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MEMORANDUM

TO: Commissioners

FROM: Eileen Fleck E.F.
Acting Chief, Specialized Services Policy and Planning

DATE: July 18, 2013

RE: Summary of Informal Comments and Staff Recommendations: Draft State Health Plan for Acute Inpatient Rehabilitation Services (COMAR 10.24.09)

Maryland Health Care Commission staff is requesting that the Commission adopt as proposed permanent regulations a replacement COMAR 10.24.09: State Health Plan Chapter for Acute Inpatient Rehabilitation Services ("Chapter"). Attached is a copy of staff's recommendation for the replacement Chapter.

I. Introduction

Background

Commission staff formed an Acute Rehabilitation Work Group that met a total of four times during 2011 and 2012 to consider possible changes to the existing Chapter of the State Health Plan (SHP). On February 11, 2013, Commission staff posted a draft Chapter for informal public comment with comments due on March 27, 2013.

Informal Public Comments Received

In response to the invitation for informal public comment, written comments were received from a total of five organizations, which are listed below. A copy of the comments from each organization is attached.

- Adventist HealthCare

TOLL FREE
1-877-245-1762

TDD FOR DISABLED
MARYLAND RELAY SERVICE
1-800-735-2258

- Calvert Memorial Hospital
- LifeBridge
- MedStar Health
- Upper Chesapeake Health System

The remainder of this document provides a summary of the written comments received and staff's analysis and recommendations.

II. Summary of Informal Comments Received on the February Draft State Health Plan for Facilities and Services: Specialized Health Care Services- Acute Inpatient Rehabilitation Services (COMAR 10.24.09)

Section .02 Introduction

D. Applicability

Adventist HealthCare (AHC) commented that clarity is needed regarding the need analysis required for a CON application. It is unclear whether an applicant must address the overall need for acute rehabilitation services or the need for acute rehabilitation services in the following categories: comprehensive, brain injury, spinal cord injury, and pediatric services.

Staff Analysis and Recommendations Regarding Section .02

Staff clarified in the need analysis section that an applicant must address in its analysis all of the following services: comprehensive, brain injury, spinal cord injury, and pediatric.

.03 Issues and Policies

Access to Care

MedStar Health commented that there is no data included in the draft Chapter to support the existence of an access problem. MedStar Health also commented that according to data from the U.S. Health Indicators Data Warehouse, Medicare inpatient rehabilitation discharges in Maryland are among the highest in the country, when discharges from Maryland hospitals that do not report to Medicare are taken into account. MedStar Health also notes that consideration of access to providers outside Maryland, such as National Rehabilitation Hospital would demonstrate even greater access.

MedStar Health also commented that the draft Chapter expressly permits projects not supported by projected need that seek to address access barriers, even though the draft Chapter does not find or substantiate that a problem exists. It notes that the Medicare Payment Advisory Commission's March 2012 Annual Report concludes that access to acute rehabilitation is not a problem for the Medicare population. MedStar Health also notes that no Maryland studies regarding distance to providers being a problem are cited. Lastly, MedStar Health commented that even if variation could be shown to exist in Maryland, it does not mean that adding new capacity is the solution. It could be that education and outreach are needed.

Staff Analysis and Recommendations Regarding Section .03, Access to Care

Although Staff did not include in the draft Chapter data to support the wide variation in use rates among Health Planning Regions (HPRs) by age groups, this information was provided when the draft Chapter was posted for review. Staff previously reviewed data from the Centers for Medicare and Medicaid Services' Chronic Conditions Warehouse for 2008 and found that the rate of Maryland discharges per 1,000 Medicare beneficiaries was similar to the national average when data from the discharge abstracts of Maryland and the District of Columbia were reviewed; the days per 1,000 Maryland Medicare beneficiaries was lower than the national average. Staff regards a measurement of utilization based on Maryland residents as a more accurate measurement of utilization rates than discharges from Maryland hospitals, which may include residents from other states. In response to comments from MedStar Health that data to support the existence of an access problem were not included in the draft SHP Chapter, Staff added footnotes and text to indicate the sources of information used to evaluate utilization of acute rehabilitation beds in Maryland.

Staff agrees that variation in the utilization of acute rehabilitation beds may not always be due to access barriers, and the draft SHP Chapter does not assume that is the case. Applicants are only given an opportunity to provide evidence of access barriers, and then an applicant must demonstrate its ability to successfully address the identified access barriers.

Quality of Care

MedStar Health commented that the draft contains an inadequate analysis of skilled nursing facilities (SNFs) as an alternative to acute inpatient rehabilitation in terms of cost and quality. It noted that many patients cannot be managed by SNFs.

Staff Analysis and Recommendations Regarding Section .03, Quality of Care

Staff agrees that some patients cannot be managed by SNFs and included conclusions from published studies regarding the use of acute inpatient rehabilitation services as compared to SNFs. The information included is primarily background material. It is not incorporated into the need methodology or standards for evaluating proposed projects. Staff recommends no changes in response to this comment.

Need for Capacity

AHC commented that access barriers should be clearly defined where they are referenced under the subsection on "Need for Capacity." A sentence states, "Access barriers need to be considered as part of evaluating changes in the delivery system for acute inpatient rehabilitation." AHC also added that the health planning process should identify access barriers based on validated studies or other sources of information.

AHC commented that more clarity needs to be provided regarding the reference to recent and anticipated changes that may alter the capacity required for acute inpatient utilization so that historic patterns are not the sole factor considered in evaluating capacity. MedStar Health also

commented that the draft SHP does not identify or analyze the impact of recent and anticipated changes that call for the significant change in policy, but this is stated as the basis for allowing projects that are inconsistent with the need methodology.

AHC commented that over and underutilization, referenced in Policy 2, should be defined. MedStar Health also commented that there is no analysis or criteria to define underutilization. It recommended that the policy should be eliminated unless supporting analysis and reasonable criteria defining underutilization are established.

Staff Analysis and Recommendations Regarding Section .03, Need for Capacity

The work group recommended that barriers to access not be specifically identified and limited to a particular list. Staff recommends no change in response to AHC's proposal that specific access barriers be referenced. Staff agrees that barriers identified by applicants should be based on validated sources of information. Staff changed the text in section .04B to note this requirement.

Staff added text to this subsection and the subsection on Cost-Effectiveness and Efficiency to further explain the basis for the need methodology. Staff also cited a recent proposed rule of the Centers for Medicare and Medicaid Services (CMS) to clarify the reference to recent and anticipated policy changes. This document describes not just a proposed policy, but also the history of changes in CMS payment policies affecting acute inpatient rehabilitation services. It is the recent and anticipated federal policy changes, the unexplained wide variation in use rates that has persisted over time, and stakeholder feedback through work group meetings that have led staff to create the new proposed bed need methodology.

.04A General Review Standards

(2) Quality of Care

MedStar Health commented that quality standards are lower in the revised draft SHP Chapter. MedStar Health cites the elimination of the requirement for accreditation as an example of this. MedStar Health proposed that this requirement should be maintained and stated that an applicant should demonstrate it has considered CARF requirements in its programmatic planning by outlining its plans for achieving CARF accreditation. Furthermore, MedStar Health recommended that accreditation be required within a specific time frame, with failure to meet the deadline resulting in the Commission revoking the provider's Certificate of Need.

MedStar Health also commented that the draft chapter fails to address CMS quality measures to which freestanding facilities are now subject. It noted that depending on the outcomes of the Medicare waiver negotiations Maryland hospitals not currently participating may need to comply with those standards as well. MedStar recommended incorporating these standards in the draft Chapter, even if facilities are not currently required to report on them.

