CMS and Transplant Program Compliance-Flagging and the Transplant Program Response

Date: Jul 21, 2019

Alexander Aussi BSN, RN, MBA
OBJECTIVES

A- Overview of the Regulatory Environment - The new 2019 CMS Interpretive Guidelines
B- CMS Center Flagging Criteria
C- The Mitigating Factors Process
D- Pre-empting a Negative Determination
Regulatory Environment


- Originated from the End Stage Renal Disease program Regs in 1973-1974 (Subpart U). Rules were later developed by organ type in the late 80s and 90s


- Focus on volume and SRTR outcomes

- Required all Tx programs to renew CMS coverage
Regulatory Environment

- CMS relies partially on UNOS for notification of Program non-compliance with volume and quality outcomes
- From 2008 to 2013, Program reviews for Initial and recertification were being conducted by State Surveyors and a Federal Provider
- From 2013 to September 2018, Program CMS Surveys were conducted by a Federal Provider. Effective Jan 2019, the Survey process is back with local State Survey Agencies
- New revisions to the COPs were proposed in 9/2018
Regulatory Environment

The COP Revision Proposal was part of efforts to remove Red Tape

- Replace the term transplant "center" to "program" (each organ type would be a program) to better align with surveyor practice and reduce provider confusion
- Remove the requirements of §482.82 as a condition for re-approval
- Remove the requirement of §482.102(a)(5) regarding informed consent to notify transplant patients and living donors "about all Medicare outcome requirements not being met by the transplant center"
- Remove paragraph (c) in §488.61 for re-approval procedures
- Remove the requirements at §488.61(f) through (h) for mitigating factors and transplant systems improvement agreements for the re-approval process for transplant centers
Regulatory Environment

- New Survey Guidelines to State Agencies were released 3/29/19 with an effective implementation date of 5/24/19 and did not include any of the Proposed revisions to the COPs. Only revisions noted were to the Interpretive Guidelines (IGs).
22 TAGS were noted to **not have any revisions or additions** to the IG’s in the released Memo:

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Regulatory Environment

<table>
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<th>TAG</th>
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<tr>
<td>X012</td>
<td>§482.74(a)(1) Change in key staff members of the transplant team, ... designated &quot;primary transplant surgeon&quot; or &quot;primary transplant physician&quot;. IG: Notification requirements to CMS</td>
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<tr>
<td>X041</td>
<td>§482.82 Condition of participation: Data Submission, Clinical Experience, and Outcome Requirements for Re-approval of Transplant Centers</td>
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<tr>
<td>X054</td>
<td>§482.90(a)(2) Before a transplant center places a transplant candidate on its waiting list, the candidate’s medical record must contain documentation that the candidate’s blood type has been determined.</td>
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<tr>
<td>X071</td>
<td>§482.92 Condition of Participation: Organ Recovery and Receipt. Transplant centers must have written protocols for validation of donor-recipient blood type and other vital data for the deceased organ recovery, organ receipt, and living donor organ transplantation processes. The transplanting surgeon at the transplant center is responsible for ensuring the medical suitability of donor organs for transplantation into the intended beneficiary.</td>
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<tr>
<td>X087</td>
<td>§482.94(c) Standard: Patient Records. Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center’s waiting list and who is admitted for organ transplantation.</td>
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<tr>
<td>X088</td>
<td>§482.94(c)(1) For each patient who receives an evaluation for placement on a center’s waiting list, the center must document in the patient’s record that the patient (and in the case of a kidney patient, the patient’s usual dialysis facility) has been informed of his or her transplant status, including notification of: (i) The patient’s placement on the center’s waiting list; (ii) The center’s decision not to place the patient on its waiting list; or (iii) The center’s inability to make a determination regarding the patient’s placement on its waiting list because further clinical testing or documentation is needed.</td>
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<td>X104</td>
<td>§482.96(b)(2)(cont’d) ...and must utilize the analysis to effect changes in the transplant center’s policies and practices to prevent repeat incidents.</td>
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<td>X109</td>
<td>§482.98 Condition of Participation: Human Resources. The transplant center must ensure that all individuals who provide services and/or supervise services at the center, including individuals furnishing services under contract or arrangement, are qualified to provide or supervise such services.</td>
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<tr>
<td>X111</td>
<td>§482.98(a)(cont’d) ... The director is responsible for planning, organizing, conducting, and directing the transplant center and must devote sufficient time to carry out these responsibilities, which include but are not limited to the following:</td>
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<tr>
<td>X115</td>
<td>§482.98(b) Standard: Transplant Surgeon and Physician. The transplant center must identify to the OPTN a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services, who are immediately available to provide transplantation services when an organ is offered for transplantation.</td>
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# Regulatory Environment

