



MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

MEMORANDUM

TO: Commissioners

FROM: Eileen Fleck *EF.*
Chief, Acute Care Policy and Planning

DATE: November 17, 2016

RE: Staff Recommendation for Proposed Permanent Regulations
State Health Plan for Facilities and Services: Freestanding Medical Facilities
COMAR 10.24.19; Analysis of Formal Comments Received

Maryland Health Care Commission (MHCC) staff is requesting that the Commission adopt as proposed permanent regulations COMAR 10.24.19: State Health Plan Chapter for Freestanding Medical Facilities (Chapter). These proposed permanent regulations match the regulations adopted by the Commission in July, with the exception of minor changes, and the references to licensing surgical capacity in an FMF as an ambulatory surgical facility (ASF) will be deleted from COMAR 10.24.19.04C, the Section covering exemptions from Certificate of Need (CON) review for a general hospital converting to an FMF. The change to Regulation .04C is necessary based on feedback from the Department of Legislative Services (DLS) staff to the Administrative, Executive, and Legislative Committee (AELR). Executive agency regulations must be reviewed by AELR prior to publication as proposed regulations. DLS noted that if surgical capacity is licensed as an ASF with two or more operating rooms, then a CON is required; surgical capacity at an FMF cannot be developed through an exemption process to establish an FMF.

After the Commission adopted proposed permanent regulations at the July 2016 Commission meeting, there was a 30-day formal comment period that ended October 3, 2016, Commission staff received comments from two organizations and one individual. The University of Maryland Medical System also submitted comments shortly after the deadline for the comment period. A copy of the comments received is available on the MHCC web site.¹ A summary of the comments received, and Staff's analysis and recommendations regarding these comments is presented below.

¹http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp.aspx

**Staff Analysis and Recommendations Regarding
Proposed Permanent Regulations for Freestanding Medical Facilities**

MHCC received formal public comments on the Chapter from the City of Takoma Park, Holy Cross Health, the University of Maryland Medical System (UMMS), and David B. Paris, Esquire. A summary of the comments submitted is presented followed by Staff's response to the comments.

.02D. Applicability

Holy Cross Health commented that it is unclear if existing freestanding medical facilities (FMFs) can only operate in their current capacity without seeking Certificate of Need (CON) approval or if these facilities can modify the scope of service, facility design, or facility size without obtaining a CON.

Staff Analysis and Recommendation

Staff recommends no changes in response to this comment. Section .02D of the Chapter explicitly states that the Chapter "applies to the establishment of a new FMF, the relocation of an FMF, and a capital expenditure made by or on behalf of an FMF that exceeds the applicable capital expenditure threshold." Staff concludes that the Chapter allows for the modification of the scope of service, facility design, or facility size without obtaining a CON, when those changes will not result in a capital expenditure that exceeds the threshold established or does not propose the introduction of a new service that is categorically regulated under the CON statute.

.04B. Project Review Standards

(1) Need

Holy Cross Health commented that the meaning of the term "expansion" in .04B(1)(c) is unclear. Holy Cross Health also stated that there should be appropriate regulatory oversight of changes to the scope or size of service at an existing FMF.

UMMS commented that this standard should be amended to provide greater flexibility in the size and design standards for FMF applicants to account for differing patient populations, service areas, and evolving, integrated health care delivery systems. UMMS specifically suggested that the Chapter should not specify that a proposed FMF should be designed to have treatment capacity and space consistent with the standard used for design of "low range" hospital emergency departments, as outlined in the current edition of *Emergency Department Design: A Practical Guide to Planning for the Future*, published by the American College of Emergency Physicians (ACEP Guidelines). As an alternative, UMMS recommends that no quantitative guidance on the size of an FMF be provided in the State Health Plan. UMMS recommends that an FMF application be evaluated on its consistency with applicable guidance in the ACEP Guidelines without any limitations on size or treatment capacity. This approach would allow an FMF to seek to justify

treatment capacity consistent with the ACEP Guidelines for a high range hospital emergency department (ED). UMMS requested specific changes to COMAR 10.24.19.04B(1)(c)(vii), shown below with underlining for added language and strikethroughs for deletions, as follows.

