

To: Mr. David Wright, Acting Director
Ms. Jan Tarantino, Deputy Director
Ms. Peggy Wilkerson, Director, Division of Continuing Care Providers
CMS Survey and Certification Group

From: Dr. James S. Allan
President

Date: May 26, 2016

Re: Additional AST Feedback on Revised CMS Interpretative Guidelines for the Organ Transplant Conditions of Participation for Transplant Centers

Thank you for the opportunity to provide further feedback in addition to our letter of April 8, 2016, attached for your convenience. As discussed on our calls with you and your colleagues, we are in some cases offering our suggested language for specific tags in addition to our original comments. You will find hyperlinks to the original letter where a specific tag is referenced in both documents. We hope this feedback is helpful to you in revising the draft guidelines, and would be happy to discuss or clarify any of these at your request.

The actual survey procedure is not outlined in the document. We would ask you to consider including the “list of lists” (requested Items) in the document. We would also suggest that surveyors be instructed to pull primarily more recent charts and to consider current compliance with a tag as compliant.

Below please find our comments, including recommended language, for specific tags:

Definitions:

We suggest the following language:

Evaluation or pre-transplant phase: From referral to decision to not accept patient as a donor or recipient to death, de-listing, voluntary withdrawal as candidate or donor, or admission for transplant/donation event.

Transplant event: Admission for transplant event to discharge

Discharge phase: Not a time-bound phase but refers to the act of discharge planning

Tag X051

The Final Rule is very explicit and probably does not need a lot of further interpretation. We suggest the following language:

Transplant centers are required to have written selection criteria to be used to determine the eligibility of candidates for organ transplant and for living donors. Tags 052- X060 describe the details of what these policies must contain.

NATIONAL OFFICE

1120 Route 73, Suite 200 • Mt. Laurel, NJ 08054
856.439.9986 • Fax: 856.581.9604
info@myAST.org • www.myAST.org

GOVERNMENT RELATIONS

William Applegate, Director of Government Relations
Bryan Cave, LLP
1155 F Street, NW • Washington, DC 20004
202.258.4989 • bill.applegate@bryancave.com

AMERICAN TRANSPLANT CONGRESS 2016

June 11–15, 2016
Boston, MA

Survey procedures:

Policy Review: Ensure that elements in tags X052-060 are in place for recipients and living donors.

Chart Review: Ensure that the program's policies and criteria are being followed in both patients accepted and those not accepted.

Cite a deficiency at Tag X051 if no policy exists.

Tag X052:

We suggest the following language:

Selection criteria must be fair and non-discriminatory. Distribution/allocation of organs themselves is out-of-scope for CMS but this tag refers to patients being accepted as recipients or donors in a way that does not discriminate on the basis of anything other than appropriate medical psychosocial, or financial criteria.

Policy review: Ensure that selection criteria are medical, psychosocial, and financial in nature.

Record review: Ensure that criteria are applied to donors and recipients consistent with policies. If inconsistencies either between selection criteria and actual listing decisions are found look for documentation in chart and/or selection committee or quality minutes as to why this occurred. No documentation of why criteria were not applied consistently could indicate unfairness.

Tag X053

We suggest the following language:

The selection policy must include psychosocial criteria and every patient should receive a psychosocial evaluation prior to being listed. In some cases, the recipient's health condition precludes such an evaluation. These exceptions should be noted in policy.

Policy review:

Program must have a policy that includes:

- Requirement for every recipient to receive a psychosocial evaluation
- Explicit exceptions based on patient's health status making the psychosocial evaluation not possible
- Qualified healthcare personnel who may perform these evaluations
- Psychosocial criteria evaluated
- Length of time for which the psychosocial evaluation is deemed current
- Referral and follow-up procedures if needed to further determine candidacy.

Cite a deficiency X051 if no policy exists or it does not contain these elements

Chart review: Ensure that every recipient has a psychosocial evaluation before listing (in the case of living donor recipients, who may not be listed but are registered with OPTN consider admission for transplant event as listing), as described in policy and that selection criteria was consistently applied. For any patients for whom no evaluation is documented, look for documentation consistent with the center's exception policy. This documentation may be in the chart or in selection or quality committee minutes. Ensure that the psychosocial criteria being used are consistent with center policy.

Cite a deficiency at Tag X053 if patients' charts do not contain psychosocial evaluations prior to listing or admission for transplantation event AND that an exception, consistent with policy did not apply.

Tag X054

We suggest the following language:

Policy review: Ensure that center has policy requiring documentation of ABO blood type before listing.

Cite a deficiency at Tag X051 if no policy

Chart review: Note: OPTN waitlist functionality does not allow patients to be listed without two person verification of ABO blood type. Chart review activity would be to ensure center's own policy was being applied consistently. Ensure that the charts contain documentation of the blood type determination prior to the listing date.

Cite a deficiency at Tag X054 if no documentation of ABO, obtained prior to listing, is found in the medical record.

Tag X055

We suggest the following language:

The selection criteria used to determine that a candidate would be accepted to be listed or transplanted must be documented in the patient's medical record.

Policy Review: No additional review required

Chart Review: Ensure that documentation of selection criteria, consistent with center's own policy, is documented in each patient's medical record.

Cite a deficiency at Tag X055 if no documentation is found.

Tag X058

Very explicit detail is found in OPTN – these should either be repeated *verbatim* in IGs (not recommended as they could be updated) OR the CMS IGs should be very high level (as suggested below) so that centers are not managing to two sets of detailed elements with the same intent.

We suggest the following language:

Transplant centers must have written selection policies (X051) for living donors which must be consistent with the general principles of medical ethics. Although these principles are not defined in the Final Rule, it is generally believed that the primary ethical principles are that the donation is fully voluntary and that the donor's interests and well-being are the primary concern, not the recipient's interests or well-being.

Specific elements assessed in psychosocial and medical evaluations must be part of the selection criteria.

Policy review:

Must contain explicit language that:

Every donor will receive a psychosocial evaluation

Every donor will receive a medical evaluation

Qualified healthcare personnel who may perform these evaluations

Psychosocial criteria evaluated

Medical criteria evaluated

Length of time for which the evaluations are deemed current

Referral and follow-up procedures if needed to further determine candidacy

Cite a deficiency X051 if no policy exists.

OPTN policies require very specific elements of both medical and psychosocial evaluations and as transplant centers are required to be OPTN members these are not repeated in these IGs, nor are additional specific elements required. Surveyors should look for policies that ensure that the donor is psychologically, socially and medically fit for donation and recovery. At a minimum the policies should include assessment of:

Donor's mental health

Donor's social support system

Donor's overall physical health by way of taking a history, performing a physical examination and review of diagnostic tests

More detailed assessment specific to the organ to be donated

Chart review: Ensure that every donor has a psychosocial evaluation before admission to the hospital for donation procedure as described in policy and that selection criteria were consistently applied. Ensure that the evaluation criteria being used are consistent with center

policy. If an exception is noted (i.e. the donor does not meet selection criteria) look for documentation of the reason for the exception in the medical record.

In the case that the donor is evaluated at another center (e.g. the case of a “swap” or an adult center that provides donation services to a pediatric center), the recipient center must also document review and approval of the medical and psychosocial evaluation of the donor prior to donation.

Cite a deficiency at Tag X058 if patients’ charts do not contain psychosocial and/or medical evaluations prior to admission for the donation procedure OR if criteria are not consistently applied without explanation in the chart, or selection committee minutes.

Tag X059

This should be combined with Tag X058

Tag X060

Suggest addition of:

Signed consent forms are not required by the Final Rule

And deletion of:

and review all dated and witnessed forms signed by the LD

Tag X073

The requirement to have this verification occur in the recipient OR is not supported in the Final Rule, which requires only verification after organ arrival at the hospital and prior to transplant. The language below reflects that. Further, it does not list specific other vital data(OVD). While that will typically be or include UNOS ID, that is not specified in the Final Rule, and further, separating OVD and UNOS ID would require centers to identify additional OVD beyond UNOS ID, which is not required.

We suggest the following language:

The verification required by this standard is intended to identify a compatible donor organ with the intended recipient. The verification is required to occur after the organ arrives at the transplant hospital and prior to transplant.

The transplant recipient’s medical record (electronic or written) must include:

1. Written evidence that the verification occurred (i.e., notations of the donor and recipient blood type (ABO) and other vital data (OVD). OVD would include any donor/recipient compatibility elements or identifiers that the transplant program has identified in its own policies and/or protocols; and
2. Authenticated electronic documentation or signature that is dated and timed of both required individuals performing the ABO and OVD verification to include:

- a. Transplanting surgeon;
 - b. Another licensed health care professional. The professionals serving as “Another licensed healthcare professional” must be identified in the transplant program’s policies and procedures.
Note: The verification must be documented in the medical record.
Note: If one or both individuals verified the organ and the recipient visually, prior to transplantation (i.e., the operation was already underway), this should be clearly documented with date(s) and time(s) of the verification occurring during the operation. Individual(s) who visually verified the donor organ with the recipient prior to transplant must follow-up with a note and corresponding authenticated electronic documentation or signature(s) attesting to the fact that the verifications were made visually prior to transplant.
3. Documentation sufficient to demonstrate the verification occurred after organ arrival at the transplant hospital and prior to transplant. This could include documentation by both licensed professionals stating the verification occurred after organ arrival and prior to transplantation, or it could be made by timing of documentation. If demonstrated by documentation time, the following times must be documented:
 - a. Time of organ arrival at transplant hospital or some specific location within transplant hospital, which must be prior to
 - b. Time of ABO and OVD verification, which must be prior to
 - c. Time of first anastomosis.
 4. Note: The verification is completed onsite at the transplant hospital and it cannot be completed via phone or performed remotely. If the organ was procured in the recipient hospital, verification is still required following excision from the donor. Verification prior to transplant and verification prior to organ recovery are two different and separate verification processes.

