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VIA EMAIL

Ms. Eileen Fleck
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Chief for Specialized Services
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore MD 21215

Re: *Proposed Draft State Health Plan for Facilities and Service—*
Freestanding Medical Facilities, COMAR § 10.24.19
Informal Comments Submitted by the University of Maryland Medical System

Dear Ms. Fleck:

On behalf of the University of Maryland Medical System ("UMMS"), I write to provide informal comments on the proposed draft State Health Plan for Facilities and Services: Freestanding Medical Facilities (the "Draft Chapter"), which was presented for informal review and comment on June 23, 2016.

UMMS supports the Draft Chapter and urges the Commission to propose and adopt the Draft Chapter as a permanent regulation with the modifications discussed below.[1]

1. The Draft Chapter Should Recognize That FMFs Converting from Acute General Hospitals May Provide Medical Services in Addition to Emergency Services.

The primary concern with the Draft Chapter is that it fails to recognize that a freestanding medical facility ("FMF") established by Certificate of Need ("CON") exemption may provide outpatient services beyond emergency services and observation services. As explained below, this failure conflicts with the legislative intent of Senate Bill 707 and is inconsistent with existing law and sound public health policy. The oversight is surprising given that one of the main purposes of Senate Bill 707 was to authorize the Health Services Cost Review Commission ("HSCRC") to regulate FMF rates for outpatient services other than emergency services (the HSCRC was already authorized to regulate emergency services provided in an FMF).

[1] In addition to the substantive edits suggested below, there are a few typographical errors that we found while reviewing the Draft Chapter: (1) the last sentence of the first paragraph on page 15 ends in a comma rather than a period; and (2) the sentence at the top of page 19 appears to contain an extra space.

The Draft Chapter addresses: (1) newly established FMFs, which require a CON; and (2) FMFs that are created through the conversion of an existing acute general hospital, which require a CON exemption. The origin of each of these two types of facilities is different and the treatment of the facilities under the State Health Plan also should be different.

The part of the Draft Chapter concerning newly established FMFs (.04B) was required because the statutory moratorium on establishing new FMFs expired on July 1, 2015 and a State Health Plan chapter was needed to govern applications for new facilities. The part of the Draft Chapter relating to exempt FMFs (.04C) was needed to provide a new type of facility for the reconfiguration of existing acute general hospitals facing declining demand for inpatient services consistent with recently enacted statutory law (Senate Bill 707). Several Maryland acute general hospitals are exploring options to reconfigure and modernize services in the face of declining utilization for acute inpatient admissions and the need to provide high quality and effective care to the communities they serve. The CON exempt FMF was intended to provide these hospitals with a feasible and cost effective alternative to continuing emergency and other outpatient services in the affected community. Unfortunately, the CON exempt FMF described in the Draft Chapter does not provide hospitals such an alternative.

As noted in the Draft Chapter, the "limited service hospital" ("LSH") was another possible option for the conversion of an acute general hospital. Draft Chapter at 14. Under current law, an LSH must: (1) be licensed as a hospital on or after January 1, 1999; (2) change the type or scope of services offered by eliminating the capability to admit or retain individuals for overnight hospitalization; (3) retain an emergency or urgent care center; and (4) comply with applicable regulations. MD. CODE ANN., HEALTH-GEN. § 19-307(a)(1)(iv). No Maryland hospital has ever been converted to an LSH, perhaps because the HSCRC is not authorized to regulate rates in an LSH, except for emergency services. MD. CODE ANN., HEALTH-GEN § 19-201(d)(2)(ii). However, if a hospital chose to convert to an LSH, it could do so through a CON exemption process and retain all of its outpatient services. For example, under existing law, a hospital converting to an LSH would not need to obtain a CON to retain outpatient surgical capacity.

Rather than authorize the HSCRC to regulate outpatient services in an LSH, the Maryland General Assembly, in consultation with the Commission, elected to use the FMF as the preferred facility type for the conversion of acute general hospitals by: (1) authorizing a CON exemption process for conversion of an existing hospital to an FMF; and (2) authorizing the HSCRC to regulate rates for outpatient services in an FMF (the HSCRC was already authorized to regulate rates for emergency services). However, the Draft Chapter recognizes only the emergency services component of an FMF, and related observation service components of an FMF. As explained below, the existing statutes and regulations governing FMFs permit an FMF to provide "medical services," which includes a much broader range of services than simply emergency services and observation services.