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~~ applicable guidance of the 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.

UMMS stated its view that future FMFs will likely serve higher acuity patients than have been historically treated at the existing FMFs. UMMS noted that ACEP guidelines provide for a 1.25 multiplier as a building square footage adjustment factor for a freestanding facility, but it may not be sufficient for an applicant's projected utilization and projected acuity level, which might be influenced by specialty programs developed at the FMF.

The City of Takoma Park commented that the Chapter should minimize the administrative burden of the CON review for the Commission and the applicant. The City of Takoma Park noted that a parent hospital that has relocated to a new site could only provide a history of the new site's service if the hospital has been in operation for at least a year, which could leave residents served at the former hospital site without services for a long period of time. The City of Takoma Park proposed that the Chapter allow the Commission to consider historic trends of the hospital's emergency department prior to the hospital's relocation.

Staff Analysis and Recommendations

Staff recommends no change in response to the comment from Holy Cross Health requesting clarification on the meaning of an expansion of an FMF. As stated in Section .02D of the Chapter, the Chapter applies only to the "establishment of a new FMF, the relocation of an FMF, and a capital expenditure made by or on behalf of an FMF that exceeds the applicable capital expenditure threshold." A change in the size or capacity of an existing FMF that does not involve any change in its services only requires a CON if it requires a capital expenditure that exceeds the applicable capital expenditure threshold. The reference to the expansion of an FMF in .04B(1)(c) is a general term for covering changes that exceed the applicable capital expenditure threshold.

Staff recommends no change in response to the comments from UMMS. Staff concludes that when a hospital is converting to an FMF, the volume and types of visits at the proposed FMF are unlikely to match those used by ACEP in its development of capacity and space guidance for high range hospital EDs. In MHCC staff's 2015 *Report on the Operations, Utilization, and Financial Performance of Freestanding Medical Facilities*, the percentage of patients admitted to a hospital ranged from 3.9% to 5.9% over the period from CY 2012 to CY 2014, well below the ACEP benchmark of 8% used as a ceiling for low range hospital emergency departments. In addition, the ACEP Guidelines describe ranges for the appropriate number of treatment spaces

based on increments of 5,000 visits that allow for sufficient flexibility to account for some variation in patient acuity, demographics, and specialty programs. Finally, specific guidance outlined in the ACEP Guidelines for freestanding emergency centers rather than hospital emergency departments recommend planning for levels of visit throughput that are consistent with the low range hospital ED, rather than the projections of high range hospital EDs. Staff concludes that the Chapter appropriately guides new FMF designs because the ACEP Guidelines are consistent with the experience of FMFs, nationally and in Maryland. Using the ACEP Guidelines, as proposed in the Chapter, will insure that overbuilding and excessive costs are avoided.

Hospital ED or FMF treatment capacity is not categorically regulated under the Maryland CON program. Both types of facilities, once established, can expand space and treatment capacity without having to obtain a CON if the cost of the project is below the capital expenditure threshold or by agreeing to forego extraordinary adjustments in their revenue base when the cost of the project exceeds the capital expenditure threshold.

Staff recommends no changes in response to comments from the City of Takoma Park on the need standards. Staff concludes that the standards are not as restrictive as described by the City of Takoma Park and notes that no hospital has stated that the standard will cause the administrative burden suggested by the City.

(4) Efficiency

The City of Takoma Park commented that the Chapter should recognize that co-locating an FMF with non-emergency medical facilities improves the efficiency of health care delivery. For example, the City stated that patients in need of psychiatric services often present at emergency facilities, and in Takoma Park such patients presenting to an FMF could immediately be transferred to a psychiatric facility.

Staff Analysis and Recommendations

Staff recommends no changes in response to this comment from the City of Takoma Park. The efficiency standard does not preclude consideration of the potential benefits of co-locating an FMF with other medical facilities.

