Process For Requesting Consideration of Mitigating Factors in CMS' Determination of Medicare Approval of Organ Transplant Centers

A. Background

Under the authority of 42 CFR §488.61 (a)(4), (b)(2) and (c)(4), a transplant program may request that the Centers for Medicare & Medicaid Services (CMS) consider mitigating factors in the initial approval and re-approval of a transplant program that does not meet one or more Conditions of Participation.

The regulation describes three general areas that will be reviewed in determining whether or not a program can be approved based on mitigating factors. These areas include (but are not limited to): 1) the extent to which outcome measures are met or exceeded; 2) the availability of Medicare-approved transplant centers in the area; and 3) extenuating circumstances that may have a temporary effect on meeting the Conditions of Participation.

In most cases CMS will schedule a conference call with the hospital to discuss the results of the CMS review about 30 days after CMS' receipt of the completed request for consideration of mitigating factors.

B. Requesting Approval Based on Mitigating Factors

A transplant program seeking approval based on the presence of mitigating factors should:

1) Submit a formal written request for approval to the CMS Central Office contact and address specified below **within 10 calendar days from the notification date on the letter accompanying the CMS-2567 form** (this form outlines survey results) in order to get timely attention before any possible enforcement action is taken on the cited deficiencies.

2) Submit any final (additional) explanatory materials **within 30 calendar days following the date of the notice accompanying the CMS-2567 form**.

For example, if the date of the notice accompanying the CMS-2567 form is August 5, 2008, the initial request for approval based on mitigating factors should be sent to Sherry Clark, the designated CMS contact noted below, by August 15, 2008, and any additional supporting documentation should be submitted by September 4, 2008 (which is a total of 30 days from the date the notice accompanying the CMS-2567 form).

The review of mitigating factors may not be requested in cases where the survey findings indicate that the deficiencies warrant a finding of Immediate Jeopardy to patient's health and safety.

A request for approval based on mitigating circumstances is <u>not</u> an appeal of the deficiencies cited in the survey. Appeals procedures for transplant programs are governed by 42 C.F.R. Part 498. The mitigating factors request is intended to allow CMS, in limited circumstances, to extend Medicare approval in cases where a transplant program sufficiently demonstrates that there are exceptional factors present which constitute grounds for Medicare approval in spite of the fact that the program does not meet the data submission, clinical experience, outcome requirements or other Conditions of Participation.

C. Difference from Plan of Correction

For any deficiencies cited during the onsite survey, the transplant program must submit a Plan of Correction (PoC) within 10 calendar days of receiving the survey results (i.e., the CMS-2567 form). The PoC will be submitted to the contact person at the State Agency or CMS Regional Office as identified on the letter that accompanies the survey results. This is a standard process for all surveys of Medicare-participating providers. The PoC should outline the specific steps the transplant program will take to correct any deficiencies.

The content and process for completing the PoC is ***completely separate*** from the process for requesting approval based on mitigating factors which is outlined in this document. The focus of the transplant program's materials submitted for each of these processes may also be different (though there may be some overlap). The focus of the PoC is to identify the process and steps the program will take to correct the deficiency. The focus of the request for approval based on mitigating factors are to identify the process and steps the transplant program has taken, but also to provide information about any factors identified by the program that support the approval based on mitigating factors (e.g., a natural disaster that is outside the hospital's control).

For example, if a program had a Condition-level deficiency related to the number of transplants performed (i.e., volume), the Plan of Correction would identify the analysis of why the volume was low, and the steps taken by the facility to increase its volume (e.g., ensure maximum outreach to referral sources, review of organ acceptance criteria, etc.). In the request for approval based on mitigating factors, the program could include some of this information to provide evidence that the program is addressing this issue, but the program could also include additional documentation geographic or demographic information if the program believed that ending Medicare approval for the program would create access issues for beneficiaries.

