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VIA EMAIL <eileen.fleck@maryland.gov>
and REGULAR MAIL

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

June 1, 2016

Re: Proposed Draft State Health Plan for Facilities and Services:
Organ Transplant Services, COMAR 10.24.15
Informal Comments Submitted by the Johns Hopkins Health System

Dear Ms. Fleck:

On behalf of the Johns Hopkins Health System ("Johns Hopkins"), I write to submit comments regarding the proposed draft State Health Plan for Facilities and Services: Organ Transplant Services Chapter, COMAR 10.24.15 ("Draft Chapter"). The draft was released for informal public comment May 5, 2016, with comments due by June 1, 2016.

We thank you and the other members of the Commission staff for a thorough review of the chapter, last revised in 2002, and for the production of a Draft Chapter that incorporates important updates and improvements. Thank you also for the opportunity to provide the comments below. Johns Hopkins respectfully requests your consideration of the following comments and suggested changes:

1. Clarify the definition of an Adult Kidney Transplant Program.

Tables 2 and 3, on pages 20 and 22, list separate threshold and minimum volumes for Adult and Pediatric kidney transplant programs. Pediatric is defined on page 26, Section .06 Definitions, (9):

“Pediatric refers to patients under age 18. A pediatric program is one that serves a majority of patients under age 18.”

We recommend the addition of the following language at the beginning of Section .06 Definitions:

“Adult refers to patients age 18 or older. An adult program is one that serves a majority of patients age 18 or older.”

Without this addition, it is unclear how the pediatric volume requirements apply to programs performing both adult and pediatric transplants. With this definition, it is clear that for programs that do some pediatric transplants but a majority of adult transplants, the adult volume requirements will apply.

2. Limit the docketing rule so that potential new market entrants are not blocked indefinitely from submitting an application for consideration.

The docketing rule in the Draft Chapter has two parts. Part B requires that all programs in the region engaged in transplantation of the same organ type as the potential applicant have been in operation for at before an application for a new program will be docketed and considered. This rule allows a new program a window of time in which to achieve sufficient case volume without the threat of another new program in the region.

Part A of the docketing rule requires that all existing non-federal programs in the health planning region be operating at or above the threshold volume requirement for at least three years before an application for a new program will be docketed and considered. An exception is made if a program in the region has been designated as a member not in good standing by the Organ Transplant and Procurement Network. The volume of such a program will not be considered when determining if the existing programs have met the threshold volume requirement for three years.

Part A creates a scenario in which it is possible that access to transplant services is inadequate but a new program is precluded from submitting an application for consideration. For instance, for kidney transplant, a new program must achieve and maintain a minimum volume of 30 transplants per year in order to remain in operation. In order for another application to be docketed and considered, however, every program in the region has to be operating above the threshold volume of 50 transplants per year for three consecutive years. Hence one program could achieve and maintain a minimum of 30 transplants per year, but never exceed 50 transplants per year, or exceed 50 transplants per year inconsistently and for fewer than three consecutive years. In these instances, all other potential new applicants would be barred from applying indefinitely.

It is possible that the intention is for Part A to function as an initial Need test, operating under the assumption that a program that meets the minimum volume but not the threshold volume is an indicator of a lack of sufficient need in the region to warrant consideration of a new program. Failure to exceed the threshold volume, though, is just as likely an indicator of inadequate performance of the program, and not of need or barriers to access to services. With Part A of the docketing rule in place, it is impossible to challenge this assumption—the evidence cannot even be considered. Removal of Part A will allow a potential new applicant to make an argument and challenge the assumption, leaving the Commission with the responsibility of evaluating the evidence and deciding whether need exists and a new program is warranted or not.

Johns Hopkins recommends elimination of Part A of the docketing rule by making these changes to the Draft Chapter:

.04 Certificate of Need Docketing Rules

The Commission will only docket an application for a new organ transplant program if:

~~A. All existing non-federal organ transplant programs in the health planning region have been operating at or above the applicable annual threshold case volume for at least three years prior to the filing of the application unless an organ transplant program in the health planning region has been designated as a member not in good standing by the Organ Transplant and Procurement Network. The volume of an organ transplant program designated as a member not in good standing will be disregarded when determining if all organ transplant programs have met the annual threshold volume requirements for the prior three years; and~~

~~B. A all of the existing non-federal organ transplant programs in the health planning region engaged in transplantation of the same organ type as the proposed new program have been in operation for at least three years.~~

3. Consider additional information and conclusions from the peer-reviewed scientific literature regarding the effects of competition on organ transplant access and outcomes.

