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DRAFT STATE HEALTH PLAN FOR FACILITIES AND SERVICES:

FREESTANDING MEDICAL FACILITIES

DRAFT FOR WORK GROUP DISCUSSION

August 21, 2015

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.01 Incorporation by Reference.

This chapter of the State Health Plan for Facilities and Services: Freestanding Medical Facilities (chapter) is incorporated by reference in the Code of Maryland Regulations.

.02 Introduction.

A. Purposes of the State Health Plan.

The Maryland Health Care Commission (the Commission) has prepared this chapter of the State Health Plan for Facilities and Services (State Health Plan) in order to meet current and future health care system needs for all Maryland residents by assuring access, quality, and cost efficiency.

The State Health Plan serves two purposes:

(1) It establishes health care policy to guide the Commission's actions. Maryland law requires that all State agencies and departments involved in regulating, funding, or planning for the health care industry carry out their responsibilities in a manner consistent with the State Health Plan and available fiscal resources; and

(2) It is the legal foundation for the Commission's decisions in its regulatory programs. These programs ensure that changes in services for health care facilities are appropriate and consistent with the Commission's policies. The State Health Plan contains policies, methodologies, standards, and criteria that the Commission uses in making decisions on applications for Certificates of Need (CON), Certificates of Conformance, and Certificates of Ongoing Performance. The CON program is intended to ensure that changes in the delivery of services by regulated health care facilities are

needed, cost-effective, and viable. The Commission also considers the impact of changes in the supply and distribution of health care facilities.

B. Legal Authority of the State Health Plan.

The State Health Plan is adopted under Maryland's health planning law, Maryland Code Annotated, Health-General (Health-General) §§19-114–19-131. This chapter partially fulfills the Commission's responsibility to adopt a State Health Plan at least every five years and to review and amend the State Health Plan as necessary. Health-General §19-118(a)(2) provides that the State Health Plan shall include:

(1) The methodologies, standards, and criteria for CON review; and

(2) Priority for conversion of acute capacity to alternative uses where appropriate.

C. Organizational Setting of the Commission.

The Commission is an independent regulatory agency, functioning administratively within the Department of Health and Mental Hygiene (DHMH), whose mission includes planning for health system needs. As enumerated in Health General §19-103(c), and of particular relevance to this chapter, the Commission is authorized to:

(1) Develop health care cost containment strategies to help provide access to appropriate quality health care services for all Marylanders, after consulting with the Health Services Cost Review Commission; and

(2) Promote the development of a health regulatory system that provides, for all Marylanders, financial and geographic access to quality health care services at a reasonable cost by advocating policies and systems to promote the efficient delivery of and improved access to health care services, and enhancing the strengths of the current health care service delivery and regulatory system.

The Commission has sole authority to prepare and adopt the State Health Plan and to issue Certificates of Need, Certificates of Conformance, Certificates of Ongoing Performance, and exemptions based on the State Health Plan. Health General §19-118(e) provides that the Secretary of DHMH shall make annual recommendations to the Commission on the State Health Plan and permits the Secretary to review and comment on the specifications used in its development. Health-General §19-110(a), however, clarifies that the Secretary does not have power to disapprove or modify any determinations the Commission makes regarding or based upon the State Health Plan. The Commission pursues effective coordination of its health planning functions with the Secretary, with State health-related agencies, and with the Health Services Cost Review Commission in order to assure an integrated, effective health care policy for the State. The Commission also consults the Maryland Insurance Administration as appropriate.

D. Applicability.

Legislation enacted by the Maryland General Assembly in 2010 provides that, after July 1, 2015, the health care facility known as a freestanding medical facility (FMF), defined in Health General § 19-3A-01, can only be established through the issuance of a CON by the Commission.[1] Under Health General §19-120 and COMAR 10.24.01.02A, a CON is required before a new health care facility is established or relocated. A CON is also required before a health care facility can make certain changes in the type or scope of health care services offered or make a capital expenditure that exceeds the applicable capital expenditure threshold found in Health General §19-120(k)(1)(i). This chapter applies to the establishment of a new FMF, the relocation of

[1] Chapters 505 and 506 of the 2010 Laws of Maryland – Freestanding Medical Facilities – Rates. Health General § 19-3A-03(a)(2)

an FMF, and a capital expenditure made by or on behalf of an FMF that exceeds the applicable capital expenditure threshold.