We urge the Commission to permit an FMF created through the hospital conversion exemption to provide outpatient services in addition to emergency services, provided that such services were already being delivered in the converting hospital. A community affected by the conversion of a general hospital to an FMF often will require more than a mere satellite emergency department to meet its health care needs. For example, the affected community may need outpatient surgical services to replace the loss of

multiple operating rooms in the converting general hospital. Yet, under the Draft Chapter, and based on oral comments made by Commission staff in the June 22, 2016 workgroup meeting, the parent hospital of the FMF may need to apply for a CON to include surgical capacity as part of the exempt FMF.[2] This approach may make sense for a newly established FMF, which seeks only to extend the emergency services of a parent hospital into a new community.[3] But for a general hospital converting to an FMF, which seeks to preserve needed outpatient services in a community that is losing an acute general hospital, limiting the scope of the FMF to emergency services will create an unwarranted obstacle to meeting the community's health care needs and will add additional burden, expense, uncertainty, and delay for the applicant hospital.

A converting hospital should not be required to pursue multiple processes at once: a full CON review to retain outpatient services that existed in the hospital prior to conversion and an exemption process to convert the hospital to an FMF to continue its emergency services. The CON exempt FMF was intended to provide an attractive alternative for hospitals with declining demand for inpatient services a viable transition option that would allow the hospital to continue providing the services needed in the community. Draft Chapter at 15. The CON exempt FMF is much less attractive to such a hospital in a community that requires continued emergency and outpatient surgical services, when the hospital is required to expend significant resources to pursue both a CON exemption to continue providing emergency services and a separate CON to continue providing outpatient surgical services. The Commission should seek to foster reconfiguration of hospitals with insufficient demand for inpatient services.

The exemption process gives the Commission the ability to assess the need for outpatient services in an exempt FMF. To the extent the Commission concludes that a converting hospital seeks to retain unneeded outpatient services, the Commission may deny the requested exemption or condition the exemption on a more limited scope of services. Under existing law, and as set forth in the Draft Chapter, the Commission may exercise its "sole discretion" to deny a requested exemption if it finds that the exemption: (1) is not consistent with the State Health Plan; (2) will not result in more efficient and effective delivery of health care services; (3) will not maintain adequate and appropriate delivery of emergency care within the statewide emergency medical services system as determined by the State Emergency Medical Services Board; or (4) is not in the public interest. MD. CODE ANN., HEALTH-GEN § 19-120(o)(3)(i)(5); COMAR § 10.24.01.04E(2); Draft Chapter .04C(8).

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[2] We recognize that a single operating room may be established under a separate CON exemption procedure. However, in many cases, a single operating room will not meet the demand for surgical services in a community that was previously served by a general hospital with multiple operating rooms.

[3] UMMS takes no position on whether the outpatient services provided in a new FMF established through the full CON process should be limited to emergency services.

The General Assembly did not intend to limit the services in an exempt FMF to emergency services. The statutory definition of FMF contemplates the facility offering much broader services than just emergency services. By statute, an FMF is defined as a facility "in which medical and health services are provided." MD. CODE ANN., HEALTH-GEN § 19-3A-01(1). "Medical services" is defined by statute to mean any of a number of categories of services, including medicine, surgery, gynecology, and addictions. MD. CODE ANN., HEALTH-GEN § 19-120(a)(5). The statutes and regulations governing licensing of FMFs do not contain any limitations on FMFs providing these additional services.

Moreover, the recently enacted legislation contemplates that other "outpatient services" may be provided at FMFs and be rate-regulated by the HSCRC. Specifically, Senate Bill 707 amended MD. CODE ANN., HEALTH-GEN § 19-201 to expand the HSCRC's jurisdiction to cover "outpatient services" provided in an FMF established by certificate of need or through an exemption. Given that the HSCRC already has jurisdiction to regulate rates for "emergency services" provided at FMFs, the legislature's expansion of HSCRC's jurisdiction over "outpatient services" provided at FMFs demonstrates that the legislature intended that FMFs be permitted to provide outpatient services other than emergency services. Indeed, the Fiscal and Policy Note on Senate Bill 707, prepared by the Department of Legislative Services, accurately summarizes the scope of services that may be provided in an exempt FMF as follows:

> Under the bill, a licensed general hospital could elect to convert into a freestanding medical facility (without obtaining a CON from MHCC) rather than closing or partially closing. <u>In addition to ED and ED-related services, freestanding medical facilities established from the conversion of a licensed general hospital could also provide (and be paid HSCRC-regulated rates for) outpatient services and observation stays</u> (a stay generally lasting no more than 48 hours that is provided as an outpatient service to allow testing and medical evaluation of a patient's condition).