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<td>§482.98(c)</td>
<td>Standard: Clinical Transplant Coordinator. The transplant center must have a clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant, and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation.</td>
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<td>§482.98(f)</td>
<td>Standard: Resource Commitment. The transplant center must demonstrate availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease control, pathology, radiology, blood banking, and patient education as related to the provision of transplantation services.</td>
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<td>§482.102(a)(8)</td>
<td>The fact that his or her transplant is not provided in a Medicare-approved transplant center could affect the transplant recipient’s ability to have his or her immuno-suppressive drugs paid for under Medicare Part B.</td>
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<td>§482.102(b)(7)</td>
<td>The possibility that future health problems related to the donation may not be covered by the donor’s insurance and that the donor’s ability to obtain health, disability, or life insurance may be affected;</td>
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<td>§482.102(b)(8)</td>
<td>The donor’s right to opt out of donation at any time during the donation process; and</td>
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<tr>
<td>§482.102(b)(9)</td>
<td>The fact that if a transplant is not provided in a Medicare-approved transplant center it could affect the transplant.</td>
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<tr>
<td>§482.102(c)</td>
<td>Standard: Notification to patients. Transplant centers must notify patients placed on the center’s waiting list of information about the center that could impact the patient’s ability to receive a transplant should an organ become available, and what procedures are in place to ensure the availability of a transplant team.</td>
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<td>§482.102(c)(2)</td>
<td>At least 30 days before a center’s Medicare approval is terminated, whether voluntarily or involuntarily, the center must: (i) Inform patients on the center’s waiting list and provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list; and (ii) Inform Medicare beneficiaries on the center’s waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center’s termination of approval.</td>
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<tr>
<td>§482.104(a)</td>
<td>Standard: End stage renal disease (ESRD) services. Kidney transplant centers must directly furnish transplantation and other medical and surgical specialty services required for the care of ESRD patients.</td>
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<tr>
<td>§482.104(b)</td>
<td>Standard: Dialysis services. Kidney transplant centers must furnish inpatient dialysis services directly or under arrangement.</td>
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# Regulatory Environment

## 3/29/19 Changes to IGs

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<td><strong>X074- §482.92(b)</strong>&lt;br&gt;Standard: Living Donor Transplantation</td>
<td>If a center performs living donor transplants, the transplanting surgeon and another licensed healthcare professional at the center must verify that the living donor’s blood type and other vital data are compatible with transplantation of the intended recipient immediately before the removal of the donor organ(s) and, if applicable, prior to the removal of the beneficiary’s organ(s).</td>
<td><strong>Guideline §482.92(b)</strong>&lt;br&gt;Verification that the living donor blood type and other vital data are compatible with the intended recipient must occur onsite, after the donor arrival in the operating room but prior to the induction of general anesthesia. The verification must be completed by the transplanting surgeon and another licensed healthcare professional. The program should identify in its protocols which categories of healthcare professional(s) may do the second verification. Verification by the transplant surgeon and another licensed healthcare professional must be documented. The documentation must include signatures and corresponding date and time of the verification. To ensure that verification is completed immediately before the removal of the donor organ(s), documentation must include the time of donor arrival into the operating room, time of organ verification and time general anesthesia was started. Verification of correct organ for the correct recipient and verification that the blood type and other vital data are compatible with the potential recipient must occur immediately before the removal of the living donor organ(s).</td>
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Review the transplant program’s policies and procedures (specific to living donor transplants) and verify the inclusion of language that the transplant surgeon and another licensed healthcare professional verify that the donor’s blood type and identifying information are compatible with the intended recipient, prior to organ recovery.