E. Effective Date.

An application or letter of intent submitted after the effective date of these regulations is subject to the provisions in this chapter.[2]

.03 Issues and Policies.

Introduction.

Use of hospital emergency departments has grown substantially in recent years. Maryland hospitals have seen the average daily number of hospital emergency department (ED) visits increase by 65% between 1995 and 2013.[3] This growth in volume has resulted in long wait times for persons seeking treatment at an ED and in overcrowded conditions that can require temporary periods of ambulance diversion and less optimal patterns of emergency transport for patients. In attempting to address these problems, Maryland hospitals have expanded their ED service capacity and improved operational management of their EDs.

Attention has also focused on the development of two alternative models for the delivery of urgent and emergency care. One model, commonly referred to as an "urgent care center," provides unscheduled, walk-in service to patients with low acuity needs for extended hours of the day. These centers are typically staffed by physicians and other

[2] Note that a new FMF may not be established in Maryland after July 1, 2015, until this chapter, which contains review criteria and standards required to be established by Section 5 of Chapters 505 and 506 of the 2010 Laws of Maryland, is in effect and the Commission issues a CON finding that the application is consistent with the standards and criteria in this chapter and with CON review criteria, COMAR 10.24.01.08G(3). A letter of intent may only be submitted in accordance with the schedule for receipt of letters of intent and applications regarding establishment of FMFs published in the *Maryland Register* in accordance with COMAR 10.24.01.

[3] *Report on the Operations, Utilization, and Financial Performance of Freestanding Medical Facilities*, MHCC, 2015

types of health care practitioners, such as physician assistants or nurse practitioners. Some of these urgent care centers have been developed by hospitals. Others have been established as part of corporate "chain" operations, ranging from highly standardized clinic facilities offering a wide range of non-complex diagnostic and treatment services to small clinics with a limited menu of specific services (e.g., vaccinations and immunizations, simple diagnostic screening, physical exams needed for school enrollment or employment) located in drugstores or other types of retail settings. A wide variety of facility, staffing, and operational clinic models can also fall within the urgent care heading, a service offering that is not regulated in Maryland as a specific category of licensed health care facility.

Another alternative to the hospital ED that has developed over the last twenty years, with higher acuity of care capabilities than the typical urgent care center, is the "freestanding emergency center," [4] which, as discussed below, is called a "freestanding medical facility" in Maryland. Typically, these facilities are distinguished from urgent care centers by the scope of services that they provide. Freestanding emergency centers have more advanced lifesaving, imaging, and laboratory capabilities, and usually operate seven days a week and 24 hours per day. In addition, these facilities have staff that includes physicians and nurses trained and certified in emergency care. Such facilities have billing and contracting arrangements similar to those of a hospital ED.

In 2005, the Maryland legislature recognized the freestanding emergency center model through the creation of the licensure category known as "freestanding medical

[4] Although a freestanding emergency center is sometimes referred to in literature as a "freestanding emergency department" or a "freestanding emergency room," Maryland law required DHMH to adopt regulations that prohibit a freestanding medical facility from using the words "emergency department," "emergency room," or "hospital." Health-General § 19-3A-02(b)(5). DHMH regulations, at COMAR 10.07.08.03, provide that an FMF may not use any of these words in its title, advertisements, or signage.

facility" (FMF), which applied to a single pilot project.[5] The use of this licensure category was expanded to a second pilot project in 2007,[6] and a third license was issued to a facility that pre-existed the 2005 law.[7] As part of the law authorizing the two pilot FMFs, the Commission was required to conduct a study of the operations, utilization, and financing of the pilot facilities, and produce a report to the General Assembly on its findings.[8] The FMF pilot period ended on July 1, 2015 and the existing FMFs are not required to obtain Certificate of Need approval.[9]

Access to Care.