Survey Procedures

Review the transplant program’s policies and procedures to ensure it has a policy that complies with these requirements, including which licensed professional(s) may perform ABO and OVD verification in addition to the transplant surgeon. The policy and procedure must specify what OVD is required to assure compatibility.

Review a sample of medical records to verify documentation of the donor ABO and OVD compatibility with the intended recipient, i.e., there is documentation verifying that these match or are an intended mismatch. Verify the documentation was attested to or completed by the transplant surgeon and another licensed healthcare professional as defined by the transplant program’s policy, with authenticated electronic documentation or signatures, dates and times, after organ arrival at the transplant hospital and prior to first anastomosis.

If multiple organs from the same donor are being implanted into the same recipient, CMS does not require that there is a separate verification for each organ. However, if the organs are being

implanted at separate times and by separate teams, additional documentation would be required. The transplanting surgeon for each organ and another licensed healthcare professional must complete the verification prior to implantation of that organ.

Visual verification confirming compatibility of the ABO and OVD between the donor organ and the recipient is permitted. All of the required information must be documented by the person attesting that the verification occurred, dated and electronically documented or signed. If visual verification is performed instead of documentation, after the transplant case is complete the transplanting surgeon and the other licensed healthcare professional must electronically document or sign, date and time that attestation. If the person documenting the attestation is the other licensed healthcare professional, he or she must document his or her own verification of this data as well as the verbal verification by the transplanting surgeon. The other licensed healthcare professional's documentation must reflect the explicit time and date the verifications occurred. The transplanting surgeon must then attest to the accuracy of this documentation following the operation.

This is a separate procedure from the verification required to be performed in the LD operating room under tag X074. If the same surgeon recovering the donor organ is going to perform the transplant surgery, the ABO and OVD must be verified by the transplanting surgeon and another licensed healthcare professional again after donor excision and prior to transplantation.

Note: The OPTN has significant policy around ABO verification, donor-recipient compatibility, labeling, and identification. It has developed and continues to develop software to facilitate this review. To the extent the OPTN provides transplant centers software to facilitate verification, and to the extent that software performs and records verification consistent with this tag, documentation from that software may be used to demonstrate compliance with these requirements.

Note: The transplant program is not precluded from beginning the recipient's operation prior to arrival of the organ at the transplant hospital. If the operation has begun and the surgeon is awaiting arrival of the donated organ, the transplant surgeon remains responsible for verifying the ABO and OVD. It is not required that the surgeon would stop the operation to enter the documentation for this verification (given the time-sensitive nature of some transplant surgeries) but may instead use the visual verification process described above.

Tag X074

We suggest the following language:

The verification required by this standard is intended to identify a compatible living donor organ with the intended recipient immediately prior to beginning donor surgery.

The transplant living donor's medical record (electronic or written) must include:

1. Written evidence that the verification occurred (i.e., notations of the donor and recipient blood type (ABO) and other vital data (OVD)). OVD would include any donor/recipient

- compatibility elements or identifiers that the transplant program has identified in its own policies and/or protocols; and
2. Authenticated electronic documentation or signature that is dated and timed of both required individuals performing the ABO and OVD verification to include:
 - a. Transplanting or recovery surgeon;
 - b. Another licensed health care professional. The professionals serving as “Another licensed healthcare professional” must be identified in the transplant program’s policies and procedures. Note: The verification must be documented in the medical record.
 3. Documentation sufficient to demonstrate the verification occurred immediately prior to the donation procedure. Immediately means with the donor present in either the operating room or pre-operative holding area. This could include documentation by both licensed professionals stating the verification occurred immediately prior to the donation procedure and in the OR suite, or it could be demonstrated by timing of documentation. If demonstrated by documentation time, the following times must be documented:
 - a. Time of living donor arrival in the operating room or pre-operative holding area, which must be prior to
 - b. Time of ABO and OVD verification, which must be prior to
 - c. Induction of anesthesia.

Note: The verification is completed onsite at the transplant hospital and it cannot be completed via phone or performed remotely.

Tag X081

We suggest the following language:

Recipients

Written patient management policies are required for recipients for the transplant event and discharge.

Policy review:

Ensure that written patient management policies are in place for the recipient from admission to the hospital for transplantation to discharge. Specific elements that must be included in these policies are found at X082.

Cite a deficiency at Tag X081 if no policies exist.

Living Donors

Written patient management policies are required for living donors for evaluation, donation and discharge.

Policy review:

Ensure that written patient management policies are in place for the donor from evaluation to the hospital admission for donation to discharge. The patient management policy for the evaluation phase begins when the donor presents for evaluation until admission for donation. The donation phase begins when the donor is admitted to the hospital for donation procedure and extends until discharge planning begins. (Note the members of the transplant team are delineated in tag X125.)

Tag X082

We suggest the following language:

Recipients

Patient management policies are required for the recipient during the transplant event admission and transplant discharge (time of admission for transplantation or transplant procedure if patient was already hospitalized for other reasons up to the discharge from that admission). Recipient management policies must describe the members of the multidisciplinary team and how they participate in the recipient's care during the transplant admission and discharge phases of care (they may also include other phases, but this is not required by the Final Rule). The policy must reflect that this care is coordinated or supervised by a physician. In addition to medicine, the multidisciplinary team must include, at a minimum, representatives of the following disciplines: (Note the members of the transplant team are delineated in tag X125)

Nursing (see Tag X112 re: training and staffing)

Nutrition (see also Tag X094 for qualifications)

Social work (see also Tags X092 and X093 for qualifications)

Transplant coordination (see also Tags X112 for training and staffing, X118-X120 for qualifications and role, Note: Tag X118 requires the Coordinator to be ensuring continuity of care for the recipient in the pre-transplant phase as well. This phase extends from the evaluation to admission for transplantation or transplantation if recipient is hospitalized prior to transplant for other reasons.

Pharmacology

Note that some management policies may be implemented as standard order sets. The Final Rule is silent on any other content of the management policies. Discharge planning is part of the hospital Conditions of Participations at 42 CFR §482.43.

Policy Review:

Ensure that written patient management policies are in place for the recipient from admission to the hospital for transplantation to discharge that include representatives from nursing, nutrition, social work, transplant coordination, pharmacology and is under the supervision of a physician. Every discipline (other than transplant coordinators and physicians) is not required to be involved in every phase but policy should reflect under what circumstances each discipline will

be involved and how care is coordinated. For example, a recipient with certain nutritional indicators such as low or high BMI could be required to have consultation with the dietitian.

Discharge planning should be included in policy. Discharge planning and instructions must include at a minimum:

Post discharge care instructions including medications, activity, diet, and wound care

Post discharge follow-up appointment(s)

How, who, and under what circumstances the patient should contact transplant center staff with concerns or questions

Provisions for additional, necessary resources such as transportation, DME, other referrals, etc. as appropriate

Cite at Tag X082 if these policies do not contain these minimal elements.

Chart Review:

Review charts for evidence of multidisciplinary care throughout the transplant hospitalization and include discharge planning consistent with the transplant center's own policies. Every discipline need not be involved in every aspect of care, but there must be evidence of coordination among disciplines.

Lack of documentation of multidisciplinary care is cited at Tag X090.

Cite deficiency at Tag X082 if documentation indicates that center is not following its own policies for multidisciplinary care.

Cite deficiency at Tag X118 for no evidence of transplant coordinator care coordination in pre-transplant phase.

Living Donors

Patient management policies for the living donor during the donor evaluation, donation admission and donation discharge (time of admission for donation procedure to the discharge from that admission). Living donor management policies must describe the members of the multidisciplinary team and how they participate in the donor's care in during the donor evaluation, donation admission and discharge phases of care (they may also include other phases, but this is not required by the Final Rule). The policy must reflect that this care is coordinated or supervised by a physician. In addition to medicine, the multidisciplinary team must include, at a minimum, representatives of the following disciplines: (Note the members of the transplant team are delineated in tag X125)

Nursing (see Tag X112 re: training and staffing)

Nutrition (see also Tag X094 for qualifications)

Social work (see also Tags X092 and X093 for qualifications)

Transplant coordination (see also Tags X112 for training and staffing, X118-X120 for qualifications and role).

Pharmacology

The ILDA is also part of the living donor team but is covered in tags X121-124.

Note that some management policies may be implemented as standard order sets. The Final Rule is silent on any other content of the management policies. Discharge planning is part of the hospital Conditions of Participations at 42 CFR §482.43.

Policy Review:

Ensure that written patient management policies are in place for the living donor for donor evaluation, admission to the hospital for donation to discharge that include representatives from nursing, nutrition, social work, transplant coordination, pharmacology and is under the supervision of a physician. Every discipline (other than transplant coordinators and physicians) is not required to be involved in every phase but policy should reflect under what circumstances each discipline will be involved and how care is coordinated. For example, donors with questions about medications that will need to be discontinued prior to donation admission, could be provided consultation with a pharmacist.

Discharge planning should be included in policy. Discharge planning and instructions must include at a minimum:

Post discharge care instructions including medications, activity, diet, and wound care

Post discharge follow-up appointment(s)

How, who, and under what circumstances the patient should contact transplant center staff with concerns or questions

Provisions for additional, necessary resources such as transportation, DME, other referrals, etc. as appropriate

Cite at Tag X82 if these policies do not contain these minimal elements.

