January 7, 2019

Ms. Linda Cole  
Chief, Long Term Care Policy & Planning  
Centers for Health Care Facilities and Services  
Maryland Health Care Commission  
4160 Patterson Avenue  
Baltimore, Maryland 21215-2299

Re: Proposed Regulations: December 7, 2018 Maryland Register  
State Health Plan for Facilities and Services: Comprehensive  
Care Facility Services: COMAR 10.24.20

Dear Ms. Cole:

Following are comments on the proposed comprehensive care facility services chapter (the "Chapter") to the State Health Plan, to be enacted at COMAR 10.24.20, published in the December 7, 2018 Maryland Register. These comments are offered on behalf of the Health Facilities Association of Maryland ("HFAM"), the largest association of providers of long-term care services in the State of Maryland. Our members provide services in nearly every jurisdiction within the State and are dedicated to the provision of quality, effective and compliant services to individuals with substantial clinical needs, as well as aged and disabled Marylanders.

We also request the opportunity to testify before the MHCC when this Chapter is considered for final adoption at a meeting.

We appreciate that the MHCC held meetings and circulated prior drafts of the Chapter, making some changes in the process. For example, including a path for CCFs to provide home health services, taking into account in the bed need methodology when there is a new facility added to the inventory, permitting an applicant to provide information about owner backgrounds to demonstrate why an application should be permitted, including an ability to explain designs that consider but vary from FGI standards and making other changes to earlier drafts.

There are a number of important issues that remain to be addressed. We urge that they be addressed before the Chapter is adopted.

Adoption of the Chapter is Premature

As HFAM has indicated to the Maryland Health Care Commission ("MHCC"), we question the decision to substantively amend the State Health Plan ("SHP") to establish this new Chapter separate from the submission of the report to the General Assembly on the modernization of the certificate of need ("CON") process generally. This is the only State Health Plan chapter that is undergoing such a concurrent revision.
An update of this new Chapter should proceed after the General Assembly has had the opportunity to receive, review and consider the MHCC report on the CON modernization process. This is not only important for comprehensive care facilities ("CCFs") in particular, but also in the context of how CCFs integrate within the full continuum of care, especially as we embark on the next agreement with the federal Centers for Medicare Medicaid Services ("CMS") under the total cost of care ("TCOC") model.

The Assumptions Stated in Support of the Proposed Chapter Are Flawed

For the reasons stated in these Comments, it is evident that assumptions stated in the preamble to the proposed Chapter are flawed. Specifically:

Under B (1) (Medicaid): The proposed Chapter does not support the State's overall policy direction for long term care services, particularly with respect to (a) its provisions permitting docketing CON applications in specific situations even though there is no CCF bed need under the SHP's established methodology and (b) maintaining a specific percentage within the Medicaid Memorandum of Understanding ("MOU"). The stated assumption fails to advise that in public meetings the MHCC convened to develop the Proposed Chapter the Medical Assistance ("Medicaid") Program representative did not support these elements of the Proposed Chapter. Yet, the MHCC asserts that there should be an assumption of positive benefit to the Medicaid program.

Under D, i.e. impact on trade associations, it is particularly puzzling and distressing that the Proposed Chapter wrongly claims an assumption of positive effect on HFAM and LifeSpan Network when, in multiple letters and comments in MHCC meetings representatives of both associations strongly opposed elements of the Proposed Chapter. While the Proposed Chapter is, as stated, "clear" in its provisions, it is "clearly wrong."

Under F, the Proposed Chapter relies on an assumption based on its use of a bed need methodology, while failing to mention that the Proposed Chapter permits the MHCC to ignore that methodology in ways that harm, and stifle innovation, among existing CCFs and the health care delivery system. Here too, the Proposed Chapter touts in this assumption the use of the MOU mandate "so that persons relying on Medicaid also have access to nursing home services" notwithstanding the MHCC's own data that there is no such access problem.

We challenge the statement in the Preamble that the proposed action has no or minimal impact on small business. This is directly contradicted by the statement in the same preamble that the Proposed Chapter will have a Moderate impact on regulated CCFs. As supported by these comments, the impact of the Chapter will be negative and substantial, jeopardizing existing CCFs.

COMAR 10.24.20.03: Certain Standard Exceptions

As a related, general comment there should be an overall provision indicating that where a specific standard would otherwise apply to an applicant for a CON, the applicant should be able to demonstrate why that standard should not apply in its particular situation.
**Medicaid MOU**

Under COMAR 10.24.20.03(B)(2) titled "Consumer Choice," there is an express statement that expanding consumer choice is more than a question of geographic access and the CCF chapter has long required a certain level of Medicaid participation. However, there is no statement of justification in the Chapter for maintaining this requirement.