...Review medical records of a sample of living donors to confirm that the transplanting surgeon and one other “licensed healthcare professional” verify that the donor’s blood type and donor identifying information were compatible with the intended recipient, PRIOR TO REMOVAL of the donor organ(s). This verification must also take place before the removal of the recipient’s organ(s), if applicable. The phrase “if applicable” refers to the fact that 1) in some cases the recipient’s organ may remain in the body even though it is being replaced by the donor’s organ; or 2) the recipient’s organ (usually a kidney) may be removed well in advance of transplantation of the living donor’s organ, based on medical necessity.
### Regulatory Environment

#### 3/29/19 Changes to IGs

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| X081 | §482.94 Condition of Participation: Patient and Living Donor Management. Transplant centers must have written patient management policies for the transplant and discharge phases of transplantation. If a transplant center performs living donor transplants, the center also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation. | Blank | **Guideline §482.94**
Transplantation and Living Donor Care Phases are generally defined as:

**Transplantation Care Phases:**
• **Transplant Phase:** Begins when the potential transplant candidate is evaluated for transplantation and continues through completion of the transplantation surgery.
• **Discharge Phase:** Begins at the transplant candidate admission to the hospital and continues through to his/her discharge from the inpatient stay.

**Living Donor Care Phases:**
• **Evaluation Phase:** Begins from first presentation by the potential donor until the time he/she enters the OR for the donation surgery.
• **Donation Phase:** Begins from the time the potential donor enters the OR for the donation surgery until the donor is discharged from the inpatient surgery stay.
• **Discharge Phase:** Begins at admission to the hospital and continues through the donor's discharge from the inpatient stay. |
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<td>X091-§482.94(c)(ii) Multidisciplinary discharge planning for post-transplant care.</td>
<td>Review written evidence by the transplant program to confirm that a multidisciplinary discharge planning effort occurred for discharge planning (after June 28, 2007). This evidence may take a variety of forms. Examples could include (but are not limited to) a completed comprehensive discharge plan in the medical record that includes the various disciplines involved in providing care. During interviews, surveyors should talk with members of the multidisciplinary team about how discharge planning occurs and where evidence of this planning would be located. Refer to Tag X082 and X125 for a discussion of the components of the multidisciplinary discharge planning process, and the personnel participating in the multidisciplinary discharge planning.</td>
<td>Guideline §482.94(c)(ii)  <strong>Discharge planning begins on admission.</strong> Each member of the dedicated multidisciplinary team must be involved in assessing the needs of the patient in preparation for discharge from the hospital. <strong>Areas of assessment for discharge planning include medical, psychosocial and financial.</strong> The recipient’s medical record must contain documentation that the dedicated multidisciplinary team participated in the development of the discharge plan to address the individual needs of the recipient. Components of a multidisciplinary discharge plan may include, but are not limited to: •A description of the recommended follow-up appointments and the practitioners expected to perform the follow-ups (such as the transplant program, a local physician, or both); •Contact numbers of transplant program staff that can be contacted for questions; •The clinical signs and symptoms indicative of a potential complication from transplantation that would necessitate a call to the doctor; •A transplant recipient/living donor specific nutrition plan, as applicable;</td>
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<td>§482.94(c)(ii) Multidisciplinary discharge planning for post-transplant care.</td>
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**IG June 13, 2008**

**IG March 29, 2019**

Components of a multidisciplinary discharge plan may include, but are not limited to: (Con’t)