D. Content of the Request

A transplant program seeking approval under this category should include the following in its request to CMS:

Within **10** calendar days of the date on the notification letter:

1. **Name**: Name of the transplant hospital;
2. **Type**: Type of organ transplant program(s) for which approval based on mitigating factors is (are) requested;
3. **Contact**: Transplant program(s) contact person (name, phone number, and e-mail);
4. **CoPs**: Those Condition(s) of Participation that the program does not meet (based on the survey findings), for which the transplant center is requesting CMS review for mitigating factors:
   §42 CFR 482.72 – OPTN Membership
   §42 CFR 482.74 – Notification to CMS
   §42 CFR 482.76 – Pediatric Transplants
   §42 CFR 482.80 – Data submission, clinical experience and outcome requirements for *initial approval* of transplant centers
   §42 CFR 482.82 – Data submission, clinical experience and outcome requirements for *re-approval* of transplant centers
   §42 CFR 482.90 – Patient and Living Donor Selection

§42 CFR 482.92 – Organ Recovery and Receipt
§42 CFR 482.94 – Patient and Living Donor Management
§42 CFR 482.96 – Quality Assessment and Performance Improvement (QAPI)
§42 CFR 482.98 – Human Resources
§42 CFR 482.100 – Organ Procurement
§42 CFR 482.102 – Patient and Living Donor Rights
§42 CFR 482.104 – Additional Requirements for kidney transplant centers

Within **30** calendar days of the date on the notification letter:

1. **Rationale**: The rationale for requesting approval of a given program based on mitigating factors;

2. **Supporting Evidence**: Any information or supporting documentation that the transplant program would like CMS to review to determine whether or not mitigating factors exist (See appendices for examples of mitigating factors that may be considered);

3. **Internal Program Improvements**: The extent to which the Condition of Participation that is out-of-compliance has been tracked and analyzed by the transplant program (e.g., through the Quality Assessment and Program Improvement System), the specific findings of the analysis, and the specific changes, if any, that have been made by the program to address the program's findings.

4. **Outcomes Data *(if applicable)*:** If the program is requesting approval based on mitigating circumstances for non-compliance with *outcomes* (the 1-year patient and/or graft survival), provide the following information *in 6-month intervals for the past 3 years*:
   a. Total number of all patients that received transplants for that organ type;
   b. Of the patients transplanted in that 6-month period, total number of patient deaths at 1-month and 1-year post-transplant;
   c. Total number of grafts transplanted (includes any re-transplants); and
   d. Total number of graft failures at 1-month and 1-year post-transplant (of the grafts transplanted in that 6-month period).

This additional information will allow us to review how prior outcomes over a given time period may be affecting the program's trends.

5. **Review by OPTN:** The extent to which the outcomes, volume, or policy compliance issue has been discussed with and reviewed by the OPTN including any steps taken to address the OPTN's concerns.

Note: In order to ensure that a request receives timely attention prior to any enforcement action required under the regulations and that the request provides complete information for a thorough review, CMS should receive the requested information regarding items 1 through 4 within 10 calendar days of the date on the notification letter, and the requested information regarding items 5 through 8 within 30 calendar days of the date on the notification letter. If a transplant program is prepared to submit items earlier than these guidelines, the program may do so.

For Transplant programs that ARE already Medicare-approved as of June 28, 2007: These transplant programs must still develop and implement an acceptable plan of correction that is submitted to the State Agency or CMS Regional Office within 10 days of the date on the notification

letter accompanying the CMS-2567 form. Additionally, the timing of Medicare termination does not change because the program has applied for approval based on mitigating factors; the number of days a transplant program has before it is terminated from the Medicare program Medicare termination remains the same. As described above, the transplant program should submit within 30 calendar days from the date on the notification letter to submit any supporting documentation that it would like CMS to review.

For Transplant programs that ARE NOT already Medicare-approved as of June 28, 2007:
Transplant programs that are not Medicare approved which are seeking initial approval under the Conditions of Participation and that have deficiencies with one or more Conditions of Participation will receive a letter that they are not Medicare-approved with the CMS-2567 form. Within 10 calendar days of receipt of that letter, a transplant program may request that CMS consider approving the program based on the presence of mitigating factors. As described above, the transplant program should submit within 30 calendar days from the date on the notification letter to submit any supporting documentation that it would like CMS to review.