We also question why the MHCC is continuing to include the MOU percentage requirement when the Maryland Department of Health Medical Assistance Program ("Medicaid Program") earlier briefed the MHCC Task Force considering the Chapter that the Medicaid Program believes the MOU should be maintained but without an identified percentage. (The Medicaid Program also took a position on the MHCC waiving docketing standards to approve a CON to permit the creation of additional capacity without a bed need, discussed below.)

We question why the Medicaid memorandum of understanding ("MOU") requirement, particularly with a mandated percentage, is maintained. No data have been presented that demonstrate Medicaid beneficiaries lack the ability to obtain placement in a Maryland CCF. There are past examples of earlier MHCC policy initiatives that outlived their usefulness. For example, formerly, the CON process provided additional beds for CCFs accepting mental health patients discharged from state psychiatric hospitals. There was also specific bed need categories for CCFs providing services to individuals with AIDS. These initiatives are no longer necessary. Similarly, the MOU requirement with a mandated percentage should be eliminated in light of the current availability of access for Medicaid beneficiaries.

Not only is the MOU requirement maintained but the formula has been made materially more complex and confusing. If there is to be any discussion about maintaining a MOU requirement, there should be public discussion and "walk-through" of the calculation of the formula that includes what percentages would likely result from it. Of course, this is not necessary if the MOU requirement would be removed.

**Issues with CMS Five-Star Ranking System**

COMAR 10.24.20.03(B)(3) Policy 3.1 states MHCC will incorporate "specific quality metrics" from CMS Nursing Home Compare into its standards and rules for CON review of CCFs. It does not explain any basis or justification for this use of Nursing Home Compare as compared to other metrics. Through the MHCC's modernization task force discussions there has been a robust dialog about problems with the CMS Five-Star ranking system, but rather than recognizing those concerns and addressing them, the MHCC would go in the opposite direction and build into the Chapter particular reliance on the CMS Five-Star ranking system. Not only is this done generally but there are specific examples that are particularly troublesome. If the Five-Star ranking system is to be used, this information should simply be considered along with other appropriate quality information that is provided by an applicant. For example, there have been CMS freezes on updates to the Five-Star ranking system and changes in the scoring categories that have caused Five-Star rankings to generally drop because of the adoption of new definitions by CMS. We would be happy to provide a separate technical paper with additional concerns about the Five-Star ranking. The general comment from our perspective is that use of this standard as articulated in the Chapter in multiple places is inappropriate.
COMAR 10.24.20.04: CCF Docketing Rules

With respect to the procedural rules under COMAR 10.24.20.04 there are, under Subsection A, various "docketing" rules. We wish to express our concern about the adherence of these provisions, permitting the docketing of applications notwithstanding an express finding that there is no need for them, with the MHCC's underlying statutory mandate and authority.

Docking of Applications for Additional Bed Capacity: Existing Facility: Five Star Ranking: COMAR 10.24.20.04B(1)(a), requiring an existing CCF seeking additional bed capacity to have a specific Five-Star ranking over an average of "refreshes" should permit the facility to demonstrate why this should be a barrier to docketing. A simple average may not be an accurate reflection of the facility's operation. Changes in owner or operator may have occurred. The application may be part of a plan to improve quality and the applicant should be able to demonstrate this in an application.

Docking of Applications Despite the Absence of Bed Need: Five-Star Rankings: We object to COMAR 10.24.20.04B(1), permitting the docketing of application proposing the addition of CCF bed capacity in a jurisdiction without an identified need for additional beds based on a percentage of facilities in a jurisdiction with fewer than three stars on a Five-Star ranking. We acknowledge the use of five quarterly refreshes for which CMS data is reported. The provision does not, for example, take into account that CMS periodically changes the Five-Star rankings in a way that lowers rankings across the board for all facilities. An otherwise high quality CCF can experience a material drop in Five-Star ranking due to one incident that scores at the J through L level even with no actual harm to any resident.

Most important, lower Five-Star rankings may be the result of actions or operations by a former owner. Thus, a new owner or operator prepared to invest substantially in improving an existing CCF may well be dissuaded from doing so due to the risk of a new, competing project in a small market for which there is no need per the MHCC's own findings. A current owner or operator would be penalized by the docking of a new project proposing additional CCF bed capacity even in the absence of bed need notwithstanding new owner or operator investments and improvements in existing facility.

The provision of the Chapter discriminates against existing CCFs in more rural jurisdictions. There are multiple counties in Maryland in which there are only two CCFs, particularly on the Eastern Shore, so that the provision in the Chapter opens the door to docketing of an application for which there is no need based on the Five-Star performance of only one or two facilities rather than fostering improvements in such existing facilities.

