ASTS
American Society of Transplant Surgeons

June 30, 2014

Thomas E. Hamilton
Director, Survey and Certification Group
Centers for Medicare and Medicaid Services
7500 Security Blvd, Mail Stop: C2-21-16
Baltimore, MD 21244

Re: [CMS-1607-P] RIN 0938-AS11; 2014 Inpatient Prospective Payment System Proposed Rule

Dear Mr. Hamilton:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed changes to the "mitigating circumstances" criteria and processes available to transplant centers (TCs), as set forth in the 2014 Inpatient Prospective Payment System Proposed Rule (the "Proposed Rule"). The ASTS is a medical specialty society comprised of over 1,700 transplant surgeons, physicians, scientists, advanced transplant providers and allied health professionals dedicated to advancing the art and science of transplantation through leadership, advocacy, education and training so as to save lives and enhance the quality of life of patients with end stage organ failure and other conditions requiring organ transplantation. Our comments and recommendations are set forth below.

Preliminarily, however, we wish to express our appreciation to CMS for the considerable time and attention that went into formulating the Proposed Rule. We are hopeful that this is the beginning of an even more comprehensive process intended to incorporate into the TC certification regulations the lessons learned over the past several years. In our view, the primary lesson of the last several years of experience is the need to further coordinate and reconcile differences between the requirements and processes used by CMS and by the OPTN in regulating the quality of services provided by TCs throughout the country. While coordinating mitigating

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circumstances processes with the screening processes used by the OPTN to identify underperforming centers (discussed in greater detail below) is certainly a necessary part of this process, additional coordination and reconciliation of review standards and processes in areas such as personnel qualifications, data submission, and quality assurance is needed. In addition, it is critical that the outcomes standards used to evaluate OPOs and TCs be better coordinated and reconciled to eliminate the disparate incentives for OPOs (to maximize the number of organs retrieved, regardless of whether they are suitable for transplantation) and TCs (to maximize outcomes and reject marginal organs). We look forward to working with CMS on both these initiatives.

I. General Observations

ASTS has a number of general observations and questions regarding the Proposed Rule. We urge CMS to clarify these issues in the final rule.

First, on May 12, 2014, CMS published a number of changes to the "mitigating circumstances" regulation in response to the President's initiative to reduce regulatory burdens and increase program efficiency. See 79 *Fed. Reg*. 27106 et seq. (May 12 Final Rule). The Proposed Rule makes no reference to the changes made in the May 12 Final Rule; however, for the purposes of these comments, we assume that the version of the mitigating circumstances provisions set forth in the May 12 Final Rule reflects current law.

Second, while the issue does not appear to be discussed in the preamble to the Proposed Rule, the Proposed Rule extends the availability of the mitigating circumstances process to initial approvals. The rationale for this change is not set forth in the Proposed Rule.

> *ASTS Recommendation: We believe that in order to become Medicare certified, a new TC should be required to be fully compliant with all Medicare conditions of participation (CoPs). While circumstances may develop over time that interfere with a TC's compliance with Medicare CoPs, it is unclear to us what circumstances would justify a new TC's failure to comply with Medicare requirements when it first begins operating.*

Third, we note that the Proposed Rule, like the current regulation, authorizes the consideration of mitigating circumstances when a TC fails to meet any Medicare CoP: The availability of the mitigating circumstances review process does not appear to be limited to failures to meet outcomes, clinical experience and data submission requirements (42 CFR § 482.82), but also appears to extend (at least theoretically) to "condition level" deficiencies related to the TC "process" CoPs (e.g. 42 CFR §§ 482.90-482.104) . However, it is not entirely clear to us when

and under what circumstances the mitigating circumstance review process is to be used when the condition level deficiency involved relates to a TC "process" CoP. Under these circumstances, it is possible, if not probable, that the deficiency may be fully redressed through the TC's submission of a plan of correction.