Timely access to quality medical service is essential for providing treatment to patients with illnesses and injuries that, if left untreated or not treated on a timely basis, may be life-threatening or may lead to impairment. Barriers to emergency care can take many forms[10], including a lack of timely access due to travel distance,[11] physical transportation barriers,[12] overcrowding in an ED,[13] or poor management of patient flow

[5] Chapters 549 and 550 of the 2005 Laws of Maryland - Freestanding Medical Facilities – Licensing and Pilot Project. Health-General §§ 19-3A-02, 19-3A-03.
[6] The 2005 law authorized the first pilot FMF project, the Adventist HealthCare Germantown Emergency Center (Germantown Emergency Center), which opened in August of 2006. In 2007, the law was amended to add a second pilot FMF project, the Queen Anne's Emergency Center, which opened in October of 2010.
[7] The Bowie Health Center, which opened in 1979,and operated under Prince George's Hospital Center's general hospital license, was issued a separate license as an FMF license in June of 2007.
[8] The Commission produced two reports on these pilot projects. The first report was submitted to the legislature on February 18, 2010. The final report, entitled "Report on the Operations, Utilization, and Financial Performance of Freestanding Medical Facilities" was submitted on February 3, 2015. http://mhcc.maryland.gov/mhcc/pages/plr/plr_hospital/documents/chcf_fmf_report_final_ltr_20150204.pdf
[9] Health-General §§ 19-3A-03(c) and 19-3A-07(c)(2).
[10] American College of Emergency Physicians (2015) Emergency Department Wait Times, Crowding and Access Fact Sheet. http://newsroom.acep.org/index.php?s=20301&item=29937
[11] American Hospital Association (2012). Prepared to Care. American Hospital Association 325 7th Street N.W. Washington, D.C. 20004. November 2012 www.aha.org.
[12] Griffin, R. and McGwin, G.(2013) Emergency medical service providers' experiences with traffic congestion. *Journal of Emergency Medicine* Feb;44(2):398-405. doi: 10.1016/j.jemermed.2012.01.066. Epub 2012 Aug 9. http://www.ncbi.nlm.nih.gov/pubmed/22883716
[13] American College of Emergency Physicians (2014). America's Emergency Care Environment. A State-by-State Report Card. http://www.emreportcard.org/uploadedFiles/EMReportCard2014.pdf

in an ED.[14] Other barriers may include cultural barriers[15] and the high cost of care services.[16]

Based on data from 2003, one study estimated that approximately 64 percent of Marylanders resided within a 30-minute travel time of a hospital ED.[17] Nationally, approximately 71 percent of the population lived within a 30-minute travel time of a hospital ED in 2003. Timely access to ED services in Maryland degraded during the 1990s because of the large increases in use of EDs. During this decade, the number of hospitals declined slightly and visits per ED treatment space increased. While visits to Maryland EDs continued to increase by nearly 40 percent, from 1.8 million to 2.5 million, during the period 2000 to 2014, the hospital systems and independent hospitals added treatment space during this last decade at a pace that has offset the growth in the number of ED visits. In 2003, the average number of visits per ED treatment space at Maryland hospitals was just under 1,400 visits per year. By 2013, the average number of visits per treatment space had declined to 1,164 visits per space, a 16% reduction. One new hospital was added in Maryland in 2014, and a replacement of two hospitals with a single facility in 2010 eliminated one ED, so there was no net change in the number of hospital EDs during this period. However, two hospitals each developed an FMF. Despite the increase in ED capacity, in January, 2014, the American College of

[14] American College of Emergency Physicians (2009) Emergency department information systems. ACEP Resolution 22(7) Task Force white paper http://www.acep.org/workarea/DownloadAsset.aspx?id=45756
[15] Scheppers, E., van Dongen, E., Dekker, J., Geertzen, J., and Dekker, J. (2006) Potential barriers to the use of health services among ethnic minorities: a review. *Family Practice* 23 (3); 325-348. http://fampra.oxfordjournals.org/content/23/3/325.full
[16] Harkin, T., and Sanders, B. (April 11, 2011). Hospital Emergency Departments: Health Center Strategies That May Help Reduce Their Use. U.S. Government Accountability Office Committee on Health, Education, Labor, and Pensions. GAO-11-414R.
[17] Carr, B.G., Branas, C.C., Metlar, J.P., Sullivan, A.F., and Camargo, C.A. (2009). Access to emergency care in the United States. *Annals of Emergency Medicine*, Aug. 54(2): 261-269. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2728684/table/T1/

Emergency Physicians, based on the most recent data available at that time, concluded that Maryland's EDs remain overcrowded with long wait times for service.[18]

The Maryland Health Care Commission's 2015 Report on the Operation, Utilization, and Financial Performance of Freestanding Medical Facilities[19] concluded that the establishment of an FMF may be appropriate: in response to overcrowding of the parent hospital's ED, if the hospital or health care system has already taken steps to reduce inappropriate utilization of the parent hospital's ED; or to improve access to emergency medical care in the service area of the parent hospital. As described in the report, Germantown Emergency Center was established to alleviate overcrowding at its parent hospital, Shady Grove Medical Center, and it appears to have significantly reduced crowding at Shady Grove Medical Center.

