Regulatory Advisory Panel for HB2316's Cooperative Agreements
Panel Minutes

June 29th, 1:00-4:00 pm
Perimeter Center
Second Floor Conference Center Board Room 4
9960 Mayland Drive,
Henrico, Virginia 23233

In attendance: Virginia Department of Health Staff: Dr. David Trump, Deputy Commissioner, Joe Hilbert, Director of Government and Regulatory Affairs, Erik Bodin, Director of the Office of Licensure and Certification, Peter Boswell, Director of the Certificate of Public Need, and Susan Puglisi, Policy Analyst. Panel Members: Rick Shinn, David Nutter, Chris Bailey, Doug Gray, Colin Drozdowski, Michael Jurgensen, and Melody Counts. Members of the public also attended.

Dr. Trump began the meeting by asking everyone to introduce themselves. He then explained the charge of the regulatory advisory panel. The State Health Commissioner (Commissioner) appointed members to the regulatory advisory panel to assist in crafting the regulations required by HB 2316 (2015). HB 2316 (2015) has an enactment clause which requires the State Board of Health to promulgate regulations implementing the provisions of the bill within 280 days of the enactment of the bill. The Department hopes to have draft regulations to lay before the Board of Health at the Board's September meeting, to ensure compliance with the bill's timeline. The Commissioner is particularly looking for guidance from the panel regarding metrics and measures to be integrated into the regulations.

Dr. Trump noted that the Commissioner and the Virginia Department of Health (VDH or Department) sought representation from a variety of stakeholders on the regulatory advisory panel; however, the Department was not successful in acquiring small business representation. The Commissioner and the Department hope to find representatives from small businesses to serve on the panel for future meetings.

Dr. Trump stressed the advisory nature of the panel and also asserted that panel meetings are not the venue to debate the language of the Code of Virginia, as it is not the task of the Department or panel members to determine statutory language. Finally, Dr. Trump noted that there will be an opportunity for public comment later in the meeting.

Dr. Trump asked if anyone had any questions. Hearing none, Dr. Trump introduced Peter Boswell to provide a review of House Bill 2316 (2015). Mr. Boswell noted that HB 2316 (2015) authorizes the Southwest Virginia Health Authority (the Authority) to receive and review applications for cooperative agreements and make recommendations to the Commissioner for approval of proposed cooperative agreements. For the purposes of the Authority, Southwest Virginia includes the Lenowisco and Cumberland Plateau Planning District Commissions and the Counties of Smyth and Washington, and the City of Bristol.

Mr. Boswell reviewed the definition of cooperative agreement within the bill. HB 2316 (2015) defines cooperative agreement as an agreement among two or more hospitals for the sharing, allocation, consolidation by merger, or other combination of assets, or referral of patients, personnel, instructional programs, support services, and facilities or medical, diagnostic, or laboratory facilities or procedures or other services traditionally offered by hospitals. Mr. Boswell stated that the bill authorizes the Authority to receive and review applications for proposed cooperative agreements submitted by two or more hospitals. Mr. Boswell observed that the Authority will review applications to determine if they are complete and, if needed, the Authority will notify the applicants in writing of additional items required to complete the application.

Mr. Boswell stated that applicants must provide copies of complete applications to the Commissioner and the Office of the Attorney General at the same time that they are submitted to the Authority. Mr. Boswell further elaborated that, after reviewing complete applications, the Authority provides recommendations to the Commissioner regarding the approval of cooperative agreement applications. The Authority shall recommend that the Commissioner approve a cooperative agreement if it determines that the benefits likely to result from the proposed cooperative agreement outweigh the disadvantages likely to result from the reduction in competition from the proposed cooperative agreement.

At that point, Mr. Boswell reviewed the Commissioner's authority under the bill. He stated that if after reviewing the recommendation from the Authority; any additional information provided or sought; the application for a cooperative agreement and after consulting with the Attorney General the Commissioner finds that the likely benefits of the requested cooperative agreement outweigh the likely disadvantages as specified in the Code of Virginia, the Commissioner shall approve the cooperative agreement. The Commissioner may reasonably condition the approval of the cooperative agreement on commitments to improve population health, access to services, quality and cost efficiencies.

Mr. Boswell also noted that the Commissioner is entrusted with actively and continuously supervising any cooperative agreement to ensure compliance with its provisions. If she has reason to believe that compliance with a cooperative agreement no longer meets certain requirements, the Commissioner will initiate a proceeding to determine if the cooperative agreement is out of compliance. In the course of such a proceeding, the Commissioner is authorized to seek reasonable modifications to the cooperative agreement with consent of the parties to the agreement, in order to ensure that it continues to meet the requirements of the Code of Virginia. The Commissioner is authorized to revoke a cooperative agreement upon a finding that: 1) the parities to the agreement are not complying with its terms or the conditions of approval; 2) the agreement is not in substantial compliance with the terms of the application or the conditions of approval; 3) the benefits resulting from the approved agreement no longer outweigh the disadvantages; 4) The Commissioner's approval was obtained as a result of misrepresentation; or 5) the parties to the agreement have failed to pay any required fee.