Where to Submit the Request for Consideration of Mitigating Factors
All requests should be sent electronically to Sherry Clark at sherry.clark@cms.hhs.gov . We request that the application materials be sequentially-numbered and sent in a single .pdf or Microsoft Word file with a table of contents. This will ensure that CMS is aware of all supporting documentation provided and will greatly facilitate the review process. Confirmation of receipt of the electronic file may be requested.

Additional contact information for Sherry Clark is outlined below:
Sherry Clark
Survey and Certification Group, CMCS
Centers for Medicare and Medicaid Services
7500 Security Blvd, Mailstop C2-21-16
Baltimore, MD 21244
Phone: (410) 786-8476
Fax: (410) 786-0194

CMS Process for Reviewing Requests for Approval Based on Mitigating Factors
Following CMS' receipt of a request for review of mitigating factors, CMS will review the request. Initial reviews will include analysis by a national panel of CMS staff with programmatic and clinical expertise to review the specific circumstances for each program on a case-by-case basis. CMS will communicate in writing to the requesting provider whether approval based on mitigating factors is warranted.

Time Period of Approval Based on Mitigating Factors

Approval based on mitigating factors is not automatically carried forward into subsequent re-approvals and may be time-limited. CMS will also review the mitigating factors at the time of re-approval to determine if the circumstances that originally warranted approval based on mitigating factors would still apply. The transplant program must request re-approval of mitigating circumstances, using the process described above, and may submit updated supporting documentation for CMS to consider.

Refer to the enclosed appendices for examples of mitigating factors that may be considered:

Appendix One: Outcome Measures
Appendix Two: Clinical Experience (Volume) Measures
Appendix Three: Other Conditions of Participation

Appendix One – OUTCOME MEASURES:
Examples of Mitigating Factors that May be Considered

Section 42 CFR §488.61 (a)(4) states:

(4) CMS will consider mitigating factors, including (but not limited to) the following in considering initial approval of a transplant center that does not meet the data submission, clinical experience, outcome requirements, or other conditions of participation:

(i) The extent to which outcome measures are met or exceeded;

(ii) Availability of Medicare-approved transplant centers in the area; and

(iii) Extenuating circumstances (e.g., natural disaster) that may have a temporary effect on meeting the conditions of participation

Sections 488.61(b)(2) and (c)(4) contain similar provisions for approval or re-approval of currently participating transplant centers. Below is a categorization and set of examples for factors that CMS might consider.

A. Extent and Nature of Outcome Measure Failure

1) ***Degree of Failure***: To what extent has risk-adjusted performance departed from the standard?

2) ***Trendline of Improvement or Failure***: To what extent has the outcome profile been improving, staying the same, or worsening? How long has the Center's outcome been below the standard?

3) ***Risk-Adjustment Anomalies:*** To what extent is there evidence that performance has been adversely affected by transplant risks not captured in the SRTR risk-adjustment methodology? To what extent does the transplant center use experimental protocols, and what would be the effect if the pertinent cases are removed from the database?

B. Access-to-Care Issues

1) ***Evidence of Access:*** To what extent is there evidence that the absence of this Medicare-approved transplant center will cause significant access-to-care problems for Medicare beneficiaries?

2) ***Population Considerations:*** Are there any special access issues related to the make-up of the population being served that create very unusual access-to-care issues (e.g., disease-susceptible ethnic or racial considerations)?

3) ***Organ-Type Considerations:*** To what extent would the absence of this Medicare-approved transplant program impact the ability to use viable organs that are recovered from this area?

C. Factors Beyond the Control of the Hospital

1) ***Natural Disasters:*** Have there been recent natural disasters that significantly affected the ability of the transplant center to meet the Conditions of Participation? Is this a temporary situation?