> *ASTS Recommendation: We urge CMS to clarify whether, and under what circumstances, a TC cited with a condition level deficiency related to a "process" CoP should redress those deficiencies through the submission of a plan of correction to the survey agency, rather than through the mitigating circumstances process. It is likewise unclear whether the time limits for filing a request for a mitigating factors review is triggered by the initial notice or upon the exhaustion of administrative appeals. We recommend that condition level deficiencies related to process CoPs be handled through plans of correction in the first instance.*

Fourth, and along related lines, the Proposed Rule requires that all of the mitigating factors set forth in the new subparagraph (f) of Section 488.61 be considered in every case. [1] While some of the mitigating circumstances set forth in proposed subparagraph (f) are sufficiently general to be potentially applicable to all condition level deficiencies, some of these factors are relevant only if the condition level deficiency involved relates to a failure to meet outcomes requirements.

> *ASTS Recommendation: We urge CMS to modify the regulatory language to specifically state that the mitigating factors to be considered depend on the CoP that is out of compliance. We further urge CMS to draft the mitigating circumstances regulation in a manner that maximizes CMS' flexibility to consider different factors depending on the situation involved. Rather than specifying a list of mitigating circumstances all of which must be considered in every case, we urge CMS to set forth examples of the types of circumstances that may be considered to be "mitigating" for each of the various types of CoPs that may be out of compliance. For example, in the event of non-compliance with the data submission requirements set forth at 42 CFR § 482.82(a), a TC's submission of the required SRTR data, along with an explanation of its failure to meet applicable time limits, should constitute a "mitigating circumstance." In the event of non-compliance with the clinical experience requirements set forth at 42 CFR §482.82(b), a TC's submission of its plan for increasing volume along with the hospital's signed statement of commitment to effectuate the plan should be considered a mitigating circumstance.*

[1] Proposed Section 488.61(f)(1) states: Except for situations of immediate jeopardy, CMS will consider mitigating factors, including (but not limited to) the following, in making a decision,---Emphasis added)

II. Recommended Changes to 42 CFR § 482.82 (Data submission, clinical experience, and outcome requirements for re-approval of transplant centers)

The Proposed Rule sets forth extensive changes to the mitigating circumstances criteria and processes; however, we believe that it would be more useful to focus on 42 CFR § 482.82, the CoP related to data submission, clinical experience and outcomes standards, since it is primarily the rigidity of this CoP that makes the mitigating circumstances process necessary. Under 42 CFR § 482.82, a TC's failure to submit SRTR data in time constitutes a condition level deficiency, as does a TC's failure to maintain an average of 10 transplants per year (even if the TC's outcomes exceed the outcomes standards). And, as we have pointed out in the past, using the OPTN's standards for flagging TCs that require further investigation as requirements that must be met in order to maintain certification turns a useful review tool into an inflexible bureaucratic requirement.

> *ASTS Recommendation: ASTS recommends that CMS modify 42 CFR § 482.82 to state that a TC is deemed to be out of compliance at the "condition" level if, but only if, the TC (a) fails to meet the data submission, clinical experience and outcomes requirements set forth in the regulation* ***and*** *(b) CMS determines that the TC should not be approved based on a mitigating circumstances review. If this change is adopted, a determination of whether or not a TC is out of compliance with 42 CFR § 482.82 would be made at the conclusion of the mitigating circumstances process rather than before mitigating circumstances are considered, as under present law. This change would make the Medicare certification process more consistent with the intent of the OPTN outcomes standards, which were intended to serve as a flag for further investigation and not as a determinant of substandard performance.*

III. Mitigating Circumstances Criteria

The Proposed Rule would make a number of changes to the "mitigating circumstances" criteria set forth in the regulations. First, the Proposed Rule requires[2] CMS to consider:

> (iv) Program improvements that substantially address root causes of graft failures or patient deaths and that have been implemented and institutionalized on a sustainable basis.

[2] As discussed above, we urge CMS to revise the Proposed Rule such that the list of mitigating circumstances set forth in the regulations is illustrative and is not exclusive, thereby affording the agency the ability to consider other factors that may be relevant in particular cases.

The current mitigating circumstances regulation, as set forth in the May 12 Final Rule, authorizes program improvements to be considered a "mitigating circumstance" if but only if, as a result of such improvements, "the number of observed events divided by the number of expected events not be greater than 1.5." By contrast, under the Proposed Rule, program improvements that identify and address root causes of graft failures and organ deaths may be considered a mitigating circumstance if they are implemented and institutionalized on a sustainable basis, regardless of whether specified outcomes criteria are met.

