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VIA EMAIL < eileen.fleck@maryland.gov >

Ms. Eileen Fleck
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:

I write to submit the University of Maryland Medical System’s informal comments regarding the proposed draft State Health Plan for Facilities and Services: Freestanding Medical Facilities (the “Draft Chapter”). The Draft Chapter was presented for informal review and comment on December 17, 2015, and January 19, 2016 was established as the deadline for informal public comment.

The University of Maryland Medical System 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 May Provide Medical Services Other Than Emergency Services.**

As drafted, the Draft Chapter recognizes only the emergency services component of FMFs. The Commission should include language in the Draft Chapter to recognize that a freestanding medical facility (“FMF”) is authorized to provide more than emergency services. While the FMF model originated as an extension of a hospital’s emergency department (“ED”), a hospital may use the FMF model strategically to provide access to a broad scope of medical services in the host community, including for example, outpatient surgery. By statute, an FMF is

¹ In addition to the substantive edits we suggest below, there is a typographical error in Standard .05B (7) (b), page 22: the word “have” should be deleted in the fifth line of the paragraph.

defined as a facility in which medical and health services are provided. MD. CODE ANN., HEALTH-GEN § 19-3A-01(1) (2015). The statutory definition does not restrict the services to be provided in an FMF to emergency services. “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) (2015).

Of particular significance, several Maryland acute general hospitals are exploring options to reconfigure and modernize services in the face of the industry’s declining utilization for acute inpatient admissions and the need to provide high quality and effective care to the communities served. The FMF model may provide these hospitals with a feasible and cost effective alternative to continuing acute care services in a hospital setting.² Under these scenarios, the FMF likely would provide more services to the community than merely emergency services. The Draft Chapter focuses on the emergency services component of FMFs and does not explicitly recognize that FMFs may be used to provide other types of medical services associated with the diagnosis and treatment of various clinical conditions.

We suggest that the introduction section of the Draft Chapter include a discussion of the medical services that are authorized to be provided in an FMF. Also, to reflect that FMFs are permitted to provide more than emergency services, we suggest the following edits in the Project Review Standards:

a. COMAR § 10.24.19.04B(2) (Access) –

- (a) A hospital shall demonstrate that its proposed FMF will improve access to emergency services and other services to be offered at the FMF for the population in the proposed service area of the FMF. This analysis shall include information on emergency transport times, return to service times, and other relevant information provided by each emergency medical system for each jurisdiction to be served by the proposed FMF.

² We understand that the Maryland Hospital Association may pursue legislation in the 2016 General Assembly Session to permit an acute general hospital to convert to an FMF, under certain conditions, through an exemption from the CON requirement. If this legislation is enacted, then the hospitals seeking this avenue will not need to obtain a CON. Nevertheless, the Draft Chapter will be relevant to these conversions because the Commission’s exemption procedures require a party seeking an exemption to provide information demonstrating that the proposed project “is consistent with the State Health Plan.” COMAR § 10.24.01.04B(6).

b. COMAR § 10.24.19.04B(3) (Cost and Effectiveness) –

- (b) With respect to the emergency services to be provided at the proposed project, the The analysis described in Paragraph (a) of this standard shall demonstrate why other less expensive models of unscheduled care delivery cannot meet the needs of the population to be served and shall account for the availability and accessibility of urgent and primary care services available to the population to be served.

c. COMAR § 10.24.19.04B(4) (Efficiency) –

- (a) With respect to the emergency services to be provided at the proposed project, the The applicant shall demonstrate that the efficiency of emergency service delivery in its service area will improve as result of its proposed project. The applicant shall:

d. COMAR § 10.24.19.04B(6) (Financial Feasibility and Viability) –

- (b) An applicant shall demonstrate that:
- (i) With respect to the emergency services to be provided at the proposed project, its Its utilization projections are consistent with observed historic trends in ED use by the population in the FMF's projected service area;
 - (ii) Its revenue estimates are consistent with utilization projections and, updated as necessary, account for the most recent HSCRC payment policies for FMFs;

(iii) With respect to the emergency services to be provided at the proposed project, its Its staffing assumptions and expense projections are based on current expenditure levels, utilization projections, and staffing levels experienced by the applicant hospital's ED and the recent experience of similar FMFs.

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

e. COMAR § 10.24.19.04B(8) (Quality Improvement) –

An FMF will provide high quality emergency medical services and continuously work to improve its quality of care. An applicant shall develop a systematic and comprehensive approach to evaluate quality of care utilizing CMS quality measures to evaluate healthcare processes and outcomes.

