State or federal law enforcement authority in the instance of unauthorized access by a data recipient. She noted that the Commission currently does not have the authority to impose fines for a data recipient's violation of a data use agreement. Staff recommended that the Commission seek statutory authority to impose fines.

Ms. Nigatu requested that the Commission adopt Commission staff's recommendation that the Commission repeal the existing regulations in COMAR 10.25.05, Small Group Market Data Collection, and adopt all new regulations, COMAR 10.25.05, Data Release, as proposed permanent regulations.

Commissioner O'Connor made a motion to repeal existing regulations in COMAR 10.25.05: Small Group Market Data Collection and adopt as proposed permanent regulations COMAR 10.25.05, Data Release, which was seconded by Commissioner Thomas and unanimously approved.

ACTION: COMAR 10.25.05, Small Group Market Data Collection, is hereby REPEALED and replaced with COMAR 10.25.05, Data Release, which is hereby ADOPTED as Proposed Permanent Regulations.

AGENDA ITEM 6.

ACTION: MDPCP Advisory Council - Term Renewals and Nominations

Anene Onyeabo, Program Manager, Innovative Care Delivery, overviewed the Maryland Primary Care Program (MDPCP), membership reappointments and nominations to the MDPCP Advisory Council (Council). The Council provides stakeholder input on operations of the MDPCP and serves a consultative and advisory role to the Secretary of the Maryland Department of Health and the MDPCP Program Management Office. Robert Berenson, MD and Stacia Cohen were proposed reappointments. Stacy Garrett-Ray, MD and Kathleen Loughran were nominated. The Commission approved the reappointments and nominations.

Commissioner Bhandari made a motion to approve the MDPCP Advisory Council- Term Renewals and Nominations, which was seconded by Commissioner Boyle and unanimously approved.

ACTION: MDPCP Advisory Council - Term Renewals and Nominations are hereby APPROVED.

AGENDA ITEM 7.

ACTION: MCDB Data Release to CRISP

Ms. Mahlet ("Mahi") Nigatu, Chief of APCD Public Reporting and Data Release, presented the application requesting Medical Care Data Base data submitted by the Chesapeake Regional Information System for our Patients (CRISP) for a project they are working on with MHCC's sister agency, the Health Services Cost Review Commission (HSCRC).

Ms. Nigatu described the project purpose, which entails comparing Maryland Medicare and Commercial spending in Ambulatory Surgery by Maryland region and comparing national averages and investigating the impact of Maryland's efforts to improve care delivery and outcomes related to the first-episode psychosis (FEP) through implementing evidence-based treatment. The project data sources will be the Maryland Medicaid Management Information System (MMIS2); Maryland Medical Care Database (MCDB); and Medicare fee-for-service (FFS). The project will be funded internally.

Furthermore, Ms. Nigatu noted that the project outcome will be published as a white paper on the CRISPHealth.Org website. She further noted that CRISP has requested a waiver for the standard fee of a total non-profit/academic rate for the requested MCDB data which would be $16,000 per year of data covering six years of data for the total amount of $96,000.

Ms. Nigatu indicated that staff reviewed and found that the application meets the regulatory requirement of research use because the projects compare Maryland Medicare and Commercial spending in Ambulatory Surgery by Maryland region and in comparison, to national averages and investigates the impact of Maryland's efforts to improve care delivery and outcomes related to first episode psychosis (FEP) through implementing evidence-based treatment. Staff also found the application meets the regulatory requirement of being in the public interest as it will enable the understanding of key questions related to Maryland’s Total Cost of Care (TCOC) model and care transformation and thus improve capabilities available to support those efforts across the State.

Ms. Nigatu stated that Commission staff recommends that the Commission vote to approve the MCDB data request application submitted by the Applicant, CRISP, and allow access to the requested data contingent on CRISP’s entry into a data use agreement with the Commission. Staff also recommended that the Commission grant the Applicant's fee waiver request in the amount of $96,000.

Commissioner Boyle made a motion to approve Commission staff’s recommendation that CRISP’s application for MCDB data and fee waiver request be approved subject to CRISP’s entry

into a data use agreement with the Commission, which was seconded by Commissioner Doordan and unanimously approved.

ACTION: CRISP'S request for MCDB Data and a fee waiver is hereby APPROVED, with the condition that the release of the requested MCDB data to CRISP be contingent on CRISP's entry into a data use agreement with the Commission.

AGENDA ITEM 8.

PRESENTATION: MHCC Logo Design

Shadae Paul, Program Manager in the Executive Office, presented on the new MHCC logo. Ms. Paul provided a brief history of past Commission logos and the current logo being used. She noted that there are currently five logos in use by the Commission. The current logos are outdated and are being used concurrently for the Commission's internal and external communications. From November 2020 to June 2021, the Commission has been working with a graphic design contractor to redesign the logo and develop a new brand identity. The redesigned logo needed to be modern, clean, simple, and communicate the story of MHCC. Ms. Paul revealed the new logo and described the meaning behind each design element. In addition, she announced the go live date: July 1. On this date, the style guide will be disseminated to staff and all previous iterations of the MHCC logo will be replaced with the new logo. The Commissioners asked clarifying questions about the cost of launching the new logo and the steps for implementing it across the agency.