Staff Analysis and Recommendations Regarding .04A(2), Quality of Care

CARF accreditation is required by statute in §19-318 of the Health-General Article. The draft Chapter does not eliminate that requirement. Staff recommends no changes in response to comments regarding CARF accreditation.

In this section, under .04A(2)(iii)(b), the draft SHP Chapter states that an applicant that currently provides acute rehabilitation services that is seeking to establish a new location or expand services shall report on all quality measures required by federal regulations or State agencies. Staff believes the existing language allows for flexibility in creating new requirements regarding quality, as needed. Staff recommends no changes in response to this comment.

.04B Project Review Standards

(1) Access

Upper Chesapeake Health System (UCHS) suggested that the requirement to optimize accessibility apply to any project, not only a new rehabilitation hospital or subunit.

MedStar Health commented that there is no guidance on how a project credibly addresses barriers to access such as travel times, travel barriers, or other access barriers. MedStar Health also stated that if the draft Chapter is going to allow new facilities not supported by the need projections, then it must clearly enunciate the policies and principles of regionalization and provide guidance on what an applicant must address in order to demonstrate that its project addresses a barrier to access. To address these concerns, MedStar recommended that the standard .04B(1) be eliminated.

Staff Analysis and Recommendations Regarding .04B(1), Access

Staff concludes that there are some projects where it may not be desirable to subject an applicant to a requirement to optimize accessibility, for example, an on-site replacement project. Staff added language to include relocation projects.

In response to MedStar's comment that there is no guidance on how to evaluate whether a project credibly addresses access barriers, Staff revised the text in .04B(1) to clarify how the credibility of an applicant's plan to address barriers to access will be evaluated.

(2) Need

UCHS commented that the language in this section should clarify that the assessment of net need does not apply to a project seeking only to relocate beds within an HPR. In addition the requirement should likewise apply to .04B(2)(d).

LifeBridge Health noted that Section .04B(2)(e) only mentions pediatric patients. LifeBridge Health recommended that applicants should also have to explain their need

assumptions if they plan to treat patients with brain and spinal cord injuries. LifeBridge Health explained that this is important for maintaining quality and consistency of care.

MedStar recommended that standard 04B(2)(d) be substantially revised to provide more guidance on an applicant's analysis of barriers to access and how the credibility of an applicant's plans to address barriers to access will be evaluated.

Staff Analysis and Recommendation Regarding .04B(2), Need

Staff agrees with LifeBridge that applicants should have to explain their need assumptions if they plan to treat patients with brain and spinal cord injuries. Staff added recommended language to Section .04B(2)(e) stating this requirement.

Staff agrees that greater guidance should be included regarding how the credibility of an applicant's plan to address barriers to access will be evaluated. Staff added text to .04B(2)(1) clarifying how the credibility of an applicant's plan to develop access barriers will be determined.

Staff does not agree that "relocation" of beds within an HPR, which may involve increasing the number of acute rehabilitation facilities in a region or replacing one site with another, should not be subject to need assessment requirements. If a region has excess beds and a reasonable distribution of facilities, "relocation" projects may not be needed. Requiring an applicant that proposes to relocate beds to demonstrate a need for the project will eliminate this problem. Staff recommends no changes in response to this comment.

(3) Impact

MedStar Health commented that the standard regarding impact does not require analysis of the impact on existing providers to maintain highly specialized medical staff. This requirement should be included.

AHC suggested that rather than referring to an "unwarranted impact" as being unacceptable, the standard should state that "[a] project shall not have an adverse impact on the financial viability of an existing provider of acute inpatient rehabilitation services."

AHC also suggested that the process for determination of impact is vague and should be spelled out more clearly so the threshold for determining impact is known. AHC also wants to know if impact is measured solely in relation to volume.

Staff Analysis and Recommendations Regarding .04B(3), Impact

Staff agrees with MedStar Health that an applicant must analyze the impact on existing providers to maintain highly specialized medical staff, as part of the impact analysis. Staff added recommended language stating this requirement.

In most cases, a new program will have at least some adverse impact on an existing program. The language proposed by AHC suggests that any adverse impact at all is unacceptable and could excessively restrict the approval of new projects. A requirement for no adverse impact is not consistent with the current approach to other regulated health care facilities and services.

Staff agrees that language could be clarified to specify which types of impact matter. Staff added language to clarify that impacts other than volume will be considered, such as changes in the average length of stay, case-mix, and quality of care at other providers.

(7) Minimum Size Requirements

AHC commented that the rationale for a 10-bed minimum is arbitrary. AHC believes that the standard should be based on an average daily census threshold. Clinical quality and financial viability depend upon a critical mass of patients. This critical mass is achieved at a higher sustained census than 10 beds would achieve.

Staff Analysis and Recommendations Regarding .04B(7), Minimum Size Requirements

Staff chose a 10-bed minimum standard based on feedback from the work group. One of the members had experience performing site surveys of acute rehabilitation providers for an accreditation body and that member's knowledge informed the discussion of the work group. In addition, Commission staff reviewed the regulations in other states and provided this information to the work group. Many states have no minimum standard. In states with a minimum standard for an acute rehabilitation unit, the range was from 8 to 30 beds. Staff agrees that clinical quality and financial viability depend on a critical mass of patients that is better reflected by the average daily census rather than the number of licensed beds. The minimum size standard is used in conjunction with a standard for the average daily census in evaluating whether an applicant will have an adequate volume of patients. Although AHC states that a higher critical mass is necessary, it based this conclusion on its own experience and did not provide any other evidence to support a specific higher standard. Staff recommends no changes in response to this comment.

.05 Methodology for Projecting Adult Acute Rehabilitation Bed Need

Data Sources for Bed Need Projection

AHC commented that the data source and definition of acute rehabilitation for DC hospitals differs from that outlined for Maryland hospitals. AHC also noted that it is unclear how this will affect analysis on out-migration between jurisdictions that border DC.

Staff Analysis and Recommendations Regarding Data Sources for Bed Need Projection

In response to this comment, Staff has changed the description of data sources to improve the consistency between the two sources of information. The Maryland discharge abstract data includes additional data fields (type of daily service and nature of admission), which are not available in the discharge abstract data for the District of Columbia, that are useful for accurately

capturing acute inpatient rehabilitation discharges, particularly at freestanding providers, even though all or almost all records are included. This result is consistent with the capture of records from National Rehabilitation Hospital in the District of Columbia.

Methodology

LifeBridge Health commented that bed need should be calculated excluding pediatric acute inpatient, brain injury, and spinal cord injury. It stated that all three subcategories should be evaluated on a case-by-case basis. It also noted that there is separate CARF accreditation for those categories and proposed that all three subcategories should not be included in the overall bed need calculation.

Calvert Memorial Hospital (CMH) commented that certain regions in Maryland have had little to no access to acute inpatient rehab services over many years. CMH proposes that, for only the Southern Maryland HPR, instead of using the minimum bed need as the rebuttable threshold for filing a CON, the median of the minimum and maximum bed need set the baseline. CMH requested this change because it believes the calculated minimum need woefully understates the need.

CMH noted that there is a very large range between the minimum and maximum bed need for the Southern Maryland HPR. CMH cited the maximum projected bed days for residents of the Southern Maryland HPR and the assumption that 70 percent of the HPR's residents could be served within the region as evidence that patients in the Southern Maryland HPR do not currently have access to high quality acute inpatient rehabilitation services.