Chart Review:

Review charts for evidence of multidisciplinary care throughout the donor evaluation, donation hospitalization and include discharge planning consistent with the transplant center's own policies. Every discipline need not be involved in every aspect of care, but there must be evidence of coordination among disciplines.

Cite deficiency at Tag X082 for lack of documentation of living donor multidisciplinary care or documentation inconsistent with transplant center's own policy

Tag X083

We suggest the following language:

Transplant programs are required to keep their waiting lists up to date to ensure to the best of their ability that active waitlist patients are ready for organ offers and transplantation based on their most recently documented clinical presentation.

Programs' policies and procedures must include, at least:

- Timeframes for documentation updates,
- Methods for updating a patient's clinical status, and
- A description of information provided to transplant candidates on the waiting list regarding the candidates' responsibility to notify the program about changes in their status that might affect their ability to accept an organ offer and proceed with transplant.

Tag X084

We suggest the following language:

The program must have policies and procedures in place for on-going assessments and evaluations required for patients to remain on their waiting lists. Transplant programs will likely have different policies and procedures for updating clinical information. The surveyors should assess whether or not the program is following its policies and procedures.

Survey Procedures

Review the transplant program's policies and procedures for updating clinical information for waiting list patients and, if needed, updating their status on the waiting list. The policies and procedures must include the timeframe within which these updates must be completed (which does not have to be the same for all patients), what type of information is updated, how the program updates the information and how the program updates status on the waiting list if necessary.

Review a sample of transplant candidate medical records currently on the program's waiting list (these may be inpatient or outpatient records) to ensure that clinical information has been updated according to the center's policy and procedures, and that it has followed its own policy and procedure for evaluating the need for any changes to listing status.

During interviews with transplant program staff, request information about the process and frequency with which the transplant program reviews and updates the clinical information of waiting list patients.

Tag X085

We suggest the following language:

Note: Some patients may be re-listed for transplant following removal from the list due to transplant if their transplant does not function or later fails.

Survey Procedures

Select a sample of transplant candidates on the current waiting list and confirm through their medical records that, based on their clinical status, they should still be on the waiting list (that is, the medical records do not show documentation of changes that would exclude them from the program's selection criteria). Additionally, the transplant candidates on the waiting list must not have already received a transplant of that organ unless they have been intentionally re-listed, and must still be living.

Tag X087

We suggest the following language:

Transplant programs must maintain medical records for all individuals evaluated by the program for transplantation or living donation. A program may have a policy and procedure to review medical information from another provider or facility prior to accepting a patient for evaluation. In such cases, the evaluation (and corresponding need for records retention) begins at the point designated in the program's policy and procedure.

If the transplant candidate or potential living donor has begun but not completed an evaluation, there is not a required timeline for when that transplant candidate or potential living donor must complete his or her clinical workup.

Tag X088

We suggest the following language:

For transplant candidates placed on the waiting list, documentation in the medical records should verify that the transplant candidate was informed of his or her status on the waiting list. In the case of kidney transplant candidates on dialysis, the dialysis facility must also be informed of the transplant candidate's waiting list status. All such notifications may be made verbally and/or in writing.

The notification of change of waiting list status for acuity changes to transplant candidates must be based on program policies and procedures, (for example, LAS, MELD or PELD score changes).

For transplant candidates placed on the waiting list that are changed from active to inactive status, transplant candidate notification must be documented in the medical record as this affects their ability to receive a transplant.

For transplant candidates evaluated but not selected for the waitlist, the transplant program must document in the medical record the selection criteria used to make the decision.

For transplant candidates evaluated, but for whom the program was unable to make a determination, the transplant program must inform the transplant candidate of the specific additional testing or documentation needed to make a determination.

Survey Procedures

Review a sample of wait list medical records to verify these patient communications have occurred.

Tag X089

We suggest the following language:

Transplant candidates that are removed from the OPTN waitlist for reasons other than death or transplantation must be notified within 10-business days of the removal, including the reason for removal. In the case of kidney transplant candidates, this notification must also be made to the patient's dialysis facility. This notification may be made verbally or in writing.

Survey Procedures

Request a list of transplant candidates removed from the waiting list during the past 12-months for reasons other than death or transplantation (do not include those placed on "inactive" status on the waitlist). Verify notification of removal from the waiting list no later than 10 business days after the date the transplant candidate was removed from the list.

Tag X090

Refer to Tag X082 – Documentation of multidisciplinary care for recipients

Tag X091

Recommend combining with Tag X090

Tag X092

We suggest the following language:

The transplant center must make social services provided by a social worker available to recipients, living donors and families. Policies for multidisciplinary care (Tags X81 and X82) must describe how the qualified social worker is involved in care of recipients and living donors.

Policy Review:

See Tags X081 and X082

Chart Review: Review recipient and living donor charts for evidence that the social worker was providing services consistent with the transplant center's own policy. Cite deficiency if there is evidence that social worker services were not available to the patient or that needs for social services issues were identified but not addressed.

Tag X093

We suggest the following language:

Qualified social worker must meet the requirements of the Final Rule including a master's degree in social work unless grandfathered in under provision of the rule. Advanced licensure is not required. The grandfathering clause ONLY applies to social workers who were:

- 1) Employed in a transplant center as of June 28, 2007
- 2) Have at least 2 years' experience as a social worker, one of which was in transplantation
- 3) Maintains a consultative relationship with a qualified social worker

Documentation of a consultative relationship could include multidisciplinary meetings with both present, supervisory relationship, participation by the qualified social worker in the performance evaluation, co-signing of charts, ongoing training and continuing education provided by the qualified social worker.

Qualified social workers may also directly supervise students, baccalaureate prepared social workers or clerical support staff in the provision of some services.

Policy review:

Review policy or job description to ensure that requirements are consistent with the Final Rule.

Chart review: Review a sample of center's social workers' personnel files to ensure that they meet the requirements of the Final Rule and if they do not, they meet the grandfathering requirements of X093.

Cite at Tag X093 if requirements are not in policy or job description OR if unqualified social worker is providing services without a consultative relationship.

Review a sample of recipient and donor charts to ensure that patients with social service indicators, per the center's own policies, received social services.

Cite at Tag X093 if center is not providing social services consistent with their own policy.

Tag X094

We suggest the following language:

This standard refers to need for availability of nutritional services, provided by a qualified dietitian to be made available to all transplant patients and living donors AND the qualifications of the dietitian.

Services, including indications for services must be described in policy as described for Tags X081 and X082.

Qualifications as outlined in the Final Rule must be reflected in policy or job description.

Policy review:

Review policy or job description to ensure that requirements are consistent with the Final Rule.

Chart review: Review a sample of center's social dietitians' personnel files to ensure that they meet the requirements of the Final Rule.

Cite at Tag X094 if requirements are not in policy or job description.

Review a sample of recipient and donor charts to ensure that patients with nutritional indicators, per the center's own policies, received nutritional services.

Cite at Tag X094 if center is not providing nutritional services consistent with their own policy.

Tag X099-X104

As outlined in our prior letter, the Quality Assurance and Performance Improvement (QAPI) section and the related focused QAPI (fQAPI) survey process, although extremely detailed and well-intended, plainly constitutes the creation of new regulation and imposes significant new burden, substantially driving up healthcare costs. The guidelines often apparently rely on hospital conditions not referenced in the document while at the same time are presented as transplant-specific rules that would not apply to other parts of the hospital who are all subject to the hospital conditions. For all these reasons, we propose this be removed from these guidelines and a joint group be assembled led by the CMS survey and certification group with representation from, at minimum, the American Society of Transplantation, the American Society of Transplant Surgeons, the OPTN contractor, and the SRTR contractor to develop an evidence-based new rule which can have its evidentiary basis and burden vetted through the public comment and OMB OIRA ICR process.

Tag X109

Would add to first paragraph, last sentence are qualified "under the Final Rule" to provide

Tag X112

We suggest the following language:

The center must show evidence of initial and ongoing transplant specific training of nurses and transplant coordinators. "Adequate" training requires the need for documentation of competency attainment.

Policy review:

Review policy and/or job descriptions for qualifications, training and experience requirements. Review policy or other documentation of training programs for nurses and transplant coordinators including competency assessment. Policy could outline a formal program or utilize a preceptor during a proscribed period of time.

Chart Review:

Review a sample of nurses' and transplant coordinator's files to ensure documentation of initial training and initial and ongoing competency assessment.

Cite a deficiency if no evidence of training or competency assessment.

Tag X119

Delete references to certification as it is not required. Refer to X112 for training.

Tag X120

This standard requires that the transplant coordinator must be involved in all phases of care of transplant patients and donors. This must be described in policy as outlined for Tags X081 and X082. The standard also requires that a transplant coordinator act as a liaison between kidney transplant program and dialysis facilities. It does not require that the same coordinator be involved in every phase, but that a transplant coordinator be involved in every phase.

Policy Review:

Review as in Tags X081 and X082. Also ensure that the transplant coordinator's role in communicating to dialysis units is described in policy.

Cite deficiency at X120 if not communication with dialysis units is not described in policy.

Cite deficiency at X118 if involvement in pre-transplant recipient care coordination is not described in policy.

Chart Review:

Review sample of charts as in X081 and X082 for documentation of transplant coordinator's involvement in care at every phase and consistent with the center's own policy.

Cite deficiency at X118 if no evidence of care coordination in pre-transplant phase for recipients is documented.

