July 13, 2018

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: Draft Regulations for Informal Public Comment:  
State Health Plan for Facilities and Services: Comprehensive Care Facility Services: COMAR 10.24.20

Dear Ms. Cole:

Thank you for the opportunity to provide comments on the working draft of the proposed comprehensive care facility services chapter (the "Chapter") to the State Health Plan, to be enacted at COMAR 10.24.20. These comments are offered on behalf of the Health Facilities Association of Maryland, the largest association of providers of post-acute and long-term care services in the state of Maryland.

Together our members care for Marylanders in need every day providing 5.7 million of the total 9 million days annually across all payer sources in Maryland. Our members provide services in nearly every jurisdiction within the state.

We value our partnership in this important work. We are committed to working with you to ensure that quality long-term and post-acute care continues to be available from our providers to Marylanders and their families. That said, we have serious concerns about the Draft Regulations, State Health Plan for Facilities and Services: Comprehensive Care Facility Services: COMAR 10.24.20. Those concerns are chronicled here in detail with the desire for our collectively getting this important work accomplished.

As a general comment, we question why there is an update to the Chapter that is proceeding concurrently with separate ongoing discussions of modernization of the certificate of need ("CON") process generally.

This is the only State Health Plan chapter that is undergoing such a concurrent revision. We believe that a revision to the Chapter is most appropriate after the modernization process has been completed. 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. This is especially important as we are embarking on the next agreement with the federal Centers for Medicare and Medicaid Services ("CMS") under the total cost of care model.
As a related general observation, the general thrust and approach in the chapter appears, in many respects, to contradict the overall approach articulated by the task force undertaking modernization of the CON process. The modernization task force has indicated that one of the goals of that process should be, for example, avoidance of duplication of activities and authority of other government agencies. Yet, there are multiple instances in which the Chapter would have an applicant for CON review be required to demonstrate to the satisfaction of the Maryland Health Care Commission ("MHCC") adherence to the regulations of other agencies, versus simply attesting to their commitment to comply with the regulations of other agencies.

**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.

A specific example of where a simple pledge of compliance with the applicable requirements of another agency should suffice without a separate "demonstration" of such compliance to the satisfaction of the MHCC concerns the application of FGI Guidelines for design and construction of residential health care and support facilities. For example, under the "Issues and Policies" section under COMAR 10.24.20.3 there is, under subsection B, the series of statements of issues and policies including adherence to FGI Guidelines. Adherence to FGI Guidelines is necessary to obtain a license from the Office of Health Care Quality ("OHCQ"). It should be sufficient for an applicant to attest to its commitment to comply with licensing standards rather than a separate demonstration requirement being established under the CON regulations. We do not refer to every example in which FGI Guidelines are referenced in the chapter but our comment applies in each such instance.

Moreover, the Chapter requires adherence to the quote "latest" FGI Guidelines even though existing facilities that may seek to apply for a CON may only be required to adhere to earlier applicable versions of such regulatory requirements. The adherence to FGI Guidelines that should be required should refer to the guidelines that apply to the specific facility and not set an additional standard. This concern is also reflected in Policy 1.1 under COMAR 10.24.20.03(B)(1).

**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 question why the Medicaid memorandum of understanding ("MOU") requirement is maintained. No data have been presented that demonstrates 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 should be eliminated in light of the current availability of access to 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.

Moreover, under Policy 2.2, existing language in the current CCF chapter at COMAR 10.24.08 includes language that enables a CCF to renegotiate its MOU at the most recently published participation rate. No explanation or justification for removing this relief and "safety valve" has been articulated.

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

COMAR 10.24.20.03(B)(3) Policy 3.1 states MHCC will incorporate "specific quality metrics" for 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 discussion about problems with the CMS five-star ranking system, but rather than recognizing those concerns and addressing them in the chapter, the chapter would go in the opposite direction and build into the chapter heavy reliance almost exclusively on the 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, it should simply be noted that this information should be available, as measured over a two-year period, not simply based on a particular quarter's data. Moreover, the five-star ranking information should simply be considered along with other appropriate quality information that is provided by an applicant; for example, there have been CMS freeze on updates to the five-star ranking system. There have been 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.

