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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

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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.

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

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 UNet^{SM}. 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 UNet^{SM} and transplant program's waiting list (if different from the list of patients on UNet^{SM})." What are surveyors going to be reviewing in UNET? In any case, surveyors should be

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

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 by a qualified social worker be made available, 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.

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.

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 UNet^{SM} 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 UNet^{SM} 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.

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.

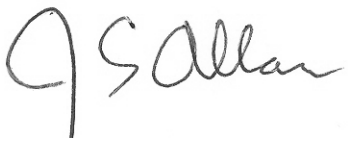
Tag X165: The Final Rule requires that living donors be provided with “national and center-specific outcomes for living donors, as data are available.” We request that more prescriptive and confusing language such as “pre-discharge and long term” and “types of outcomes for LDs that are not calculated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



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