> *ASTS Recommendation: We believe that program improvements that address the root causes of patient and graft failures and that are institutionalized on a sustainable basis should be considered a mitigating circumstance regardless of whether the TC's outcomes meet the test set forth in the current rule. The requirement that changes be "implemented and institutionalized on a sustainable basis" provides sufficient assurance that the program improvements involved will improve graft and patient survival. In addition, since the mitigating circumstances process may be used for condition level deficiencies that do not implicate the outcomes standards, we do not believe that it would be appropriate to require particular outcomes to be met in order for sustainable program improvements to be considered a mitigating circumstance.*

Second, the Proposed Rule would mandate the consideration of:

> (v) Recent patient and graft survival data to determine whether there is sufficient clinical experience and survival for CMS to conclude that the program is in compliance with CMS requirements, except for the data lag inherent in the reports from the Scientific Registry of Transplant Recipients (SRTR).
>
> *ASTS Recommendation: We strongly agree that recent patient and graft survival data should be considered in the mitigating circumstances process and that if that data indicates compliance with Medicare outcomes requirements, this improvement should be considered a mitigating circumstance warranting continued participation in the Medicare program. It should be noted, however, that under 42 CFR §482.82(c)(1), a TC's compliance with outcomes requirements is based on a two and a half year cohort of data. The Final Regulation should clarify that CMS may find mitigating circumstances based on a TC's most recent patient and graft survival data, without regard to data for prior periods.*

Third, CMS proposes to add the following additional mitigating circumstance to those set forth in the regulations:

(vi) Whether the program has made extensive use of innovative transplantation practices relative to other transplant programs, . . .where CMS finds that the innovative practices are supported by evidence-based published research literature or nationally recognized standards or Institution Review Board (IRB) approvals, and the SRTR risk-adjustment methodology does not take the relevant key factors into consideration;

ASTS Recommendation: ASTS strongly supports the inclusion of this provision in the list of mitigating circumstances set forth in the regulations.

Fourth, CMS proposes to add the following mitigating circumstance to the list of those set forth in Section 482.82:

vii) Whether the program's performance, based on the OPTN method of calculating patient and graft survival, is within the OPTN's thresholds for acceptable performance and does not flag OPTN performance review under the applicable OPTN policy.

While ASTS is concerned that CMS' use of an outcomes standard different from that used by the OPTN will create confusion among TCs and among potential recipients, we understand CMS' reluctance to implement new outcomes standards for TCs without any experience regarding the potential impact of the new methodology. We further understand that the OPTN has determined that the new criteria, which were adopted during the OPTN's June meeting, are to be monitored carefully over the next year and may be revised based on the efficacy of the new methodology in flagging underperforming TCs. For this reason, we believe CMS' proposal to continue to apply the current methodology while considering a TC's performance under the new OPTN outcomes standards as a "mitigating circumstance" constitutes a reasonable accommodation for the time being. However, we strongly believe that, once this initial one year trial period is elapsed, and assuming that the OPTN continues to apply flagging criteria based on the Bayes methodology, it is critical that CMS harmonize the outcomes standards used for Medicare certification purposes and those used by the OPTN to "flag" underperforming TCs as soon as practicable. Since Medicare updates inpatient prospective payment system rates and policies on an annual basis, we would anticipate no more than a year's delay in harmonizing the OPTN and CMS outcomes standards once the one year trial period has concluded.

During this one year trial period, it is especially important that mitigating circumstances be considered BEFORE a TC is determined to be out of compliance with Medicare CoPs at the "condition" level. We believe that it would be entirely inappropriate for a TC that meets the new Bayes criteria to be publicly labeled as deficient simply because its performance is flagged for review under OPTN outcomes standards that the OPTN itself has determined to be overly

broad. For this reason, during this trial period it is especially critical that CMS make no public finding of a condition level deficiency without first engaging in a mitigating circumstances review.

We also believe that, during this one year interim period, it is critical that CMS provide notice and an opportunity to comment to any TC that is found to be out of compliance with the outcomes CoP. It is unclear to us what process CMS plans to use to make this determination. Presumably, it would be necessary for CMS to obtain some input from the OPTN and the SRTR in applying the current outcomes standards during this one year trial period. This process should be totally transparent and provide adequate notice to any affected TC.

