



Dimensions Healthcare System

October 21, 2013

Eileen Fleck
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Maryland Health Care Commission
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RE: Informal Public Comment on Draft State Health Plan for Facilities and Services:
Specialized Cardiovascular Services COMAR 10.24.17

Dear Ms. Fleck,

I am writing to you on behalf of Dimensions Health Corporation d/b/a Dimensions Healthcare System ("Dimensions"), a non-profit corporation which manages the health care system located in Prince George's County, Maryland. We thank you for the opportunity to comment on the draft regulations for the State Health Plan for Facilities and Services: Specialized Cardiovascular Services COMAR 10.24.17 published by the Maryland Health Care Commission ("MHCC") on its website on September 30, 2013 (the "Draft Regulations"). We applaud the MHCC for its efforts to ensure the availability of high quality health care services for Maryland's residents particularly cardiac surgery and percutaneous coronary intervention ("PCI") services. However, Dimensions is offering its own recommendations for more flexible standards which ensure high quality. Further, we believe the MHCC's oversight processes, such as Plans of Correction and Focused Review, need to be clarified and streamlined so that hospitals are fully aware of the applicable processes and their rights. Finally, the Draft Regulations needs clarification and some internal inconsistencies should be addressed before they are finalized. Dimensions appreciates your consideration of our concerns and recommendations.

I. Prospective Application of Certain Standards

The Draft Regulations incorporate numerous new standards to ensure high quality of the cardiac surgery and PCI services offered by Maryland hospitals. Dimensions presumes that the standards would apply prospectively so that programs will not be penalized for failing to meet a standard at a time when it did not exist. However, the standards do not clearly specify how they will be applied. The Draft Regulations should clarify that the standards will be applied prospectively, not retroactively, as the MHCC evaluates Maryland hospitals' cardiac surgery and PCI programs via a completely new program.

One of these standards requires Maryland hospitals to adopt and utilize the Society of Thoracic Surgeons Adult Cardiac Surgery Database software system (the “STS-ACSD”) to capture its Cardiac Surgery data and compare it to national clinical performance. Adopting and implementing this system takes significant time and resources, involving coordination among health care professionals and information technology specialists. Further, although the STS-ACSD can collect some data retroactively, the data may be imperfect as they were not originally generated to be coordinated with STS-ACSD. The Draft Regulations should ensure that Maryland hospitals have the time to adopt and implement the STS-ACSD properly so the most accurate data is available for the MHCC’s review. Therefore, Dimensions recommends that the MHCC only require hospitals to begin collecting this data upon the effective date of the final regulations.

The minimum volume standard for an established cardiac surgery and/or PCI program to obtain a Certificate of Ongoing Performance requires that the hospital maintain a minimum volume on an annual basis. It is unclear whether the MHCC would look retrospectively to past years in considering applications for a Certificate of Ongoing Performance or apply this standard prospectively. As this is a new standard, the MHCC should only apply the minimum volume standard as of the effective date of these regulations. Prospective application of the minimum volume standard would be fair to Maryland hospitals to ensure sufficient notice for Maryland hospitals to achieve compliance with this new standard.

Therefore, Dimensions recommends that the provision regarding the Effective Date, as set forth in Proposed MD. CODE REGS. 10.24.17.02E, remain unchanged except for the addition of the following language: “The Data Collection Requirement, Performance Standards and Volume Requirements for a hospital to obtain a Certificate of Ongoing Performance shall only be applied prospectively as of the Effective Date of these regulations.” (p. 4).

II. Clarification of Health Planning Region as Distinct from Regional Service Area

The Draft Regulations newly define four health planning regions for planning and regulating cardiac and PCI services based on utilization patterns, geographic proximity, and “the volume of cardiac surgeries for the population in each jurisdiction in the region.” Proposed MD. CODE REGS. 10.24.17.03, pg. 5. Dimensions would like the MHCC to clarify whether the “volume of cardiac surgeries” measures only current volumes or accounts for public health data on actual community need. Dimensions is concerned that the MHCC may base its decisions regarding certification of programs on these newly configured health planning regions, which do not reflect the actual community needs of each hospital’s general Service Area.

Further, the Draft Regulations also define “Service Area” based upon the hospital program’s projected or actual patient population for use in Utilization Projection Methodology for Cardiac Surgery.

Dimensions recommends that the Draft Regulations specify that the MHCC’s decisions on granting certification will include consideration of public health and other assessments of actual community need within the Service Areas of the hospital’s Cardiac Surgery and PCI Programs.