(a) The applicant shall describe an appropriate quality assurance program and performance measures that will be used by the proposed FMF and parent hospital or that are used by the existing FMF on an ongoing basis to monitor and improve the quality of care provided. At a minimum, with respect to emergency services to be provided at the proposed project, an applicant shall provide information on the following time-based performance measures for ~~the~~ each hospital and existing FMF involved in the project:

* * * * *

(b) With respect to emergency services to be provided at the proposed project, the

~~The~~ applicant shall:

- (i) Include a description of each quality measures used in its quality assurance program for its ED and existing or proposed FMF, including any algorithms that will be used; and
- (ii) Identify performance targets for each such quality measure for its ED and existing or proposed FMF.
- (iii)The applicant shall detail mechanisms it will use for monitoring outcomes of patients discharged from its ED and the FMF.

2. The State Health Plan for General Surgical Services Should be Amended to Account for FMFs Providing Surgical Services.

In addition to the comments to the Draft Chapter above, we request that the Commission consider amendments to the State Health Plan Chapter for Facilities and Services: General Surgical Services, COMAR § 10.24.11 (“General Surgical Services Chapter”), in light of the anticipated use of the FMF model to provide access to a broad scope of medical services as an alternative to acute inpatient care hospital services and proposed legislation to amend Health General § 19-201 to allow the Maryland Health Services Cost Review Commission (“HSCRC”) to regulate emergency and other outpatient services provided by FMFs. If this legislation is enacted, the existing General Surgical Services Chapter does not account for establishing, relocating, or expanding surgical services within an FMF.

Specifically, the General Surgical Services Chapter is applicable to all matters regarding CON review of surgical facilities and services except for open heart surgery and organ transplantation. COMAR § 10.24.11.02(D). The General Surgical Services Chapter, however, refers only to “hospitals” and “ambulatory surgical centers,” and each of these entities is defined to exclude freestanding medical centers. COMAR § 10.24.11.07(B)(13) defines a “hospital” as “a nonfederal facility in Maryland with one or more beds licensed for acute general or special care, as defined in Health-General Article § 19-301(f), Annotated Code of Maryland.” Because freestanding medical centers will not be licensed for acute general or special inpatient care, they presumably would not meet this definition.

On the other hand, COMAR § 10.24.11.07(B)(2) defines an “ambulatory surgical facility” as health care facility that, among other things, “seeks reimbursement from payors as an ambulatory surgical facility, as defined in Health-General § 19-3B-01[.]” If outpatient services at freestanding medical facilities, including surgical services, are regulated by the HSCRC, however, freestanding medical facilities could not satisfy the provisions of Health General § 19-3B-01(b)(2)(ii), which excludes from the definition of “ambulatory surgical facility,” “[a]ny

facility or service owned or operated by a hospital and regulated under Subtitle 2 of this title” governing HSCRC rate regulation.³

Therefore, assuming the proposed legislation is enacted and the HSCRC regulates outpatient procedures performed at freestanding medical facilities, including outpatient surgeries, it does not appear that a freestanding medical facility could satisfy the General Surgical Services Chapter’s definition of either a “hospital” or an “ambulatory surgical center.” As a result, if the current proposed changes to Health General § 19-201 are enacted, we recommend that the definition of “hospital” as set forth in COMAR § 10.24.11.07(13) be amended to state: “‘Hospital’ means, a nonfederal facility in Maryland with one or more beds licensed for acute general or special care, as defined in Health-General Article § 19-301(f), Annotated Code of Maryland, or a freestanding medical facility under Health-General Article § 19-3A-01, Annotated Code of Maryland.” Such an amendment would permit freestanding medical facilities to seek to establish, relocate, or expand surgical service lines and the Commission to consider such applications in accordance with the General Surgical Services Chapter.

We believe that permitting freestanding medical services to perform outpatient surgical procedures is consistent with the use of the FMF model to provide hospitals seeking to operate high quality and cost effective alternatives to acute hospital services and furthers the mandate of Health General § 19-118 to give priority to conversion of acute inpatient capacity to alternative uses.

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

Sincerely yours,



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Senior Vice President & Chief Strategy Officer
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cc: Donna Jacobs, Esq.
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³ The licensing requirements set forth in COMAR § 10.05.05.01(B)(2)(b)(ii) also state that a “freestanding ambulatory surgical facility” does not include: “(ii) A facility or service owned or operated by a hospital and regulated under Health-General Article, Title 19, Subtitle 2, Annotated Code of Maryland.”