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The Honorable William A. Hazel, Jr., M.D.
Secretary of Health & Human Resources
Commonwealth of Virginia
1111 E. Broad Street, Suite 4001
Richmond, VA 23219-1922

Dear Secretary Hazel:

I appreciate and have valued the opportunity to serve on the Certificate of Public Need ("COPN") Work Group that you have convened. I have found the Work Group's meetings to be both instructive and stimulating, resulting in some very meaningful dialogue. As of this point, the meetings have affirmed my opinion that the COPN program should remain in place as a matter of sound health policy for the state. I have yet to identify a burning platform that would call for repeal. What has become abundantly clear to me is that serious process reforms are needed at this time.

Much of the Work Group discussion to date has focused on ideological differences about certificate of need regulation and health care regulation more generally. Our Work Group meetings have clearly demonstrated that reasonable minds can disagree about the best approach to meeting the state's policy goals underlying the COPN program. However, the Pat Finnerty presentation provided at our first meeting recapping the 2000 plan for comprehensive deregulation of COPN in the context of addressing the underlying challenges confronting our health care delivery system are still very relevant today. Until these challenges are addressed, it is critical that the COPN program remains intact.

That being said, it clearly is not a perfect program and there is much that we can do to make sure that the COPN process itself is meeting the needs of the Commonwealth. This seems to be in direct alignment with the charge of our Work Group as directed by the General Assembly, in passing the legislation to create the Work Group. I am hopeful that the Work Group can focus its efforts on identifying meaningful process reforms and improvements.

In anticipation of preparing a draft report to the General Assembly, I would like to share my thoughts on process reforms that will have the potential to significantly improve COPN review while additionally addressing several concerns raised by Work Group members. These reforms focus primarily on the State Medical Facilities Plan ("SMFP"), application of charity care conditions on COPNs, and measures to streamline COPN review.

State Medical Facilities Plan

i. Enforce Statutory Review Requirements and Amend Statute to Require Review Every Year and Updates Every Two Years to be sure intended policy goals are being met

The Board of Health should ensure that the SMFP Task Force it appoints and convenes complies with Virginia Code Section 32.1-102.2:1, which requires periodic review and updating of the SMFP. It could require the SMFP Task Force to provide status updates to the Board of Health on a quarterly or biannual basis. Additionally, the statute should be amended to require the SMFP Task Force to review the SMFP every year and update or validate existing criteria at least every two years. The current requirement states the SMFP must be updated or validated at least every four years which is not often enough to stay abreast of changes in medical care facilities and services. The statute could also be amended to require the SMFP Task Force meet a certain number of times each year (*e.g.* quarterly) in order to ensure work on the SMFP progresses.

ii. Appoint a Third Party to Lead SMFP Task Force

The SMFP Task Force has traditionally been led by a DCOPN staff member. Given the small size of DCOPN's staff and DCOPN's current duties and responsibilities it is apparent that additional resources are required. Consideration should be given to having the technical work associated with developing the SMFP completed by a private firm with health planning expertise as is done in Michigan. Additionally, accountability for timely review and updates to the SMFP would be improved if the SMFP Task Force was to be led by an individual or group of individuals outside of DCOPN. Accordingly, oversight of review and updates to the SMFP should be assigned to a third party appointed by the Board of Health. The third party should be an individual or group of individuals with policy and health planning experience familiar with Virginia's COPN law and regulations. Such third party could develop a process, schedule, and expectations for completion of the SMFP review, with support provided by DCOPN staff or other technical experts assigned to revise the SMFP.

iii. Create a Robust SMFP that is More Objective and Data-Driven

The structure and content of the SMFP should be revised to make it more robust, objective, and data-driven. A SMFP with more specific definitions and formulas for determining need, utilization data, and service expansion requirements would help to minimize the amount of discretion required in DCOPN and Hearing Officer recommendations and Commissioner decisions. The current SMFP leaves room for interpretation and thus greater discretion and variation in the COPN review and decision making process. Outcomes such as these lead to some of the frustration with the process and confusion over the policy goals it is intended to meet.

Charity Care

i. Continue Application of Conditions

Because Virginia continues to have a large number of uninsured, particularly those at low-income levels, the need for the Commonwealth to ensure an adequate safety net continues to be necessary. Charity care conditions are one mechanism the Commonwealth currently has available to fulfill this policy goal. In light of this continuing need, charity care conditions should continue to be applied.

Furthermore, consideration should be given to whether there are other policy goals that could be addressed through COPN conditions. For example, to the extent policymakers are concerned that there is inadequate supply of primary care or specialist physicians accepting Medicaid patients, the statute and regulations could be modified to include the ability to condition an application on an agreement by the applicant to participate in Medicaid and accept Medicaid patients.

ii. Charity Care Reporting Guidelines Should be Revised to be Consistent with Industry Standards and Practices

The established procedures and definitions used to demonstrate compliance with conditions should be revised to be consistent with industry standards and practices. For example, DCOPN's guidance document defines "charity care" as "health care services delivered for which it was determined at the time of service provision that no payment was expected." As a practical matter, health care providers are more often than not unable to definitively ascertain at the time services are delivered whether or not payment should be expected and whether or not a patient is eligible for charity care. Health benefits information is often outdated or cannot be verified on a real-time basis and income levels and other information needed to determine eligibility under charity care policies may not be available or complete prior to the need to render services to the patient. In the instance of a hospital emergency department, the Emergency Medical Treatment and Active Labor Act (EMTALA) specifically prohibits a hospital from assessing a patient's ability to pay prior to offering a medical screening examination or stabilizing treatment.