III. Relocation Requirements

The Commission Program Policies Section of the Draft Regulations includes requirements for a hospital which “seeks to relocate,” including its Cardiac Surgery and/or PCI Programs. Proposed MD. CODE REGS. 10.24.17.04C, pg. 13. Specifically, the Draft Regulations would require a hospital to “demonstrate compliance with all standards for a Certificate of Ongoing Performance for both cardiac surgery and PCI services.” The requirements are redundant because any hospital with cardiac surgery and PCI programs must comply with the Certificate of Ongoing Performance standards already in order to maintain its programs, regardless of whether it seeks to relocate. The additional requirements, set forth in Proposed MD. CODE REGS. 10.24.17.04C(1)(a), should be deleted.

If the MHCC determines not to remove the relocation requirements, it should clarify when and how the requirements would be applied. As for timing, Dimensions presumes that the requirements will apply when the hospital applies for a Certificate of Need to relocate, not when the hospital physically relocates. Dimensions recommends that the Draft Regulations clarify that the relocation requirements apply when the hospital applies for a Certificate of Need to relocate all of its services to a new hospital. Applying relocation requirements at a single time, when the MHCC already is reviewing the Certificate of Need application for the hospital seeking to relocate, would be most efficient for all parties.

Also, Dimensions seeks further clarification of what is required for a relocating hospital to “demonstrate compliance” with Certificate of Ongoing Performance standards and if this is distinct from obtaining a new Certificate of Ongoing Performance and general Certificate of Need review. Dimensions recommends that a hospital may “demonstrate compliance” simply by holding a Certificate of Ongoing Performance.

IV. Concerns & Recommendations Regarding Certain Standards for Cardiac Surgery & PCI Services

a. Minimum Case Volume Requirements

The Draft Regulations set forth minimum case volume requirements for a hospital to maintain a Certificate of Ongoing Performance for cardiac surgery services, elective PCI services, and primary PCI services, respectively. Dimensions appreciates that this minimum volume standard has been developed in order to ensure a program is well-experienced and capable of continuously delivering high quality services. However, Dimensions is concerned about the clarity of and inconsistencies within these minimum case volume requirements, as explained below.

Further, Dimensions believes a strict volume requirement may harm smaller, but needed hospital programs if a high-volume physician performing these services leaves. Any hospital program, especially a smaller one, would face substantial difficulties in recruiting a replacement physician before the former physician’s absence negatively impacts program volume. Dimensions recommends that the MHCC treat volume as a flexible factor in its decision to grant or deny a Certificate of Ongoing Performance, allowing for and incorporating other considerations such as probable success in recruiting a new physician, measuring the volume of cases each individual

physician performs, or accounting for other appropriate variations in case volume. That approach would be in keeping with the studies showing that lower volume programs can offer high quality services.

i. Cardiac Surgery Services

The Draft Regulations state that a Cardiac Surgery program “shall maintain an annual volume of 200 or more cases.” Proposed MD. CODE REGS. 10.24.17.07A(6)(a), pg. 25. However, it appears that only if the program “fails to reach an annual target volume of 100 cardiac surgery cases” will the MHCC have the authority to order a focused review of the program. Proposed MD. CODE REGS. 10.24.17.07A(6)(b), pg. 25. The Draft Regulations seem to state that a hospital is required to maintain an annual volume of 200 cases but will not be subjected to a focused review unless the hospital fails to perform 100 cardiac surgery cases. Dimensions supports the adoption of the 100 case volume as a factor to be considered for a potential focused review. However, it is not clear how the 200 case volume requirement will be enforced and what consequences will result from performing between 100 and 200 cases a year. Dimensions recommends that the Draft Regulations delete the reference to the 200 case volume due to the fact that it is confusing and not necessary.