CMH stated that a majority of patients in the HPR currently have to leave the region or are being placed in alternative settings that frequently are less appropriate. CMH also noted that the sole source of acute inpatient beds in Southern Maryland is Laurel Regional Hospital, at the extreme northern edge of the HPR, more than 50 miles from Calvert Memorial Hospital and approximately 70 miles from St. Mary's Hospital in Leonardtown. CMH explained that Laurel Regional Hospital is more closely linked to the Baltimore-Washington corridor and the Central Maryland and Montgomery County HPRs, not Southern Maryland and the Southern Maryland HPR.

CMH also commented that the geographical limitation will only become more significant as there is a move towards formalizing population health management and clinical integration networks. CMH noted that the ability to treat patients in a coordinated and comprehensive fashion is negatively impacted by the limitations of the location of the currently approved beds.

MedStar Health commented that the methodology results in an overstatement of need because it uses base year discharges and trend data prior to the full implementation of the Medicare rule on admission criteria for admitting patients to inpatient rehabilitation. In 2010, SNF utilization increased for orthopedic patients especially and hospital admissions decreased. The Commission should use 2011 and 2012 base year data to eliminate the anomaly.

MedStar Health also commented that the need projections fail to account for the acute inpatient rehabilitation beds in the District of Columbia. As a result, there is positive bed need projection in Montgomery County. The draft Chapter states at .04B(2)(d)(iii) that it will consider cross-regional travel as a reason to ignore its own need projections, but fails to do so in calculating need.

MedStar Health also commented that the need projection is based on physical bed capacity rather than licensed capacity and it should be based on licensed capacity. Excluding beds not actually being used could result in another applicant filing a CON application to seek those beds.

Staff Analysis and Recommendations Regarding Methodology

Staff does not have the information necessary to precisely calculate a bed need projection that excludes brain and spinal cord injury patients as proposed by LifeBridge. The discharge abstract data for hospitals in the District of Columbia does not currently include information on the impairment codes that identify the reason for a patient's inpatient rehabilitation hospitalization in the Maryland discharge abstract data. Another challenge to LifeBridge's proposed approach is that beds are not licensed for specific types of patients, so projecting the capacity needed to serve these patients is not a straight forward calculation. For these reasons, staff concludes that the approach in the draft Chapter works best. An applicant who does not plan to develop specialized programs to serve patients with brain and spinal cord injuries generally would be expected to exclude those patients from its justification of the need for the proposed project. To the extent that such patients migrate to facilities in other HPRs or surrounding states with these specialized services, the bed need projection accounts for those patients.

Staff concludes that using the median for only the Southern Maryland HPR as the basis for the rebuttal threshold for filing a CON, as proposed by CMH, is not an equitable approach. In addition, an applicant has the opportunity to present evidence regarding access barriers as part of the CON review process. A wide bed need range in the Southern Maryland HPR does not constitute evidence that there is underutilization of inpatient rehabilitation services by residents of the HPR due to a lack of access to services. The wide range results from the very high percentage of patients who seek care outside the Southern Maryland HPR and a bed need projection that acknowledges the possibility that with less out-migration, there could be a greater need for inpatient rehabilitation beds in the HPR.

Although MedStar Health stated that the methodology overstates need due to changes in Medicare payment policy that encourage a shift of certain patients to SNFs and should only use two years of recent data for the base utilization calculation, the methodology reflects what Commission staff regards as a reasonable period to review historic trend information, given the work group feedback received. Commission staff also notes that the methodology produces a range of need and should be a reasonable one from a long range perspective. Changes should not be made to address a potential short-term problem that may disappear in a couple of years.

Commission staff disagrees with MedStar Health's view that the need projection ignores cross-regional travel. Migration patterns across Maryland's health planning regions and the adjacent states is considered and reflected in the need projection. The inventory of beds available is only based on Maryland providers for the need projection, but by incorporating the current migration pattern into the need projection, the use of beds at hospitals in the District of Columbia is taken into account. In addition, an applicant that proposes to establish or expand new adult acute rehabilitation beds need must account for in-migration and out-migration patterns among Maryland health planning regions and bordering states. This information is intended for use in evaluating the reasonableness of the applicant's projection of need, when the applicant proposes to ignore the official need projection. Cross-regional travel alone is not a basis for ignoring the official need projection; access barriers must exist that the project will credibly address.

Although MedStar Health recommends using only licensed bed capacity to calculate the net need for acute rehabilitation beds, Staff's intent is to make sure that the available capacity is accurately reflected in the net bed need projected. A hospital may be licensed for more beds than it physically possesses and may have no intention of developing and staffing additional beds. In this circumstance, using the physical capacity rather than licensed capacity is the most accurate way to calculate the need for additional capacity. Staff concludes that no change is necessary.

Other Comments

Planning Principles for Specialized Services

MedStar Health commented that the SHP Chapter retreats from core principles and supporting standards, giving preference for increasing access without demonstrating that there is currently a problem with access. MedStar Health commented that there are no standards that support the purpose of designating a service as specialized and regionalized and only a brief discussion of the concept of specialization in Section.03, under the sub-section regarding "Cost-Effectiveness and Efficiency of Care." MedStar Health commented that the current Chapter contains policies and standards that enforce core principles regarding specialized services. For this reason and based on its other comments, MedStar Health recommended that the Commission not move forward with the draft Chapter.

Staff Analysis and Recommendations Regarding the Deletion of Planning Principles for Specialized Services

The following four principles of specialization are included in the current State Health Plan Chapter:

> 1. Determination of the level, type, and number of health care resources should consider (a) health status indicators, and (b) the relative cost and effectiveness of alternatives that significantly reduce disparities among groups and improve the health of the total population.

2. Specialized health care services should be assessed as part of the overall health care delivery system.

3. Any expansion of the number or distribution of specialized health care services should allow the proposed existing services within the region to achieve and sustain the volumes associated with optimal health outcomes and cost-efficiency.

4. Equity of access to specialized health care services of sufficient quality and at reasonable rates should be assured.

Commission staff concludes that while these principles are not stated, the draft SHP Chapter is informed by them. From its perspective, Commission staff has considered special health status indicators such as the needs of patients with spinal cord and traumatic brain injuries by setting the expectation that these patients should be served by specialized rehabilitation programs. Commission staff also believes the revised draft SHP Chapter is promoting a reduction in disparities among groups by creating an opportunity for applicants to address access barriers. Commission staff also has assessed acute rehabilitation services as part of the overall health care delivery system by including standards regarding the level of impact on other providers, including providers located in a different state or health planning region. These standards should also serve to promote optimal health outcomes and cost-efficiency, the stated goal of the third principal listed. With regard to the fourth principal, the revised draft Chapter promotes greater equity of access by allowing applicants the opportunity to propose projects intended to address barriers to access, when historical utilization trends do not support the need for a project.

Effective Date of SHP Chapter

UCHS suggested that language stating that the draft Chapter does not apply to CON reviews pending at the time of adoption. UCHS explained that under Maryland law the general rule is that a statute is only applied prospectively. However, there are exceptions, as in zoning cases and when the legislature indicates its intent that a new law apply retroactively. UCHS noted that adding an explicit statement is consistent with what the Commission did with the recent update to the SHP Chapter on General Surgical Services in 2012. UCHS's specific proposed language is shown below.

.07 Effective Date.
A. An application submitted after the effective date of these regulations is subject to the provisions of this chapter; and

B. A request for a determination of coverage that is submitted after the effective date of these regulations is subject to the provisions of this Chapter.

Staff Analysis and Recommendations Regarding the Effective Date of the SHP Chapter

Commission staff agrees that adding an effective date is reasonable. Staff added language to stating that an application submitted after the effective date of these regulations is subject to provisions of this Chapter.

