DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

June 9, 2008

Goran Klintmalm, MD, PhD
President
American Society of Transplant Surgeons
2461 South Clark Street, Suite 640
Arlington, VA 22202

Dear Dr. Klintmalm:

I am writing to follow-up on the issues you raise in your letter we received dated May 12, 2008. We appreciate your feedback as we implement our oversight responsibilities under the new regulation. The primary issues you raise and our responses to these issues are outlined below:

Survey Protocol

You identify that in the Survey Protocol dated August 2007, the surveyors are directed to review medical records and other documents pre-dating June 28, 2007 the effective date of the new regulations. We agree with your comments. The version of the survey protocol you reviewed has been revised. A later version of the survey protocol and instructions to the surveyors have made it clear that their review should be limited to a transplant program's policies and practices after June 28, 2007. If you are aware of any situation in which surveyors have cited deficiencies prior to June 28, 2007, we would appreciate hearing about these cases so that we may take appropriate follow-up steps. See **Attachment A** for additional comments regarding your feedback on the Survey Protocol.

Citation of Condition and Standard-Level Deficiencies for Outcomes

You raise three primary concerns about the outcomes standard including: 1) the criteria that CMS uses to differentiate between Standard-Level and Condition-Level deficiencies; 2) the process to evaluate mitigating circumstances that would justify the center's failure to meet the outcomes standard; and 3) the ability for a program to take effective action within the 210 days provided for corrective action. Each of these areas is discussed below.

Criteria differentiating between standard-level and condition-level deficiencies: The description of the criteria in your letter is slightly different than ours in a few areas. We thought a brief overview of the process would be helpful to clarify.

Surveyors are directed to review the current SRTR report for compliance with the outcomes standard. If the standard is not met (outcomes are significantly worse than would be expected), they are instructed to review the 4 previous SRTR reports. If the program, meets the outcome requirements for the 4 reports prior to the most recent, the deficiency would be cited at a Standard-level. If the program does not meet the outcomes standard for one or more of the 4 reports prior to the most recent, the program would be cited at a Condition-level.

We had included the survival rate of 100% (though it would be an unlikely scenario) following the SRTR's release to allow for the possibility that a program could be cited at a standard-level where more recent unadjusted survival rates are without question, better than would be expected. However, we will rescind this guidance to surveyors due to the confusion that may be caused by this percentage and rely on the SRTR reports as described above.

We do not believe that the threshold for citing a Condition-level deficiency is unrealistic. Meeting the outcomes requirements is an important component for compliance with Medicare's Conditions of Participation. Based on the most recent SRTR outcome reports, only 5% to 10% of transplant programs nationwide for any organ type would be cited at the Condition-level if all programs were evaluated immediately. We expect that this percentage will decrease as we move through the three-year process for initial surveys and as transplant programs actively monitor their outcomes and analyze where changes in the program may be needed in order to achieve full compliance.

Process to evaluate mitigating circumstances

It is vital to distinguish between (a) the survey process and its function of making objective determinations about a program's fulfillment of quality and safety standards as of the time of the survey and (b) actions that will be taken based on the survey findings. "Mitigating factors" have no role in the first function. In other words: "what is - is." It is not appropriate for the onsite surveyors to review mitigating factors in making their findings about whether the standards have been met.

"Mitigating factors" are indeed pertinent to the second process, the process of determining appropriate actions that will be taken based on the survey findings. Transplant programs do have the opportunity, therefore, to request that CMS consider approval based on mitigating factors after the survey is completed. This provision is outlined in the regulation under 42 CFR §488.61(a)(4) and §488.61(b)(4). We will post more information on our website shortly that will describe the "mitigating factor" review process in more detail. However, a transplant program is not required to wait for any more information before they request such a review. Any program wishing to submit this type of request may contact Karen Tritz at (410) 786-8021, as the initial determinations will be made through a process managed by CMS Central Office in order to maximize national consistency. The timing of any such request should not occur before completion of the onsite survey.

Our current plans are to establish a panel of CMS officials with programmatic and clinical expertise to review all requests for approval based on mitigating circumstances should they arise. We believe this type of review will allow for a nationally consistent, standardized and objective review of any request of this type. We invite your thoughts as to the types of requests for consideration of mitigating factors that we may encounter, as well as ideas relevant to the process itself.

We also expect to release a CMS Survey and Certification Letter that will outline the "mitigating factors" provision in more detail. We invite and would benefit from your thoughts prior to issuance of such a communication. Please note that our intent is to construe this provision quite narrowly given the factors for consideration outlined in the regulation and our

responsibilities to ensure compliance with the Medicare's Conditions of Participations for transplant programs that participate in Medicare.
Finally, the "mitigating factors" provision is not intended as a substitute for a transplant program's ability to appeal a survey finding (either formally or informally) if it believes the finding itself is in error.

Program's ability to take effective action within the 210 days
Transplant programs analyze their outcomes on an ongoing basis, and should know whether their outcomes have been better or worse than expected given the type of patients they are transplanting and the donors they have accepted. In addition, a program that does not meet the outcomes standard for a single SRTR report should review and analyze why this occurred. It is only after the second poor outcomes report that CMS would identify the program as having a deficiency at the Condition-level.