2) ***Other Factors:*** For example, have there been any personnel changes that have affected compliance with the Conditions of Participation (e.g., the primary transplant surgeon leaving the program where delays in replacement were beyond the control of the hospital)?

D. Quality Improvement and Management Interventions

1) ***Analysis:*** To what extent has the center analyzed the root causes of poor outcomes?

2) ***QAPI***: To what extent have <u>all three</u> of the following occurred:

a. There have been significant improvements in the transplant hospital's Quality Assessment and Improvement Program (QAPI) that the hospital believes will lead to outcomes that meet the outcome standards;
b. The improvements have been implemented;
c. Insufficient time has elapsed since implementation to allow improved outcomes to become manifest in the SRTR reports.

3) ***Governing Body and Management:*** To what extent have <u>all three</u> of the following occurred:
a. Management: There have been significant improvements in the transplant hospital's management interventions and involvement of the Governing Body that the hospital believes will lead to outcomes that meet the outcome standards;
b. The improvements have been implemented;
c. Insufficient time has elapsed since implementation to allow improved outcomes to become manifest in the SRTR reports.

What is the relationship of the above factors (A-D) (cited by the hospital) to the root causes of failure to meet the Conditions of Participation??

Appendix Two – CLINICAL EXPERIENCE (VOLUME) MEASURES:
Examples of Mitigating Factors that May be Considered

Section 42 CFR §488.61 (a)(4) states:

(4) CMS will consider mitigating factors, including (but not limited to) the following in considering initial approval of a transplant center that does not meet the data submission, clinical experience, outcome requirements, or other conditions of participation:

(i) The extent to which outcome measures are met or exceeded;

(ii) Availability of Medicare-approved transplant centers in the area; and

(iii)Extenuating circumstances (e.g., natural disaster) that may have a temporary effect on meeting the conditions of participation.

Sections 488.61(b)(2) and (c)(4) contain similar provisions for approval or re-approval of currently participating transplant centers. Below is a categorization and set of examples for factors that CMS might consider.

A. Extent of Non-compliance with Clinical Experience (Volume) Measures

1) ***Degree of Failure***: To what extent has the number of transplants performed departed from the standard?

2) ***Trendline of Improvement or Failure***: To what extent has the number of transplants been increasing, staying the same, or declining? How long has the transplant program's volume been below the standard?

3) ***Progress in Increasing the Number of Transplants:*** To what extent is there evidence that the program has analyzed the *specific* factors contributing to the low number of transplants? Has the program taken steps to address those areas under the hospital's control to increase the number of transplants (e.g., outreach to referral sources, etc.)?

B. Compliance with Outcome Measures

1) ***Comparison of Observed and Expected Performance:*** To what extent has risk-adjusted observed performance met or exceeded the expected survival rates outlined in the most recent SRTR reports?

2) ***Outcome tracking:*** To what extent is the program tracking its performance to ensure that any outcomes issues are identified promptly?

C. Access-to-Care Issues

1) ***Evidence of Access:*** To what extent is there evidence that the absence of this Medicare-approved transplant center will cause significant access-to-care problems for Medicare beneficiaries?

2) ***Population Considerations:*** Are there any special access issues related to the make-up of the population being served that create very unusual access-to-care issues (e.g., disease-susceptible ethnic or racial considerations).

D. Factors Beyond the Control of the Hospital

1) ***Natural Disasters:*** Have there been recent natural disasters that significantly affected the ability of the transplant center to meet the Conditions of Participation? Is this a temporary situation?

2) ***Other Factors:*** Have there been any personnel changes that have affected compliance with the Conditions of Participation (e.g., the primary transplant surgeon leaving the program where delays in replacement were beyond the control of the hospital)?

E. Quality Improvement and Management Interventions

1) ***Analysis:*** To what extent has the center analyzed the root causes of low volume?