The urgent care center model is evolving, and some hospital and non-hospital developers and operators of urgent care centers are likely to establish more centers that approach the staffing and service sophistication of the FMF model. MHCC staff's analysis of patient acuity at Maryland FMFs suggests that FMFs and urgent care centers both serve large numbers of low acuity patients, but urgent care centers manage these patients with lower overhead and staffing costs. The higher acuity patients that FMFs serve bring the patient mix at FMFs closer to the patient mix for EDs, but the average patient acuity at FMFs is still well below the average patient acuity at EDs. Although many patients who utilize FMFs could be adequately served by urgent care centers at a lower cost than that typically experienced in the FMF setting, most urgent care centers in

[18] American College of Emergency Physicians (2014). America's Emergency Care Environment, A State-by-State Report Card-2014 http://www.emreportcard.org/uploadedFiles/EMReportCard2014.pdf

[19] Maryland Health Care Commission (January 15, 2015). Report on the Operation, Utilization, and Financial Performance of Freestanding Medical Facilities.

Maryland lack the necessary resources to treat the higher acuity patients that FMFs can handle. In addition, most urgent care centers are not open 24 hours a day and seven days a week. FMFs have the advantages of accessibility and capability over typical urgent care centers.

Maryland's initial regulatory policy with respect to development of FMFs should be structured to require meaningful analysis of a full spectrum of clinical facilities where non-complex medical care can be handled without appointments as part of the applicant hospital's justification for proposed development of an FMF. The State's objective in regulation of FMFs should guide creation of the best combination of settings covering the full range of emergent and urgent medical care needs: (1) hospital EDs, critical for those with the most acute medical and surgical needs; (2) FMFs in areas where access to emergency department care is limited; (3) urgent care centers, which offer greater access and convenience for lower acuity care compared with a conventional physician's office and lower cost than an ED or an FMF; and (4) primary care practitioners in non-facility office settings for routine outpatient care of a less urgent nature. The lowest cost for a large volume of unscheduled medical care sought by the market would be primary care practitioners (a category that has a "soft border" with so-called urgent care centers) but organizing primary care practitioners to offer more convenient walk-in services, even during the standard 40-hour work week, may not be feasible in the near term.

Cost- Effectiveness and Efficiency of Care

Hospital emergency departments play a vital role in delivering emergent care services. However, the cost of providing these services is high due to the requirement for availability of trained staff and equipment needed for the full range of emergency

scenarios 24 hours a day seven days a week. The requirement to provide service to all patients, regardless of a patient's ability to pay and the difficulty of redirecting some patients to more appropriate treatment facilities also raises the cost of EDs. In recognition of the high overhead cost of providing emergency services at EDs and FMFs, these facilities are allowed to charge a facility fee, unlike urgent care centers or physicians' offices. Thus, a service provided at an ED or an FMF is usually more costly than the same service provided at an urgent care center or in a physician's office.

In order to promote the efficient use of health resources, patients should be served in the lowest cost setting that meets their needs. Unfortunately, for some patients, financial barriers lead them to seek care at an FMF or ED, instead of at an urgent care center. Unlike FMFs, which must treat all patients, urgent care centers and private physicians can limit the payer types that they will accept and can require upfront payment. For patients without insurance or the ability to pay upfront, an urgent care center is usually not an available alternative to an FMF. In the Maryland Health Care Commission's 2015 Report on the Operation, Utilization, and Financial Performance of Freestanding Medical Facilities, MHCC staff concluded that the two pilot FMFs in Maryland often treated patients with low acuity medical needs that likely could have been treated in a lower acuity setting, such as an urgent care center.