CON for Subcategories of Specialized Inpatient Rehabilitation Services

MedStar Health commented that it is unclear if a CON must be obtained for each specialized program and what the applicable standards are.

Staff Analysis and Recommendations Regarding CON for Subcategories of Specialized Inpatient Rehabilitation Services

Staff added language under .04B to clarify that the standards apply to all inpatient rehabilitation projects.

Research Requirements

MedStar Health commented that the draft Chapter is silent on research and there is no discussion of why this requirement was eliminated. The existing Chapter requires providers of acute inpatient rehabilitation services to participate in research projects, and this requirement should be retained.

Staff Analysis and Recommendations Regarding Research Requirements

The work group unanimously agreed that the requirement should be eliminated. Staff agrees that the requirement should be eliminated.

Adventist HealthCare

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APR 0 2 2013

March 27, 2013

CHS-5520

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

RE: Request for Informal Public Comment, Draft State Health Plan Chapter for Facilities and Services: Specialized Health Care Services – Acute Inpatient Rehabilitation Services
COMAR 10.24.09

Dear Ms. Fleck:

Adventist HealthCare, through its affiliate Adventist Rehabilitation Hospital, which operates 77 inpatient rehabilitation beds in Maryland, appreciates the opportunity to respond to the request for informal public comment on the above referenced draft state health plan. The Maryland Health Care Commission is to be commended for its efforts to help meet the current and future health system needs of all Maryland residents by establishing health care policy and ensuring that changes in the delivery of services by regulated health care facilities are needed, cost-effective and viable along with considering the impact of changes in the supply and distribution of health care facilities.[1]

Below are our comments related to the proposed draft State Health Plan chapter, "Specialized Health Care Services – Acute Inpatient Rehabilitation Services"."

> COMAR 10.24.09.02: **Introduction**
> **D. Applicability - this Chapter is applicable to all of the following subcategories of acute rehabilitation: comprehensive; brain injury; spinal cord injury and pediatric services.**

Comment #1: We believe clarity needs to be provided on how to stratify acute rehabilitation discharges by the above mentioned subcategories, given the data sources outlined in E. Data Sources (1) (a) and (b). Given the Commission's indication that "Pediatric patients and individuals who have spinal cord and brain injuries should be served by programs staffed and equipped to best meet their need" it's unclear if facilities should be able to provide need analysis based not only on overall rehabilitation, but also the mentioned sub categories.

> COMAR 10.24.09.03 **Issues and Policies**
> **Need for Capacity - Due to recent and anticipated changes that may significantly alter the capacity required for acute inpatient utilization, a need projection based on historic patterns should not be the sole factor used to determine whether additional acute inpatient rehabilitation capacity is required.**

[1] COMAR 10.24.09.02A

Comment #2: More clarity needs to be provided on what the "recent and anticipated changes" are, that significantly alter capacity, so that historic patterns are not the sole factor considered in evaluating capacity. Reference is made to PAC-PRD that draws numerous conclusions based on a data collection instrument that has not been studied for reliability or validity. It is our position that Acute Rehabilitation is far more beneficial to patients in need of rehabilitation than either the SNF or Home setting. This conclusion has been validated in numerous other studies using reliable and valid measures. Therefore, PAC-PRD should not be the only outcome study referenced and if it continues to be referenced it should be noted that reliability and validity has not been established and PAC-PRD continues to be a controversial source. How recent are the changes identified and which changes have not yet occurred but are sufficiently anticipated with validity that they should affect an evaluation of capacity? Such changes should not be used for policymaking unless they are identified and validated.

"Access barriers need to be considered as part of evaluating changes in the delivery system for acute inpatient rehabilitation"

Comment #3: There is no definition of 'access barriers.' These should be clearly defined. For example, are these barriers related to payer definitions of covered services? Barriers related to patient characteristics? There needs to be an identification of studies or other validated sources of information identifying the barriers referenced and how access to them is affected.

Policy 2: The efficient use of resources will be promoted: over and under-utilization of inpatient rehabilitation services will be discouraged.

Comment #4: The State Health Plan Chapter should clarify how 'over and under-utilization' will be defined. It is too vague as stated. What studies or other validated sources of information identify the characterization of acute rehabilitation services as over or underutilized? Is this based on coverage criteria of particular payers? Validated clinical practice guidelines? Efficiency is a priority and should be promoted, but the measure of efficiency needs to be identified or else the Chapter lacks sufficient guidance to providers.

COMAR 10.24.09.04 **Standards**

A. General Review Standards
B. Project Review Standards
(1) Access
An applicant that seeks to justify the need for a project on the basis of barriers to access shall present evidence to demonstrate that barriers to access exist ...

Comment #5: The definition of 'barriers' needs to be identified and clearly specified. Again, this statement too vague without more specificity. A barrier could be anything from distance, to transportation access to existing capacity or the lack thereof. Otherwise, it is left to individual applicants to self-define barriers, without any common benchmark that applies to the community and health care providers. For example, travel time may be a greater barrier in some parts of Maryland than in other parts of the State. If there are barriers that applicants need to address, the health planning process should identify them based on validated studies.

(3) Impact
A project shall not have an unwarranted adverse impact on the ..... financial viability of an existing provider of acute inpatient rehabilitation services

Comment #6: The determination of "unwarranted" adverse impact and how that determination will be made should be specified. Adventist HealthCare's position is that this statement should exclude "unwarranted" and merely state, "A project shall not have an adverse impact on the financial viability of an existing provider of acute inpatient rehabilitation services. Adverse financial impact and financial viability should be defined and specified by the Commission.

(3a) Its estimate of the impact of the proposed project on the utilization of other acute inpatient rehabilitation providers"

Comment #7: Again, the process for determination of the impact on other providers is vague and should be spelled out more clearly so all understand in advance the threshold for determining impact. Otherwise, the Chapter provides insufficient guidance. For example, is impact measured solely in relation to volume, or are there other forms of impact?

(7) Minimum Size Requirements
(a) **A proposed acute inpatient rehabilitation unit in a hospital shall contain a minimum of 10 beds and should be projected to maintain an average daily census consistent with the minimal occupancy standard in this Chapter within three years.**

Comment #8: The rationale for the 10 bed minimum standard is arbitrary. Adventist HealthCare urges the standard to be based upon an average daily census threshold. Clinical quality and financial viability depend upon a critical mass of rehabilitation patients. It is our experience that this critical mass is achieved at a higher sustained census then the proposed 10 beds would achieve. On what basis has the Commission determined that a 10 bed unit with a census at a minimum occupancy level will provide an effective , efficient level of care with the appropriate complement of staff that ensures maximum benefit to patients?

E. Data Sources
(b) For discharges from District of Columbia hospitals, for all years, only patients age 18 and older are included. In 2006 all discharges, except those under age 18, from National Rehabilitation Hospital are included and any discharges with DRG 462 from a general hospital with licensed acute rehabilitation beds. For years 2007-09, records with DRG 462 are counted as acute rehabilitation discharges. For years 2010 to the present, acute rehabilitation discharges with updated DRG codes that correspond to DRG 462 will be counted. In version 28 of DRG codes, the DRG 462 is replaced by DRGs 945 and 946.

Comment #9: This data source and the definition of rehabilitation differs from that outlined for Maryland hospitals. This appears to be an "apples-to-oranges" comparison and it is unclear how this will affect analysis performed on out-migration between jurisdictions that border Washington D.C. We ask the Commission to clarify this issue.