Senate Bill 707 Fiscal and Policy Note, p. 5 (underline added). As written, the Draft Chapter fails to honor and implement the intent of the General Assembly.

In sum, there exists neither a legal basis nor a public policy rationale for the Commission to limit the outpatient services that may be provided in an exempt FMF. Accordingly, the Commission should include language in the Draft Chapter to recognize that a CON exempt FMF is authorized to provide outpatient services other than emergency services. We suggest the following edits to the Draft Chapter to reflect that exempt FMFs are permitted to provide more than emergency and observation services:

a. <u>COMAR § 10.24.19.03</u>

1. Cost-Effectiveness and Efficiency of Care

We suggest adding the underlined language to the first sentence on page 12: "In some areas of the State, efficient and effective provision of emergent and urgent care, <u>and other outpatient services as may be designated by the HSCRC,</u> may involve development of an FMF as an alternative to a general hospital that has become too underutilized to be efficient, as the demand for hospitalization has declined."

2. Conversion of General Hospital Campuses to Outpatient Care Centers

We suggest adding the underlined language to the last sentence on page 15: "The FMF is a facility that can handle a substantial proportion of the demand for care currently provided at a typical hospital emergency room, or can provide other outpatient services needed by the community."

b. COMAR § 10.24.19.04C(7)

We suggest the following edits to §10.24.19.04C(7):

(7) (f) Demonstrate the need for operating room capacity consistent with COMAR 10.24.11.06;

(g)~~(f)~~ Provide utilization, revenue, and expense projections for the FMF, along with a comprehensive statement of the assumptions used to develop the projections, and demonstrate that:

(i) The utilization projections for emergency services are consistent with observed historic trends in ED use by the population in the FMF's projected service area;

(ii) The revenue estimates are consistent with utilization projections and the most recent HSCRC payment policies for FMFs;

(iii) The staffing assumptions and expense projections are based on current expenditure levels, utilization projections, and staffing levels experienced by the applicant hospital's ED and relevant outpatient services ~~with the recent experience of similar FMFs~~; and

(iv) Within three years of opening, the combined FMF and parent hospital will generate net positive operating income.

(h)~~(g)~~ Demonstrate that the proposed construction cost of the FMF is reasonable and consistent with current industry cost experience in Maryland, as provided in Regulation .04B(5) of this chapter.

(i)~~(h)~~ Demonstrate that the conversion to an FMF will result in the delivery of more efficient and effective health care services including an explanation of why the services proposed for the FMF cannot be provided at other area

hospitals ~~EDs~~ or FMFs and why other less expensive models of care delivery cannot meet the needs of the population to be served.

(j)~~(i)~~ Demonstrate that the conversion to an FMF will maintain adequate and appropriate delivery of emergency care within the statewide emergency medical services system, as determined by the State Emergency Medical Services Board, as documented by submission of this determination to the Maryland Health Care Commission.

(k)~~(j)~~ Demonstrate that the conversion is in the public interest, based on an assessment of the hospital's long-term viability as a general hospital through addressing such matters as:

(i) Trends in the hospital's inpatient utilization for the previous five years in the context of statewide trends;

(ii) The financial performance of the hospital over the past five years and in the context of the statewide financial performance of Maryland hospitals;

(iii) The age of the physical plant relative to other Maryland hospitals and the investment required to maintain and modernize the physical plant;

(iv) The availability of alternative sources for acute care inpatient and outpatient services that will no longer be provided on the campus after conversion to a freestanding medical facility; and

(v) The adequacy and appropriateness of the hospital's transition plan;

2. The Draft Chapter Should Provide a Specific Time Period for which Applicants Should Submit Financial Projections.

Section .04B(3)(a)(i) of the Draft Chapter, asks the applicant to "[d]etail the capital cost estimates and operational revenue and expense projections for its proposed FMF project, over a time period appropriate for evaluating cost effectiveness[.]" (underline added). The underlined portion of this standard is vague and does not provide sufficient guidance to determine an "appropriate" time period. The standard, as drafted, could result in applicants submitting cost projections for substantially different time periods.