Quality of Care

In the most recently published report card by the American College of Emergency Physicians, Maryland EDs had the highest ranking in the nation in Maryland for "Quality

and Patient Safety Environment."[20] The Institute of Medicine defines quality emergency care as being safe, timely, efficient, effective, equitable, and patient-centered.[21] Thus, care delivered at an FMF should be performed safely while avoiding harmful delays.[22]

Because the timeliness of emergency care is associated with the quality of care, two process measures, "throughput time" and "time to hospital admission" will be used to evaluate the quality of services provided in FMFs in Maryland. It is also essential to evaluate care coordination for patients treated in hospital EDs and FMFs. According to the National Quality Forum (NQF), poor care coordination is associated with higher costs, increased medical errors, unnecessary patient suffering, and increased ED readmissions. NQF reported that care coordination initiatives could result in an estimated $240 billion in savings throughout the U.S.[23]

Policy Objectives

The broad policy objectives guiding the Commission's regulation of freestanding medical facilities in Maryland serve as a foundation for the specific standards of this State Health Plan chapter and are as follows:

Policy 1: **Emergency medical services shall be financially and geographically accessible to Maryland's population.**

Policy 2: **Emergency medical services shall be provided in the most cost-effective manner possible consistent with safely and effectively**

[20] American College of Emergency Physicians (2014). America's Emergency Care Environment, A State-by-State Report Card-2014 http://www.emreportcard.org/uploadedFiles/EMReportCard2014.pdf, p. 57.
[21] Welch, S.J., Asplin, B.R., Stone-Griffith, S., Davidson, S.J., Augustine, J., and Schuur, J. (2010). Emergency department operational metrics, measures and definitions: Results of the second performance measures and benchmarking summit. Annals of Emergency Medicine Vol. xx.
[22] International Federation for Emergency Medicine (2012) Framework for Quality and Safety in the Emergency Department. International Federation for Emergency Medicine (IFEM) Symposium for Quality and Safety in Emergency Care, 15th/16th November 2011. http://www.ifem.cc/site/DefaultSite/filesystem/documents/Policies%20and%20Guidelines/Framework%20for%20Quality%20and%20Safety%20in%20the%20Emergency%20Department%202012.doc.pdf
[23] NQF-Endorsed Measures for Care Coordination: Phase 3, 2014.

meeting the health care needs of patients needing emergency medical care.

Policy 3: **Resources shall be used efficiently in producing emergency medical services. Both development and maintenance of excess emergency medical service capacity in the most expensive settings, a general hospital or FMF, and insufficient capacity development of lower cost settings, should be avoided. Resource capacity development shall match the acuity of patients' needs.**

Policy 4: **An FMF shall provide high quality care. Each FMF shall adopt performance measures and improve and adapt them over time, measure the FMF's level of achievement on the performance measures, and seek to continuously improve its level of achievement.**

Policy 5: **An acute care general hospital operating an FMF shall assess the primary care needs of the population in its service area and maximize the number of people in its service area who have a regular source of primary care. The hospital shall also be engaged in educating individuals and families in its service areas about appropriately using emergency medical facilities in order to reduce avoidable use of emergency services.**

Policy 6: **A hospital operating an FMF shall continuously and systematically work to improve the quality and safety of patient care. This includes planning, implementing, and optimizing the use of electronic health record systems and an electronic health information exchange to reap the contribution to improved care coordination, patient safety, and quality improvement that adoption of these tools affords.**

.04 Standards

A. General Standards.

(1) An applicant for a Certificate of Need to establish, relocate, or expand a freestanding medical facility shall address and meet the applicable general standards in COMAR 10.24.10.04A, in addition to the applicable standards in this chapter.

(2) An applicant for a Certificate of Need to establish, relocate, or expand a freestanding medical facility shall document that it is consistent with the licensure standards established by the Maryland Department of Health and Mental Hygiene.

B. Project Review Standards

(1) Need.

An applicant shall demonstrate that the proposed establishment, relocation, or expansion of an FMF is needed by the parent hospital's service area population.

(a) An FMF may only be established in or relocated to an area within the parent hospital's service area, upon a showing that the FMF is needed by the population of the service area.

(b) The burden of demonstrating the need for a new FMF or for the expansion of an FMF rests with the applicant. Closure of an existing FMF, in and of itself, is not sufficient to demonstrate the need to establish an FMF.

(c) An applicant for a new FMF, the relocation of an existing FMF, or the expansion of an FMF shall include the following information as part of its demonstration of need for the project, and fully explain how this information supports its demonstration of need for the project being proposed:

(i) A description of the target population in the existing service area or the projected service area of the proposed FMF and the characteristics of that population including gender, age, insurance status, and physical and mental chronic conditions.