Mr. Boswell remarked that activities conducted pursuant to cooperative agreements approved and supervised by the Commissioner are immunized from challenges or scrutiny under state antitrust laws. The bill also states that it is the intention of the General Assembly that the bill also

immunizes cooperative agreements approved and supervised by the Commissioner from challenge or scrutiny under federal antitrust law.

Next, Mr. Boswell reviewed the requirement of the bill that the Board of Health promulgate emergency regulations. The bill requires that the emergency regulations address: 1) the review of applications for proposed cooperative agreements; 2) the process by which applications for proposed cooperative agreements shall be approved or denied; 3) post-approval monitoring; and 4) fees to cover costs of supervising an approved cooperative agreement. The regulations are to be effective 280 days from enactment of the amendment to the Code, which is January 20, 2016. Emergency regulations are effective for up to a year. The promulgation of emergency regulations follows a five step process: 1) Development of regulatory language by VDH, which Mr. Boswell noted the Department is currently doing by convening regulatory advisory panels; 2) Executive Branch review, which includes review by the Office of the Attorney General, the Department of Planning and Budget, the Secretary and the Governor; 3) Notice to the Virginia Regulatory Town Hall; 4) Publication in the Virginia Register; and 5) Filing of a Notice of Intended Regulatory Action (NOIRA) to replace the emergency regulations with permanent regulations.

Finally, Mr. Boswell described the standard regulatory process in detail, which is a three step process: a NOIRA, a Proposed Stage and a Final Stage. Mr. Boswell noted that this process generally takes between 18 and 24 months.

Colin Drozdowski asked since the application does not yet exist can the regulatory advisory panel recommend what an application would look like and what elements would be needed to consider it complete. Mr. Bodin noted that determining what the application looks like and whether it is considered complete is the Authority's responsibility. Mr. Bodin noted that the Code of Virginia states that the Commissioner receives the completed application from the Authority but may request additional information from the applicants. Dr. Trump noted that the Code of Virginia is specific about the requirements of the Authority regarding the application but the regulatory advisory panel can provide recommendations about what additional types of information the Commissioner should consider. Dr. Trump noted that the purpose of the regulations is to explain what the regulator expects of the applicant; the regulations will inform the applicant but will not define the application. He further noted that if an application is submitted before the regulations are promulgated the Code requires that the application be considered. Should that occur, the application would be considered based on the language of the bill. Doug Gray noted that HB 2316 (2015) states, "the Commissioner may request from the applicants such supplemental information as the Commissioner deems necessary to the assessment of whether to approve the proposed cooperative agreement." Mr. Gray noted that this language is quite broad and the panel would have leeway in advising what type of information the Commissioner should consider.

Mr. Gray noted that the bill contains the language, "The Commissioner's decision to approve or deny an application shall constitute a case decision pursuant to the Virginia Administrative Process Act." He asked what this language signifies. Mr. Bodin stated that it means from an appeal standpoint the Administrative Process Act (APA) must be followed for an appeal of the Commissioner's decision, and the APA provides certain rights and parameters for judicial review of case decisions. Mr. Gray asked if this language conflicts with the timeline requirements of the

bill. Mr. Bodin stated the timeline requirements within the bill are the process for making a case decision, this language is related to the appeal of a case decision. Mr. Bodin provided other examples of case decisions, such as the Commissioner's decision regarding a certificate of public need.

Hearing no further questions, Dr. Trump introduced Ms. Puglisi. She stated that the draft regulatory language is in the packets in front of each panel member. Ms. Puglisi noted that the Office of Licensure (OLC) created this draft based on HB2316 (2015) and using the model of the certificate of public need regulations. The draft provided is intended to be a starting point, a tool for the panel to use for discussion. Ms. Puglisi stressed that the Department is particularly interested in the panel's suggestions regarding measures and metrics that will assist the Commissioner in making her decisions. Ms. Puglisi noted that the regulations will not attempt to regulate the Southwest Virginia Health Authority but will rather address the Commissioner's role and authority.

Mr. Gray asked if a timeline could be created so that the panel members can have a better understanding as to how these elements come together. He noted that it was stated that the Department hopes to have regulations to present to the September Board of Health meeting, but what would occur if an application comes forward prior to that? VDH staff addressed Mr. Gray's questions, stating that if an application were to be received prior to regulations being promulgated that the provisions of the bill would control. Ms. Puglisi offered to create a graphic of the timeframes within the bill as well as the Emergency regulatory process for the panel members. Mr. Hilbert and Dr. Trump clarified that the Board of Health will vote on the regulations placed before them at the September Board meeting. There were additional follow up questions regarding the timeline requirements within the bill. A panel member asked if any member of the public can see applications submitted. Mr. Bodin noted that should an application contain proprietary information that is required to remain confidential the applicant is required to submit both a redacted and un-redacted copy of the application. The redacted copy it to be used for release to the public.