Tag X123

We suggest the following language:

The independent living donor advocate (ILDA) or living donor advocate team (ILDA team) must demonstrate:

- Knowledge of living organ donation, transplantation, medical ethics, and informed consent; and
- Understanding of the potential impact of family and other external pressures on the prospective living donor's decision whether to donate and the ability to discuss these issues with the donor.

Survey Procedure

Review the program's policy and procedure and/or ILDA job description(s) to ensure these requirements are present.

Interview the ILDA or members of the ILDA team and ensure they can speak to these elements of their knowledge and understanding, and to how they discuss those things with donor candidates.

Tag X124

We suggest the following language:

The independent living donor advocate or living donor advocate team is responsible for

- Representing and advising the donor
- Protecting and promoting the interests of the donor
- Respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion.

Survey Procedure

Review the program's policy and procedure and/or ILDA job description(s) to ensure:

- They require the ILDA to be responsible for these three requirements
- The evaluation process includes ILDA conversations with potential donors
- The donor selection process involves input from the ILDA

Review a sample of donor charts to look for evidence of ILDA involvement in donor education and assessment and for involvement in discussions related to donor selection.

Interview the ILDA or members of the ILDA team and ensure they have an understanding of their role in representing, advising, protecting, and promoting the best interests of the donor as well as assuring the transplant program respects the donor's decision and assesses whether that decision is informed and free from coercion.

Tag X125

Delete all content after 2nd paragraph

Replace with:

Policy review:

See Tags X 081 and X082 for responsibilities of each team member

Review policy and/or job descriptions for qualifications, training and experience requirements.

Team members must include:

Nursing (see Tag X112 re: training and staffing)

Nutrition (see also Tag X094 for qualifications)

Social work (see also Tags X092 and X093 for qualifications)

Transplant coordination (see also Tags X112 for training and staffing, X118-X120 for qualifications and role).

Pharmacology

The ILDA is also part of the living donor team but is covered in tags X121-124.

Cite deficiency at appropriate tag or for pharmacology tag X125

Chart review:

Review a sample of personnel files to verify that staff have qualification, training and experience consistent with Final Rule and center's own policy.

Cite deficiency at appropriate tag and this tag or for pharmacology tag X125

Review a sample of medical records of donors and recipients to ensure documentation of multidisciplinary involvement consistent with center's over policy and tag X081 and X082. Cite lack of documentation at this tag and tag X090.

Tag X126

We request minor revision of: "A recipient's transplant program must have a copy of the Medicare approval letter for the transplant program providing LD care with which it has a contract or agreement and have documented evidence that the CMS website was reviewed prior to accepting the LD organ to ensure that the program is a Medicare-approved program." We suggest changing the underlined "and" to an "or".

Tag X139

We suggest the following language:

Surveyors are not required to review the OPO agreement with the hospital. If during the survey there is concern with the OPO agreement, such as evidence of improper use of organs, problems with obtaining organs, problems with referral of organ offers or organ allocation, review the following below and contact your contract PO and CMS CO. The written agreement must identify the specific responsibilities of the hospital and the OPO and how they commit to work collaboratively.

Tag X150

We suggest the following language:

For each of the subparagraphs identified in the standard (1) through (8), the transplant program's policies and procedures should delineate:

- 1) Who is responsible for discussing the informed consent process with the patient
- 2) Documentation process

3) The methods used by the program to document patient consent

4) When the discussion will take place.

A transplant candidate's/recipient's signed informed consent form and/or hospital surgical informed consent form should not be considered by itself sufficient evidence that the informed consent process was complete. The informed consent process is expected to involve multiple discussions with the transplant candidate/transplant recipient at different points in time. The medical record and interviews must validate that appropriate discussions were held. Transplant candidates/recipients must be given an opportunity to ask questions and the level of transplant candidates'/recipients' understanding must be assessed. Signed informed consent forms are not required.

Note: The informed consent requirements in this regulation are in addition to the requirements for a properly executed informed consent form under the hospital CoPs. The hospital CoPs require that a surgical informed consent form is signed and documented in the medical record for surgery and other medical treatments.

Policy review:

Review policy regarding informed consent to be consistent with above description and at subparagraphs 1-8 (Tags X151-X158).

Cite a deficiency at this and the appropriate tag if policies are missing required elements.

Chart Review:

Review a sample of recipients' charts for documentation of the informed consent process consistent with the Final Rule and the center's own policy. Also consider patient educational materials including written, PowerPoint slides, websites, software applications or videos as part of informed consent process if referenced in policy and documentation of attendance or provision of materials to patients is documented in the medical record.

Cite a deficiency at this and the appropriate tag if medical records are missing required elements.

Tag X152

We suggest the following language:

Discussions with the transplant candidate about the surgical procedure should occur on several occasions prior to the surgery, if practical. For example, a patient with acute fulminant liver failure may only have time for a single discussion. Prior to placement of the transplant candidate on the UNetSM waiting list, the transplant program must, at a minimum, provide an overview of the surgical procedure and potential risks.

Prior to transplant surgery, a detailed discussion of the surgical procedure, anesthesia risks, and risks involved with the use of blood or blood products, expected post-surgical course and

possible complications; and benefits/risks of transplant surgery relative to other alternatives should occur.

Tag X153

We suggest the following language:

The options for alternative treatments will vary by organ type and by the transplant candidate's specific medical condition. For example, kidney transplant candidates have dialysis options.

The discussion of these alternative treatments should occur before placement on the UNetSM waiting list. The discussions of alternative treatments should be reviewed again with the transplant candidate subsequently if the program becomes aware of changes to the candidate's medical condition that would change the alternative treatments available or make the transplant less desirable than the alternative. For example, a patient's condition may have become deteriorated to the point that transplant is no longer a viable option or improved to the point that medical management would be better for the patient.

Tag X154

We suggest the following language:

Discussions regarding potential medical and psychosocial risks should occur early in the evaluation process, on several occasions prior to the surgery, if practical. For example, a patient with acute fulminant liver failure may only have time for a single discussion. Prior to placement of the transplant candidate on the UNetSM waiting list, the transplant program must, at a minimum, provide an overview of the medical and psychological potential risks.

Discussion of potential medical risks should include, at a minimum:

Short and long term risk associated with:

- Immunosuppression
- Anesthesia
- Organ rejection, failure or re-transplant
- Potential for long term disability or death

Discussion of potential psychosocial risks should include, at a minimum:

- Depression
- Generalized anxiety
- Issues associated with dependence
- Feelings of guilt

Tag X155

Delete LD outcomes- not in Final Rule nor applicable to this tag

Tag X156

Delete reference to malaria in third bullet – replace with “other infection”

Delete entire sentence beginning with “This discussion” and ending with “suitable for transplant candidate.” The discussion of donor – derived risks should be had in general terms with the candidate at the beginning of the process and again in very specific terms when an organ has been offered and deemed suitable for the candidate.

Tag X158

Delete the last sentence as it outside the Final Rule.

Tag X159

Delete final two paragraphs

Add the following:

Policy review:

Review policy regarding informed consent to be consistent with above description and at subparagraphs 1-9 (Tags X160-X168).

Cite a deficiency at this and the appropriate tag if policies are missing required elements.

Chart Review:

Review a sample of recipients’ charts for documentation of the informed consent process consistent with the Final Rule and the center’s own policy. Also consider patient educational materials including written, PowerPoint slides, websites, software applications or videos as part of informed consent process if referenced in policy and documentation of attendance or provision of materials to patients is documented in the medical record.

Cite a deficiency at this and the appropriate tag if medical records are missing required elements.

Tag X160

We suggest the following language:

The recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient.

Tag X161

Elements in the proposed IGs do not pertain to the evaluation process but are general risks of donation and should be removed.

We suggest the following language:

The evaluation process begins at the time an individual is identified as a LD candidate and continues until donation occurs or the potential LD is no longer a LD candidate. The center must have policy describing the center's evaluation process.

Tag X162

We suggest the following language:

Discussions with a potential LD about the surgical procedure must occur on several occasions prior to surgery. The initial discussions should, at a minimum, provide the potential LD with an overview of the surgical procedure and potential risks and complications. A more detailed discussion of the surgical procedure should occur prior to the organ recovery surgery.

At a minimum, the more detailed discussion of the surgical procedure occurring prior to the surgery should include:

- Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure
- Abdominal symptoms such as bloating, nausea, and developing bowel obstruction
- Death

Tag X164

Discussions regarding potential medical or psychosocial risks to the potential LD should occur early in the evaluation process prior to obtaining the surgical consent for donation. Discussion of the potential medical risks must include, at a minimum:

- Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure
- Abdominal symptoms such as bloating, nausea, and developing bowel obstruction
- Organ –specific risks factors including short or long term organ failure
- Death

Discussion of the potential psychosocial risks must include, at a minimum:

- Problems with body image
- Post-surgery depression or anxiety
- Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies
- Changes to the donor's lifestyle from donation

Tag X165

Change first paragraph to:

Discussions regarding the transplant program's outcomes must be done prior to the potential LD's consent for donation. If a new SRTR cohort has been released between consent for

donation and the scheduled timeframe for the organ donation surgery, discussions to update the data must be held with the potential LD.

Delete second paragraph (it is redundant)

Retain third paragraph

Delete 4th paragraph (it is redundant)

Delete 5th paragraph (it is redundant)

Tag X167

We suggest the following language:

Documentation in the medical record must verify that the potential LD was advised of his or her right to withdraw consent for living donation at any time during the process.

Tag X169

We suggest the following language:

The transplant program's policies and procedures must clearly delineate how the program notifies the transplant candidate of the availability of key personnel for transplants, and other transplantation services, and how the transplant candidates will be informed of changes to this availability.