ii. PCI (Both Elective and Primary) Services

The Draft Regulations regarding volume requirements for both primary and elective PCI services need further clarification. In the Section governing solely Elective PCI, the Draft Regulations state that the “target volume” for existing programs “with *both primary and non-primary PCI services*” is 200 cases annually. Proposed MD. CODE REGS. 10.24.17.07B(7)(a), pg. 29 (Emphasis Added). Further, if the PCI program, providing “both primary and elective PCI” fails to reach the target volume of 200 cases, the hospital program may be subjected to focused review by the MHCC. Proposed MD. CODE REGS. 10.24.17.07B(7)(b), pg. 29. In a section that governs Elective PCI Programs only, this volume standard is required for both elective and primary PCI services. The Draft Regulations set forth two different standards for Primary PCI programs: (a) fewer than 49 cases for non-rural providers will “trigger” a focused review; and (b) target volume for “primary PCI operators” should be “at least 11 primary PCI cases annually.” Proposed MD. CODE REGS. 10.24.17.07C(8), pg. 34. Thus, of the 200 elective and primary PCI cases, the Draft Regulations require that a hospital’s program perform only 49 primary PCI cases each year. Further, “primary PCI operators” who are required to perform at least 11 primary PCI cases annually is undefined. This latter standard also appears to focus on the individuals physicians performing the PCI services in the program, not program’s overall case volume. These inconsistencies in terminology need clarification.

The MHCC should refine these volume requirements for PCI programs in the final regulations. Dimensions recommends that the target volume of 200 cases apply to a program that offers both elective and primary PCI services, at least 49 of which must be primary PCI cases for programs without Cardiac Surgery. The Draft Regulations are not clear how the 49 PCI case volume requirement will be enforced and what the consequences will be from performing less than 49 PCI cases a year. Further, the minimum volume standards for PCI services should be defined as a factor for the MHCC to consider before subjecting a PCI program to a focused review.

The undefined term “primary PCI operators” further confuses the application of the 11 primary PCI case target volume for primary PCI programs. The Draft Regulations need clarification that (1) the 50 case requirement is the desired total each individual physician performs each year, regardless of where the cases are performed; and (2) of those 50 PCI cases, the individual physician should perform 11 primary PCI cases each year. Further, the minimum volume standards for PCI services performed by each individual physician should be defined as a factor for the MHCC to consider in its overall evaluation of the physician’s competency. If an individual physician fails to meet these recommended volume standards to maintain his or her competency, then the MHCC will consider other performance measures to ensure the quality of these individual physicians’ PCI services before subjecting the physician or the program to a focused review.

b. Performance Standards

i. STS-ACDS Score

Like the minimum volume requirements for the Cardiac Surgery Program, the Draft Regulations also use inconsistent standards for the hospital’s performance measures for the Cardiac Surgery Program. In measuring the program’s performance for a Certificate of Ongoing Performance, the Draft Regulations would require that a hospital “shall maintain” a composite score of “two stars or higher” according to the STS-ACSD. Proposed MD. CODE REGS. 10.24.17.07A(5)(a)(i), pg. 24. However, in accordance with the Draft Regulations, the MHCC may close the program which receives a score of one star “for four consecutive six-month reporting periods.” *Id.* It is not clear how the two star requirement will be enforced in MHCC’s certification decisions and what consequences may result from achieving one star in less than four consecutive six-month reporting periods. Dimensions recommends that the Draft Regulations delete the reference to the two star score due to the fact that it is confusing and unnecessary. If the MHCC declines this suggested change, the Draft Regulations should at least clearly identify the potential consequences for a program fluctuating between a one star and two star composite score over a two year period.

Further, as discussed in Section I above, this Performance Measure should only apply as of the effective date of the regulations to allow hospitals sufficient time to adopt and implement the STS-ACSD. Dimensions also recommends that the MHCC weighs as a factor in its certification decisions the time needed to implement a fully functional STS-ACSD with the most up to date and accurate data to analyze.

ii. Risk-Adjusted Mortality

The Draft Regulations are unclear as to what standard will be used for the risk-adjusted mortality performance measure for purposes of determining whether to issue a Certificate of Ongoing Performance for Cardiac Surgery and PCI programs. Under the Draft Regulations, a hospital is required to maintain a risk-adjusted mortality rate that is consistent with the overbroad, vague, and subjective “high quality patient care.” Proposed MD. CODE REGS. 10.24.17.07A(5)(a)(ii), pg. 24. Further, if the risk-adjusted mortality rate exceeds the “statewide average” beyond the

acceptable margin of error calculated by the MHCC for the hospital, then the program is subject to a focused review by the MHCC. Proposed MD. CODE REGS. 10.24.17.07A(5)(b), pg. 24; Proposed MD. CODE REGS. 10.24.17.07B(5)(b), pg. 27; Proposed MD. CODE REGS. 10.24.17.07C(6)(b), pg. 33. Dimensions urges that, like the nationally based STS-ACSD composite scoring, a hospital's risk-adjusted mortality rate should be compared to the national average, not the state average. This change would propel all Maryland cardiac surgery programs to achieve better than the national average for Maryland's residents instead of internally competing with one another. Also, using the statewide (or national) average will result in a very large number of programs being subject to a focused review at any given time because, as a matter of mathematical calculation, roughly half of the programs will not achieve the average.