Here too, at a meeting of the MHCC Task Force the Medicaid Program opposed the MHCC waiving docketing standards to approve a CON to permit the creation of additional capacity without a bed need.

Docking of Applications Despite the Absence of Bed Need: Hospital Agreement: HFAM objects to COMAR 10.24.08.04B (2), that would permit docketing of an application to add CCF bed capacity in the absence of identified bed need based on a hospital agreement, a Health Service Cost Review Commission ("HSCRC") process relating to the TCOC model and other factors. We are concerned that there are no corollary regulations proposed by the HSCRC outlining the process by which that agency would review and approve such an arrangement.
Existing CCFs are already innovating and adapting to support the TCOC model, at great effort involving training, expense and other resources. This may include an agreement with one or more hospitals, but these positive efforts are not dependent on such a contractual relationship. Yet, the Chapter provision opens the door to applications for which there is no need without any consideration of these existing efforts.

Moreover, the introduction of such new bed capacity for which there is no need, specifically linked to a hospital agreement jeopardizes the principal source of CCF admissions to existing facilities, which are hospital discharges. Funneling admissions to a facility for which there is no need, diverting such admissions and revenues (particularly those dependent on Medicare reimbursement) from existing facilities, risks substantial harm in ways that have jeopardize resources on which such facilities depend to maintain services, enhance quality, and adapt to the TCOC model. Precisely at the time when CCFs need to adapt to the new Medicare Patient Driven Payment Model reimbursement system for skilled nursing facilities, the MHCC proposes to introduce harmful disruption by docketing applications for CCF capacity for which there is no need in ways that will divert essential Medicare admissions and revenues from existing facilities.

In the MHCC process leading to the development of the Chapter HFAM proposed additional language to address these concerns that would assure the MHCC that, before docketing such an application, there would be a demonstration of prior hospital efforts to contract with existing providers. There was even a discussion at one such meeting that would assure such a requirement is part of the process. Yet, none of this language or assurance is included in the Chapter.

There has been no discussion of any process by which such additional facilities would be provided. If this is being considered in the context of the total cost of care agreement with CMS, this should occur more broadly as it relates to all CCFs and not give preference to building additional new buildings based on an agreement with the HSCRC. This provision should not be included. Rather, additional discussion is essential.

While it is important to mention that the Maryland Hospital Association (MHA) has not commented on the CCF Chapter recommendations, I would point out that MHA in its December 14 public comment letter on CON modernization, did not support MHCC’s recommendation to waive CON requirements for capital projects endorsed by the HSCRC, including alternative models for post-acute care.

We would also point out that staff leaders from the Maryland Department of Health earlier briefed the MHCC Task Force in agreement with our positions, opposing creating new capacity absent need, and to include the MOU but without an identified target.

As noted above, at a meeting of the MHCC Task Force the Medicaid Program opposed the MHCC waiving docketing standards to approve a CON to permit the creation of additional capacity without a bed need. Yet, the provision is maintained.
Authorizing Waiver Beds

COMAR 10.24.20.04D(2)(c), establishing a one-year rule for licensure of waiver beds is restrictive in a very problematic way. A bed addition that includes waiver beds may be delayed for legitimate reasons. Construction may take longer than a year for zoning, permits, bids, weather considerations and other valid factors. There is no valid reason for such waiver beds to be jeopardized in mid-implementation due to a fixed one-year period, coupled with a two-year "lock out." Where development is initiated it should be permitted to continue. Executive Director extensions should also be permitted. Moreover, if waiver beds are requested but not implemented, there is no stated, valid rationale for a two year "lock out" for two additional years. This is inconsistent with the underlying statutory provision supporting the waiver beds, i.e. if waiver beds are not used, the statute permits the addition of the beds without a new two-year period being established.

The MHCC should return to approving "fractional" waiver beds by rounding up in the calculation as it did for many years. Waiver beds should be permitted to be added in pieces during a particular two-year period.

There is no basis stated for the provision in COMAR 10.24.20.04C(2)(d) indicating that the facility that has beds in the inventory as of the effective date of the regulations that were authorized more than a year before will be considered null and void. The specific beds that the MHCC is seeking to eliminate should be identified and this should be discussed before beds be taken away with broad, general language such as this.

CCF Acquisitions

The entire process in the Chapter pertaining to the acquisition of a CCF should be reevaluated. This should include a discussion of the MHCC's form that is currently required which seeks information which is not relevant under the underlying CON law. The thrust of the MHCC's CON modernization process is, to a substantial degree, to make the process more efficient. For example, under COMAR 10.24.08.04D (1), information about each person with an ownership interest of any amount, even though there is a 5% threshold used by CMS for similar purposes. Also, there is no articulated basis for explaining why, under COMAR 10.24.20.04D(2)(b), purchase price needs to be disclosed. Neither is there any explanation of why "market share" calculations must be provided. This is an example of the MHCC mandating disclosure and review of information in the acquisition process over which the MHCC has no authority to regulate.