Thank you for the opportunity to provide these comments. We look forward to continuing to work with the MHCC on the development of this State Health Plan chapter for acute inpatient rehabilitation services.

Sincerely,

Paula S. Widerlite
Vice President, System Strategy

Cc: Brent Reitz
Terry Forde
Peter Mbugua

Calvert Memorial Hospital
Tradition. Quality. Progress.

CHS-5553

March 19, 2013

Eileen Fleck
Specialized Services Policy & Planning
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215-2299

Dear Ms. Fleck:

I would like to express my appreciation to you in forwarding me a copy of the DRAFT SHP for Acute Rehabilitation that our committee has been working on over the last few years. Overall the document captures most of the issues our committee reached consensus on and the proposed improvement to the SHP reflects the consensus of our group.

As you are well aware, there are certain regions in the State of Maryland that have experienced little or no access to acute inpatient rehab services over many years. My biggest concern is the proposed threshold for assessing Bed Need for the Southern Health Planning Region ("HPR"). We are proposing that, for this HPR alone, instead of using the "Minimum Bed Need" as the rebuttable threshold for filing a Certificate of Need, the median of the Minimum and maximum Bed Need set the baseline. This is because, for the reasons set forth below, we view the calculated Minimum as woefully understated and completely inadequate to deal with the actual needs of the patients in our region.

It is clear that the Commission's staff implicitly recognize the problems inherent in the projected minimum due to the extreme range between minimum and maximum bed needs for the Southern HPR. The maximum projected bed need is more than 450% of the projected minimum – the next closest HPR has a variance of only 41% (Eastern HPR). As set forth in the Note for Table 1, the minimum is set based on actual utilization between 2006 -2010 and the maximum, almost 18,000 patient days higher, presumes that 70% of the HPR's residents could be served within the region is the capacity was available. The data is clear that the patients in Southern HPR do not currently have accessible availability to high quality acute inpatient rehabilitation services.

That a majority of patients in the HPR currently have to leave the region and/or are being placed in alternative, frequently less appropriate, settings is both clear and understandable when the geography is considered. Currently, the sole source of acute inpatient rehabilitation beds in the HPR is located at Laurel Regional Hospital in Laurel, Maryland, the extreme northern edge of the HPR – more than 50 miles from Calvert Memorial Hospital and approximately 70 miles from St. Mary's Hospital in Leonardtown. As the Draft Revision notes, the "research suggests that the distance to Providers, relative to a patient's residence may be a more powerful predictor of the use of acute inpatient rehabilitation services than the clinical characteristics of patients." In the minds of patients

and ordering providers, Laurel is far more linked to the Baltimore-Washington Corridor and the Central and Montgomery HPRs, not Southern Maryland and the Southern HPR. It is not surprising that, with geography a major determining factor in utilization, the patients and providers in Southern Maryland are choosing not to place their patients in acute inpatient rehabilitation beds in the HPR.

This geographical limitation will only get more significant as we move more towards formalizing population health management and clinical integration networks. The ability to treat patients, particularly in areas more amenable to acute inpatient rehabilitation like stroke as noted in the Draft Revision, in a coordinated and comprehensive fashion is negatively impacted by the limitations of the location of the currently approved beds.

By using the median projected bed needs of 51, there would be the opportunity and expectation that an additional 23 beds in the Southern HPR would be created. If applications for those beds were judged in line with Policy 4, promoting financial and geographic accessibility, and Policy 6, maximizing the use of electronic systems designed to drive quality and improve outcomes, the needs of the patients of the Southern HPR and the wide disparity and under- utilization in the Southern HPR set forth in Table 2 would be addressed.

Again, thank you for your extensive work in revising this chapter, and again for the opportunity to comment and participate in the revision process. We look forward to an interactive process in reviewing the comments and crafting solutions, and I am available to participate in whatever capacity would be helpful.

Sincerely,

JAMES J. XINIS
President & CEO

cc: Barry Rosen

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CHS-5561

March 27, 2013

SENT VIA ELECTRONIC TRANSMISSION

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

Re: Draft State Health Plan for Facilities and Services: Specialized Health Care Services – Acute Inpatient Rehabilitation Services, COMAR 10.24.09

Dear Ms. Fleck:

This letter is written to provide the comments of MedStar Health (MedStar) on the Draft State Health Plan for Facilities and Services: Specialized Health Care Services – Acute Inpatient Rehabilitation Services (the "Draft Chapter").

MedStar supports the update of this Plan chapter, and the use of a stakeholder workgroup to assist in answering some of staff's questions during the plan development process. However, as discussed below, MedStar objects to the Draft Chapter in its current form. Our objection to the Draft Chapter is as much a result of what it does not contain as what it does contain. The existing Chapter governing acute inpatient rehabilitation recognizes this service as a specialized health care service for which planning is regionalized, and, like other chapters of the State Health Plan that govern specialized health care services, contains policies and CON standards that enforce these core principles. Without even acknowledging that it is doing so, let alone providing support for doing so, the Draft Chapter retreats from these core principles and supporting standards. Instead, it would adopt what amounts to a preference for increasing access, at the expense of the principles underlying specialization and regionalization, without demonstrating that there is a problem with access currently. While the Draft Chapter pays lip service to acute inpatient rehabilitation as a specialized service and designates the same five planning regions as the existing Chapter, the Draft Chapter contains no standards that support the purposes of designating a service as specialized and regionalized. Indeed, it would adopt standards that undercut these purposes.

For these and the other reasons set forth below, we request that the Commission not move forward with the Draft Chapter and develop a new Chapter that retains and provides for enforcement through the CON process of the core principles of specialization and regionalization.

1. MedStar's Acute Inpatient Rehabilitation Programs

MedStar Good Samaritan Hospital (MGSH) operates 51 licensed rehabilitation beds, and provides inpatient rehabilitation services to over 1,500 patients annually. MGSH is accredited by CARF for Comprehensive Integrated Inpatient Rehabilitation. MGSH also has a CARF accredited specialty program for Stroke. MGSH has a long history and strong reputation as one of the largest, most experienced and successful medical providers of inpatient rehab services in the state. The Comprehensive Integrated Inpatient Rehabilitation Program (CIIRP) at MGSH was established in 1968 in partnership with the Johns Hopkins University School of Medicine and the Johns Hopkins Department of Physical Medicine and Rehabilitation. The CIIRP provides rehabilitation care for all types of patients including those with some with the most medically complex and disabling conditions i.e., stroke, spinal cord injury/dysfunction, heart surgery, amputation, and orthopedic injury and surgery. MGSH's CIIRP is also a leader in the treatment of rehabilitation patients who are ventilator-dependent and those requiring renal dialysis. The CIIRP has an experienced medical team that includes board-certified physiatrists, specialty therapists, rehabilitation nurses, neuropsychologists, case managers, and other professionals who manage these high acuity patients. Through its partnership with Johns Hopkins, MGSH is able to host a strong residency program that provides invaluable training in physical medicine and rehabilitation physiatry, rehabilitation psychology, and neuropsychology.

MedStar Union Memorial Hospital (MUMH) offers a Comprehensive Integrated Inpatient Rehabilitation Program with 18 licensed beds. As a member of MedStar Health, an integral part of the program is partnership with MedStar National Rehabilitation Network. MUMH provides rehabilitative care with integrated medical, nursing and therapy services to patients with medically complex and disabling conditions, including those caused by open heart surgery, cardiovascular disease, spine surgery, joint replacements, stroke, amputation and neurological disorders. MUMH's CIIRP was nationally ranked by the national outcome reporting agency Uniform Data System (UDS). The score of 79.3 places this rehabilitation program in the top 20% of 850 rehab facilities. This CIIRP is also accredited by the CARF.