(ii) A description of the historic trends in ED visits and FMF visits by residents of the existing service area of the applicant hospital or FMF and the projected service area of the FMF, the number and location of EDs and FMFs in the applicant hospital's service area, and urgent care services in the hospital's service area and the existing service area or projected service area of a proposed FMF.

(iii) An estimate of the number of uninsured, underinsured, indigent, and otherwise underserved patients in the existing or projected service area and an analysis of the impact of each of these patient groups on ED visits and FMF visits in the existing service area of an existing FMF or the projected service area of a proposed FMF;

(iv) A description of each problem to be addressed through the establishment of a proposed FMF or the relocation of an existing FMF or the expansion of an existing FMF.

a. If overcrowding at the parent hospital's ED is the justification for establishing, relocating, or expanding an FMF, the applicant shall provide pertinent information regarding the capacity of the parent hospital's ED and current utilization patterns including: patient volume; acuity levels; number of treatment spaces; wait times; the percentage of patients who spent greater than four hours in the ED or another temporary location after being admitted to the hospital; the average amount of time patients spent in the ED before being sent home; the percentage of patients leaving the ED without being seen; and the history of ambulance diversion at the parent hospital ED.

b. If inadequate access and availability of emergency medical services form the basis of the applicant's justification to establish, relocate, or expand an FMF, the applicant shall demonstrate that access barriers exist based on studies or other validated sources of information and shall present a detailed, credible plan for addressing each barrier consistent with the proposed project;

(v) An explanation of how the proposed new, relocated, or expanded FMF will address each problem identified by the applicant;

(vi) A demonstration that the proposed project is consistent with the hospital's community health needs assessment;

(vii) A demonstration that the number of FMF treatment spaces and the space proposed by the applicant is within the range indicated by reasonably projected levels of visit volume, consistent with guidance provided 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; and

(viii) A demonstration that the applicant hospital, in cooperation with its medical staff and other public and private health care organizations in its community, has attempted to reduce use of its ED and, if applicable, its FMF for non-emergency medical care. This demonstration shall, at a minimum, address: the feasibility of reducing or redirecting individuals in the service area who have non-emergent illnesses, injuries, and conditions, to lower cost alternative facilities or programs; and the actions taken by the hospital to accomplish those goals.

(2) Access.

An applicant shall address the following standards regarding access:

(a) A hospital shall demonstrate that its proposed FMF will improve access to emergency medical services for the population in the proposed service area of the FMF.

(b) The applicant shall identify problems with access to emergency medical services by underserved groups including low-income persons, racial and ethnic

minorities, and persons with disabilities residing in its existing or proposed service area, and shall develop a plan to overcome barriers to access for each underserved group identified; and

(c) A new or relocated FMF shall be located to optimize accessibility for patients who are currently served by the applicant hospital.

(3) Cost and Effectiveness.

An applicant proposing establishment, relocation, or expansion of an FMF shall demonstrate that the FMF project will cost-effectively achieve appropriate objectives. The applicant shall compare the costs and effectiveness of the proposed project with the costs and effectiveness of alternative approaches for achieving project objectives and demonstrate that the project is the most cost effective way to achieve those objectives.

(a) The applicant shall identify the primary objectives for the proposed FMF or relocated project and identify at least two alternative approaches that it considered for achieving each of the project's primary objectives. The applicant shall:

(i) Detail the capital cost estimates and operational revenue and expense projections for its proposed FMF project, over a time period appropriate for evaluating cost effectiveness;

(ii) Describe and quantify, to the extent feasible, the measures used to evaluate the cost-effectiveness of the proposed project and alternative projects; and

(iii) Provide, for each alternate approach, estimated capital costs, operational costs, and revenue, for a time period appropriate for evaluating cost effectiveness.

(b) 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) The applicant shall explain its basis for selecting its proposed FMF project and for rejecting each alternative approach identified for achieving the project's primary objectives.

(d) The applicant shall describe each measure that it has taken or will take to comply with the Maryland State Health Improvement Process plan at its existing emergency department including reducing the number of visits due to diabetes, hypertension, asthma, and mental health conditions and its plans to attain such reductions at its proposed FMF.

(e) The applicant shall describe the processes that it has taken or will initiate to promote the coordination of care with providers of primary care, with particular attention to management of chronic disease and mental health conditions, and detail its evaluation of the success of these processes at its existing ED and address its plans to coordinate care at its existing or proposed FMF and to evaluate the success of those efforts.