ACTION: NO ACTION REQUIRED

AGENDA ITEM 9.

PRESENTATION: Grant Award Announcement - Advancing Practice Transformation in Ambulatory Practices

Melanie Cavaliere, Chief, Innovative Care Delivery, presented an update on the Announcement for Grant Applications to identify a Care Transformation Organization (CTO) to engage primary care and specialty practices (practices) in a practice transformation program (program). The program will prepare select practices to deliver high-quality care while improving health outcomes, provide the foundation for team-based and patient-centered care, and prepare practices to participate in emerging advanced care delivery models. Ms. Cavaliere announced that MedChi CTO was selected to receive grant funding.

ACTION: NO ACTION REQUIRED

AGENDA ITEM 10.

PRESENTATION: Innovative Initiatives
Health System – Hospice Joint Ventures
Hospital at Home
Ambulatory Surgery Facilities

Linda Cole and Paul Parker of the Center for Health Care Facilities Planning and Development updated the Commission on some recent innovation initiatives in health care facility services delivery and regulation. Ms. Cole began with a discussion of joint ventures formed by hospices and hospitals (or health systems). Based on initial meetings and discussions with proponents of the innovation, staff posted guidance on the provision of general hospice services by joint ventures on the Commission's website in May (link below):
https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs/documents/hcfs_guidance_innovative_hospice programs.pdf

Under the model outlined in the guidance:

1. The joint venture includes a licensed Maryland general hospice and a licensed Maryland hospital or health system as partners in the venture;
2. The licensed general hospice must have at least five years of experience;
3. A new licensed hospice cannot be established;
4. Provision of care is limited to those jurisdictions where the hospice is already authorized to provide care;
5. The joint venture must fully detail the inter-provider partnership and a cost-reducing agreement, designed to lower the total cost of care for patients receiving hospice and other health services provided by the joint venture; and
6. If the joint venture ceases operations, any authority that is involved in the provision of hospice services would revert to the existing Maryland general hospice.

Ms. Cole noted that the Commission staff was reviewing a request for a determination of coverage intended to implement the type of joint venture model addressed by the guidance. The Commission currently has received a proposal from Gilchrist Hospice and Luminis Health Care to provide services under a joint venture in Anne Arundel and Prince George's Counties. This proposal is currently under review and no action has yet been taken by Commission staff.
Mr. Parker continued with a discussion of Hospital at Home.

Mr. Parker updated the Commission on implementation of a study report mandated by the General Assembly earlier this year. The study will examine a model of delivering acute inpatient hospital care for a selected patient population in the patient's home. The model is called "Hospital at Home" (HaH) and the report is to be a joint effort of MHCC and HSCRC. It will examine the efficacy of the HaH model, how it fits into Maryland's TCOC model for regulating hospital revenue, barriers to HaH in existing law and regulation, and the cost implications of HaH for payers. The report is due in December.

Mr. Parker described the expected benefits of an HaH program model developed by Dr. Bruce Leff of Johns Hopkins Medicine. These are reduced care cost, equivalent or improved outcomes (mortality and patient satisfaction), "decanting" of hospitals and, thus, freeing bed capacity, and reducing the need for capital investment, and, thus, increasing scalability.

Mr. Parker reported that HSCRC staff is taking the lead in development of the report, given the greater direct implications of HaH for that agency's regulatory function. Mr. Parker recommended that MHCC should consider and adopt a position on CON regulation for the report later this year to meet the legislators' mandate to address any legal or regulatory barriers to the HaH model of care.

Mr. Parker described the last innovation as greater flexibility for acute general hospitals to co-locate with distinctly licensed ambulatory surgical facilities while maintaining their separate status as rate-regulated (hospital) and unregulated (ASF) entities. He described two hospital projects that have emerged in the past year:

The MHCC issued a CON to UMMC Midtown Surgicenter, LLC to establish an Ambulatory Surgical Facility (ASF) with three operating rooms (ORs) on the first floor of a new building under development on the Midtown campus in October 2020. The HSCRC determined that this project was well situated to function separately from the hospital surgical facilities and, with adequate representations from UMMS on its operational characteristics in hand, the ASF could operate as an unregulated facility.

In May 2021, MHCC issued a determination that Johns Hopkins Surgery Centers Series did not need a CON to establish an ASF with two ORs by reconfiguring existing hospital surgical facilities and ancillary space at Howard County General Hospital. The hospital surgical space and proposed ASF space will be reconfigured to function independently. An HSCRC determination had not been issued prior to MHCC's determination or at the time of the June Commission meeting.

Mr. Parker noted that an enhanced ability for hospitals to implement projects like these appear to be supportive of the regulatory policy direction adopted by MHCC in recent years to encourage development of surgical facilities in a manner that will encourage more use of lower charge settings for delivery of outpatient surgery.

ACTION: NO ACTION REQUIRED

AGENDA ITEM 11.

Overview of Upcoming Activities

Mr. Steffen stated that the July's Commission meeting may include at least one Certificate of Need (CON), an advance directive application, and that Wear the Cost data may be available to the Commission at the September meeting.

AGENDA ITEM 12.

ADJOURNMENT

There being no further business, the meeting was adjourned at 3:39 p.m. upon motion of Commissioner Boyle, which was seconded by Commissioner Sergent and unanimously approved.