We recommend revising the underlined portion of this standard to provide a specific time period for which applicants should submit projections. This would allow the Commission to more easily compare an application to previous FMF projects, by providing an "apples to apples" comparison for evaluating financial projections. Requiring applicants to submit projections for the construction period through three years after the date of the FMF's opening may be an appropriate time period for evaluating financial projections given that applicants are already required to demonstrate in Sections .04B(6)(b)(iv) and .04C(2)(f)(iv) that "within three years of opening" the FMF and parent hospital will generate net positive operating income. However, a somewhat longer time period may also be appropriate to show longer-term financial prospects of the proposed FMF.

3. The Draft Chapter Should Not Create a New Procedural Mechanism for a Third Party to Comment on an Applicant's CON Application.

Section .04B(4)(a)(i) of the Draft Chapter requires an applicant to provide an analysis of how the project will "affect the efficiency of emergency services delivery for the patient population in the FMF's proposed or existing service area" to the "emergency medical system for each jurisdiction to be served by the proposed FMF, and to all of the hospitals in the proposed or existing service area for the opportunity to comment[.]" (underline added).

This standard is problematic in that it may create a new channel for a third party to assert procedural rights in a CON proceeding for a proposed FMF, when the CON statutes and regulations already provide a mechanism for a party to participate in the CON proceeding where it meets the statutory and regulatory definition of "interested party" and follows the proper procedural steps for becoming an interested party. The Draft Chapter standard ostensibly could allow a third party that would not ordinarily be permitted to participate in a CON proceeding because it did not meet the definition of "interested party" (*i.e.*, because it was not "adversely affected" within the meaning of COMAR 10.24.01.01B(2)) or because the party failed to follow the proper procedures for becoming an interested party (*i.e.*, by failing to file written comments on an application within 30 days of its docketing as required by COMAR 10.24.01.08) to participate in the CON proceeding.

Moreover, the legislation authorizing the FMF exemption does not enable parties other than the State Emergency Medical Services Board to determine whether the FMF will maintain adequate and appropriate delivery of emergency care. Specifically, the new statutory provision states that the FMF exemption may be granted if the Commission finds, among other things, that the converted hospital "will maintain adequate and appropriate delivery of emergency care within the statewide emergency medical services as determined by the State Emergency Medical Services Board." MD. CODE ANN., HEALTH-GEN § 19-120(o)(3)(i)(5)(C) (underline added). Thus, the General Assembly expressly authorized the State Emergency Medical Services Board alone to determine the question of adequacy and appropriateness of the delivery of emergency care.

To comply with statutory law and to maintain the regulatory prescribed limits and procedures for third party participation in CON proceedings, we recommend that Section 04B(4)(a)(i) be amended to read as follows:

.04B(4)(a)(i): "Provide an analysis of how the establishment, relocation, or expansion of the FMF will affect the efficiency of emergency services delivery for the patient population in the FMF's proposed or existing service area. This analysis shall encompass both emergency transport and hospital ED and FMF operations in the FMF's proposed or existing service area. This analysis shall be presented to the emergency medical system for each jurisdiction to be served by the proposed FMF~~, and to all of the hospitals in the proposed or existing service area~~ for the opportunity to comment."

4. <u>The Draft Chapter Should Clarify the Financial Feasibility and Viability Standard.</u>

As drafted, the introductory language in Section .04B(6) on Financial Feasibility and Viability could be misconstrued by applicants or reviewers. This section reads: "The proposed establishment, expansion, or relocation of an FMF shall be financially feasible and shall not have an <u>undue negative effect</u> on the financial viability of the parent hospital." (underline added). The Commission recently summarized in its 2015 Report on the Operations, Utilization, and Financial Performance of Freestanding Medical Facilities (the "Report") that "Maryland freestanding emergency centers have not generated positive income from their operations, in general, when viewed as distinct, stand-alone business units." The Report also noted that "losses experienced by FMFs, when viewed in this somewhat narrow way, may not reflect positive impacts that sponsoring hospitals may attribute to the operation of FMFs, in terms of increasing use of other hospital facilities and services, differentiating the hospital or hospital system from its competitors in a positive way, increasing market share, or improving relationships with physicians." Given the experience of Maryland FMF pilot projects to date and the fact that some of the positive financial impacts that an FMF may have on a parent hospital may be difficult to measure, it seems that a more nuanced drafting of this standard that focuses on the viability of the hospital and the FMF as a unit and the long-term viability of such unit would be more suitable.