Note: A transplant program may not have continuous availability if the program is served by a single transplant surgeon. This is permissible if transplant candidates are notified and acknowledge understanding of this fact. Transplant candidates must be notified if the program is not accepting organ offers or if the transplant candidate's ability to receive an organ offer is in any way affected. In essence, the transplant surgeon must be available or the transplant candidate must be notified. The Coverage plan required by OPTN is generally how centers meet the need to ensure availability of the transplant team.

Policy review:

Review the program's policy and procedures for compliance with the Final Rule.

Cite deficiency if policies are not compliant.

Chart review:

Review a sample of the medical records of transplant candidates on the waiting list, and verify that in each case, the transplant candidate was informed about any aspects of program operations that could impact patients' ability to receive a transplant and procedures in place to ensure availability of a transplant team.

Cite deficiency if there is evidence that candidates were not informed that the center had potential unavailability issues due to single surgeon or physician.

Tag X170

Policy Review: Review the center's policy as in X169 for notification procedure.

Chart review:

Review a sample of the medical records of transplant candidates on the waiting list, and verify that in each case, the transplant candidate was informed about potential unavailability of single surgeon or physician and possible alternatives.

Cite deficiency if there is evidence that candidates were not informed that the center had potential unavailability issues due to single surgeon or physician.

Tag X186

A kidney transplant center must have written policies and procedures for ongoing communications with dialysis patients' local dialysis facilities.

Survey Procedure

Review the center's policy and procedure to ensure it has provisions for ongoing communication with dialysis facilities. The frequency, content, and method of these communications is left to the discretion of the center. Centers should only be cited for not addressing in policy and procedure, or for failure to follow their own policy.

Interview program staff identified in the policy and procedure about their role in ongoing communication with dialysis facilities.

AST Board of Directors 2015-2016

PRESIDENT

James S. Allan, MD, MBA
Massachusetts General Hospital

PRESIDENT-ELECT

Anil Chandraker, MD, FRCP
Brigham and Women's Hospital

IMMEDIATE PAST-PRESIDENT

Kenneth A. Newell, MD, PhD
Emory University

SECRETARY

Ronald G. Gill, PhD
University of Colorado, Denver

TREASURER

Thomas C. Pearson, MD, DPhil
Emory University

COUNCILORS-AT-LARGE

Sharon M. Bartosh, MD
University of Wisconsin

Richard N. Formica, Jr., MD
Yale University School of Medicine

John S. Gill, MD, MS
University of British Columbia

Deepali Kumar, MD, MSc, FRCPC
University of Toronto

Josh Levitsky, MD, MS
Northwestern University

Larry B. Melton, MD, PhD
Hackensack University Medical Center

David P. Nelson, MD
Integrus Baptist Medical Center of Oklahoma

Jesse D. Schold, PhD, M.Stat, M.Ed.
Cleveland Clinic

Alexander C. Wiseman, MD
University of Colorado, Denver

EXECUTIVE VICE PRESIDENT

Libby McDannell, CAE

April 8, 2016

Via E-mail

Mr. Thomas E. Hamilton
Director, Survey and Certification Group
CMS Center for Clinical Standards and Quality
Department of Health and Human Services

Mr. Hamilton,

Members of the American Society of Transplantation have reviewed your March 11, 2016 memorandum to state survey agency directors and the attached advance copy revised Interpretive Guidelines for the Organ Transplant Conditions of Participation for Transplant Centers. Although we commend you and your team for your work in clarifying and updating the guidelines, your efforts to better align OPTN and CMS regulations, and most importantly, your dedication to transplant quality, we strongly urge you to postpone the planned Monday implementation of the guidelines and to re-issue them at a later date. This pause would allow the transplant community to have an opportunity to collaborate with you on resolving what appear to be errors/typographical errors and inconsistencies, as well as bringing these interpretive guidelines in line with the Final Rule, established evidence, and best practices.

We appreciated the opportunity to work with CMS in establishing the 2007 Final Rule and subsequent interpretive guidelines and believe a similar collaborative effort now would result in a stronger and more effective set of regulations than those proposed last month. We have not had enough time to digest the regulations at this point to offer a full comment; however, we have identified some specific concerns which are detailed below.

We would like to stress that given the short timeline, we are not including positive comments and so this letter may seem more negative than is intended. Many of the new guidelines are clearer and more effective and we applaud them. If we are given adequate time to submit more detailed comment, we will provide more thorough feedback, including the many areas in which we are supportive of the guidelines.

General Concerns Not Specific to Any Tag:

It is our understanding that centers are expected to implement the guidelines announced on March 11 by April 11. The single month of notice does not give transplant centers adequate time to change policy and practice and hire staff

NATIONAL OFFICE

1120 Route 73, Suite 200 • Mt. Laurel, NJ 08054
856.439.9986 • Fax: 856.581.9604 • info@myAST.org • www.myAST.org

GOVERNMENT RELATIONS

William Applegate, Director of Government Relations • Bryan Cave, LLP
1155 F Street, NW • Washington, DC 20004
202.258.4989 • bill.applegate@bryancave.com

AMERICAN TRANSPLANT CONGRESS 2016

June 11-15, 2016
Boston, MA

Thomas E. Hamilton
Director, Survey and Certification Group
April 8, 2016
Page 2

in response to guidelines which substantially change the prior standards for survey.

The guidelines in many places exceed authority under the Final Rule. Specific examples of this are discussed in detail by tag elsewhere in our letter.

The guidelines in many places create new burden on transplant centers well in excess of anything approved, to the best of our knowledge, by the Office of the Management and Budget. The currently active OMB ICR (TITLE: Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers to Perform Organ Transplants and Supporting Regulations in 42 CFR 482.74, 482.94, 482.100, 482.102, 488.61; OMB CONTROL NUMBER: 0938-1069), for instance, suggests the total nationwide burden created by these regulations is 2523 hours. That is less than ten hours per transplant center per year.

The guidelines contain sections with errors in greater-than and less-than signs, apparent cut-and-paste artifacts, typographical mistakes, and the like. These errors should be corrected before adoption to prevent confusion and implementation errors.

The guidelines contain occasional sections labeled “note” or “for information only”. We are concerned at the vagueness of some of these sections and whether surveyors will incorrectly construe them as regulations to be cited during surveys.

The Quality Assurance and Performance Improvement (QAPI) section and the related focused QAPI (fQAPI) survey process, although extremely detailed and well-intended, plainly constitutes the creation of new regulation and imposes significant new burden, substantially driving up healthcare costs. The guidelines often apparently rely on hospital conditions not referenced in the document while at the same time are presented as transplant-specific rules that would not apply to other parts of the hospital who are all subject to the hospital conditions. For all these reasons, we propose this be removed from these guidelines and a joint group be assembled led by the CMS survey and certification group with representation from, at minimum, the American Society of Transplantation, the American Society of Transplant Surgeons, the OPTN contractor, and the SRTR contractor to develop an evidence-based new rule which can have its evidentiary basis and burden vetted through the public comment and OMB OIRA ICR process.

Concerns Related to Specific Tags:

Definitions: The transplant phases are confusing. There are four phases, with the fourth (post-transplant/post-donation) limited to the QAPI rules only. The second phase (inpatient) is defined in a manner that makes it wholly inclusive of the third phase (discharge). The guidelines later use other names for phases other than those present in definitions. Furthermore, CMS staff have publically presented these phases as “really only three.” We find this very confusing. Consistency and clarity is needed.

Thomas E. Hamilton
Director, Survey and Certification Group
April 8, 2016
Page 3

Tag X035: Greater-than and less-than signs are reversed in the IG text and should be corrected before implementation.

Tag X052: Requiring country of primary residence is a new requirement not supported by the Final Rule. We request it be removed. It is an unnecessary additional data collection.

Tag X053: We request removal of “The psychosocial evaluation is not complete until the selection committee has heard and considered the findings prior to transplant candidate placement on the waitlist.” There is no Final Rule requirement for a selection committee. Additionally, the language “heard” implies an audible reading of the findings. Other members of the multi-disciplinary team making a selection decision could certainly read the findings.

Tag X053: We request the IGs direct surveyors to allow centers to determine who may perform psychosocial assessments. Several places, lists (most prefaced with e.g., but one not so prefaced) include specific professionals. The authors of the Final Rule prudently left that judgment to the transplant centers. Surveyors should assess whether centers have policies on who may perform assessments, and whether they follow those policies and procedures. We request that this be a clear instruction to surveyors.

Tag X060: The guidelines include the statement: “review all dated and witnessed forms signed by the LD” Although the IG as written is not problematic, we are concerned surveyors might interpret this as a requirement for signed and witnessed informed consent (IC) forms, which are not a requirement. We are concerned about the substitution of signed documents for a robust process of informed consent. We request removal or clarity.

Tag X073: Verification of UNOS ID is added to the verification process. By separating the UNOS ID from Other Vital Data (OVD), we are concerned that surveyors will expect other data be verified. Many centers currently consider the UNOS ID the “Other Vital Data”, which is consistent with the Final Rule. We request removal or clarity that this does not represent a new requirement.

Tag X073: Documentation requirement is added for “Dates and times of organ receipt in the operating room, organ verification and first anastomosis.” Recording these times is unsupported in Final Rule and so constitutes new rulemaking requiring public comment. It is possible to comply with the Final Rule without recording these times. This constitutes an additional data collection requiring approval from the OMB. We request removal of the new requirement.