MedStar National Rehabilitation Hospital (NRH) is a private, not-for-profit facility located in Northwest Washington, D.C. MedStar NRH is fully accredited by The Joint Commission and the Commission on Accreditation of Rehabilitation Facilities (CARF), and has CARF accredited specialty programs for Brain Injury, Spinal Cord Injury, and Stroke. NRH is licensed for 137 beds (128 for adults and 9 for children), with approximately 2,200 inpatient visits annually. Nearly 50% of these patients live in Maryland, making NRH one of the largest acute inpatient rehabilitation providers chosen by Maryland residents. The MedStar National Rehabilitation Network also includes 34 outpatient sites located in Washington, D.C., Maryland and Northern Virginia. NRH treats patients between the ages of 6 and 18 years of age on its 9

bed pediatric unit. The National Center for Children's Rehabilitation is a joint service of MedStar NRH and Children's National Medical Center. MedStar NRH's services are designed specifically for the rehabilitation of individuals with disabling injuries and illnesses such as stroke, brain injury, spinal cord injury and disease, arthritis, amputations, post-polio syndrome, chronic pain, back and neck pain, occupational injuries, cancer and cardiac disease that require medical rehabilitation, and other neurological and orthopedic conditions. MedStar NRH has appeared on the "Best Hospitals" list in U.S. News & World Report for 18 consecutive years and is currently ranked among the top hospitals for medical rehabilitation in America.

2. Acute Inpatient Rehabilitation: A Specialized Service In Name Only Under The Draft Chapter

The Draft Chapter continues to identify acute inpatient rehabilitation as a specialized service, but contains almost no definition or discussion of the concept of specialization. The Draft Chapter contains one paragraph regarding specialization (under .03—Cost-Effectiveness and Efficiency of Care). The Draft Chapter contains five policies for acute inpatient rehabilitation services (p. 5). None of those policies recognizes acute inpatient rehabilitation service as a specialized health care service, and several of them run contrary to specialization by prioritizing greater access. In contrast, the existing Chapter, like other specialized service chapters, contains an entire set of principles related to specialization (.03 –Principles for Planning Specialized Health Care Services). There is no explanation or support in the Draft Plan for this change in course. An added level of complexity that defines specialized services clearly applies to acute inpatient rehabilitation - not only specially trained nurses and physicians, a separate "special hospital" license category, and an accrediting body to assure high standards of quality, but also accreditation is required for licensure of acute inpatient rehabilitation programs in Maryland.

The absence of these principles has substantive consequences. As explained in the existing Chapter governing acute inpatient rehabilitation (.03A):

> *The rationale for identifying a set of principles for specialized health care service is to serve as a guide in developing strategies to achieve the Commission's mission. The principles build on that basic framework and relate to what the Commission considers to be its most important objectives. The principles encourage a consistent approach to planning the development of specialized health care services and contribute to setting priorities for the allocation of health resources in general.*

The same guiding principles are found in chapters governing other specialized health care services. The existing Chapter recognizes as a core principle of acute inpatient rehabilitation as a specialized health care service that "any expansion of the number or distribution of specialized health care services should allow the proposed and existing services within the region to achieve and sustain the volumes associated with optimal health outcomes and cost-efficiency." By failing to adopt this or the other guiding principles for specialized services, the Draft Chapter does not serve as guide for strategies to achieve any mission, nor encourage a consistent approach to planning.

Not only does the Draft Chapter fail to adopt any guiding principles of specialization applicable to other specialized health care services, it adopts standards that undercut those principles. Specifically, as will be discussed further below, it adopts standards to promote increased access to acute inpatient rehabilitation at the expense of specialization and quality of care, without any finding, let alone substantiating, that any access problem currently exists.

3. The Departure from Regionalization In The Draft Chapter

As little as the Draft Chapter contains in terms of policies supporting acute inpatient rehabilitation as a specialized service, the Draft Chapter is virtually silent regarding the complementary concept of regionalization. Regionalization means shared resources to avoid costly duplication and promote quality, efficiency and availability of essential services. While the concept is prominent in the existing Chapter, it is difficult to find any mention of regionalization in the Draft Chapter, let alone supporting standards. The existing Chapter explains (.02D):

> *The concept of health care regionalization refers to the appropriate distribution of services with regard to their geographic location and level of care. It implies an organized and integrated hierarchy of services with levels of care that are coordinated and mutually supportive. Within the health care delivery system, the population is directed to appropriate staffed and equipped services based on the nature and severity of illness.*

In contrast, while the Draft Chapter retains the five health planning regions for need projections, it never mentions regionalization or its purpose, and contains only a single, somewhat oblique reference to serving a "regional population base." The Draft Chapter contains no policies promoting, supporting or even defining the benefits of regionalization.

Further, the Draft Chapter adopts standards that undercut the concept of regionalization. As will be discussed further below it adopts an entirely new project review standard .04(B(1)) to promote increased access to acute inpatient rehabilitation at the expense of regionalization and specialization as well as quality of care.

The Draft Plan also departs from regionalization in failing to take into account acute inpatient rehabilitation capacity in neighboring jurisdictions like the District of Columbia. As in other areas of public policy, such as emergency preparedness, regionalization crosses the Washington/Maryland line. The existing Chapter recognizes (.03b(4)) that "[a] portion of the State's population achieves reasonable geographic access to specialized health care services by using out-of-state services...." There is no rational basis for the Draft Plan to ignore the utilization of regional resources outside of the State.

4. The Unsubstantiated Access Problem Underlying the Draft Chapter

The Draft Chapter largely abandons specialization and regionalization in favor of increased access. Specifically, it adopts a new review standard entitled "Access" which requires that a new unit "shall be located to optimize accessibility for its likely service area population." .04B(1). The need projections in the Draft Chapter demonstrate that there is *no net need* in any region except Montgomery County.[1] Yet the Draft Chapter also expressly permits projects not supported by projected net need in order to address "access barriers." .04B(2)(d).

While it creates a new pathway for projects unsupported by the need projections in order to address "access barriers," the Draft Chapter does not find, let alone substantiate, that an access problem exists. Indeed, it cites (in .03, p. 4) the Medicare Payment Advisory Commission's March 2012 annual report for the conclusion that "access to acute inpatient rehabilitation services is *not a problem* for the Medicare population, which comprised approximately 60 percent of discharges from acute rehabilitation providers in 2010, because of the relatively stable number of providers and available beds." (emphasis supplied). The Draft Chapter goes on, however, to state that there is a "wide variation in the use and availability of these services nationally and in Maryland...." It cites national data for this but cites *no data* for the statement that this "wide variation" exists in Maryland. It also cites non-Maryland research as "suggest[ing] that the distance to providers, relative to a patient's residence may be a more powerful predictor of the use of acute inpatient rehabilitation services than the clinical characteristics of patients." While this is no doubt an issue in the larger states where travel times are significant, it may not be relevant to such a small state as Maryland.

[1] As discussed below net need in Montgomery County appears to be inflated by the failure to account for National Rehab Hospital in the District of Columbia and the use of 2010 baseline data.

Even if this variation could be shown to exist in Maryland, it does not follow that Maryland has an "access barrier" let alone one that can only be addressed by adding new capacity. The Draft Chapter is silent about other more cost effective means to address access barriers, such as education and outreach.