(6) Financial Feasibility and Viability

UMMS proposed specific changes to COMAR 10.24.19.04B(6)(b)(iii) based on its concern that a proposed FMF may be compared to existing FMFs that are not truly comparable. UMMS proposed specific changes that are shown below with underlining for added language and strikethroughs for deletions.

Its staffing assumption 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~~ similar FMFs with

similar projected visit volumes, projected patient acuity, demographics, and specialty programs.

The City of Takoma Park commented that the Chapter should allow a parent hospital that seeks to establish an FMF at its prior location to demonstrate financial feasibility by adjusting and supplementing the financial projections accepted by the Commission in the relocation proceeding rather than requiring completely new financial projections.

Staff Analysis and Recommendations

Staff recommends no changes to COMAR 10.24.19.04B(6)(b)(iii) based on these comments because the standard appropriately refers to comparing the proposed project to similar FMFs, and the standard does not state that only existing FMFs in Maryland will be considered comparable. In addition, the proposed changes refer inappropriately to comparisons with FMFs with similar projections. The actual experience of similar FMFs is most relevant.

Staff recommends no changes to address the changes proposed by the City of Takoma Park. Staff concludes that it is necessary to have accurate financial projections, and the standards do not explicitly preclude the approach proposed by the City of Takoma Park.

(7) Impact

Holy Cross Health commented that the impact of a proposed project on the future accessibility and affordability of health care be included as a component of this standard. Holy Cross Health also requested certainty that the global budget impact on the supporting hospital and other hospitals near the proposed FMF be analyzed in the context of a longer time period and the potential for longer-term volume shifts.

Staff Analysis and Recommendations

Staff recommends no changes in response to Holy Cross Health's comment. Staff notes that there are separate project review standards for access and cost effectiveness, and incorporating access and affordability into the impact standard is unnecessary. A timeframe for evaluating a proposed project is not explicitly specified in the impact project review standard, and Holy Cross Health has not explained how it defines "the long term." Staff concludes that the standard allows for consideration of the impact of a proposed project over several years, and the appropriate time frame to consider may vary for projects, so a flexible, rather than fixed, time frame is best.

(8) Quality Improvement

The City of Takoma Park commented that when a relocating hospital proposes the establishment of an FMF on its old campus, the Commission should deem the quality assurance program proposed by the applicant for the FMF to be satisfied if it is identical to that already approved by the Commission in a CON for the relocated hospital.

Staff Analysis and Recommendations

Staff recommends no changes in response to this comment. The City is proposing changes in the standard to fit a specific project that the hospital in question is not sponsoring at this time but that the City is eager to support. The specific performance standards referenced are appropriately tailored for general use in the types of project reviews that are reasonably anticipated for FMF development and this will usually not involve relocation of a hospital.

.04C. Exemption from Certificate of Need Review to Convert a General Hospital to a Freestanding Medical Facility

Timing of the Exemption Process

UMMS commented that the Chapter does not comply with the exemption process established by the General Assembly. UMMS noted that the exemption process could take as long as 135 days, but the Commission would be required to make a determination on the application within a mere 90 days of docketing for an uncontested application or within 150 days of docketing for a contested application. UMMS requested that requirements in COMAR 10.24.19.04C(3)(c) be eliminated to address this issue. In addition, UMMS suggested that the Commission accept an application from a hospital seeking to convert to an FMF in accordance with the exemption schedule established by statute and that the Commission review the application in concert with the Maryland Institute for Emergency Medical Services Systems (MIEMSS), rather than accepting an application only after MIEMSS has made a determination that the conversion will maintain adequate and appropriate delivery of emergency care within the statewide emergency medical services system.

ACEP Guidelines

UMMS requested specific changes to COMAR 10.24.19.04C(8)(d) based on its concern that a proposed FMF may not appropriately be evaluated according to the ACEP Guidelines for a low-range hospital emergency department. UMMS proposed specific changes as shown below with underlining for added language and strikethroughs for deletions.

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.

UMMS also asked for specific changes to COMAR 10.24.19.04C(8)(f) based on its concern that it may be inappropriate to evaluate a proposed FMF in accordance with the ACEP Guidelines for a low-range hospital emergency department. The specific changes suggested by UMMS are shown below with underlining for added language and strikethroughs for deletions.