With no further questions, Ms. Puglisi suggested that the panel review the draft regulations section by section and provide suggestions. Mr. Bodin again stressed that the draft has taken the Code language present in the bill and put it into regulatory context, utilizing the certificate of public need regulations as a guide. Rick Shinn and Mr. Gray both expressed concern regarding a legal review of the regulations before they are promulgated. Both Mr. Bodin and Mr. Hilbert noted that it is standard practice for the Attorney General's Office to review the regulatory language informally before it is presented to the Board of Health, and formally after the Board of Health votes on the regulatory action.

Chris Bailey suggested rather than going through the regulatory language step by step perhaps it would be best for the panel to tackle the measures and metrics by which the Commissioner makes a decision. He stated that he believes providing suggestions regarding criteria would be the manner in which the panel could be the most helpful. Mr. Shinn noted that this is the first time that the panel has had an opportunity to review the draft and asked VDH staff if the regulations accurately reflect what is in the bill, or if there is any language the panel need be aware of. Ms. Puglisi stated there is nothing within the draft that is not present in the bill.

Dr. Trump asked the panel if they would like to hear public comment before discussion. The panel affirmed. No individuals signed up for public comment and no one in the audience indicated they would like to make public comment.

Mr. Bailey provided a suggestion for framework. He stated that there is one concrete circumstance "in front of us" (referring to the merger between Wellmont and MSHA), however the panel is tasked with determining performance metrics, some of which are long term in nature and can be influenced by factors outside of the applicant's or the Commissioner's control. Mr. Bailey stated there is a need to strike a balance between laying out concrete measures and retaining a flexibility to address future applications. Also, there needs to be a discussion and determination as to whether a baseline is set, how progress is measured and how success is defined. What should be considered the optimum result? Finally, he stated that there would be value in ensuring that there is overlap or consistency of these measures with other health metrics; commonality would allow the measures to be used together in follow up studies.

Mr. Colin Drozdowski stated that Mr. Bailey makes a lot of sense, but stressed that what a "COPA" (certificate of public advantage) allows is effectively a monopoly. He stated creation of such monopolies also creates a set of circumstances which could possibly have decades of negative ramifications. He noted that although there is a need for flexibility it would be borderline irresponsible not to place a very tight leash on those who are provided a "COPA." He stated that once a certificate is issued and a monopoly created it cannot be undone rapidly. Mr. Bailey agreed that it is important to hold parties accountable to a higher level of expectation but the Department and the Commissioner need flexibility in the regulations in case of unforeseen events.

Mr. Shinn noted that applicants can't be held accountable for episodic outbreaks that are outside of the norm and stressed it would be wise to look into what is coming out of the State Innovation Model grant in terms of metrics, population health and how to measure effectively without penalizing an organization for elements outside of their control. He stated he is wary of the language of the bill regarding the classification of advantages. Mr. Bodin asked if it helps that the advantages listed within the bill are to be measured against the disadvantages. Mr. Bailey noted that the bill provides different elements to be measured in the advantages than in the disadvantages. He stated that it is hard to measure different metrics against each other.

Mr. Bailey suggested beginning with performance measures for the advantages. He stated that it is important to ensure a baseline, as the "relative to what" question is important when creating metrics. Both Mr. Drozdowski and Mr. Bailey stressed the importance of active and ongoing regulatory oversight.

Mr. Drozdowski noted that it is possible to normalize for the "unexpected shocks" Mr. Shinn expressed concern about earlier, such as disease outbreaks and other factors outside of the applicant's control. He stated actuaries do so every day, he stated it's not difficult as those "actuarial gymnastics" are done routinely. Mr. Drozdowski advised against utilizing charges as a metric, as they are not very accurate or reflective of costs. Mr. Gray noted an exception, it is

advisable to utilize charges to see the value of services applicants are giving away, as the charge reflects what the individual patient is being benefited.

Melody Counts noted that in terms of creating baseline and measuring progress, she would advise against utilizing the rest of the state of Virginia as a benchmark or comparison. She stated that southwest Virginia ranks the lowest in terms of health across the state, and it would be unreasonable to expect them to "shoot up" to the rest of the state. Mr. Drozdowski noted some improvement should be expected but agreed that "you can't flip a switch" and expect them to be performing at the same level. He stated that the level of improvement depends on the timeline. Mr. Gray stated that for this type of program ongoing monitoring would be necessary to ensure an actual benefit to the public. He stressed that such a program would require much more monitoring than occurs for the certificate of public need program.