Another example is that the definition of "indigent" is limited to a person whose gross annual family income is equal to or less than 200 percent FPL. However, many hospitals have charity care policies that provide financial assistance to patients above 200 percent FPL, some up to 400 percent FPL.

Charity care reporting guidelines also overlook bad debt and uncollectable amounts. These figures are on the rise at hospitals and physician offices, due in part to the increasing popularity of high-deductible insurance plans that have more significant out-of-pocket costs. In 2013, bad debt at Virginia hospitals and health systems totaled \$533 million. These amounts should be taken into account or factored in when assessing the amount of charity care provided by an applicant and compliance with charity care conditions.

The definition of “charity care” should be revised to be compatible with industry standard definitions and practices related to the provision of care to individuals without an ability to pay. To the extent possible, mechanisms for reporting charity care information should be consistent with or incorporated into mechanisms already in place for health care providers. Health care providers routinely report financial information through a variety of mechanisms, including requirements to electronically submit to Virginia Health Information (“VHI”) data on utilization for services reviewable under the COPN law pursuant to Va. Code § 32.1-276.5, as well as, reporting of efficiency and productivity information through the Efficiency and Productivity Information Collection System (EPICS) maintained by VHI pursuant to Va. Code § 32.1-276.7. Hospitals that have federal tax exempt status are required to file IRS Form 990, Schedule H, which requires classification of spending for charity care and bad debt, as well as how much of their activities should be considered as community benefit. These existing mechanisms may provide an alternative or streamlined approach for charity care reporting to reduce the need to maintain a separate process and set of definitions for COPN charity care reporting.

iii. *Increase Transparency in Application of Charity Care Conditions*

The methodology for determining application of charity care conditions should be set forth in regulation or sub-regulatory guidance. Facility-wide or system-wide conditions that streamline and simplify reporting and compliance should be applied where appropriate to avoid variations in how charity care conditions are applied and satisfied within a facility or system.

iv. *Improve Monitoring and Enforcement of Conditions*

Because charity care conditions play an important role in supporting the health care safety net, DCOPN should develop and maintain more timely information on compliance with charity care conditions. The availability of this information would allow DCOPN to more effectively monitor and enforce compliance and would also allow the Office of Licensure and Certification to incorporate this information into review of licensing applications. Current licensing regulations for hospitals require applications for initial licensure to include a statement of any COPN charity care conditions imposed on the applicant and renewals are conditioned upon demonstrating substantial compliance with such conditions as well as paying any civil penalties for failure to comply.¹ More timely information would also allow the state to better assess possible gaps in the health care safety net and improve the ability to enforce compliance, both of which are needed in order for the state to achieve the policy goal of making needed health care services available to low-income uninsured.

Streamlining COPN Review

As has been previously discussed in Work Group meetings, the COPN review process can be time consuming and resource-intensive for both the Commonwealth and COPN applicants. Looking at the various components of the COPN review process overall and

¹ Va. Code Ann. § 32.1-102.4; 12 Va. Admin. Code § 5-410-70(A)(6); 12 Va. Admin. Code § 5-410-70(B).

different mechanisms available under current law, it is evident that there are options available to streamline the process.

i. Consider Limiting Need for Public Hearing

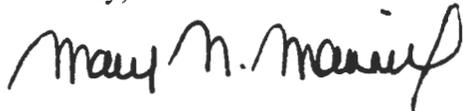
One option is to eliminate the public hearing for all but limited exceptional circumstances. Previous experience with these public hearings tells us that they are rarely attended by members of the general public, except for those that are attending at the request of the applicant, and thus often fail to meet their intended objective. In the process, staff preparation time, travel, and other expenses are incurred by the Department of Health as well as by the applicant. In addition, applicants often feel the need to have legal counsel present at the public hearings, which adds additional costs. There are other less time and resource consuming means of eliciting public comment that should be considered as an alternative.

ii. Make Greater Use of Expedited Review

Under current regulations, expedited review is currently only available for applications for certain capital expenditures by medical care facilities other than a general hospital or bed relocations between existing medical care facilities with a cost of \$5 million or less. 12 Va. Admin. Code § 5-220-280, *et seq.* For all other project types, a full COPN review is required. The Work Group should consider other project types for which the far less time consuming and resource-intensive expedited review process might be appropriate. This recognizes that a “one-size-fits-all” approach to COPN review is not the best use of resources and may create unnecessary barriers to development of needed health care services.

Thank you for the opportunity to comment on this matter of great importance to our health care delivery system in Virginia. I am confident that there is much we can do to make sure the COPN process produces the right results for all Virginians. I look forward to continuing to work with you in developing recommendations in response to the charge set forth by the General Assembly.

Sincerely,



Mary N. Mannix, FACHE
President & CEO, Augusta Health

cc: Eva Teig Hardy (via email only at evahardy1@gmail.com)