Tag X073: Section four requires “Documentation that the verification occurred in the recipient operating room with both the organ and the intended recipient present.” The Final Rule requires that the verification take place after organ arrival at center and prior to transplant. This additional restriction is more proscriptive than the Final Rule. In centers which are currently performing a verification compliant with the Final Rule which

Thomas E. Hamilton
Director, Survey and Certification Group
April 8, 2016
Page 4

they have determined best-suited to their patients' safety, this additional redundant required verification constitutes new burden requiring OMB approval, which we would suggest should be denied as duplicative of existing recordkeeping. We request removal of the new requirement

Tag X074: This section repeats the problems mentioned for Tag X073 on the living donor side.

Tag X074: The note makes reference to a UNOS matching process from the deceased donor side in reference to living donor verification. No such process exists. In part, this highlights the problem of bringing OPTN regulations into the CMS IGs. The IGs should remain silent on OPTN policy issues and allow the OPTN contractor to handle compliance with their own policies. We request removal of the reference to the UNOS process.

Tag X081: As noted in definitions, the phases are somewhat confusing. The phases noted in the Final Rule should be maintained.

Tag X082: IGs should be clear in directing surveyors that recipients are NOT required under the Final Rule to be under the care of the multidisciplinary team in the pre-transplant phase. We understand that surveyors have, in some cases, misinterpreted this requirement prior to the publication of these revised Interpretive Guidelines, however the Final Rule clearly states "Each transplant patient is under the care of a multidisciplinary patient care team coordinated by a physician throughout the transplant and discharge phases of transplantation" (underline added). In the comment section of the Final Rule, it was explicitly discussed that the pre-transplant phase was removed in recognition of the fact that many candidates in the pre-transplant phase are under the care of non-transplant care providers. Living Donors are required by the Final Rule to have multidisciplinary transplant team participation in the pre-event phase, but recipients are not.

Tag X082: Surgery and medicine have been separated as two different disciplines, contrary to the Final Rule which treats them (correctly) as specialists in the same discipline. This constitutes rule revision requiring public comment and burden analysis as it will create new documentation requirements. We request that the distinction be removed in the guidelines.

Tag X082: Financial coordination has been inserted into the multidisciplinary team in contradiction to the Final Rule which did not include it in the list of members of the multidisciplinary team. This constitutes rule revision requiring public comment. We request removal of the new requirement.

Tag X082: Post-discharge care was excluded from the Final Rule. "In cases where the discharge plan or discharge instructions in the medical record are not clear, then the surveyor may review the policies or transplant recipient education materials of the outpatient clinic so that the surveyor can assess the discharge plan and instructions that

are given to transplant recipients.” extends beyond the scope of the Final Rule and should be removed. If a center’s discharge plan and instructions are not compliant, that should be cited rather than opening a door for survey outside scope.

Tag X082: Post-discharge care was excluded from the Final Rule. “If a discharge plan was written and required follow-up is documented, review the post-transplant records to see that all tasks have been completed. If that is not the case, the deficiency should be cited under discharge planning.” This plainly exceeds the scope of the Final Rule. It would require new rulemaking, including public comment and burden analysis. We request removal of the new requirement.

Tag X082: Pre-transplant patient management was removed from the Final Rule during the public comment process. “If the multidisciplinary team does not conduct actual meetings for transplant recipient care planning, the surveyor should evaluate the evidence (e.g., medical records, interviews) that the multidisciplinary team members conducted joint discussions, issue identification, and joint planning efforts throughout the evaluation (to include time on the wait list), transplant and discharge processes. It is not necessary for all members of the team to be involved in all aspects of clinical care so long as the medical record, viewed as a whole, has documentation that each member of the team performed the duties and responsibilities accorded to him or her by the transplant regulations and by the program’s own policies and procedures.” The evaluation and wait-list component of this needs to be removed as it is not covered by the Final Rule.

Tag X082: Post-discharge care was excluded from the Final Rule. “If the transplant recipient’s local physician is responsible for his/her postoperative care, the transplant program is responsible for documenting coordination with that local physician to ensure continuity of care.” This is outside the scope of the Final Rule, both in that it related to post-discharge care and is a completely invented requirement finding no basis in the Final Rule. Such a requirement would require rulemaking including public comment and burden justification. We request removal of the new requirement.

Tag X082: Pre-transplant recipient management was removed from the Final Rule during public comment and post-discharge care was excluded from the Final Rule. “Review the transplant program’s written clinical management policies for the pre-transplant evaluation, transplant and discharge phases of transplantation, including the routine follow-up visit schedules.” Reference to pre-transplant evaluation and routine follow-up visits need to be removed from these instructions. Including them would require new rulemaking including public comment and burden justification. We request removal of this unsupported requirement.

Tag X082: The Final Rule does not list specific elements required in the discharge plan. Many of the required specific elements, although generally reasonable, are in no way necessary to comply with any Final Rule requirement. The authors of the Final Rule wisely left the judgment on clinical specifics to transplant centers, who should be free to determine their own policies regarding the discharge phase, their own templates for

discharge plans, and their own clinical decisions regarding plans for specific patients. These requirements are exemplary of the prudence of a Final Rule that is silent on such specifics: many of the listed items are not needed for all patients. Specifying elements of a discharge plan other than any needed to comply with Final Rule text constitutes new rulemaking requiring public comment. We request removal of the new requirement.

Tag X083: Although we are in full agreement with this laudable goal (and indeed struggle with the frustration of it in our centers every day), this statement is to the best of our knowledge impossible, (and not authorized by the Final Rule): “Transplant programs are required to keep their waiting lists up to date to ensure that all active waitlist patients are ready for organ offers and transplantation based on their current clinical presentation” (underline added). Centers can make best-practice efforts to reduce the rates of patients who are unable to accept organ offers, but there is no way to assure all patient are ready at all times. We request removal of this statement.

Tag X083: Similarly, “A description of information provided to transplant candidates on the waiting list regarding the candidates’ responsibility to notify the program about changes in their medical and psychosocial status. The policies and procedures must specify the medical and psychosocial conditions requiring notification to the program and the methods for notification.” is not realistic. We can provide examples of conditions requiring notification, but not an exhaustive list. Furthermore, this guideline represents the adding of a new requirement outside the authority of Final Rule which requires the updating of waiting list patients’ clinical information but does not proscribe the manner in which this be accomplished. We ask that this instruction to surveyors be removed.

Tag X083: We are confused by this guideline: “The program should consider seeing patients on the waitlist at least annually.” How will a surveyor assess what a program should have considered doing? It seems more likely this is actually a desire to prescribe practice well in excess of Final Rule authority that had to be reworded into so soft a requirement as to be essentially meaningless. It should be removed. The IGs are not an appropriate place for CMS to offer advice to transplant professionals.

Tag X083: We request removing: “In addition, OPTN has certain requirements for updating clinical information based on the patient’s characteristics.” This is the responsibility of the OPTN contractor.

Tag X083: We are confused by this guideline: “Review a sample of transplant candidate medical records currently on the program’s waiting list (these may be inpatient or outpatient records) to ensure that the clinical information in the medical record corresponds to the transplant program’s waiting list information identified in UNetSM. During interviews with transplant program staff, request information about the process and frequency with which the transplant program reviews and updates the clinical information of waiting list patients, both in the patient’s medical record and on the transplant program’s waiting list. Request a demonstration of updating both the UNetSM and transplant program’s waiting list (if different from the list of patients on UNetSM).” What are surveyors going to be reviewing in UNET? In any case, surveyors should be

Thomas E. Hamilton
Director, Survey and Certification Group
April 8, 2016
Page 7

ensuring centers have a policy for updating the waiting list and are following it (as evidenced by medical record). The OPTN contractor is responsible for UNET data entry accuracy. And we do not understand why the surveyors will seek a demonstration from staff on how to perform UNET updates, nor what text in the Final Rule requires them to be able to perform such a demonstration. Doing demonstrations would certainly constitute additional burden to be justified through OMB. We certainly hope CMS does not intend to start including demonstrations as part of surveys in other areas as well. We request removal of the new requirement.

Tag X085: We request rewrite of: "Some transplant recipients may remain on the waiting list due to a need to be re-transplanted due to rejection or malfunction of the previously transplanted organ. It should be documented for the patient who currently has a transplanted organ whether the patient is listed for retransplant due to graft loss or is listed for multiple organs." For primary non-function (PNF)/early failure organs, centers remove and relist patients. The multiple organ reference is correct and could remain. This again illustrates the pitfalls of duplicative regulation and burden. This is the responsibility of the OPTN contractor, and CMS should consider excluding it from its survey as it is a duplicate burden.

Tag X087: We request removal of: "A record must be maintained, even if the evaluation is limited to review of a referral and medical information from another provider or facility and a determination is made that the individual is not a candidate for transplant or living donation. Review of medical information indicates the beginning of an evaluation for transplant, and therefore accurate and current records must be kept and may be requested by CMS for survey review purposes." The Final Rule does not specify when an evaluation begins, and centers should be able to decide this in their best judgment, and outline that in policy. Further, this significant additional recordkeeping requires burden justification through the OMB process.

Tag X087: The text "If the patient is not accepted by the program for its waitlist, the program should counsel the patient on the decision and any circumstances that would enable reconsideration, and this must be reflected in the medical record." is not supported by any text in the Final Rule. It should be removed.

Tag X088: The text "any changes that the transplant candidate could make to meet the program's selection criteria (for example, smoking cessation, changes to alcohol consumption, weight changes, etc.)" is not supported by any text in the Final Rule. It should be removed.

Tag X088: The statement: "and the expected timeframe for completing the determination." is not supported by any text in the Final Rule. Further, such timeframes are often not predictable, especially when these timeframes depend upon the actions of patients and specialists outside the program. It should be removed.