Our own view is that neither the current method nor the Proposed Bayesian method strikes the right balance between over-identifying and under-identifying programs for review. We are troubled that the current standards appear to misidentify as deficient a substantial number of TCs (especially smaller TCs). The proposed Bayesian method, like the current method, likely would result in approximately one out of eight programs being flagged. We are hopeful that, at the conclusion of the one year trial period, the OPTN will have sufficient experience with the Bayesian methodology to narrow the flagging criteria to focus more narrowly on TCs that are true underperformers, thereby facilitating the adoption of a single, statistically valid and appropriate standard for use in both certification and OPTN regulatory reviews.

> *<u>ASTS Recommendation</u>: Regardless of which threshold is used to "flag" centers for further review by the OPTN or by CMS, we strongly believe that a Membership and Professional Standards Committee (MPSC) decision indicating that a transplant center is performing at acceptable levels should be considered a mitigating circumstance. The MPSC has significant expertise in the evaluation of transplant center quality and outcomes and if, after review, it concludes that a transplant center's performance is acceptable, that determination should be considered a "mitigating factor."*

IV. Content of Mitigating Circumstances Review Request

The Proposed Rule sets forth in extraordinary detail examples of the type of data, analyses and information that a mitigating circumstances review request may require.

> *<u>ASTS Recommendation</u>. Since a mitigating circumstances request may be filed in conjunction with a TC's failure to meet outcomes, clinical experience, data submission, and other CoPs, we believe that the regulatory requirements related to the content of the request should be extremely flexible. In fact, we believe that the regulations should*

require simply that the request include sufficient information to permit an adequate review and understanding of the TC's failure to meet the CoP at issue. We do not believe that it is appropriate for the regulation to specify detailed examples of the type of information that should be included, since the content of each request is likely to be highly idiosyncratic. Instead, we recommend that the regulations set forth a process for the TC and CMS to confer regarding the types of supporting data and other information that would be required to support the request. Any additional details that CMS wishes to provide to TCs pursuing mitigating circumstances reviews should be set forth in a guidance document that can be modified as CMS gains additional experience with the process, without going through notice and comment rulemaking.

V. Timing of Request.

The Proposed Rule provides that, within 10 days after CMS has issued formal written notice of a condition-level deficiency to the program, CMS must receive notification of the program's intent to seek mitigating factors approval or re-approval. Under the proposal, CMS must receive all information for consideration of mitigating factors within **30** days of the CMS written notification for any deficiency that is not for insufficient clinical experience or outcomes, and **120 days** of the CMS written notification for a deficiency due to clinical experience or outcomes. Failure to meet these timeframes may be the basis for denial of the request.

ASTS Recommendation: While we believe that the time limits set forth in the Proposed Rule are likely to be sufficient in most cases, some clarification regarding the interrelationship between the mitigating circumstances review process and the normal appeals process is necessary. For example, a TC may be notified based on an onsite survey by CMS or a CMS contractor that it is out of compliance with a CoP at the condition level and that it is to file a plan of correction within a specified time period. Under these circumstances, it is unclear whether the TC also must file notification of intent to seek mitigating factors review within 10 days of the initial determination by the survey agency; within 10 days of a decision on the plan of correction; or within 10 days of the exhaustion of administrative remedies. We urge CMS to clarify this issue in the final rule. We also urge CMS to include language authorizing CMS to grant good cause exceptions for any failure to meet applicable time deadlines.

We also note that, in some cases, the 30 day and 120 day deadlines for the submission of supporting data may be insufficient. For example, it may be difficult for a TC to submit all supporting data relating to a condition level deficiency related to its QAPI plan within 30 days, depending on the timing of its QAPI meetings and related reports. Likewise, if it is necessary for a TC to conduct a staffing analysis, complete a root cause analysis, obtain its

most recent outcomes information from the OPTN and obtain a complete OPTN review report, 120 days after notification of a condition level outcomes deficiency may be insufficient.