On pages 17-18 of the Draft Chapter there is a discussion of the relationship between competition among organ transplant programs and patient outcomes. This relationship is complex, with multiple variables, and studies are ongoing. Johns Hopkins feels strongly that the Draft Chapter should accurately reflect the current state of the scientific literature, and so requests review and consideration of the publications and comments below in addition to that reflected in the Draft Chapter as currently written.

- Adler, Joel T., et al. "Temporal Analysis of Market Competition and Density in Renal Transplantation Volume and Outcome." *Transplantation* 2016; 100:670-677.

Citing this article, the Draft Chapter states:

"Market competition was not associated with a higher number of transplants." Draft Chapter, page 18.

From the same article, though, is the following contradictory statement:

"A DSA with more kidney transplant centers was associated with more kidney transplants without compromising kidney allograft survival." Adler et al., page 676, final paragraph.

The article continues:

"Despite the high barrier of entry, these market models demonstrate an important and measureable association between transplant center density, competition, and the number of transplants performed." Adler et al., page 676.

We note these differences as evidence of the complexity of the issues and the findings. Johns Hopkins requests that the language in this section of the Draft Chapter reflect the conclusion of the cited article that more transplant centers was associated with more kidney transplants without compromising the success of the procedure.

- Adler, Joel T., et al. "Market Competition and Density in Liver Transplantation: Relationship to Volume and Outcomes." *J Am Coll Surg* 2015; 221:524-531.

This is a second article by the same lead author, examining liver transplant in this case instead of kidney. From the conclusion at the end of the article:

"More liver transplantation centers were associated with more liver transplants, and these market factors had complex interactions with patient and graft survival after transplantation. From the patient perspective, market variables impact patient and graft survival, but baseline comorbidities remain important. Transplantation center density has a measurable impact on the number of transplants performed and outcomes, and its role deserves continued study." Pages 530-531.

- Dzebisashvili, Nino, et al. "Following the Organ Supply: Assessing the Benefit of Inter-DSA Travel in Liver Transplantation." *Transplantation* 2013; 95:361-371.

This article examines disparities in access related to socioeconomic and insurance status and states:

“High SES and inter-DSA travel are strongly associated with increased LT access and reduced mortality. Travelers are more likely to be sociodemographically advantaged and privately insured and to live in regions with reduced access to deceased-donor organs.”
Dzebisashvili et al., page 361, “Conclusion” from the abstract.

We bring to the attention of the Commission these two additional scientific journal articles as evidence that competition among transplant centers has been found to play a role in the number of transplants performed, and that the presence or absence of a high-performing center in a given geographic area has been shown to have a disparate impact on mortality based on socioeconomic status and ability to travel for care.

4. Clarify the requirements for obtaining FACT accreditation.

Accreditation requirements for hematopoietic stem cell bone marrow transplant programs are described in two different standards, on pages 20 and 24 of the Draft Chapter. The required timeframes described in the two standards appear to be inconsistent. Johns Hopkins would appreciate clarification of these requirements.

Page 20, A. General Standards

(2) Each Maryland transplant program shall agree to comply with all requirements of CMS and UNOS certification and, if applicable, accreditation by the Foundation for the Accreditation of Cellular Therapy.

(b) Each hematopoietic stem cell bone marrow transplant program shall be accredited by the Foundation for the Accreditation of Cellular Therapy within the first two years of operation.

Page 24, B. Project Review Standards, (6) Certification and Accreditation

(b) An applicant for a hematopoietic stem cell transplant program shall meet accreditation requirements of the Foundation for the Accreditation of Cellular Therapy (FACT) within the first three years of operation. An applicant shall apply and be FACT-accredited within 12 months of becoming eligible to apply for accreditation and shall maintain its accreditation thereafter.

5. Reinstate the language from the previous chapter asserting that a transplant program should be located in, or closely affiliated with, a teaching hospital.

The previous version of the Transplant Chapter included the following language:

“A transplant program should be located in, or closely affiliated with, a teaching hospital with a graduate medical education program and residency training.” Policy 7, page 19 of the existing version of COMAR 10.24.15.

Johns Hopkins supports this policy and requests that the language be added to the Draft Chapter.

Thank you again for undertaking this important revision and for the opportunity to comment. We look forward to the review process and ultimately the enactment of a new and improved Transplant chapter.

Sincerely,

A handwritten signature in black ink, appearing to read 'Anne Langley', written in a cursive style.

Anne Langley