Mr. Bailey asked if it would be at all possible to have individuals from the State Innovation Model grant join the panel for future meetings. It was noted that the regional health goals discussed within the bill are established by the Authority. Melody Counts noted that the Authority's current goals were established in 2011 and the Authority is in the process of updating them.

Mr. Gray posed the question, how do you establish the value of health care improvement? Mr. Drozdowski stated that he has experience with "COPA" and suggests that the application start on a macro level for the proposed benefits and a description of the rationale for the agreement. He recommends that the application also require a detailed description of how the applicants hope to achieve these benefits and what the applicant has done in the past to achieve those benefits. Further he suggests requiring the applicant describe why these benefits can only be achieved through the agreement, and how the applicant proposes monitoring, including benchmarks and retention of data. Mr. Drozdowski stressed the need for data and documents, as the process needs to be very structured and transparent for all parties. He stated that he is happy to submit specific examples subsequent to this meeting.

Mr. Gray suggested that in addition to consulting with the Attorney General's office, consulting with the federal trade commission should also be a part of the process. Mr. Gray noted that interested parties should be made aware of the draft regulations and provided opportunity for input. He expressed concern that they are not mentioned. He stated for transparency, when an application is received there needs to be a method for members of the community to participate, and they should be able to provide input at each step in the process. He stressed that employers are an interested and impacted party.

Mr. Gray also stated concern about access; he stated he's not sure that it is currently within the Code or in the regulations. Other members of the panel stated that access is noted in both the advantages and disadvantages to be considered in both the Code and the regulations. Mr. Gray said that he didn't believe that the language present addresses his concern. He stated if a provider can affect a health plan's ability to create a network, then the provider can affect that health plan's ability to provide to the community and the consumer. Mr. Drozdowski noted that the panel may have to contemplate some sort of "any willing payer clause" otherwise providers may be able to remove competition through purposeful action. A regulatory balance would prevent

payers from be precluded from contracting with the entity. Otherwise the hospital could create a cooperative monopoly that could eliminate competing payers. He posed the question, where would that leave the payer community? The consumer? What would it do to the affordability of health care?

Mr. Shinn noted that the issue Mr. Gray is discussing is irrelevant for those who are uninsured, which is a large segment of the southwest Virginia population. He stated that it is impossible to improve overall population health within the area without also improving access to charity care. He asked how the merging and expanding of hospitals will impact safety net providers. If those entities begin taking the insured patients away from safety net providers will that make safety net providers financially unstable? Mr. Shinn reiterated his concern that such a program will leave the uninsured and underinsured with reduced access to care.

Mr. Gray asked what the language "Preservation of hospital facilities in geographical proximity to the communities traditionally served by those facilities to ensure access to care" means. He asked if this language indicates that only one facility may close. Dr. Trump indicated that this language was pulled from the Code and is a good example of why the expertise of the panel is needed. Mr. Gray suggested utilizing an MCHIP (Managed Care Health Insurance Plan) metaphor within these regulations. He stated that MCHIP utilizes a formula related to distance and time in order to determine access to care. Mr. Bailey agreed.

Mr. Drozdowski suggested that there should also be clarification regarding price, charge and cost. Mr. Bailey stated one way to measure costs would be to look at trends in health plan premiums prior to and after the agreement takes effect. Mr. Bailey also stated that he does not agree with the "any willing payer" idea. He stated that providers shouldn't be required to say yes to every payer, that it should be sufficient if there is a reasonable amount of diversity through the lens of the consumer. Mr. Drozdowski disagreed. Mr. Gray asked if the two entities which are considering merging have ownership in a health plan or interest in health plan ownership. Dr. Trump and Mr. Bodin stated that VDH was not aware but would research the issue.

Dr. Trump suggested a ten minute break.

When the group reconvened, Dr. Trump noted that it is clear that things would not be resolved today. He suggested that the panel consider conditions to be placed on cooperative agreements, monitoring, and metrics for measuring advantages and disadvantages.

Dr. Trump noted that VDH sought representation from employers and small businesses from southwest Virginia for the panel but so far has been unsuccessful in getting representation. He asked the panel if they would see value in meeting in southwest Virginia.

Mr. Bodin asked how long the panel members would need to come up with proposals and ideas in a written vetted format. The panel suggested that they convene with their stakeholders, gather their suggestions, organize them in a written format, and submit them to the VDH OLC by July 24th. The panel also suggested meeting the first week of August. Following that meeting, the panel can meet the week of August 17th in southwest Virginia. Dr. Trump noted that Ms. Puglisi would be the point of contact and that all panel members should provide their suggestions and

availability to her. Ms. Puglisi noted that she would send an electronic version of the draft regulations to the panel members later that afternoon.

The panel adjourned.