There is a requirement for commitment to Medicaid participation in the acquisition process. This was discussed above in the context of Medicaid MOU requirements. No basis for mandating Medicaid participation has been articulated.

COMAR 10.24.20.05: Standards

Medicaid MOU

Above, we demonstrated why the MOU, or at least the MOU percentage, should be eliminated or reduced. Under COMAR 10.24.20.05A a consistent change should be made to eliminate or modify this requirement.
FGI Guidelines

In some, but not all, places the Chapter identifies where a reference to FGI standards is required coupled with an applicant’s ability to demonstrate why adherence was not used in the design. This should be done in all places where an FGI reference is included, such as under COMAR 10.24.20.05A(5)(d) under specialized unit design. We suggest a general statement be used in the Chapter to state that there can be justification of why FGI guidelines where not used in any place where there is such a reference.

Quality Rating System

The "quality rating" section under COMAR 10.24.20.05A(8)(b) is flawed. It requires applicants to document Five-Star compliance as a condition of CON approval. Here, again, the MHCC should simply be taking Five-Star information into account along with other quality metrics developed by the MHCC with interaction with stakeholders. Only the Five-Star ranking of the individual facility should be considered. An individual CCF should not be penalized by denying a CON opportunity due to the performance of other CCFs. This should not be a docketing standard, even if it is retained as a factor in the CON review. In a CON review, it may be relevant to take into account relevant factors such as the degree of responsibility of the current operator for the current Five-Star ranking as well as other efforts under way to demonstrate quality.

Similarly, COMAR 10.24.20.05A(8)(c) would require applicants to "demonstrate" adherence to a quality assurance plan that is already consistent with OHCQ requirements. It should be sufficient for the applicant to commit to complying with applicable federal and state licensing and certification laws governing quality assurance program. It is an improper use of the CON process to require that an applicant "demonstrate" that it has "an effective quality assurance program" in every comprehensive care facility owned or operated by the applicant. The MHCC should identify why this is not a duplication of existing OHCQ authority and whether the MHCC has the infrastructure and capabilities to evaluate that an applicant has sufficiently demonstrated compliance with this requirement to the licensing agency.

We suggest that the MHCC restore to the Chapter language, present in prior working drafts, that permit an existing facility engaged in a capital project that will improve conditions in the facility to be able to include "shell space."

COMAR 10.24.20.06: Calculating CCF Bed Need

Under COMAR 10.24.20.06C (2), the first bed need calculation should run for seven years until 2022 and then five years thereafter.

MHCC does not explain under COMAR 10.24.20.06(G)(2) why it is relying on Minimum Data Set data even though the MHCC does its own survey. No explanation is offered as to why the MHCC is not using its own data.

There is also a problematic provision, under COMAR 10.24.20.06(H)(8), in step 7 of the calculation of occupancy in the bed need calculation. At step 7 it states that if a positive bed need projection is identified but the jurisdictional occupancy for the most recent 24-month period is below 90% of the bed need, it is
adjusted to zero. This is not an arithmetic calculation. Rather, it is a policy statement. There should be an ability of an applicant to demonstrate why it should not apply. Low occupancy may be affected by a physical plant or other factors that should be taken into account. It should not change an arithmetic calculation based on occupancy. Similarly, applicants proposing capital projects that will not add capacity but will add beds to an existing facility by the relocation of existing facilities should not need to meet a 90% occupancy standard. Moreover, the existing language in the comparable chapter should be restored which permits an applicant to demonstrate why the standard should not be imposed.

The calculation of errors is addressed under COMAR 10.24.20.06(J)(3). There may be additional errors other than the ones articulated in the current language. Any errors should be capable of correction.

Thank you for the opportunity to provide these comments. We would appreciate the opportunity to discuss them in person. We urge that the chapter not be adopted in its current form and that there be specific detailed discussions in a meeting of stakeholders about the need to make these changes.

Sincerely,

Joseph DeMattos
President and CEO

cc: The Honorable Lawrence J. Hogan, Jr., Governor of Maryland
The Honorable Robert R. Neall, Secretary, Maryland Department of Health
The Honorable Thomas V. Miller, President, Maryland Senate
The Honorable Delores G. Kelley, Chair, Senate Finance Committee
The Honorable Michael E. Busch, Speaker, Maryland House of Delegates
The Honorable Shane Pendergrass, Chair, Health and Government Operations Committee
Howard L. Sollins, Esq., Baker Donelson
HFAM Board