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October 3, 2016

**VIA EMAIL**

Ms. Eileen Fleck
eileen.fleck@maryland.gov
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*
*Public 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 comments on the proposed draft State Health Plan for Facilities and Services: Freestanding Medical Facilities (the "Draft Chapter"), which was published in the Maryland Register on September 2, 2016. October 3, 2016, was established as the deadline for formal public comments.

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

**1. The Draft Chapter Should Provide Greater Flexibility For Sizing and Design and Account for Differences in Proposed FMF Projects.**

For some time, several Maryland acute general hospitals have been exploring options to reconfigure and modernize facilities in the face of declining utilization for acute inpatient admissions, aging physical plants, and the need to provide high quality and effective care in communities they serve. Through recently enacted legislation, Senate Bill 707, the General Assembly elected to use the freestanding medical facility ("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) and authorizing the Health Services Cost Review Commission ("HSCRC") to regulate rates for outpatient services in an FMF, including observation services and outpatient services other than emergency services.

In preparing the Draft Chapter, the Commission appears to have incorporated standards and other benchmarks based on the size, design, clinical programs, and patient acuity levels at the three existing Maryland FMFs established through the 2005 pilot program, MD. CODE ANN., HEALTH-GEN. §§ 19-3A-02, 19-3A-03. As explained in more detail below, however, the existing FMFs in Maryland are an imperfect benchmark for assessing the capabilities of hospitals converting to FMFs and should not

constrain the size, scope, configuration, ancillary services, or acuity of patients that may be served by a hospital converting to an FMF. As contemplated by Senate Bill 707, acute general hospitals converting to FMFs are authorized to provide a much broader array of services in order to treat patients with more complex and more acute health care needs than at the three currently established Maryland FMFs. Imposing such limitations on hospitals converting to an FMF could result in hospital closures that leave substantial gaps in health care services needed by communities formerly served by these hospitals.

To this end, a rigid "one-size-fits-all" standard applicable to FMF design and staffing is inappropriate and could result in the Draft Chapter becoming outdated shortly after its adoption. Instead, the Draft Chapter should be amended to: (1) provide greater flexibility in size and design standards for FMF applicants seeking to treat higher acuity patients, (2) propose different programs than currently exist at FMFs, and (3) account for differing patient populations, service areas, and evolving, integrated health care delivery systems. Staffing assumptions and expense projections by a hospital converting to an FMF should also only compared to existing FMFs that are truly similar in terms of projected visit volumes, patient acuity, demographics, and that offer similar clinical programs.

As the Draft Chapter recognizes, FMFs "have more advanced lifesaving, imaging, and laboratory capabilities [than unregulated urgent care centers], and usually operate seven days a week and 24 hours per day." Draft Chapter at 6.[1] Other than walk in patients, however, existing Maryland FMFs have been limited in the acuity of patients that they serve due to protocols issued by the Maryland Institute for Emergency Medical Services Systems ("MIEMSS"). In its protocols, MIEMSS does not utilize the five-acuity level Emergency Severity Index triage algorithm developed by the Agency for Healthcare Research & Quality. Rather, MIEMSS protocols assign patients to four clinical priority levels. *See* MIEMSS, *The Maryland Medical Protocols for Emergency Medical Services Providers* at 31 (July 1, 2016) ("MIEMSS Protocols"). A priority 1 patient is defined as a"[c]ritically ill or injured person requiring immediate attention; unstable patient with life-threatening injury or illness." *Id.* In contrast, a priority 2 patient is defined as a patient suffering from a "less serious condition yet potentially life-threatening injury or illness, requiring emergency medical attention but not immediately endangering the patient's life." *Id.* Finally, a priority 3 patient suffers from a "non-emergent condition, requiring medical attention but not on an emergency basis[,]" and a priority 4 patient "does not require medical attention." *Id.*

Under existing MIEMSS jurisdictional optional protocols, with certain limited exceptions, EMS providers may only transport stable patients categorized as priority 3 or 4 who do not need a time-critical intervention to the FMFs located at Bowie and Germantown. *See* MIEMSS Protocols at 417.[2] Thus, EMS providers may generally only transport patients who either do not require medical attention at all or who suffer from non-emergent conditions to two of the three existing FMFs in Maryland.

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[1] Under MD. CODE ANN. HEALTH-GEN. § 19-3A-02(b)(1), an FMF must be "open 24 hours a day, 7 days a week."

[2] Under the existing MIEMSS jurisdictional optional protocols, a priority 1 patient "with an unsecured airway or *in extremis* that requires stabilization beyond the capability of the EMS crew (e.g., cardiac or respiratory arrest)" may be sent to an FMF. MIEMSS Protocols at 417.