Tag X088: The survey procedures: "Review a sample of wait list medical records to verify these patient discussions have occurred and are documented." The Final Rule

Thomas E. Hamilton
Director, Survey and Certification Group
April 8, 2016
Page 8

does not require a discussion. Written notification can be appropriate and compliant in many cases. This new requirement should be removed.

Tag X089: The standard: "The notification must be by letter, but it should provide an opportunity for the transplant candidate to have further discussion (either by telephone or face-to-face) with the transplant program." The further discussion component of this standard is not supported by any text in the Final Rule. It should be removed.

Tag X092: The Final Rule requires that social services be made available by a qualified social worker, not that every patient see a qualified social worker. The guideline's statement: "Survey Procedures: Review a sample of post-transplant recipient and post-LD medical records to verify that the social work consultation and/or progress notes reflect the social worker's participation in the initial assessment, care planning, intervention, reassessment, and discharge planning as reflected by documentation in all phases. It is reasonable to expect different levels of intervention and services based on the needs of the transplant candidate/recipient or potential LD/LD. Cite a deficiency if there is evidence in the medical record that (1) social services were not provided; or (2) the medical record reflects that social service issues were identified, but not addressed." The survey procedures far exceed the requirement to "make available". Centers may determine the manner in which they make these services available. (1) above should be rephrased to say "social services were not made available;".

Tag X093: A physician is ultimately responsible for the care of transplant recipients and living donors. The guideline's statement: "The MSW is ultimately responsible for the care of transplant recipients and LDs." Is not accurate nor consistent with Final Rule. It should be removed.

Tag X093: The consultative relationship information should be moved down to section 2.

Tag X093: The student supervision requirements appear to be entirely made-up, with no basis in the Final Rule. The center should decide its policies regarding how to make social services available, how to assure involvement of the multidisciplinary team in transplant and discharge phases (recipient) and pre-donation, donation, and discharge phases (LD), and how and who may perform psychosocial assessments. These statements should be removed.

Tag X094: Similarly, this section overextends "make available". Centers need to have policies and follow them to make nutrition assessments and counseling available. Those policies may vary, and the centers are best qualified to develop the best policies for their patients. We request removal of the new requirement.

Tag X099-X103: Please see the comments above regarding QAPI. This is a new rule and a substantial new burden. It is plainly not interpretive guidance of the transplant Final Rule.

Thomas E. Hamilton
Director, Survey and Certification Group
April 8, 2016
Page 9

Tag X102: In many places, and in comments made by CMS staff at the UNOS Transplant Management Forum, it appears CMS is suggesting that every single death and graft failure, whenever it occurs, requires a Root Cause Analysis. We are deeply troubled by this. Every single human being eventually dies. This means that we will be required to perform an RCA on every single transplanted patient. Even more troubling than the monstrous burden this creates (and the inevitable dilution of the strength of RCAs that will occur when they become routine administrative activities regarded rightly as a waste of time to check a regulatory box rather than the opportunity to learn and improve that they currently can be when limited to the cases that actually warrant it), recasting the inevitable and ultimate death of human beings as automatically constituting adverse events contributes to one of the drivers of elevated suffering, ineffective care, and cost in the US healthcare system. Death is the outcome of every human life. A transplant patient who had been at death's door and who instead receives additional years of good quality of life and who then passes on naturally should not be investigated as an "adverse event" to be "corrected" for the future. Such an outcome is exactly what we are hoping to achieve.

Further, death in and of itself plainly does not meet CMS' own definition of Adverse Event. "Note: As defined in CMS regulations at 42 CFR 482.70, an "adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof." Death is not the adverse event, the adverse event must cause death (or injury, or risk thereof). Nor is death always untoward and unanticipated. Indeed, it is anticipated that every patient will eventually die. Our goal is to help patients have as much quality and quantity of life as possible prior to that anticipated end. We request that there be no new requirement to perform a RCA on every death or graft failure outside of an adverse event as consistent with the CMS definition and the institution's own policy and that this be made explicit in the guidelines.

Tag X102: "Organizations utilize various terminologies to describe these occurrences, such as incidents, serious preventable events, serious safety events, never events, and sentinel events." These terms actually mean very different things and are not universal synonyms for adverse event. We are required at the hospital and transplant center level to investigate adverse events, which is defined clearly by CMS. It should be left at that.

Tag X103: The elements of thorough analysis change from prior delineation. We request clarity and consistency.

Tag X110: We request removal of: "The Director of a transplant program is permitted to delegate day-to-day operations to an Administrator." The Final Rule does not mention administrators, and provides no limitation on how a director may delegate operations, only that he or she must provide general supervision.

Tag X111: Same issues as X110.

Tag X112: The details in the IGs far exceed the Final Rule related to training. "Successful completion of an orientation program that provides an opportunity to raise

questions (for example, didactic, hands-on learning, direct observation), including: • Clinical assessment of transplant candidate/transplant recipients; • Clinical assessment of potential LDs/LDs (if applicable); • Monitoring for signs and symptoms of organ rejection, and transplant-related infection; • Monitoring for signs and symptoms of complications following living donation (if applicable); • Providing patient education related to signs and symptoms of organ rejection and complications following living organ donation; • Providing donor education related to complications following living organ donation; • Providing patient education about immunosuppressive therapy; and • Monitoring of immunosuppressive therapy” The Final Rule lists neither specific elements of training nor the manner of the training. That decision is best left to the experts at the transplant centers, as evidenced by this list which includes multiple elements that only apply to post-transplant or pre-transplant coordinators and which is missing elements most if not all of us would consider essential to orientation. We request the removal of any language mandating the content or teaching methodology regarding training staff.

Tag X112: Section three describes one approach to compliance with the Final Rule, not a requirement. Assuring coordinators receive ongoing training can be accomplished in a number of ways, many of which do not include scheduling internal training and taking attendance but rather leveraging more advanced and more individualized training from internal and external sources. Again, the details are deliberately – and best – left to individual centers. We request the removal of any language mandating the content or teaching methodology regarding training staff.

Tag X112: The contract nurse language appears to be an entirely made-up set of rules not present in the Final Rule. Again, this is best left to individual programs to create policies and procedures for assuring adequate training. We suggest striking all the text, except: “For transplant programs that use traveling nurses, contract nurses, or float pool nurses: Traveling, contract, or float pool nurses are expected to have specific training and/or experience in the care of transplant candidates/transplant recipients and potential LDs/LDs.”

Tag X114: The IGs need to account for one qualified transplant surgeon relieving another (should not require same surgeon be present whole case). Requiring attending surgeon presence for the whole procedure is a new requirement, but seems consistent with the Final Rule.

Tag X115: We request deletion of: “Review the program’s policies to ensure that proper delegation procedures are in place to formally transfer the primary transplant surgeons and primary transplant physician’s responsibilities to alternative qualified surgeons and physicians, if necessary. For example, the on-call schedule can be evidence of delegation.” The OPTN handles this through coverage plan. The presence of an approved primary surgeon or physician by the OPTN necessarily means the OPTN contractor has received an acceptable coverage plan. Surveyors can review this via TPQR rather than creating a duplicated burden.

Tag X115: We request amendment of “To verify that the primary transplant surgeon and primary transplant physician are immediately available, review the on-call schedule for the past month and compare the surgeons’ and physicians’ names to their place of residence in their personnel files to ensure that the response time is possible.” This needs to allow for alternatives to living within an hour (call-room, backup qualified MD, etc.). There is no Final Rule requirement on where transplant surgeons or physicians live.

Tag X115: We request amendment of: “The on-call transplant surgeon and transplant physician must be reachable by cell phone and/or pager, and must be able to be physically present on the unit within 60 minutes of notification to provide transplantation services.” The IGs should not be specifying technology. It is quite possible to comply with the Final Rule using methods other than cell phones / pagers (such as landline phones, and computer-based communications). Further, new technologies could be developed.

Tag X118: We request removal of: “There must be policies and procedures in place for CTC communication throughout the phases.” There is no Final Rule requirement for a policy on CTC communication. This is a new rule that would require public comment and burden analysis.

Tag X119: We request removal of: “Review their training and years of experience with transplantation, time with preceptor for transplant or any certifications with the American Board for Transplant Certification (ABTC) and, if applicable, living donation experience.” Although some (but not all) elements of this are somewhat supported elsewhere, none are supported by this tag, and some (e.g. ABTC certification) cannot be found anywhere in the Final Rule.

Tag X120: Post-discharge care was excluded from the Final Rule. We request removal of: “Transplant candidates/transplant recipients will require intensive follow-up for some period of time following the transplant depending on the type of transplant involved. This follow-up can include in-person visits, lab work, phone calls, etc. which may be performed either by the transplant program or by another entity that is charged with following the patient post-transplantation. There must be evidence that the CTC is involved in and ensures the coordination of the clinical aspects of any follow-up conducted by the transplant program. Increasingly, after the first 6 months, post-discharge care may be handled by a local physician. There must be evidence that the CTC ensured coordination of the clinical aspects of care throughout discharge planning, especially in instances where the care of the patient would be shared with the transplant recipient’s local physician, to appropriately transition follow-up activities.” Although we agree with most of this as best practice, it has no place in the IGs as it is out of scope. It would require rulemaking with public comment and burden analysis.