Although improving "access" is a prominent part of the Draft Chapter, there is no data in the Draft Chapter to support the existence of an access problem. Moreover, readily available data demonstrates that there is no access problem in Maryland. According to Medicare data from the U.S. Health Indicators Data Warehouse, Medicare inpatient rehabilitation discharges in Maryland are among the highest in the country when discharges from Maryland hospitals (that do not report to Medicare) are taken into account. Consideration of discharges from out-of-State providers such as NRH (which the Draft Chapter fails to do) would demonstrate even greater access to this service on the part of Maryland residents. Approximately fifty percent of NRH's discharges last year were Maryland residents, making it one of the largest providers of acute inpatient rehabilitation services for Maryland residents, yet the Draft Chapter ignores the critical role of this regional resource.

The Draft Plan includes a new policy section entitled "Need for Capacity" that also refers to, but does not substantiate or define, "access barriers" to service. Referring to the longstanding approach of looking at historic data to project demand, this section refers to "recent and anticipated changes that may significantly alter the capacity required for acute inpatient utilization" as justification to consider "access barriers" in addition to historic patterns in determining whether additional capacity is needed. Nothing in the Draft Chapter identifies, let alone analyzes the impact of the "recent and anticipated changes" that call for this significant change in health planning policy. Yet this cryptic reference is the basis for allowing for projects that are inconsistent with the need methodology, the need for which will, under the Draft Chapter, be determined by unspecified standards of demonstrating an "access barrier."

Similarly, the Draft Chapter includes a new policy that this service will be "geographically accessible," and allows for the consideration of applications not supported by need in order to "credibly" address "barriers to access." Yet the Draft Chapter provides no guidance on how a project "credibly" addresses barriers to access, such as travel times, travel barriers, national comparisons, consideration of out-of-State providers, and similar matters. Moreover, as discussed above, the Draft Chapter fails to adequately recognize acute inpatient rehabilitation as a regional service intended to serve a larger population base in order to promote quality and efficiency, and avoid costly duplication. If the Draft Chapter is going to allow for new facilities not supported by the need projections, then it must clearly enunciate the policies and principles of regionalization and provide guidance on what an applicant must address in order to demonstrate that its project addresses a barrier to access.

Accordingly, MedStar Health requests that review standard .04B(1) be eliminated, and .04B(2)(d) be substantially revised to provide guidance as to the extent of an applicant's analysis that will be required for consideration of an access problem in the absence of an identified need.

5. The Weakening of Quality Standards Under The Draft Chapter

The Draft Chapter contains inadequate analysis of the skilled nursing facility (SNF) alternative to acute inpatient rehabilitation settings in terms of cost and quality. Many patients cannot be managed by SNFs because many SNFs lack 24-hour nursing availability with rehabilitation nurses, regular physician visits, more intensive, individualized daily therapy, and the capability to manage patients medically on site.

The Draft Chapter eliminates the requirement that specialized programs be accredited as such, only requiring that facilities serving pediatric patients and individuals with spinal cord or brain injuries should be "staffed and equipped to best meet their specific needs" and "should serve a sufficient number of patients with specialized or complex needs that a proficiency in care delivery can be developed." The existing Chapter (Policy 2.0) requires an inpatient brain injury program or spinal cord rehabilitation system of care to "demonstrate an adequate number of admissions to maintain accreditation as a specialized program or system." The accreditation requirement should be retained to ensure quality of care in these programs and be validated on an annual basis.

The Draft Chapter should state that CARF accreditation is a requirement of obtaining a special hospital license. It should also require an applicant to demonstrate that it has considered CARF requirements in its programmatic planning by outlining its plans for achieving CARF accreditation, and require a provider that is issued a CON to become accredited by CARF within a specified time frame or the MHCC may take action to revoke the CON.

Finally, the Draft Chapter fails to address the CMS quality measures to which freestanding facilities are now subject. Depending on the outcome of the Medicare waiver negotiations, Maryland hospitals not currently participating in the Inpatient Rehabilitation Facility prospective payment system may need to comply with these standards as well. These standards should be incorporated into the State Health Plan. Hospital-based rehab providers should be tracking their outcomes on these measures, even if they are not now required to report them.

6. Need Methodology Issues

The need methodology in the Draft Plan results in the overstatement of net need because it uses base year discharges and trend data prior to the full implementation in 2010 of the Medicare rule on admission criteria for admitting patients to inpatient rehabilitation. Starting in 2010, hospital admissions decreased and SNF utilization increased, particularly for orthopedic patients. The Commission should use a 2011 or 2012 base year to eliminate this anomaly.

The need projections fail to account for acute inpatient rehabilitation beds in the District of Columbia in the available inventory. As a result, there is a net positive bed need projection in Montgomery County. These beds are a regional resource and should be included in the inventory and the need projection recalculated on that basis. The MedStar National Rehabilitation Hospital in the District of Columbia (located approximately six miles from Montgomery County) has 128 adult rehab beds that are available to patients from D.C., Maryland and Virginia. Excluding these beds from the need methodology in Maryland understates available capacity and overstates need in Montgomery County. The Draft Chapter states (at .04B(2)(d)(iii) that it will consider cross-regional travel *as a reason to ignore its own need projections*, but fails to do so in calculating need.

The calculation of net bed need in the need methodology (.05F(5)(d)) is based on "physical capacity" rather than "licensed capacity." "Physical capacity" is inappropriate as a basis for calculating net bed need. The need methodology should be based on licensed capacity, which is a well-understood, official number. Further, using licensed capacity is consistent with the rest of the State Health Plan, including the occupancy rate definition and occupancy standards. A hospital has the right to use all of its licensed beds, even if it is not using all of them at any given point in time. Excluding licensed beds not actually being used at a given point of time could result in another applicant filing a CON application to seek those beds. That possibility does not exist in any other context in the State Health Plan.

7. Other Concerns

Underutilization. The Draft Chapter introduces a new policy against "underutilization" of acute inpatient rehabilitation services (Policy 4). Once again, there is no analysis or criteria to define underutilization. This policy should be eliminated unless supporting analysis and reasonable criteria defining underutilization are established.

Research. The Draft Chapter is silent on research. The existing Chapter recognizes the importance of research in this area and even requires providers of these acute inpatient rehabilitation services to participate in research projects. There is no discussion of why this requirement was eliminated and it should be retained.

Impact. The standard regarding impact (.04B(3)), does not require an analysis of the impact on the ability of an existing provider to maintain highly specialized medical staff necessary to provide this specialized health care service. This requirement should be included.

Subcategories of acute inpatient rehabilitation. The Draft Chapter states that it applies to all subcategories of acute inpatient rehabilitation services (including brain injury, spinal cord injury, and pediatric) (.02D), but is unclear as to whether a CON must be obtained for such specialized programs and what the applicable standards are. The Draft Chapter should address these issues.

For the above stated reasons, MedStar Health strongly urges the Commission not to move forward with this draft chapter, and instead develop a new chapter that retains, and provides for, enforcement through the CON process of the core principles of specialization and regionalization for acute inpatient rehabilitation services.

Thank you for the consideration of our comments.

Sincerely,

Marta D. Harting

Marta D. Harting

MDH:rlh

SINAI HOSPITAL
a LifeBridge Health center

CHS-5562

Eileen Fleck
Acting Chief for Specialized Services
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

March 26, 2013

Re: Comments on Draft State Health Plan for Facilities and Service: Specialized Health Care Services- Acute Inpatient Rehabilitation Services, COMAR 10.24.09

Dear Ms. Fleck:

We at LifeBridge commend the Commission's decision to update the Chapter. The more detailed Chapter will better serve the current and future health system needs of Maryland's residents. It will promote quality, financial and geographic access, cost containment, and efficient utilization of resources. It has been my privilege to participate in the acute rehabilitation work group which you led.