Therefore, Dimensions recommends that MHCC require Cardiac Surgery and PCI programs be required to maintain a risk-adjusted mortality rate "that is not less than the 25th percentile nationally." If a program falls below the 25th percentile (beyond the acceptable margin of error), then the MHCC may initiate a focused review.

c. Physician Resources

For both elective and primary PCI services, the Draft Regulations require that each physician who "performs primary PCI" at a hospital that provides "primary PCI without on-site cardiac surgery" perform 50 PCI procedures (unspecified as to either elective or primary) annually as averaged over a 24 month period. Proposed MD. CODE REGS. 10.24.17.07B(6)(a) & C(7)(a). However, the language in Sections .07B(6)(b) and .07C(7)(b), standing alone, seems to require all PCI physicians to perform a minimum of 50 PCI cases annually average over 24 months, including physicians who perform procedures in a hospital with on-site cardiac surgery.

Dimensions recommends that the MHCC clearly state that these standards apply only to PCI services provided "without on-site cardiac surgery." This is appropriate because hospitals with both PCI and Cardiac Surgery programs should have adequate physician support from the Cardiac Surgery program for the PCI program.

d. Definition of Cardiac Surgery

The Draft Regulations broadly defines Cardiac Surgery as "surgery on the heart or major blood vessels of the heart, including both open and closed heart surgery." Proposed MD. CODE REGS. 10.24.17.09, pg. 41. However, the Draft Regulations directly reference the International Classification of Diseases ("ICD") procedure codes in its definition for Percutaneous Coronary Intervention. Proposed MD. CODE REGS. 10.24.17.09, pg. 42. Dimensions recommends that the cardiac surgery definition also reference the applicable ICD procedure codes.

V. Clearly Defined MHCC Oversight Processes, including Plans of Correction and Focused Review, Broadly Applicable to All Standards

Currently, in the Draft Regulations, the language referencing and standards regarding focused review, plans of correction, and closure varies by each performance, quality, and volume standard for Cardiac Surgery and PCI programs. Such variation may lead to confusion over

MHCC expectations and hospital rights. For clarity and adequate notice of MHCC oversight processes and hospital rights, Dimensions recommends that the MHCC consider consolidating all references to plans of correction, focused review, and closure in one separate regulatory section broadly applicable to all Certificate of Need, Certificate of Conformance, and Certificate of Ongoing Performance standards for Cardiac Surgery and PCI services.

a. Initial Certificate of Need and Certificate of Conformance Review

For those hospitals seeking to build a new Cardiac Surgery or PCI program, the MHCC should apply similar review processes and appeal rights available for all other Certificates of Need. The general Certificate of Need review processes and appeal rights should be incorporated into these regulations.

b. Oversight of Certificates of Ongoing Performance

i. Plans of Correction

Dimensions requests that the MHCC develop a broadly applicable standard for when a plan of correction is available to the hospital program and appropriate time tables for developing the plan and completing the corrective activities. Furthermore, the Draft Regulations state that a hospital must submit “an acceptable plan of correction to the Commission within 30 days of receiving notice of the failure from the Commission Staff.” See as an example Proposed MD. CODE REGS. 10.24.17.07A(5)(c), pg. 24. Plans of Correction may require data collection and analysis, the recruitment of staff, or other actions that may not be able to be completed within 30 days. Dimensions proposes that this be changed to 60 days. Dimensions recommends the following:

- A hospital may develop a plan of correction when the Commission first cites any deficiencies of the program meeting its applicable standards. The Commission will not take any final action pending the Commission’s receipt of the hospital’s plan of correction.
- The plan of correction must be submitted within 60 days of the hospital’s receipt of notice of deficiencies from the Commission, including the hospital’s approximate time tables for completing each corrective action.
- The Commission will review the proposed plan and, if it deems it acceptable, the Commission will issue notice of accepting the plan with appropriate timetables for completion of each corrective action.
- The Commission will re-review the program after all corrective actions should have been completed by the hospital in accordance with the agreed upon plan. In reviewing deficiencies, the Commission will consider whether the hospital has completed a substantial majority of the corrective actions as to indicate the program will be in full compliance with the standards in the foreseeable near future.

ii. Focused Review

The MHCC should develop a single set of focused review standards, consolidating them to be broadly applicable to all Certificates of Ongoing Performance. Dimensions recommends the following:

- If the Commission has substantial evidence of non-compliance with applicable program standards, it may initiate a focused review to investigate the quality of patient care or the accuracy of the data Commission has received. The following are grounds for the Commission to initiate a focused review: (1) reported patient safety concerns; (2) an aberration in data identified by Commission staff; or (3) other objective evidence of the program's alleged non-compliance with an applicable standard including (a) failure to meet the minimum volume requirement of 100 cases per year for a Cardiac Surgery Program; and (b) a one-star composite score from the STS-ACSD for four consecutive six-month reporting periods.
- The Commission will provide thirty (30) days written notice to the hospital that it is initiating focused review of the hospital's program, including a general statement of the grounds triggering the focused review.
- In a focused review, Commission staff will audit the program's clinical records for the purpose of auditing data. A hospital must cooperate with Commission Staff, and other persons acting on behalf of the Commission, and must timely provide all information and data requested.

The MHCC may also include additional grounds for initiating a focused review such as failure to meet target minimum volume standards.

iii. Closure of an Existing Program

There appears to be a drafting error in the section of the Draft Regulations regarding the MHCC's closure of a cardiac surgery program. The right of the cardiac surgery program to be "given an opportunity to address deficiencies identified by the Commission" is listed incorrectly as subsection (d), indicating it is one of several "circumstances" under which the MHCC will evaluate closing a program. Proposed MD. CODE REGS. 10.24.17.04B(1), pg. 12-13. To correct the error, the language currently set forth in subsection (d) should stand-alone without a subsection designation. In other words, the hospital's right to address deficiencies through a plan of correction process should be available regardless of the circumstances of the MHCC's evaluation of possible closure. Further, Dimensions recommends the provision read: "Prior to closure of the cardiac surgery program, the Commission will confirm that the cardiac surgery program has been given an opportunity to address deficiencies identified by the Commission through an approved plan of correction."

Also, under the Cardiac Surgery program performance standards, the Draft Regulations provides the MHCC the authority to close a program if the composite score from the STS-ACSD registry

is one star for four consecutive six-month reporting periods. Proposed MD. CODE REGS. 10.24.17.07A(5)(a)(i), pg. 24. This authority is distinct from the more balanced approach in the proposed Section 10.24.17.04B, which permits the hospital an opportunity to address identified deficiencies. Dimensions recommends that the Draft Regulations require that the MHCC provides a hospital with the opportunity to submit a plan of correction upon its Cardiac Surgery program receiving an STS-ACSD composite score of one star for two consecutive six-month reporting periods. This would balance the hospital's right to address deficiencies with the MHCC's prerogative to close programs that continually fall markedly below acceptable performance measures.

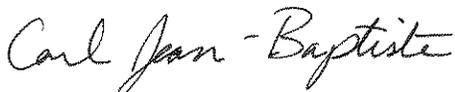
iv. Appeal Rights

Under the Volume Requirements and Performance Measures for each program's Certificate of Ongoing Performance, the Draft Regulations essentially require that a hospital "voluntarily relinquish" its authority to provide cardiac surgery or PCI services if it does not successfully and timely complete a plan of correction. See as an example of the standard at Proposed MD. CODE REGS. 10.24.17.07A(6)(d), pg. 25. Maryland law permits the MHCC to impose, as a condition of granting a Certificate of Conformance for PCI services, that the hospital agree to voluntarily relinquish its authority to provide PCI services if it fails to meet applicable standards. MD. CODE ANN., HEALTH-GEN § 19-120.1(g)(2)(v) (2012). However, there is no similar statutory authority to require a hospital to voluntarily surrender its cardiac surgery program. Also, voluntarily relinquishing a program may compromise a hospital's appeal rights. Dimensions recommends that such references be rephrased so that "the Commission shall have the authority to revoke" the applicable Certificate if the hospital fails to successfully and timely complete its plan of correction.

VI. Conclusion

On behalf of Dimensions Health Corporation, I respectfully request that the MHCC consider the concerns and recommendations set forth above regarding the State Health Plan for Facilities and Services: Specialized Cardiovascular Services proposed for COMAR 10.24.17. In particular, Dimensions requests that the MHCC address its concerns regarding clarity in standards and processes so hospitals may strive to achieve all applicable quality and performance measures. Dimensions applauds the MHCC's goal to provide accessible high quality specialized cardiovascular services to Maryland residents.

Respectfully submitted,



Carl Jean-Baptiste
Senior V.P. & General Counsel

MES