VI. Administrative Action based on Mitigating Circumstances Review

The Proposed Rule provides that, based on its review of a TC's mitigating circumstances request, CMS may approve initial approval or re-approval of a program's Medicare participation, deny the program's request for Medicare approval or re-approval based on mitigating factors, or offer a time-limited Systems Improvement Agreement (if but only if the TC waives its appeals rights and takes certain actions as further specified in the Proposed Rule). The Proposed Rule, like the current regulations, provides that CMS will not approve any program with a condition level deficiency but may approve a program with a standard level deficiency upon receipt of an acceptable plan of correction.

ASTS Recommendation: For the reasons set forth above, we believe that the mitigating circumstances process should not be available for initial approvals and urge CMS to modify the Proposed Rule accordingly.

VII. Systems Improvement Agreements.

The Proposed Rule includes detailed provisions related to Systems Improvement Agreements (SIA), requiring, among other things, that in order for a TC to be eligible for an SIA, it must waive its appeal rights, implement substantial program improvements that address root causes and are institutionally supported by the hospital's governing body on a sustainable basis, and request more time to design or implement additional improvements or demonstrate compliance with CMS outcome requirements.

ASTS Recommendation: ASTS urges CMS not to require a TC to waive its appeal rights in order to enter into an SIA. We note that only TCs that do not pose a threat to patient health or safety are eligible for an SIA. In fact, in order to be eligible for a SIA, the program must conduct a root cause analysis and institute meaningful and sustainable program improvements. We believe that it is overly onerous to require a TC that has met this condition to agree to waive its appeal rights and would appreciate CMS' explaining the rationale for such a requirement.

The Proposed Rule further requires that any SIA include specified content. Under the Proposed Regulation, all SIAs must include requirements that the TC:

- Notify patients of the TC's noncompliance with Medicare CoPs and provide assistance to any wait listed patient who wishes to be listed with another program;
- Engage an external independent peer review team (consisting of individuals with particular expertise specified in the Proposed Rule) that conducts an onsite assessment of the program and provides a report to both CMS and the TC;
- Provide an action plan that addresses systemic quality improvements and is updated after the onsite peer review;
- Engage an "onsite consultant whose qualifications are approved by CMS and who provides services for 8 days per month on average for the duration of the agreement" (with certain exceptions);
- Conduct a comparative effectiveness analysis that compares policies, procedures, and protocols of the TC with those of other programs in areas of endeavor that are relevant to the center's current quality improvement needs;
- Develop increased proficiency, or demonstrate current proficiency, with patient-level data from the SRTR and the use of registry data to analyze outcomes and inform quality improvement efforts;
- Conduct a staffing analysis that examines the level, type, training, and skill of staff in order to inform transplant center efforts to ensure the engagement and appropriate training and credentialing of staff;
- Engage in activities to strengthen performance of the QAPI program;
- Engage in monthly (unless otherwise specified) reporting and conference calls with CMS; and
- Conduct additional or alternative requirements specified by CMS, tailored to the transplant program type and circumstances.

ASTS Recommendation: ASTS strongly urges CMS not to adopt such detailed and onerous SIA requirements. While we understand that CMS believes that SIAs should impose substantial obligations on TCs seeking additional time to comply with Medicare CoPs, we believe that SIAs are likely to be maximally effective when the agency has the flexibility to tailor the requirements to the particular situation involved. We also note that, under the Proposed Rule, in order to even be eligible for a SIA, a TC must already have demonstrated to CMS substantial program improvements that address the root causes of the condition level deficiency at issue: Only TCs that have instituted such program improvements on a sustainable basis are even eligible for an SIA. Under these circumstances, we believe that it is highly likely that some of the actions included in the SIA laundry list set forth in the Proposed Rule will already have been addressed by the time a mitigating circumstance determination is made. Moreover, some of the items included on the list (e.g., a staffing

analysis, proficiency with SRTR data analysis) may be unnecessary or irrelevant based on the root cause analysis. We believe that it is counterproductive for the agency to include so comprehensive a list of SIA requirements in the regulations: Since all agencies are legally obligated to comply with their own regulations, this approach effectively eliminates the agency's ability to reduce administrative burdens both for the TC and for CMS. Thus, for example, the Proposed Rule may require a TC to expend time and resources on SIA studies, analyses and consultant fees that both CMS and the TC agree would be more productively spent on patient care. ASTS supports those provisions of the Proposed Rule that authorize a one year term for an SIA (extendable for an additional six months).