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.

Surgical Services at an FMF

UMMS commented that requiring surgical services at an FMF to be separately licensed as an ambulatory surgical facility conflicts with regulations of the Centers for Medicare and Medicaid for provider-based status, and FMFs in Maryland are required to obtain provider-based status. UMMS also noted that the requirement for a separate license as an ambulatory surgical facility would preclude the Health Services Cost Review Commission (HSCRC) from exercising its discretion to regulate rates at FMFs. UMMS stated that the Office of Health Care Quality would need to amend licensing regulations applicable to FMFs and not require separate licensure as an ambulatory surgical center to provide surgical services at an FMF.

UMMS commented that the State Health Plan Chapter for general surgical services, COMAR 10.24.11 refers only to hospitals and ambulatory surgical centers and not FMFs. UMMS also noted that Health General §19-3B-01(b)(2)(ii) 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. UMMS requested that the definition of hospital in COMAR 10.24.11 be amended to state that a 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.” UMMS stated its view that this change to the definition would permit FMFs to seek to establish, relocate, or expand surgical service lines. UMMS also requested several other changes to COMAR 10.24.19.04C(9). The changes requested by UMMS are shown below with strikethroughs for deleted text and underlining of added text.

(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~~ (*sic*) 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

(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 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.

Staff Analysis and Recommendations

Timing of the Exemption Process

The regulatory process proposed by UMMS is not feasible. For a hospital seeking to close and convert to an FMF, Health General §19-120 requires that a public informational hearing be held within 30 days after the health care facility files with the Commission a notice of its proposed closing or partial closing. Within 10 working days after a public informational hearing the hospital is required to provide a written summary of the hearing to the Commission and several other named public officials and governing bodies. Thus, under these statutory mandates for the review process, which UMMS is recommending as a replacement for the draft State Health Plan process, there could potentially be fewer than 20 days for the Commission to make a final finding on establishment of the FMF as a hospital conversion because within 60 days of receiving notice of a hospital's intent to convert, the Commission is required by statute to notify the applicant hospital of the Commission's findings. If we assume that the Commissioners should have at least a week to review Staff's evaluation of the exemption request before issuing a decision, this means that very little time would be available following the information hearing for Staff to obtain all the necessary input and prepare an evaluation and recommendation.

An important additional problem is created by the responsibilities the law assigns to the Maryland Institute for Emergency Medical Services and Systems (MIEMSS) in the process. MIEMSS's required assessment of a proposed hospital conversion to an FMF should precede Commission action, rather than being undertaken simultaneously as proposed by UMMS. This is necessary because, under Health-General §19-120(o)(3)(i)5c, the Commission cannot approve a conversion to an FMF unless MIEMSS finds that the conversion will maintain "adequate and appropriate delivery of emergency care within the statewide emergency medical services system ..." Staff also notes that adequate information must be provided by an applicant in order for Commission staff to make a competent recommendation. The experience of Commission staff, regarding both exemption requests and Certificate of Need applications shows that, often, an applicant does not initially provide the clear and complete information needed for Staff to make

a recommendation to the Commission. The process outlined in the draft is designed to assure that there is sufficient time for MHCC staff to evaluate and for the Commission to consider the proposal after receipt of all the necessary information from the applicant and all the important input from the affected community, public officials, and MIEMSS. The UMMS proposal could result in a process where the time left for analysis and consideration after all the information and reaction to the project is transmitted to MHCC will be impossibly compressed. Finally, it would be appropriate for HSCRC to provide input to MHCC on a request to convert one type of rate regulated facility, a hospital, to another type of rate regulated facility, an FMF. While this is not a specific mandate of the statute, the process in the draft plan would makes this consultation more feasible.

Staff has concluded that the exemption process will typically be a much faster process than a CON review because there can be no interested parties, there are fewer review standards, and the review standards are of a different nature. The process outlined in the draft would not require 135 days, as stated by UMMS, if the applicant fulfills its responsibilities in the process prudently and expeditiously by filing a complete application that includes a credible transition plan, and conducting the public informational hearing, because the 60-day clock would begin shortly after these steps are accomplished.