Our comments deal with the importance of including all subcategories of acute rehabilitation: comprehensive, brain injury, spinal cord injury, and pediatric consistently in the chapter. We feel patients in all of these subcategories have specialized needs and require, and benefit from, specialized staff, care methods, equipment, and environment.

The Applicability section .02, D. and the Quality of Care section .03 appropriately include the subcategories and describe the importance of providing specialized care.

However, the Need section .04, B, (2), (e) only mentions pediatric patients. We feel applicants should also have to explain their need assumptions if they plan to treat patients with brain injury and spinal cord injury. Quality and consistency of care would best be maintained when an applicant can both show need and the ability to meet that need with a high quality program for these specialized populations.

In addition, the Methodology for Projecting Adult Acute Rehabilitation Bed Need section .05, first paragraph, the bed need should be calculated excluding pediatric acute inpatient, brain injury, and spinal cord injury. All three subcategories should be evaluated on a case-by-case basis. CARF International, the international accrediting body for rehabilitation, has separate accreditations for brain injury, pediatric, and spinal cord injury programs. All three require specialized services and shouldn't be included in an overall bed need calculation.

We support the balance of the chapter update and thank you for the opportunity to participate on the rehabilitation work group and to comment on this latest draft. Please do not hesitate to contact me if you have any questions or would like to discuss further.

Sincerely,

Scott Brown, M.D.,
Chief, Department of Physical Medicine & Rehabilitation
LifeBridge Health

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March 27, 2013

VIA EMAIL < eileen.fleck@maryland.gov >
and **FACSIMILE (410-358-1236)**

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

Re: Proposed Draft State Health Plan for Facilities and Service – Specialized Health Care Services – Acute Inpatient Rehabilitation Services, COMAR 10.24.09
Informal Comments Submitted on behalf of Upper Chesapeake Health System

Dear Ms. Fleck:

I write on behalf of Upper Chesapeake Health System ("UCH") to provide comments regarding the proposed draft State Health Plan for Facilities and Services: Specialized Health Care Services – Acute Inpatient Rehabilitation Services (the "Proposed Draft Chapter"). The Proposed Draft Chapter was presented for informal review and comment on February 11, 2013, and March 27, 2013 was established as the deadline for informal public comment.

INTRODUCTION

UCH supports the Proposed Draft Chapter and urges the Commission to propose and adopt the Proposed Draft Chapter as a permanent regulation. However, UCH requests that the Commission include language in the regulations stating that the new regulation does not apply to CON reviews pending at the time of adoption.

DISCUSSION

I. UCH Supports the Commission Staff's Approach to Permit an Applicant to Credibly Address Barriers to Access as an Alternative to Establishing Need in the Applicable Health Planning Region.

UCH commends the Commission staff for recognizing that access barriers must be considered in evaluating need for capacity. In particular, UCH supports the proposed language permitting project approval without a showing of regional net need for acute rehabilitation beds in the applicable health planning region ("HPR") if, among other requirements, the applicant "credibly addresses identified barriers to access." Proposed Draft Chapter, 10.24.09.04.B.(2)(d)(i). As the Commission staff notes, research shows that geographic

"distance to providers relative to a patient's residence may be a more powerful predictor of the use of acute inpatient rehabilitation services than the clinical characteristics of patients." Proposed Draft Chapter, at 4 (footnotes omitted).

Low use caused by lack of geographic access is demonstrated in UCH's service area, comprised of 29 zip code areas in Harford, Cecil, and Baltimore Counties. The acute inpatient rehabilitation use rate of 0.34/1000 in the UCH service area is a small fraction of the Maryland average of 2/1000 because there are no geographically accessible programs. UCH's service area is part of the Central Maryland HPR, containing seven acute inpatient rehabilitation programs, all located in Baltimore City and none in the other four jurisdictions. It is appropriate to permit an applicant to demonstrate that geographic barriers to access warrant approval of a new project even if the need projections for the applicable HPR are not satisfied.[1]

UCH suggests the following clarifications to the language of the Proposed Draft Chapter:

- On page 8, Section .04.B(1), the language should clarify that the requirement to optimize accessibility applies to any project, not only a "new rehabilitation hospital or subunit."

- On page 8, Section .04B(2), the language in the lead paragraph should clarify that the assessment of net need identified by the need methodology does not apply to a project seeking only to relocate beds within an HPR, rather than establish new acute rehabilitation beds within the HPR. This clarification is consistent with the language of Section .04B(2)(d), which provides an alternative showing for an applicant "proposing to establish or expand acute rehabilitation beds." The requirement for the project to be consistent with net need as identified in the new need methodology should likewise apply only to an applicant "proposing to establish or expand acute rehabilitation beds."

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[1] UCH's affiliate, Harford Memorial Hospital, has a pending application for the approval of the relocation of 18 acute inpatient rehabilitation beds from Maryland General Hospital to Harford Memorial Hospital (Docket No. 12-12-2335). Because the application has been docketed already, any change in the regulation should not apply to the application. Also, the applicant proposes to relocate beds within the HPR, not add new beds to the HPR, so the assessment of bed need is not relevant. However, even if the project involved the addition of new beds in the HPR and the new regulation applied to the application, the project should be approvable if Harford Memorial Hospital can demonstrate that the project "credibly addresses identified barriers to access."

II. The Proposed Draft Chapter Should Explicitly State That the New Regulation Will Not Apply to CON Applications Docketed Before the Effective Date.

The Commission should include language stating that the Proposed Draft Chapter will not apply to CON applications docketed prior to the effective date.

Under Maryland law, the general rule is that a statute is only applied prospectively. *McHale v. DCW Dutchship Island, LLC*, 415 Md. 145 (2010). However, there are exceptions, as in zoning cases and when the legislature indicates its intent that a new law apply retroactively, *i.e.*, to pending cases. The Proposed Draft Chapter does not address whether it will apply to pending CON reviews upon adoption. As noted above, in June 2012, the Commission docketed a CON application filed by Harford Memorial Hospital, proposing to relocate 18 inpatient acute rehabilitation beds, within the same HPR, from Maryland General Hospital to Harford Memorial Hospital. Two entities filed written comments and sought interested party status, which was granted. A reviewer was appointed and has made several preliminary decisions. If the Commission adopts the Proposed Draft Chapter, it should state that the regulation applies only to CON applications docketed after the Proposed Draft Chapter become effective.

Adding an explicit statement as to the applicability of the new capacity standards is consistent with what the Commission has done before. Most recently, in adopting the State Health Plan Chapter on General Surgical Services late last year, the Commission included language to make clear that the provisions of the new regulations do not apply to applications submitted before the effective date of the regulations. COMAR 10.24.11.04C.

Also, the Nursing Home Standards portion of the Nursing Home, Home Health Agency and Hospice Services Chapter of the State Health Plan provides that "[t]he bed need in effect when the Commission receives a letter of intent … will be the need projection applicable to the review". COMAR 10.24.08.05A(1).

Accordingly, UCH urges the Commission to include the following language, which is identical to the language recently adopted in the General Surgical Services Chapter, as a new subsection .07:

.07 Effective Date.

A. An application submitted after the effective date of these regulations is subject to the provisions of this chapter; and

B. A request for determination of coverage that is submitted after the effective date of these regulations is subject to the provisions of this chapter.

Thank you for your consideration of UCH's comments. Please contact me if you have any questions.

Sincerely,

Thomas C. Dame

cc: Dean C. Kaster
Joy D. Hoover
Andrew L. Solberg
Jack C. Tranter, Esquire