(4) Efficiency.

(a) 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:

(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;

(ii) Address how process improvement will affect the per visit cost of emergency services and how the process improvement will be accomplished at the FMF; and

(iii) Describe the actions it has taken to accomplish process improvement in ED service delivery at the parent hospital and the results of those actions.

(b) An applicant shall detail specific actions that it will take to improve the integration of care in ways that reduce the need for costly episodic visits to the proposed or existing FMF and its ED for persons with chronic medical conditions.

(5) Construction Costs.

The proposed construction cost of the project shall be reasonable and consistent with current industry cost experience in Maryland. The projected construction and renovation costs per square foot of the project shall be compared to the most applicable benchmark cost of good quality Class A health care facility construction of hospital emergency department space, given in the Marshall Valuation Service® guide, updated using Marshall Valuation Service® update multipliers, and adjusted as shown in the Marshall Valuation Service® guide as necessary for departmental cost differential, site terrain, number of building levels, geographic locality, and other listed factors. If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost, any change in a global budget revenue or total patient revenue cap proposed by the hospital that accounts for the capital cost of the project shall not include the amount of

the projected construction cost that exceeds the Marshall Valuation Service® benchmark and those portions of the contingency allowance, inflation allowance, and capitalized construction interest expenditure that are based on the excess construction cost.

(6) Financial Feasibility and Viability.

The proposed establishment, expansion, or relocation of an FMF shall be financially feasible and shall not have an undue negative effect on the financial viability of the parent hospital.

(a) The applicant shall provide financial projections that outline each assumption used to develop the projections.

(b) An applicant shall demonstrate that:

(i) 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) 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 FMF and the parent hospital will generate net positive revenue, on a combined basis.

(c) The applicant shall provide documentation of community support for the proposed FMF.

(d) The applicant shall describe any current and projected regional workforce shortages including shortages of emergency-trained physicians, nurses, and ancillary staff, and describe how the applicant will address these recruiting challenges.

(7) Impact.

The proposed establishment, expansion, or relocation of an FMF shall not have an undue negative effect on existing hospitals or other FMFs.

(a) The applicant shall project the impact of the FMF project on the FMF's parent hospital's:

(i) ED patient volume;

(ii) ED payer-mix;

(iii) Financial performance;

(iv) Ability to maintain specialized staff; and

(v) Ability to deliver care to indigent and underserved populations.

(b) The applicant shall project the impact of the FMF project on other health care facilities in the parent hospital's service area, the projected service area of the proposed or existing FMF, or health care facilities located outside of the parent hospital's or FMF's service area that have service areas with a significant overlap of the parent hospital's or FMF's service area. A project shall not have an undue adverse impact on the financial viability of any hospital or other FMF.

(c) An applicant shall provide an analysis of how the cost of emergency services for the health care system will change as a result of the proposed establishment, expansion, or relocation of an FMF, quantifying those projected changes to the extent possible.

(8) Quality Improvement

An FMF will provide high quality emergency medical services and continuously work to improve its quality of care.

(a) The applicant shall describe an appropriate quality assurance program and performance measures that will be used by the proposed FMF or that are used by the existing FMF on an ongoing basis to monitor and improve the quality of care provided. At a minimum, applicants shall provide information on the following performance measures for the FMF parent hospital and, if applicable, existing FMF(s):

(i) Median time from ED or FMF arrival to ED or FMF departure, for patients admitted to the hospital or transferred from an FMF to a hospital for admission;

(ii) Median time from ED or FMF arrival to ED or FMF departure for discharged patients; and

(iii) Admit decision time to ED or FMF departure time for patients admitted to the hospital or transferred from an FMF to a hospital for admission.

(b) The applicant shall include a description of all quality measures used in its quality assurance program for its ED and existing or proposed FMF, including any algorithms that will be used.

(c) The applicant shall detail mechanisms it will use for monitoring outcomes of patients discharged from the ED and the FMF.