ACEP Guidelines

As noted, Staff recommends no changes to COMAR 10.24.19.04C(8)(d) because Staff concludes that when a hospital is converting to an FMF, the volume and types of visits at the proposed FMF are unlikely to be those typically experienced by higher range hospital EDs, as described in the ACEP Guidelines. MHCC produced two reports evaluating FMF operations in Maryland that support the draft standards limitations on the size and cost of newly established FMFs and development of additional space and treatment capacity can be developed, if needed, over time and would not necessarily require additional CON review and approval.

Staff recommends no changes to COMAR 10.24.19.04C(8)(f) because the standard appropriately refers to comparing the proposed project to similar FMFs, and the standard does not imply that only existing FMFs in Maryland will be considered comparable. In addition, the proposed changes refer inappropriately to comparisons with FMFs with similar projections. The actual experience of similar FMFs is most relevant.

Surgical Services at an FMF

Although UMMS commented that requiring surgical services at an FMF to be separately licensed as an ambulatory surgical facility conflicts with regulations of the Centers for Medicare and Medicaid Services (CMS) for provider-based status, HSCRC staff has advised MHCC staff that CMS exempted Maryland from that provision. Commission staff concludes that changes to the definition of an ASF in Health General § 19-3B-01 and § 19-114 would eliminate the conflict identified by UMMS. Staff notes that parallel changes would then need to be made in the definition of a freestanding ambulatory surgical facility in COMAR 10.05.05.01. The alternative approach suggested by UMMS as a way to resolve the conflicts with CMS regulations and State regulations, amending the definition of hospital in COMAR 10.24.11 to state that a 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,” would likely require additional changes in the draft Chapter for FMFs. Staff prefers to change the definition of an ASF because we do not believe that current law mandates creation of the hybrid medical care facility as desired by UMMS that combines unscheduled urgent, emergent medical care, scheduled ambulatory surgery and other yet to be defined services under a single FMF license.

The establishment of FMFs in Maryland law and the regulations of the Office of Health Care Quality never envisioned that FMFs would have operating rooms and all of the ancillary and support space necessary for operation of a surgical facility. These types of surgical facilities are common and long-established in Maryland as a different category of facility, the ambulatory surgical facility. These surgical facilities require CON review and approval under Maryland law if they include two or more operating rooms.

MHCC staff is planning to propose revisions to the State Health Plan chapter for general surgical services to establish an exemption process that would allow for an ASF with up to two operating rooms to be developed on the campus of an FMF that is being established through the conversion of a general hospital. MHCC staff has formed an Ambulatory Surgery Work Group to assist in considering these changes. MHCC staff believes that the statute provides the authority to establish an exemption process for an ASF with two operating rooms, as stated in Health General § 19-120. MHCC staff also plans to create an exemption process for an existing physician office surgery center (POSC), which has one operating room, to add a second operating room and become an ASF and for two one-operating room POSCs to consolidate and establish a two-operating room ASF. The SHP chapter for general surgical services would establish standards for both types of exemption review. These exemption reviews would require that applicants meet fewer standards compared to a CON review; there would be no interested parties, and the reviews would be completed within a shorter time frame.

DLS, like UMMS, noted a conflict between the proposed Chapter for FMFs and the SHP Chapter for surgical services, COMAR 10.24.11. DLS noted that if surgical capacity is licensed as an ASF with two or more operating rooms, then a CON is required. In order to address the conflict noted by DLS, Staff suggests deleting language that references the addition of surgical capacity at an FMF developed through an exemption process. The proposed deletion is shown below with strikethroughs.