Beginning in July 2014, MIEMSS instituted a pilot program at the Queenstown FMF that designates that facility as an EMS base station and allows for EMS providers to transport stable priority 2, 3, or 4 patients to the facility. *See* MIEMSS Protocols at 355. We understand that the Queenstown FMF pilot protocol has been highly successful and that MIEMSS is likely to expand the Queenstown pilot protocol to existing and future FMFs.

Likewise, "provider-based freestanding emergency departments," as FMFs are called outside of Maryland, have been created in states around the country and have proven to play a pivotal role in the delivery of emergency medical services to, and successful treatment of, high acuity patients. Indeed, beginning on October 1, 2015, the Joint Commission has allowed off-site, hospital-owned freestanding emergency departments to apply for and obtain Acute Stroke-Ready Hospital Certification. Since that date, UMMS understands that no fewer than seven freestanding emergency departments have been certified by the Joint Commission as Acute Stroke-Ready. Recognizing these certifications and the capacity of such facilities to provide time sensitive treatment necessary to improved stroke patient outcomes, several states have recently revised statutes, regulations, and protocols governing emergency medical services to allow transport of stroke patients to freestanding emergency departments.

As a result of the anticipated expansion of the MIEMSS Queenstown pilot protocol, future MIEMSS pilot protocols or protocol amendments to respond to the evolving FMF model, and the ability of FMFs to now keep patients for observation stays and to have surgical capacity, UMMS expects that future FMFs will likely serve higher acuity patients than have historically been treated at the existing FMF pilots. Thus, an FMF applicant's reasonable utilization projections, projected patient volumes, and patient acuity levels will likely not be consistent with historic trends at existing FMFs and may no longer fall within the "low range" guidance set forth in the most current edition of *Emergency Department Design: A Practical Guide to Planning for the Future*, published by the American College of Emergency Physicians ("ACEP Guidelines").

The ACEP Guidelines categorize emergency department designs into low, mid, and high range. Among the factors to categorize a facility in the "low range" are: (a) less than 8% of patients will be expected to be admitted to a hospital; (b) the average length of stay is projected to be less than 2.25 hours; (c) patients admitted to the hospital are expected to be transported out of the FMF in 60 minutes or less after disposition; (d) more than 45% of patients are expected to be classified as ESI 4 and 5 combined; (e) and less than 10% of patients are expected to be older than 65. Jon Huddy, *Emergency Department Design: A Practical Guide to Planning for the Future* at 109-11 (2d Ed. 2016). To continue to provide adequate, high quality, effective emergency services to the community, a hospital converting to an FMF may present supportable utilization projections, projected patient volumes, and patient acuity levels that would place the proposed facility outside the ACEP Guidelines' "low range." And the Commission should not rigidly apply the ACEP Guidelines to circumscribe the design or size of a hospital converting to an FMF.

A strict application of the "low range" ACEP Guidelines could also preclude FMFs from offering specialty emergency care programs. For example, a hospital that previously served psychiatric patients that plans to convert to an FMF and that may be near or co-located with a psychiatric special hospital may seek to establish a specially designed program to treat patients experiencing behavioral health emergencies. The ACEP Guidelines "low range" design and size standards, however, indicate that

facilities in the "low range" would have fewer than 3% of behavioral health patients and the size and design standards do not account for specialty suites to accommodate behavioral health patients. *Id.* at 111. Likewise, depending on an FMF's service area demographics, an FMF may seek to have a pediatric specialty area but the ACEP Guidelines "low range" design and size standards do not factor in the need for family consultation rooms or other support. *Id.* at 112.

Also, the ACEP Guidelines "low range" size and design standards provide that "imaging studies will not be performed within the department, so there is no need to add space for imaging rooms" and only allow for "minimal" administrative offices within the emergency department. *Id.* at 111-12. Furthermore, the "low range" standards contemplate that "[clinical decision units]/observation space will be located outside of the emergency department and [are] not part of [the] architectural project." *Id.* at 110. Because imaging equipment, including CT and MRI, may be required to provide high quality care to more acute patients and an FMF will necessarily require observation space and administrative offices to be included at the standalone facility, the Commission should not inflexibly apply the "low range" ACEP Guidelines. Although the ACEP Guidelines provide for a 1.25 multiplier as a building square footage adjustment factor for a freestanding facility, this adjustment factor may prove inadequate given an applicant's utilization projections, projected patient volumes and acuity levels, and specialty programs.

Finally, it should be noted that the ACEP Guidelines themselves indicate that the low, mid, and high ranges are "general guideline[s]" used to set "preliminary benchmarks for sizing emergency departments," which can be adjusted for "each unique emergency department project" and that the size parameters are merely "estimates." *Id.* at 109, 116-117. The low, mid, and high ranges are also not exacting tiers but represent a continuum based on projections. *See id.* at 109. In sum, the ACEP Guidelines were not designed nor intended to serve as inflexible construction standards. And applying the ACEP Guidelines and staffing and expense projections at existing FMFs "across-the-board" to all future FMFs will fail to accommodate hospitals seeking to maintain the highest and best levels of care as they convert to FMFs. Communities would be best served by allowing hospitals converting to FMFs to seek to treat higher acuity patients, propose different programs than currently exist at FMFs, and account for differing patient populations, service areas, and evolving, integrated health care delivery systems.