One specific example concerns opening the door to bed need when a certain number of facilities in a particular jurisdiction have, in one quarter, a five-star ranking system level at one or two stars. There are multiple jurisdictions in Maryland with only two nursing facilities. Also, facilities with five-star ranking systems can make strong commitments to improve their scoring. Sometimes CCFs have a long history of strong rankings but face a drop due to a specific incident that is readily addressed. Yet, the MHCC's approach is to open the door to additional facilities without any bed need being demonstrated.

**COMAR 10.24.20.4: CCF Docketing Rules**

With respect to the procedural rules under COMAR 10.24.20.4 there are, under Subsection A, various "docketing" rules. One restricts docketing an application that would involve the increase in bed capacity absent an identified bed need. We suggest that the chapter include provisions that permit an existing facility engaged in a capital project that will improve conditions in the facility to be able to include both "shell space" that is supported by a net present value analysis, as well as to accommodate available "waiver beds" in newly constructed space. This would benefit facilities undertaking capital projects that will improve conditions for residents throughout the facility.
We have serious concerns about section COMAR 10.24.20.4(A)(2)(a)(i). First the MHCC proposes that the chapter prohibit docketing an application that would be based on a finding regarding sanctions imposed on a current or former owner or senior manager of the facility or operator of the management company of any related or affiliated entity within the last 10 years. This is highly problematic. There may well be situations in which an individual is a former owner of any of these entities and is no longer involved in it. The involvement of a currently unrelated individual would seem to prohibit docketing an application being sought by the existing entity. This runs the risk of a CON application not being permitted that will improve quality of care based on something over which the current owner has no control. Moreover, the vague and broad references to senior managers, any former owner no matter how small the ownership interest might have been, related or affiliated entities is overly broad. There is no discussion in the chapter about why this stricter standard is required or how the current chapter is problematic.

Moreover, there is reference to something called a "best interest plea of guilty." There is no citation or definition provided. We suspect it refers to what is called an "Alford Plea" but this is unclear.

There's some highly problematic "Docketing Rule Exceptions" under COMAR 10.24.20.4(B). These should be the subject of substantial discussion if not elimination. This includes for example, the MHCC docketing an application based on existing facility five-star rankings. Often, lower five-star rankings may be the result of actions or operations by a former owner. Yet, the current owner or operator would be penalized by the approval of a new project even in the absence of bed need notwithstanding investments and improvements in the existing facility. Moreover, there are multiple counties in Maryland, particularly on the Eastern Shore, in which there are only two CCFs.

HFAM objects to the provision that would permit a facility to be constructed without any identified bed need based on a Health Service Cost Review Commission ("HSCRC") process. There's 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.

Authorizing Waiver Beds

We have serious reservations about the statement that MHCC would not authorize waiver beds for a facility that has patient rooms with "two or more" beds unless the facility agrees to eliminate or reduce to the maximum extent possible the number of multi-bed rooms. This current provision wrongly suggests that semi-private rooms are disfavored by the MHCC and that waiver beds are only going to be granted unless the entire facility is moving to private rooms to the maximum extent possible. This is a major change in policy. The provision should be changed to "three or more" beds.

Under COMAR 10.24.20.4(B)(2)(d) there is a restriction based on the addition of beds more than one year before the effective date of the regulations. This should be explained if not eliminated. The chapter should make clear that, as permitted by statute, a CCF can add the lesser of 10 beds or 10% in the form of waiver beds. 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's no basis stated for the provision in the Chapter 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 should 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 that is not relevant under the underlying CON law. For example, there is no articulated basis for explaining why purchase price needs to be disclosed. Neither is there any explanation of why "market share" calculations must be provided.