~~(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 with the FMF or adjacent to the FMF, and 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 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~~

~~(iii) That the design of the operating room and ancillary space for the 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 an ambulatory surgical facility, based on the existing staffing levels for outpatient surgery at the converting hospital.~~

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

~~(d) The ambulatory surgical facility outpatient surgical capacity approved by the Commission to be co-located with 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.~~

Other Comments

The City of Takoma Park proposed that the Chapter provide special consideration, as reflected in its comments on specific standards, for FMF applicants that have recently had a parent hospital relocate within the preceding five years when the hospital has a record of compliance with licensure standards and requirements that demonstrate its ability and commitment to provide quality health services, and the FMF CON application is consistent with the State Health Plan.

Holy Cross Health requested clarification on how the Commission would view multiple hospitals in a jurisdiction coming together and determining that an additional FMF is needed to better service the population. Holy Cross asked how the Chapter would be applied if such partnering were to take place.

David B. Paris, Esquire, proposed that licensing of combined freestanding emergency and urgent care centers be required unless proponents of isolated urgent care centers provide compelling documentary evidence of the efficacy of a segregated facility. He stated that these integrated facilities discourage the use of hospital EDs for sporadic crisis visits by promoting the establishment of long-term relationships with primary care providers and specialists.

Mr. Paris also proposed that the Chapter require comprehensive resolution of all issues regarding the provision of hospital services relating to a hospital relocation. He expressed concern about the lack of a precise methodology for providing sustainable services at the former sites of general acute care hospitals.

Mr. Paris commented that the State of Maryland should mandate impact studies for any proposed hospital closing or downsizing to be integrated into the CON review process. Mr. Paris recommended legislation be passed to provide for objective medical impact studies, rather than proposing specific changes to the draft Chapter.

Staff Analysis and Recommendations

Staff recommends no changes in response to the City of Takoma Park's request for special consideration of FMF applicants in certain circumstances. Staff addressed the comments of the City of Takoma Park on individual standards and recommended no changes in response to its comments.

Staff recommends no change in response to Holy Cross Health's comment requesting clarification on how partnering among multiple hospitals in a jurisdiction where the hospitals agree a freestanding medical facility is needed would affect the regulatory process for establishing an FMF. These requirements place no impediment on hospitals partnering to develop FMFs. In addition, Staff concludes that the regulatory process would not be affected because only one hospital may be the parent hospital for an FMF because administratively an FMF is part of a specific hospital.

Staff recommends no changes in response to the suggestion of Mr. Paris that the State require licensing of combined freestanding emergency and urgent care centers. Staff concludes that by requiring that an applicant for a CON to establish an FMF describe the steps that it has taken or will initiate to promote the coordination of care with providers of primary care, as well as, its evaluation of the success of these processes, the draft Chapter is promoting the goals that Mr. Paris identified in his comments. The mechanism that Mr. Paris proposes for achieving these goals is only one of several possible mechanisms and Staff concludes that it is appropriate to give an applicant flexibility. If hospitals perceive that Mr. Paris is correct, they may seek to develop combination FMFs and urgent care centers as a better care model under the draft regulations. Staff does not believe that a mandate for this model is appropriate at this time.

Staff recommends no changes in response to Mr. Paris's request that this SHP Chapter require comprehensive resolution of all issues regarding the provision of hospital services relating to a hospital relocation. Staff concluded that the CON process provides adequate opportunities for interested parties, public feedback, and consideration of the needs of the community. The CON exemption process for converting a hospital to an FMF also includes opportunities for public feedback and consideration of the needs of the community.

Staff recommends no changes in response to Mr. Paris's proposal that objective impact studies be integrated into the CON process. The impact of proposed CON projects is evaluated based on information provided by an applicant and by interested parties but Staff also undertakes its own research and analysis, which is objective. Staff concludes that the proposed process and standards are adequate for an objective evaluation of the impact of a proposed CON project.

Other Changes

Staff recommends that language be added to the draft Chapter for FMFs at COMAR 10.24.19.04B(1)(c)(viii) in order to have consistent standards for the review of both CON applications to establish an FMF and requests for exemptions to establish an FMF, with regard to the amount of observation space proposed. The proposed additional language is shown below with underlining.

(viii) A demonstration that the number of observation spaces and the size of the observation spaces are consistent with 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; and