For the reasons set forth above, UMMS suggests the following revisions to the Draft Chapter to allow greater flexibility in size and design standards and to ensure that staffing and expense projections are compared to only existing FMFs that are truly comparable:

**a. COMAR § 10.24.19.04(B)(1)(c)(vii)[3]**

(vii) A demonstration that the number of FMF treatment spaces, including observation spaces, and the size of the facility proposed by the applicant are consistent with ~~the low range~~

[3] The Draft Chapter also fails to include a standard applicable to CON reviews for an FMF proposing to establish observation space.

applicable guidance of the most current edition of *Emergency Department Design: A Practical Guide to Planning for the Future*, published by the American College of Emergency Physicians, consistent with reasonably projected levels of visit volume, patient acuity, demographics, and specialty programs;

**b. COMAR § 10.24.09.04(B)(6)(b)(iii)**

(iii) 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 with similar projected visit volumes, projected patient acuity, demographics, and specialty programs;

**c. COMAR § 10.24.09.04(C)(8)(d)**

(d) Demonstrate that the number of treatment spaces and the size of the facility proposed by the applicant are consistent with ~~the low range~~ applicable guidance included in the most current edition of *Emergency Department Design: A Practical Guide to Planning for the Future*, published by the American College of Emergency Physicians, based on reasonably projected levels of visit volume, patient acuity, demographics, and specialty programs;

**d. COMAR § 10.24.19.04(C)(8)(f)(iii)**

(iii) The staffing assumptions and expense projections for emergency services 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 with similar projected visit volumes, projected patient acuity, demographics, and specialty programs.

**2. Timing of The Commission's "Acceptance" of a Notice of Intent to Convert an Acute General Hospital to an FMF**

As noted above, Senate Bill 707 amended MD. CODE ANN., HEALTH-GEN. § 19-120 to authorize an exemption process for a hospital that seeks to convert to an FMF. *See* MD. CODE ANN., HEALTH-GEN. § 19-120(o)(3)(i). As the Draft Chapter explains, a CON exemption is a "regulatory process designed to be quicker, less complex, and less litigious than CON review." Draft Chapter at 13 (describing the CON exemption process applicable to a hospital conversion to a limited service hospital). As drafted, however, exemption process in the Draft Chapter is not quicker and less complex.

Revised MD. CODE ANN., HEALTH-GEN. § 19-120(l)(2)(ii) states that a public informational hearing must be held within 30 days after a hospital files a notice of intent with the Commission to convert to an FMF. Under the amended statute, the same notice of intent to convert to an FMF starts the 60 day statutory timeline for a determination by the Commission that that the conversion is consistent with the State Health Plan, will result in the delivery of more efficient and effective health care services, and is in the public interest. *Id.* § 19-120(o)(3)(i)(4)-(6). MIEMSS is separately charged by statute with making a determination that the conversion will maintain adequate and appropriate delivery of emergency care within the statewide emergency medical services system. *See id.* § 19-120(o)(5)(C).

The Draft Chapter does not comply with the exemption process established by the General Assembly. Instead, the Draft Chapter states that a "notice of intent to seek an exemption from Certificate of Need review to convert a general hospital to an FMF" will "[o]nly be accepted by the Commission for filing after:" (i) the converting hospital publishes a proposed transition plan at least 14 days prior to holding a public informational hearing; (ii) the converting hospital holds a public informational hearing after consultation with the Commission; (iii) the hospital provides a written summary of the public informational hearing within 10 days to identified executive, legislative, and regulatory entities; and (iv) MIEMSS makes a determination that the conversion will maintain adequate and appropriate delivery of emergency care within the statewide emergency medical services system. Draft COMAR § 10.24.19.04(C)(3)(c)(i)-(iv). By separate proposed regulation, MIEMSS proposes to make its statutorily required determination within 45 days after the public informational hearing required by the Commission's regulations.

Thus, the exemption process contemplated by the Draft Chapter and proposed MIEMSS regulations could take as long 135 days or approximately 4 ½ months. By contrast, under the Commission's regulations, a hospital could simply file a CON application to establish an FMF and the Commission would be required to make a determination on the application within a mere 90 days of docketing for an uncontested application and within 150 days of docketing for a contested application with an evidentiary hearing. COMAR § 10.24.01.09(E)(1). And notably, when an FMF is established through a CON application – as opposed to the CON exemption process – neither the statute nor the Draft Chapter requires a determination by MIEMSS that an FMF will maintain adequate and appropriate delivery of emergency care within the statewide emergency medical services system.