We recommend revising the introductory language in Section .04B(6) to read as follows:

.04B(6): "The proposed establishment, expansion, or relocation of an FMF shall be financially feasible and shall not ~~have an undue negative effect on the financial~~ <u>jeopardize the long-term</u> viability of the parent hospital."

Consistent with .04B(6)(iv), this revised language would require that the combined operations of the FMF and the parent hospital be financially feasible, replacing the "undue negative impact" language. Based on the experience of Maryland's FMF pilot projects, they could be described as having a "negative effect" on the financial performance of the parent hospital most of them are not generating net positive income. This standard, as drafted, incorrectly focuses on the negative impact the FMF may have on the

parent hospital, rather than on the overall long-term financial performance of the two facilities as a combined unit, which encompass a broader array of financial factors, including any attenuated positive financial impacts that an FMF may have on the parent hospital. We recommend the Commission adopt a standard that focuses on the long-term viability of the FMF and parent hospital as a unit.

5. The Draft Chapter Should Not Require Applicants to Obtain Information on Other FMFs.

Section .04C(7)(f) of the Draft Chapter requires an applicant seeking a CON exemption to convert to an FMF to demonstrate that: "the staffing assumptions and expense projections are based on current expenditure levels, utilization projections, and staffing levels experienced by the applicant hospital's ED and with the recent experience of similar FMFs[.]" (underline added). As a practical matter, it may be difficult or impossible for an applicant to obtain the recent staffing assumptions, expense projections, expenditure levels, and utilization projections of "similar FMFs," particularly if those FMFs are owned or operated by the applicant's competitors. This information is likely considered proprietary and it is unlikely that other FMFs would be willing to share it.

Consistent with our suggested edits set forth in Section 1 above, we recommend revising what is now Section .04C(7)(f)(iii) to read:

(7) (g)(iii) the staffing assumptions and expense projections are based on current expenditure levels, utilization projections, and staffing levels experienced by the applicant hospital's ED and relevant outpatient services ~~and with the recent experience of similar FMFs~~[.]

6. The Draft Chapter Should Clarify that Only One Public Hearing is Required for the Conversion of a General Hospital to a Freestanding Medical Facility.

Section .04C(2)(c) of the Draft Chapter requires a converting hospital to hold a public informational hearing and submit a summary of this hearing to the Commission before the Commission will accept the converting hospital's notice of intent to seek an exemption for conversion to a FMF. Presumably, the public hearing requirements in the Draft Chapter are meant to satisfy the public hearing requirements that were enacted as part of Maryland Senate Bill 707, which amends Maryland Code, Health-General § 19-20(l), by adding a mandatory public hearing requirement for hospitals located in counties with fewer than three hospitals that file a notice of proposed closing or partial closing or request an exemption to convert to a FMF. As drafted, the Draft Chapter could be construed as requiring a hospital to hold a public hearing prior to filing its notice of intent to seek an exemption for conversion to an FMF, and hold another public hearing once the exemption has been granted, since the conversion would constitute a closure or partial closure of a hospital.

We suggest that the Commission revise the Draft Chapter to clarify that an applicant satisfying the public hearing requirements in Maryland Code, Health-General, § 19-120(l)(2)(ii) and COMAR

10.24.19.04C(2)(c), would not also need to hold an additional hearing once the Commission granted an exemption for conversion. This could be accomplished by adding subsection (v) following Section .04C(2)(c)(iv):

> "(v) A hospital that has been granted an exemption by the Commission to convert to a freestanding medical facility under Health-General § 19-120(o)(3) and this Section .04C, need not hold additional public informational hearings under Health-General § 19-120(l)(2) before closure or partial closure of the hospital if such closure or partial closure is pursuant to the exemption granted by the Commission to convert to a freestanding medical facility."

Thank you for your consideration of these comments. Please contact me if you have any questions.

Sincerely yours,

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