2) ***QAPI***: To what extent have all three of the following occurred:

a. There have been significant improvements in the transplant hospital's Quality Assessment and Improvement Program (QAPI) that the hospital believes will lead to an increase in the number of transplants

b. The improvements have been implemented;

c. Insufficient time has elapsed since implementation the improvements to allow it to be reflected in the number of transplants performed.

3) ***Governing Body and Management:*** To what extent have all three of the following occurred:

a. Management: There have been significant improvements in the transplant hospital's management interventions and involvement of the Governing Body that the hospital believes will lead to an increased number of transplants;

b. The improvements have been implemented;

c. Insufficient time has elapsed since implementation the improvements to allow it to be reflected in the number of transplants performed.

What is the relationship of the above factors (A through E) cited by the hospital to the root causes of failure to meet the Conditions of Participation?

Appendix Three – OTHER CONDITIONS OF PARTICIPATION:
Examples of Mitigating Factors that May be Considered

Section 42 CFR §488.61 (a)(4) states:

(4) CMS will consider mitigating factors, including (but not limited to) the following in considering initial approval of a transplant center that does not meet the data submission, clinical experience, outcome requirements, or other conditions of participation:

(i) The extent to which outcome measures are met or exceeded;

(ii) Availability of Medicare-approved transplant centers in the area; and

(iii) Extenuating circumstances (e.g., natural disaster) that may have a temporary effect on meeting the conditions of participation.

Sections 488.61(b)(2) and (c)(4) contain similar provisions for approval or re-approval of currently participating transplant centers. Below is a categorization and set of examples for factors that CMS might consider.

A. Extent of Non-compliance with the Condition of Participation

1) ***Degree of Failure***: To what extent has the transplant program's performance departed from the minimum requirements under the Condition of Participation?

2) ***Progress in Addressing Issues Regarding Non-compliance:*** To what extent is there evidence that the program has analyzed the root causes of noncompliance with the Condition of Participation and identified the systemic issues that have contributed to that noncompliance? Has the program taken steps to address those areas?

B. Compliance with Outcome and Clinical Experience Measures

1) ***Comparison of Observed and Expected Performance:*** To what extent has risk-adjusted observed performance met or exceeded the expected survival rates outlined in the most recent SRTR reports?

2) ***Outcome tracking:*** To what extent is the program tracking its performance to ensure that any outcomes issues are identified promptly?

3) ***Clinical Experience:*** To what extent has the number of transplants performed met the standard outlined in the regulation for that program type?

C. Access-to-Care Issues

1) ***Evidence of Access:*** To what extent is there evidence that the absence of this Medicare-approved transplant center will cause significant access-to-care problems for Medicare beneficiaries?

2) ***Population Considerations:*** Are there any special access issues related to the make-up of the population being served that create very unusual access-to-care issues (e.g., disease-susceptible ethnic or racial considerations)?

D. Factors Beyond the Control of the Hospital

1) ***Natural Disasters:*** Have there been recent natural disasters that significantly affected the ability of the transplant center to meet the Conditions of Participation? Is this a temporary situation?

2) ***Other Factors:*** Have there been any personnel changes that have affected compliance with the Conditions of Participation (e.g., the primary transplant surgeon leaving the program where delays in replacement were beyond the control of the hospital)?

E. Quality Improvement and Management Interventions

1) ***Analysis:*** To what extent has the center analyzed the root causes of noncompliance with the Condition of Participation?

2) ***QAPI***: To what extent have both of the following occurred:

a. There have been significant improvements in the transplant hospital's Quality Assessment and Improvement Program (QAPI) that the hospital believes will lead to an increased focus on compliance with the Condition of Participation; and

b. The improvements have been implemented.

3) ***Governing Body and Management:*** To what extent have both of the following occurred:

a. Management: There have been significant improvements in the transplant hospital's management interventions and involvement of the Governing Body related to the Condition of Participation that is not in compliance;

b. The improvements have been implemented.

What is the relationship of the above factors (A through E)(cited by the hospital) to the root causes of failure to meet the Conditions of Participation?