- A plan for addressing psychosocial issues (for example available supports, adaptation to stress of transplant, etc.);
- Activity restrictions and limitations (for example driving after taking pain medication);
- Need for coordination of other health services (for example physical or occupational therapies, home care, etc.) and assistance in securing these health services;
- Medication and administration, including the transplant recipient’s schedule for taking medication and the process to obtain the medication; and
- Any assistance required to access local medical care, equipment or support.
Regulatory Environment
3/29/19 Changes to IGs

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| X094- §482.94(e) Standard: Nutritional Services. | Verify that the transplant program’s current policies and procedures for nutritional services outline how the transplant program will determine when a complete nutritional assessment, dietetic counseling, or nutritional intervention is warranted. For transplant patients and living donors, depending upon their health, nutritional status and the type of organ transplant they are receiving, various levels of nutritional assessment and interventions may be warranted at different points in the transplantation or donation phases. It is expected that, at a minimum, the multidisciplinary team would discuss and determine the appropriate level of assessment and intervention to ensure that the nutritional needs for all transplant recipients and living donors are adequately addressed. As necessary, any follow-up for referrals for further assessment or intervention are the responsibility of the qualified dietitian. | **Guideline §482.94(e)**
Transplant programs must have a process in place to ensure that a qualified dietician is available to provide nutritional assessments or diet counseling to all transplant patients and living donors that require such services. Nutritional services include consultation, assessment, intervention(s) and education. If a need is identified by any member of the multidisciplinary team, and a request is made for nutritional services, but the requested services are not provided due to the lack of nutritional staff available in the hospital, a deficiency would be cited. |
Coordinating with the hospital in which the transplant center is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors.

**Guideline §482.98(a)(1)**

Care of transplant patients and living donors is unique and complex, requiring clarification of roles and responsibilities and appropriate training for nursing staff and clinical transplant coordinators. **The director of the transplant center is responsible for coordination with the hospital’s Nursing Department to determine the appropriate depth and type of orientation and training that will be provided to nursing staff that care for the transplant patients.** Evidence of coordination should include:

1. The transplant director has participated in the development of training and orientation plans for nurses who work or will work with transplant recipients and living donors;
2. The transplant director offers ongoing training opportunities for nursing staff; and
3. The transplant director provides feedback to the Nursing Department on the clinical competency of those nursing staff working with transplant recipients or living donors.
X-114 §482.98(a)(3) Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon in accordance with §482.98(b).

- A transplant surgeon must be credentialed by the hospital in which the transplant program is located to perform transplant surgeries.

- If a fellow or a resident participates in a surgery, the attending transplant surgeon must remain in the operating room or be physically present in the operating suite.
X-112 §482.98(d), (d)(1), (d)(2) ILDA or ILDAT

- The ILDA or ILDAT interview with the Live Donor to take place prior to the initiation of the evaluation.

- The ILDA or the ILDAT must not be associated with the Transplant Program in any capacity even on a temporary or intermittent basis.

- The ILDA or ILDAT must discuss with the LD expected outcomes for the recipient.
X-125 §482.98(e) Multidisciplinary Team (MDT)

- While it is desirable that each MDT include a transplant pharmacist, there may be other disciplines on the team who are qualified to provide pharmacy services
X-153 §482.102(a)(3) Discussion of Alternative Treatments

- It is expected that discussions related to alternative treatments occur prior to a candidate undergoing an evaluation for transplant
Regulatory Environment
3/29/19 Changes to IGs

X-155 §482.102(a)(1), (a)(5) Candidate Informed Consent
X-161 §482.102(b)(2), (b)(3) Live Donor Informed Consent
X-165 §482.102(b)(2), (b)(6)

- Ensuring that the candidate understands what the evaluation process entails prior to its initiation
- Prior to evaluation, the program informs the recipient of the location of the SRTR website and explains how the website may be used
- Ensuring that the live donor understands what the evaluation process entails prior to its initiation
- Ensuring that the live donor understands how the surgery is expected to improve the potential recipient’s health or quality of life, and how long the recipient expected to be hospitalized
- The program informs the live donor of the location of the SRTR website and explains how the website may be used
OBJECTIVES