This is another example in which the MHCC is seeking to duplicate an overlapping process with another agency. The licensing provisions under state law, as well as the federal certification rules, are enforced by OHCC. Yet, without articulating why the present CON process is not functioning well, the MHCC seeks to establish its own "vetting" process for acquisitions of healthcare facilities. It is seeking explanation for highly restrictive requirements on who can acquire a CCF. This includes obtaining information beyond the 5% percentage ownership interest that is already established by the OHCC. There is vague language about including the identity of persons in an acquiring entity or "related or affiliated entity" including equally vague language about the "history" of each such person's "experience and ownership and operation" of "healthcare facilities." There's no reliable way to undertake this process; furthermore, it overlaps with the OHCC's process.

There's 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.

There's also a reference, again, to a "best interests pleaded guilty" without definition. The language also includes a statement that a CCF may not be acquired by any entity with an owner or member of senior management meeting certain language.

**CCF Construction & Design**

The MHCC also indicates under COMAR 10.24.20.5(A)(4)(a)(iv) regarding how a design will provide a cluster/neighborhood design or a connected household design. This establishes a process under which the MHCC will dictate how nursing homes should be designed as opposed to simply requiring that licensing requirements be met. Information about design may be relevant but the MHCC is not in a position to establish how nursing homes should be designed.

Similarly, there is a separate section COMAR 10.24.20.5(A)(4)(b) that would require an applicant to eliminate any resident rooms where more than two residents share a toilet rather than reduce the number of rooms. This may simply be infeasible in an existing facility. It is another example in which the MHCC should be simply obtaining a commitment to meet licensing and certification requirements as opposed to requiring applicants to demonstrate how they will design facilities in ways that the MHCC has identified.
**Quality Rating System**

The "quality rating" section under COMAR 10.24.20.5(A)(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, where the five-star information is viewed over a two-year period, taking into account other 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. An isolated, sporadic incident can cause a dramatic drop in five-star ranking systems. These incidents do not necessarily reflect any negative overall quality. This information is not taken into account at all in the MHCC's chapter.

Similarly, the chapter would require applicants to "demonstrate" adherence to a quality assurance plan that is already consistent with OHCQ requirements. Why isn't it sufficient for the applicant to commit to complying with applicable federal and state licensing and certification laws governing quality assurance programs? 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.

In terms of collaborative relationships, the list of possible relationships should be linked by "or" and not "and" so the applicant does not have to have the entire range of collaborative relationships. Moreover, there is a requirement that applicants will be required to demonstrate that it is meeting a commitment to effective collaboration with hospitals. However, there are no standards, guidelines or other measures that would be used to substantiate the effectiveness of those efforts as measured by the MHCC.

**COMAR 10.24.20.05: Shell Space**

With respect to shell space, referenced in COMAR 10.24.20.5(A) (10), the requirement should not be any stricter than they are for other health care facilities. Shell space that is more cost effective based on the net present value of construction should be permitted.

**COMAR 10.24.20.6: Calculating CCF Bed Need**

Significant work needs to be done on the bed need calculation under COMAR 10.24.20.6. The current provision is extremely complex. The MHCC should hold a special meeting to walk through a sample calculation identifying what a projected bed need projection should look like. This step-by-step public work session is important. The concern is not hypothetical. In an earlier certificate of need review in St. Mary's County, it was revealed that MHCC had been calculating bed need incorrectly for many years. Those using the bed need calculation should be able to replicate how it is being performed and MHCC has an obligation to demonstrate how this should be done.

We also note that Charlotte Hall was eliminated from the chapter in terms of being accorded special treatment under the bed need calculation. No explanation was offered. Moreover, MHCC eliminated existing language permitting small bed need increments in adjacent counties to be aggregated in one of those counties for bed need calculation purposes. No explanation for this change was offered. It was
simply eliminated. We also note that the community-based services adjustment has been eliminated.

The planning horizon needs to be changed. The Chapter proposes to use 2015 data but with a five-year planning horizon. This would mean that MHCC would be running the first bed need projection through 2020 which is a very short timeframe. The first bed need calculation should run for seven years until 2022 and then five years thereafter.

MHCC does not explain under COMAR 10.24.20.6(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 10.24.20.6(H) (10), in step 9 of the calculation of occupancy in the bed need calculation. At step 9 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. If it is a policy statement, then it should be separately articulated and 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 10.24.20.6(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 P. DeMattos
President and CEO

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