The Commission frequently engages with other regulatory agencies, including the Health Services Cost Review Commission ("HSCRC") and the Office of Health Care Quality ("OHCQ"), after docketing an application for a certificate of need or accepting an application from CON review when a determination

by such a regulatory agency is relevant or a condition precedent to a proposed project. Although we recognize that a hospital seeking to convert to an FMF must hold a public informational hearing and obtain a determination from MIEMSS that the conversion will maintain adequate and appropriate delivery of emergency care within the statewide emergency medical services system, there is no reason the Commission will be unable to coordinate with MIEMSS while considering an exemption application by a hospital to convert to an FMF.

Accordingly, we suggest that the Draft Chapter be amended to incorporate requirements for a public informational hearing for a hospital that seeks to convert to an FMF but that the Commission eliminate the requirement that it will not "accept for filing" an exemption application until after a hospital has held a public informational hearing and received a favorable determination from MIEMSS that the conversion will maintain adequate and appropriate delivery of emergency care within the statewide emergency medical services system. Rather, we suggest that the Commission accept an application by a hospital seeking to convert to an FMF in accordance with the exemption schedule established by statute and that it review the application in concert with MIEMSS.

**3. Surgical Services at an FMF.**

The Draft Chapter provides that a hospital converting to an FMF through the exemption process may seek authorization for outpatient surgical capacity to be co-located with the FMF or adjacent to the FMF, and licensed as a freestanding ambulatory surgical facility. For the reasons discussed below, requiring that surgical services at an FMF be separately licensed as an ambulatory surgical facility gives rise to statutory and regulatory issues.

Specifically, Maryland FMFs are required to obtain provider-based status under CMS regulations, 42 C.F.R. § 413.65. MD. CODE ANN., HEALTH-GEN. § 19-3A-01(4). An ambulatory surgical center cannot be a provider-based facility for payment purposes under CMS regulations. *See* 42 C.F.R. § 413.65(a)(2). Thus, requiring that surgical services at an FMF be separately licensed as an ambulatory surgical facility will preclude the HSCRC from exercising its discretion to regulate the rates of such a facility. This would conflict with to the intent of Senate Bill 707. Accordingly, it would be appropriate for the OHCQ to amend licensing regulations applicable to FMFs to adopt by reference standards applicable to ambulatory surgical centers and not require separate licensure as an ambulatory surgical center to provide surgical services at an FMF.

Additionally, the State Health Plan Chapter for Facilities and Services: General Surgical Services, COMAR § 10.24.11 ("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 FMFs. 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 surgical services at an FMF are regulated by the HSCRC, however, the FMF could not satisfy the provisions of MD. CODE ANN., HEALTH-GEN. § 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" which governs HSCRC rate regulation.[4]

On the other hand, 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 FMFs will not be licensed for acute general or special inpatient care, they presumably would not meet this definition. As a result, 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 FMFs to seek to establish, relocate, or expand surgical service lines.

We also propose the following changes to the Draft Chapter:

**a. COMAR 10.24.19.04(C)(9).**

Retention of part of the converting hospital's outpatient surgical capacity.

(a) A converting hospital may, through the exemption process by which a general hospital is authorized to convert to an FMF, seek authorization for outpatient surgical capacity to be co-located within the FMF or adjacent to the FMF, and if adjacent to the FMF, in a separately licensed as a freestanding ambulatory surgical facility. Applicants seeking authorization for ambulatory surgical capacity during the exemption review, shall demonstrate:

(i) That surgical services that it proposes to provide in the FMF or any separately licensed ambulatory surgical facility will be high quality, and comply with COMAR 10.24.11.05A(3);

(ii) That the proposed outpatient surgical capacity is needed, will be properly utilized, and complies with COMAR 10.24.11.05B(2) and .06B; and

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[4] In proposed regulations, the HSCRC has left open the possibility of allowing surgical services provided at an FMF to be rate regulated. *See* Draft COMAR § 10.37.10.07-2.

(iii) That the design of the operating room and ancillary space for the surgical services or at a separately licensed ambulatory surgical facility is consistent with Section 3.7 of the most current guidelines of the Facility Guidelines Institute.

(b) The converting hospital shall demonstrate the reasonableness of its staffing assumptions for the surgical services to be provided in the FMF or in ~~an~~ a separately licensed ambulatory surgical facility, based on the existing staffing levels for outpatient surgery at the converting hospital.

(c) The converting hospital shall demonstrate that ~~the~~any separately licensed ambulatory surgical facility will be financially viable.

(d) The ~~ambulatory surgical facility~~ outpatient surgical capacity approved by the Commission to be co-located within or adjacent to an FMF created through the conversion of a general hospital shall meet licensure requirements determined by the Office of Health Care Quality to be appropriate.

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

Sincerely yours,

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