We appreciate the opportunity to submit these comments on the Proposed Rule. For your convenience, proposed language incorporating these changes into regulatory language along with ASTS comments are attached as **Appendix A**. If you have any questions regarding ASTS' position on these important issues, please contact Kimberly Gifford, ASTS Executive Director, at *kim.gifford@asts.org* or 703-414-7870.

Sincerely yours,

Alan N. Langnas, D.O.
President
American Society of Transplant Surgeons

Appendix A – Proposed Language related to ASTS Comments

§ 482.82 Condition of participation: Data submission, clinical experience, and outcome requirements for re-approval of transplant centers.

~~Except as specified in paragraph (d) of this section, and § 488.61 of this chapter, transplant centers must meet all data submission, clinical experience, and outcome requirements.~~ - A transplant center shall be determined to be out of compliance with this section if it- *fails to meet the data submission, clinical experience and outcomes requirements set forth at paragraphs (a), (b) and (c) of this section (except as specified in section (d) of this section) and CMS determines that the transplant center is not eligible for continued approval pursuant to the processes set forth at section 488.61 of these regulations*~~-~~.

(a) ***Standard: Data submission.*** No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of the required data submissions on all transplants (deceased and living donor) it has performed over the 3-year approval period. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant beneficiary registration and follow-up, and living donor registration and follow-up.

(b) ***Standard: Clinical experience.*** To be considered for re-approval, an organ-specific transplant center must generally perform an average of 10 transplants per year during the re-approval period.

(c) ***Standard: Outcome requirements.*** CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants if applicable. Except for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using data contained in the most recent SRTR center-specific report.

(2) The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.

(3) CMS will not consider a center's patient and graft survival rates to be acceptable if:

(i) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate and graft survival rate; and

(ii) All three of the following thresholds are crossed over:

(A) The one-sided p-value is less than 0.05,

(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.5.

Mitigating Circumstances as Proposed in 2015 IPPS Proposed Rule

62. Section 488.61 is amended by—
a. Revising paragraphs (a)(4) and (c)(4).
b. Adding new paragraphs (f), (g), and (h).
The revisions and additions read as follows:

§ 488.61 Special procedures for approval and re-approval of organ transplant centers.

* * * * *

(a) * * *

(4) CMS will consider mitigating factors in accordance with paragraphs (f), (g), and (h) of this section.

* * * * *(c) * * *

(4) CMS will consider mitigating factors in accordance with paragraphs (f), (g), and (h) of this section.

* * * * *

(f) Consideration of mitigating factors in ~~initial approval and~~ re-approval survey, certification, and enforcement actions for transplant centers.

(1) Factors. Except for situations of immediate jeopardy, CMS ~~will consider~~ will consider such mitigating circumstances as may be appropriate in light of the nature and extent of the deficiency. For example, such factors may include:

(i) The extent to which outcome measures are not met or exceeded;

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

(iii) Extenuating circumstances (for example, natural disaster) that have a temporary effect on meeting the conditions of participation;

(iv) Program improvements that substantially address root causes of graft failures or patient deaths and that have been implemented and institutionalized on a sustainable basis;

(v) Recent patient and graft survival data to determine if there is sufficient clinical experience and survival for CMS to conclude that the program is in compliance with CMS requirements, except for the data lag inherent in the reports from the Scientific Registry of Transplant Recipients (SRTR);

(vi) Whether the program has made extensive use of innovative transplantation practices relative to other transplant programs, such as a high rate of transplantation of individuals who are highly sensitized or children who have undergone a Fontan procedure compared to most other transplant programs, where CMS finds that the innovative practices are supported by evidence-based published research literature or nationally recognized standards or Institution Review Board (IRB) approvals, and the SRTR risk-adjustment methodology does not take the relevant key factors into consideration; and

(vii) Whether the program's performance, based on the OPTN method of calculating patient and graft survival, is within the OPTN's thresholds for acceptable performance and does not flag OPTN performance review under the applicable OPTN policy and

(viii) Whether the Membership and Professional Standards Committee of the OPTN has reviewed the program's performance and found it acceptable. ~~.~~

(2) Content. A request for consideration of mitigating factors must include sufficient information to permit an adequate review and understanding of the transplant program, the factors that have contributed to outcomes, program improvements or innovations that have been implemented or planned, and in the case of natural disasters, the recovery actions planned and such other information as may be required by requested by CMS. ~~. Examples of information to be submitted with each request include (but are not limited to) the following:~~

~~(i) The name and contact information for the transplant hospital and the names and roles of key personnel of the transplant program~~;

~~(ii) The type of organ transplant program(s) for which approval is requested; (iii) The conditions of participation that the program does not meet for which the~~

Comment [P1]: ASTS believes that mitigating circumstances review should be available for TCs seeking re-approvals only.