Tag X120: Post-discharge care was excluded from the Final Rule. We request removal of: “There are no minimum standards for follow-up with LDs. Post-donation follow-up activities are sometimes handled by a local physician; there must be evidence of the

coordinator's role in ensuring the effective transition of follow-up care. After the first 6 months, the frequency and intensity of involvement by the clinical transplant coordinator may decrease; however there must still be evidence of ongoing communication, intervention and coordination, as indicated by the care plan." Although we agree with most of this as best practice, it has no place in the IGs as it is out of scope. It would require rulemaking with public comment and burden analysis.

Tag X120: We request removal of: "Survey Procedures Review multidisciplinary care plan notes and progress notes in the transplant candidate/transplant recipient and potential LD/LD medical records to ensure that the CTC(s) fulfills the responsibilities of coordinating the clinical care of transplant candidates/transplant recipients and potential LDs/LDs by: • Addressing elements identified in the pre-transplant or pre-donation assessment and care plan; and in the peri-operative and postoperative care plans; • Educating patients, LDs, and families about treatment options and post-operative care or therapies as necessary; • Monitoring patients' and LDs' medical, surgical and psychosocial status and ensuring the provision and coordination of needed care; and • Providing feedback to other team members. Look for evidence that the CTC(s) carried out these responsibilities in all phases of transplantation and donation (as described in tag X082)." This section is far too prescriptive, including detailing where documentation must exist and specific tasks that may or may not be needed on each patient. This far exceeds the Final Rule, which prudently left the specifics of patient management to the judgment and policies of the transplant center experts. The surveyors should be reviewing the medical records to ensure there is evidence that CTCs are coordinating care in accordance with the center's evaluation, waitlist, and patient management policies, understanding that management of recipients pre-transplant and recipients and donors post discharge are all out of scope without new rulemaking.

Tag X121: There are typos in the acronym. We request inclusion in the job description OR policy, not specifying which. It is possible to use either job description or policy to comply with this requirement.

Tag X123: None of the IGs here relate at all to the tag, which describes the required knowledge and understanding the ILDA must demonstrate. They are related to documentation. Furthermore, they are not accurate. For instance: "Demonstrating knowledge of medical ethics means the following: • Ensuring the potential LD's/LD's welfare is of primary importance; • Respecting the decisions and autonomy of the potential LD/LD in his/her decision to donate and the care the potential LD/LD receives; • Understanding the donation process, acknowledging current and future risks for the potential LD/LD, and identifying the methods/ process to ensure that the potential LD/LD has the opportunity to ask questions and receive additional information about those risks; • Maintaining confidentiality of the communication between the potential LD/LD and the transplant program; • Setting and maintaining standards of competence and integrity; and • Ensuring that one's knowledge and skills concerning living donation and transplantation issues are up-to-date." These things do not demonstrate knowledge of medical ethics in any way. One could easily comply with these bullet points while being entirely ignorant of medical ethics.

Thomas E. Hamilton
Director, Survey and Certification Group
April 8, 2016
Page 13

Tag X123: Regarding the survey procedure: Nothing in Tag X123 can be reviewed in medical records. It relates to the qualification of the ILDA/ILDA team members. It would have to be demonstrated in education/training, competency assessment, policy, job description, and/or interview of the ILDA/ILDA team.

Tag X125: We request addition of an instruction to surveyors that policies and procedures detailing roles of team members is adequate and that those same details do not necessarily need to be specified in job descriptions.

Tag X125: We request removal of: "Review the training records of the multidisciplinary team members and the upcoming training schedules to ensure that the professional staff are provided with and have participated in comprehensive and ongoing transplant-specific training. The training should include areas such as: new technology, changes in the field of potential transplant candidate/transplant recipient and potential LD/LD care, other transplant-specific training sessions, updates and sharing best practices learned during relevant conference attendance, and other individual training opportunities required by the transplant program and overall hospital policies" As discussed in the program director tag, the manner of training and education should be left to the center to determine, and need not be education events at the center. The Final Rule does not detail specific training topics, nor may the IGs. The Final Rule correctly leaves that to the expert judgment of the center director. We request the removal of any language mandating the content or teaching methodology regarding training staff.

Tag X126: We request minor revision of: "A recipient's transplant program must have a copy of the Medicare approval letter for the transplant program providing LD care with which it has a contract or agreement and have documented evidence that the CMS website was reviewed prior to accepting the LD organ to ensure that the program is a Medicare-approved program." We suggest changing the underlined "and" to an "or".

Tag X139: We request removal of: "Common responsibilities for the transplant hospital should include (but are not limited to): • Providing current personnel contact information to the OPO, and notification of changes in key personnel; • Reporting inactivation and reactivation of transplantation services to the OPO; • Describing the method of communication with the OPO regarding organ acceptance or declinations; • Notifying the OPO of adverse events, as applicable; • Updating the UNetSM data system in a timely manner with information about transplant candidate/transplant recipients, potential LD/LD status, and determinations regarding organ offers; • Providing a surgical recovery team to recover donor organs as appropriate, and transmitting licensure and/or credentialing information for the recovering surgeons to the OPO; and • Outlining a process for identifying and resolving issues, complaints, and concerns. Common responsibilities for the OPO are expected to include (but are not limited to): • Determining the medical suitability of the potential donor; • Describing the method and timeliness of communication with the transplant hospital; • Notifying the transplant program of policy and procedure changes by the OPO that may affect organ recovery, placement, packaging, labeling, perfusion, and transport; • Ensuring the proper composition and credentialing of the organ recovery team; • Ensuring that proper

documentation is provided to the transplant program about the recovered organ(s), which includes the blood type and other identifying information; and • Outlining a process for identifying and resolving issues, complaints and concerns.” Review (if warranted) should be limited to adhering to the Final Rule, not looking for specific elements that “should” be present or are “common”. The Final Rule correctly leaves this to the judgment of the transplant center and OPO as they negotiate a contract or agreement.

Tag X152: We suggest modification of: “Discussions with the transplant candidate about the surgical procedure should occur on several occasions prior to the surgery. Prior to placement of the transplant candidate on the UNetSM waiting list, the transplant program must, at a minimum, provide an overview of the surgical procedure and potential risks. Prior to transplant surgery, a detailed discussion of the surgical procedure, anesthesia risks, risks involved with the use of blood or blood products, expected post-surgical course and possible complications; and benefits/risks of transplant surgery relative to other alternatives should occur.” The Final Rule does not require having “several” discussions. We request removing the first sentence.

Tag X155: We request removal of: “The program’s outcomes for LDs, including rate and type of complications (pre-discharge and long-term) and LD deaths. • National outcomes for LDs, as available.” These two items are not available from SRTR PSRs, and as such, exceed the Final Rule.

Tag X156: We request removal of specific disease. We are surprised that malaria made the list for instance, but this will change with new disease threats and should be left general and to the judgment of the experts at transplant centers who understand the credible disease transmission threats.

Tag X156: We are confused by this section: “After an organ offer is made to a transplant candidate, the transplant program must discuss with the transplant candidate the possible risks associated with transplantation of that specific organ. The discussion of risks should include any issues that could affect the success of the organ transplant (e.g., the condition of the organ), and any issues that could potentially place the health of the transplant candidate at risk (e.g., known high-risk behaviors in the deceased donor’s or potential LD’s background). This discussion should be documented prior to the transplant and again when the organ is determined suitable for a transplant candidate”. This appears to require discussion twice between the offer and transplant. This is not supported by the Final Rule, nor supported by any evidence or best practice of which we are aware. This constitutes new rulemaking and burden which would require public comment and burden justification. We request removal of the new requirement.

Tag X158: We request removal of: “This information should be provided to the transplant candidate after an organ offer is made to the transplant candidate and prior to the transplant candidate accepting the organ offer for transplant.” The Final Rule does not require centers to tell patients this twice. Further telling a patient immediately prior to transplant at a Medicare-approved center the consequences of having a transplant at a non-approved center makes no sense. It will serve only to create confusion.

Thomas E. Hamilton
Director, Survey and Certification Group
April 8, 2016
Page 15

Tag X161: We request removal of: “The potential LD must be advised that the transplant program cannot require him or her to pay for post-donation testing or examination for follow-up purposes. (See Tag X166).” Although we wholeheartedly support such a law, none exists, and IGs may not create new laws, appropriating authority that resides with the legislature.

Tag X162: We request removal of: “Discussions with a potential LD about the surgical procedure must occur on several occasions prior to surgery.” The Final Rule does not require several occasions of discussion.

Tag X165: The Final Rule requires that living donors be provided with “national and center-specific outcomes for living donors, as data are available.” We request that more prescriptive and confusing language such as “pre-discharge and long term” and “types of outcomes for LDs that are not calculated due to insufficient national data” are outside the Final Rule and should be removed.

Tag X168: There is no need to survey for the cited statement. It was errantly included in the Final Rule. We encourage CMS to go through the rulemaking process to remove this rule, and not to expend public funds nor impose burden on centers surveying for it.

Tag X186: We request removal of specifics and simplification of this section. It is far too prescriptive. This is not supported by the Final Rule or any evidence of which we are aware, and it constitutes a new documentation burden on centers and dialysis units which would require OMB burden justification.

As noted above, we have not had time to thoroughly review this document. We will have more comment once we have had more time to review, digest, and discuss with our members. But we wanted to call out some of the things that were apparent on early review, and considered problematic by our members. Given the short timeline and scale of concerns, we re-iterate our strong view that these IGs as written should not be made effective next week as planned. We would be happy to discuss any of this at your convenience. Thank you for your collaboration in making transplant as available, safe, and effective as possible for as many people as possible.

Sincerely,

A handwritten signature in black ink that reads "J S Allan". The signature is written in a cursive, flowing style.

James S. Allan, MD, MBA
President