A- Overview of the Regulatory Environment - The new 2019 CMS Interpretive Guidelines

B- CMS Center Flagging Criteria
CMS Flagging Criteria

Triggers for CMS Flagging include but are not limited to:

- Non Compliance with CMS – COPs
- Patient Grievances and Complaints
- §482.80 & 482.82 **Condition of Participation:** Data Submission, Clinical Experience, and Outcome Requirements for Initial Approval & Re Approval of Transplant Centers.
CMS Flagging Criteria

§482.80 & 482.82 **Condition of Participation:**

*Data Submission, Clinical Experience, and Outcome Requirements* for Initial Approval and re Approval of Transplant Centers. Except as specified in paragraph (d) of §482.80, and §488.61, transplant centers must meet all data submission, clinical experience, and outcome requirements to be granted initial approval and re approval approval by CMS.
§482.80(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 required data on all transplants (deceased and living donor) it has performed. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up and living donor registration and follow-up.
CMS Flagging Criteria

§482.80(b) Standard: *Clinical Experience*. To be considered for initial approval, an organ-specific transplant center must generally perform 10 transplants over a 12 month period.

- Adult Heart-Only
- Adult Lung-Only
- Adult Liver
- Adult Intestinal and/or Multivisceral

A kidney transplant center is required to perform at least 3 transplants over a 12-month period prior to its request for initial approval then maintain an average of 10 transplants over a 12 month period to remain certified.
§482.82(c) Standard: *Outcome requirements*. CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable.
CMS Flagging Criteria

(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. Generally speaking, 2 consecutive SRTR flags trigger contact with the center.

(2) 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 1.85.
CMS Flagging Criteria

- **Standard** – If the most recent SRTR report shows that the program did not meet outcome requirements, but none of the four SRTR reports prior to the most recent one show that the program was out of compliance, a deficiency would be cited at the standard-level.

- **Condition** – If the most recent SRTR report shows that the program has not met outcome requirements in two consecutive reports and there is either unchanged or a decline in outcome data, a deficiency would be cited at the condition-level.
CMS Flagging Criteria

- Any one of the three primary triggers may include a site survey.
- Should the site survey result in citations which include up to 2 Conditional level variances where one of the citations is related to §482.80 and or §482.82, then the program should expect that this represent grounds for CMS coverage termination.

A CMS Letter will Follow
OBJECTIVES

A- Overview of the Regulatory Environment - The new 2019 CMS Interpretive Guidelines
B- CMS Center Flagging Criteria
C- The Mitigating Factors Process
Mitigating Factors

Remember 90, 10, 120, and 210

- A CMS Letter will be sent to the program outlining deficiencies

- The plan of corrections is expected to be implemented in 90 days (except for outcomes correction which is expected in 210 days)

- The program has 10 days to reply to CMS with an acknowledgement of receipt of the letter with intent to file under Mitigating Factors

- The Mitigating Factors application is expected within 120 days from request
Mitigating Factors

• CMS will make a final determination whether to Grant approval and rescind coverage termination or proceed with program’s Medicare coverage termination in 210 days from initial letter.

• Generally speaking, if a noticeable correction is not realized by the next SRTR report, or is clearly reflected in the Mitigating factors application, Medicare coverage termination will follow.
Mitigating Factors

OBJECTIVES

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B- CMS Center Flagging Criteria
C- The Mitigating Factors Process
D- Pre-empting a Negative Determination
CONCLUSION

A- Transplant Programs are facing tighter Regulatory requirements

B- We are unclear if the recent Executive Order will bring some relief to transplant programs as pertains to §482.80 and or §482.82

C- Program Administration working in concert (and harmony) with clinical leaders are critical to ensure Program compliance with CMS-COPs.

D- It takes a long time and 2 conditional level citations to place a program in immediate jeopardy. One is outcome based but the second one is operational

E- Remember 90, 10, 120 and 210 when in CMS jail. There will be a cost to change the culture and re-center the program on a compliant path
THANK YOU

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