Comment [P2]: This language appears to REQUIRE CMS to consider all of the factors listed, whether or not they are relevant.

Comment [P3]: ASTS believes that instructions related to the information to be included in a mitigating factors review should not be included in regulations but in instructions that can be more easily modified as TCs and CMS again additional experience with the types of information that may be useful. In addition, the relevance of these examples depends on the nature and extent of the deficiency.

~~transplant center is requesting CMS' review for mitigating factors;~~
~~(iv) The rationale and supporting evidence for CMS' review may include (but is not limited to)—~~
~~(A) Root Cause Analysis for patient deaths and graft failures, including factors the program has identified as likely causal or contributing factors for patient deaths and graft failures;~~
~~(B) Program improvements or innovations (where applicable) that have been implemented and improvements that are planned;~~
~~(C) Patient and donor/organ selection criteria and evaluation protocols, including methods for pre-transplant patient evaluation by cardiologists, hematologists, nephrologists, and psychiatrists or psychologists to the extent applicable;~~
~~(D) Organizational chart with full-time equivalent levels, roles, and structure for reporting to hospital leadership;~~
~~(E) Waitlist management protocols and practices relevant to outcomes;~~
~~(F) Pre-operative management protocols and practices;~~
~~(G) Immunosuppression/infection prophylaxis protocols;~~
~~(H) Post-transplant monitoring and management protocols and practices;~~
~~(I) Quality Assessment and Performance Improvement (QAPI) Program meeting minutes from the most recent four meetings and attendance rosters from the most recent 12 months;~~
~~(J) Quality dashboard and other performance indicators;~~
~~1387~~
~~(K) Recent outcomes data for both patient survival and graft survival; and~~
~~(L) Whether the program has engaged with the OPTN to review program outcomes, the status of any such review, and any steps taken to address program outcomes pursuant to the OPTN review.~~

(3) Timing. Within 10 days after CMS has issued formal written notice of a condition-level deficiency to the program, CMS must receive notification of the program's intent to seek mitigating factors approval or re-approval, and receive all information for consideration of mitigating factors within **30** days of the CMS written notification for any deficiency that is not for insufficient clinical experience or outcomes, and **120 days** of the CMS written notification for a deficiency due to clinical experience or outcomes. Failure to meet these timeframes may be the basis for denial of mitigating factors.

(g) Results of mitigating factors review.

(1) Actions. Upon review of the request to consider mitigating factors, CMS may take the following actions:

(i) Approve ~~initial approval or~~ re-approval of a program's Medicare participation based upon approval of mitigating factors;

(ii) Deny the program's request for Medicare ~~approval or~~ re-approval based on mitigating factors.

(iii) Offer a time-limited Systems Improvement Agreement, in accordance with paragraph (h) of this section, when a transplant program ~~has waived its appeal rights,~~ has implemented substantial program improvements that address root causes and are ~~i~~institutionally supported by the hospital's governing body on a sustainable basis, and has requested more time to design or implement additional improvements or demonstrate compliance with CMS outcome requirements. Upon completion of the Systems Improvement Agreement or a CMS finding that the hospital has failed to meet the terms of the Agreement, CMS makes a final determination of whether to approve or deny a program's request for Medicare ~~approval or~~ re-approval based on mitigating factors. A Systems Improvement Agreement follows the process specified in paragraph (h) of this section.

(2) Limitation. CMS will not approve any program with a condition-level deficiency. However, CMS may approve a program with a standard-level deficiency based on mitigating circumstances, upon receipt of an acceptable plan of correction.