The 210 day plan of correction allows the program the opportunity to demonstrate that it has been taking the *process* steps necessary to analyze the information and make any changes needed to improve the outcomes, and allows additional time for the next SRTR outcomes report to be released to determine if the program is back in compliance with this Medicare requirement.

If the next SRTR meets the outcome standard, the deficiency is corrected. If the next SRTR report does not meet the outcomes standard (which would mean that 3 or more out of the past 6 SRTR reports have been out of compliance with Medicare's minimum requirements), CMS will look at this on a case-by-case basis to determine whether Medicare approval would be terminated. "Mitigating factors" may be relevant in such a review process. Some of the areas CMS would review include whether the survival rate had improved and to what extent and when changes were implemented by the program.

We would reiterate, however, that it is our expectation that programs are reviewing their outcomes and the process to improve these outcomes on an ongoing basis. We expect that this process would not wait for a 2nd SRTR report to show that the outcomes requirement is not met and would not wait for surveyors to identify for the program that repeated failure to fulfill the outcomes requirement will be cited at the Condition-level.

SRTR Methodology for Calculating Observed versus Expected Outcomes

The final issue you raise is the distinction between the 1-sided p value that CMS and the OPTN's Membership and Professional Standards Committee (MPSC) use, and the 2-sided p value that is published in the SRTR center-specific reports available at www.ustransplant.org.

It is our understanding that the SRTR publishes the 2-sided p-value to be able to identify programs where the outcomes are both significantly better and significantly worse than would be expected given the patient and donor characteristics. It is reasonable that the SRTR would want to make this information available to the public and to patients who may be trying to determine which program they should seek for placement on their waiting list.

The SRTR calculates a 1-sided p value for the OPTN MPSC Committee to identify programs where the outcomes are significantly worse than expected and follow-up is needed. This information is also provided to CMS and other payers. CMS' regulations mirror OPTN's MPSC methodology. The CMS regulations specifically require that we use the 1-sided p value from the SRTR reports. The 1-sided p value is an appropriate statistical function given that both CMS and the MPSC's role is to identify programs whose outcomes are significantly worse than expected given the patient and donor characteristics.

The extent to which transplant programs are aware of this distinction is unknown. Transplant programs that wish to calculate a 1-sided p value may apply appropriate calculations to gain a sense of the 1-sided value (e.g. dividing the 2-sided p value by 2). So for example, a 2-sided p value of 0.08 divided by 2 will inform the transplant center that their 1-sided p-value is 0.04. Transplant programs may also access their survival rates and the 1-sided p-value on a secure website run by the SRTR for transplant programs at https://secure.ustransplant.org. We would encourage any transplant program seeking additional information about these calculations or instructions about how to access the secure website to contact the SRTR directly at 1-800-830-9664. or by email at srtr@arborresearch.org.

We also received the attachments to your letter with feedback on the survey protocol and the interpretive guidelines. Additional information will be forthcoming responding to your comments on the Interpretive Guidelines. Please note that we are in the process of finalizing both of these documents for surveyors' use. We will be sure to notify you of any public release of these documents so that you can share the information with your membership.

We hope this information is helpful. If you have any questions about any of the responses, please feel free to contact Karen Tritz (Karen.tritz@cms.hhs.gov, (410) 786-8021).

We also appreciate your latest suggestions relevant to the Interpretive Guidance for surveyors and your continued close attention to the survey process. We are making clarifications and adjustments in the final Guidance in response to many of your most recent suggestions. Those suggestions that we are not accepting will be the subject of a separate communication which we look forward to discussing with you.

Sincerely,

Thomas Hamilton
Director

Attachment A: Response to Survey Protocol

Response to comment page 3: If transplant programs are applying for separate approval of their adult and pediatric programs, then the regulatory requirements in §482.76 apply (i.e., the predominant program must be approved before the related program can be approved). If the transplant program has applied for a single program such as an adult program, then this provision does not apply. Under the auspices of that adult program, the program is permitted to do a fewer number of pediatric transplants provided it is not the pre-dominant type of transplant. The instructions make this clear by outlining "if both an adult and pediatric program are present"

Response page 4 and 13: We do not specify which specific personnel the hospital will bring to the entrance or exit conference. Surveyors defer to the hospital administration's preferences in this regard.

It is unreasonable for surveyors to provide a projected interview time for each interview that will take place and interviews may vary based on the results of the survey. It is sufficient for surveyors to identify the staff that will need to be interviewed. If there are schedule conflicts with the staff that have been identified, we expect that transplant program staff will make the surveyors aware of these conflicts early in the survey (preferably at the entrance conference).

Response page 5: We expect that an organizational chart of the transplant program will be available in all cases. This is a standard component of an operating business and will assist surveyors in understanding the organizational/supervisory relationships between staff.

Response page 10: As previously discussed, surveyors are very aware of the need for sensitivity in interviewing patients, we will include language that reinforces this issue.

Response page 12: The regulation requires that the hospital's resources be available (labs, blood banks, etc.). Given the nature of transplantation which can occur in the middle of the night, 24-hour availability is a reasonable interpretation of the term "available." When 24-hour availability is not required, as in the case of tissue typing, we have noted this in the guidelines and will include language to this effect in this section.