(**9) Preference in Comparative Reviews.**

In the case of a comparative review of two or more applications to establish or relocate an FMF in which at least one applicant obtains interested party status in opposition to a proposed FMF project or in which FMF projects are proposed by

hospitals with overlapping service areas, the Commission shall give a preference in its decisions to a proposed project's application that best demonstrates:

(a) Cost effectiveness;

(b) The proven ability to reduce low acuity visits and inappropriate use of the parent hospital's ED and an effective plan for limiting low acuity visits and inappropriate use of the proposed FMF;

(c) Effective outreach to minority, indigent, and underserved patients in the hospital's service area;

(d) The existence of research, training, and educational components designed to meet regional needs and for which the applicant's circumstances offer special advantages; or

(e) The ability to integrate its FMF with primary care delivery so that FMF patients without a primary care practitioner will be referred to appropriate and accessible primary care practitioners for future care.

.05 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(2) "Acuity Level" means a five-level emergency department triage algorithm that uses the Emergency Severity Index (ESI) developed by the Agency for Healthcare Research & Quality that provides clinically relevant stratification of patients into five groups from the most to the least urgent, with Level 1 life-threatening, Level 2-emergent/high-risk, Level 3-urgent, Level 4-less urgent, and Level 5-nonurgent.

(3) “Acute care general hospital” or “hospital” means a hospital classified as a general hospital and defined in Health General § 19-307(a)(1)(i.)

(4) “Community health needs assessment” means the assessment made at least once every three years by a hospital that qualifies as a nonprofit organization under Section 501(c)(3) of the Internal Revenue Code of 1954 and that is required by the Patient Protection and Affordable Care Act, 42 U.S.C. 18001, in which the hospital must define the community it serves and assess the health needs of that community.

(5) "Emergency medical condition" means a medical condition that manifests itself by acute symptoms of sufficient severity including severe pain, psychiatric disturbances, and symptoms of substance abuse such that the absence of immediate medical attention could result in:

(a) Placing the health of the individual in serious jeopardy;

(b) Placing the health of a pregnant woman or unborn child in serious jeopardy;

(c) Serious impairment to any bodily function;

(d) Serious dysfunction of any bodily organ or part; or

(e) With respect to a pregnant woman who is having contractions:

(i) Inadequate time to effect a safe transfer to another hospital before delivery; or

(ii) The transfer posing a threat to the health or safety of the woman or the unborn child.

(6) “Emergency services” means health care services provided to evaluate and, as appropriate, treat emergency medical conditions.

(7) "EMTALA" means the Emergency Medical Treatment and Active Labor Act, 42 U.S.C. §1395.

(8) "Freestanding medical facility" means a health care facility that: provides medical and health care services; is an administrative part of an acute care general hospital; and is physically separated from the hospital or hospital grounds.

(9) "Global budget revenue" or "global budgeting" means the methodology of the Health Services Cost Review Commission that: is central to achieving the three-part aim set forth in Maryland's all-payer model of promoting better care, better health, and lower cost for all Maryland patients; focuses on controlling increases in total hospital revenue per capita; and encourages hospitals to focus on population-based health management by prospectively establishing a fixed annual revenue cap for each hospital that has a global budget revenue agreement with the Health Services Cost Review Commission.

(10) "Maryland State Health Improvement Process plan" means the most current plan developed by the Maryland Department of Health and Mental Hygiene and currently found at http://dhmh.maryland.gov/ship/SitePages/Home.aspx.

(11) "Median time from ED or FMF arrival to ED or FMF departure, for patients admitted to the hospital or transferred from an FMF to a hospital for admission" means the National Quality Forum, National Voluntary Consensus Standard for Emergency Care- Phase 2 measure ID 0495.

"Parent hospital" means the acute care general hospital applying to establish, relocate, or expand an FMF in its service area.

(12) "Quality assurance program" means health care activities and programs intended to assure or improve the quality of care.

(13) “Quality measures” includes evidence-based performance measures, accountability measures, and outcome measures endorsed by the National Quality Forum, CMS, Agency for Healthcare Research and Quality, and the Centers for Disease Control.

(14) "Service Area" means the zip code areas from which, cumulatively, 85% of patient visits to a hospital’s ED or an FMF originate, inclusive of the zip code areas ranked from highest to lowest providing the highest proportion of the hospital ED or FMF’s total patient visits in the most recent twelve-month period for which patient origin information is available.

(15) “Time to hospital admission” refers to the discharge of patients from an FMF to the next phase of care as appropriate including admission to the parent hospital or transfer to another hospital or facility.

(16) “Throughput time” is the length of time patients spend in an ED or FMF during triage, registration and care processes.

(17) “Urgent care” means the provision of medical services on a walk-in basis for primary care, acute or chronic illness, and injury.