(h) Transplant Systems Improvement Agreement. A Systems Improvement Agreement is a binding agreement, entered into voluntarily by the hospital and CMS, through which CMS extends a prospective Medicare termination date and offers the program additional time to achieve compliance with the conditions of participation, contingent on the hospital's agreement to participate in a structured regimen of quality improvement or other activities to address the condition-level deficiency involved. ~~, demonstrate improved outcomes, and waive the right to appeal termination based on the identified deficiency or deficiencies that led to the Agreement in consideration for more time to demonstrate compliance~~. In some cases, transplant programs may enter a period of inactivity—voluntarily, or imposed as a condition of the Systems Improvement Agreement. The content of the SIA shall depend on the nature and extent of the deficiency involved and such other factors as may be determined on a case by case basis by CMS.

~~(1) Content. In exchange for the additional time to initiate or continue activities to achieve compliance with the conditions of participation, the hospital must agree to a regimen of specified activities, including (but not limited to) all of the following:~~

~~(i) Patient notification about the degree and type of noncompliance by the program, an explanation of what the program improvement efforts mean for patients, and financial assistance to defray the out-of-pocket costs of copayments and testing expenses for any wait-listed individual who wishes to be listed with another program;~~

~~(ii) An external independent peer review team that conducts: an onsite assessment of program policies, staffing, operations, relationship to hospital services, and factors that contribute to program outcomes; that suggests quality improvements the hospital should consider; that provides both verbal and written feedback to the hospital; and that provides a verbal debriefing to CMS. Neither the hospital nor the peer review team is required to provide a written report to CMS. The peer review team must include a transplant surgeon with expertise in the relevant organ type(s), a transplant administrator, an individual with expertise in transplant QAPI systems, a social worker or psychologist or psychiatrist, and a specialty physician with expertise in conditions particularly relevant to the applicable organ types(s) such as a cardiologist, nephrologist, or hepatologist. Except for the transplant surgeon, CMS may permit substitution of one type of expertise for another individual who has expertise particularly needed for the type of challenges experienced by the program, such as substitution of an infection control specialist in lieu of, or in addition to, a social worker;~~

~~(iii) An action plan that addresses systemic quality improvements and is updated after the onsite peer review;~~

~~(iv) An onsite consultant whose qualifications are approved by CMS, and who provides services for 8 days per month on average for the duration of the agreement, except that CMS may permit a portion of the time to be spent offsite and may agree to fewer consultant days each month after the first 3 months of the Systems Improvement Agreement;~~

~~(v) **A comparative effectiveness** analysis that compares policies, procedures, and protocols of the transplant program with those of other programs in areas of endeavor that are relevant to the center's current quality improvement needs;~~

~~(vi) Development of increased proficiency, or demonstration of current proficiency, with patient-level data from the Scientific Registry of Transplant Recipients and the use of registry data to analyze outcomes and inform quality improvement efforts;~~

~~(vii) **A staffing analysis** that examines the level, type, training, and skill of staff in order to inform transplant center efforts to ensure the engagement and appropriate **training and credentialing of staff.**~~

~~**(viii) Activities to strengthen performance of the Quality Assessment and Performance Improvement Program** to ensure full compliance with the requirements of § 482.96 of this chapter;~~

Comment [P4]: Not all condition level deficiencies subject to an SIA may relate to outcomes requirements: Presumably, TCs with other condition level deficiencies may be eligible for an SIA.

Comment [P5]: Many of these requirements already may have been performed during the course of the mitigating circumstances review, and others may be inapplicable, depending upon the nature and extent of the deficiency. In this regard, please note that a SIA is available only to TCs that have In fact, since a SIA is available only if the TC has "implemented substantial program improvements that address root causes and are institutionally supported by the hospital's governing body on a sustainable basis."

~~(ix) **Monthly (unless otherwise specified) reporting and conference calls with CMS** regarding the status of programmatic improvements, results of the deliverables inthe Systems Improvement Agreement, and the number of transplants, deaths, and graft failures that occur within 1 year post-transplant; and~~

~~(x) **Additional or alternative requirements specified by CMS, tailored to the transplant program type and circumstances.**~~

(2) Timeframe. A Systems Improvement Agreement will be established for up to a 12-month period, subject to CMS' discretion to determine if a shorter timeframe may suffice. At the hospital's request, CMS may extend the agreement for up to an additional 6-month period.