October 4, 2017

Via E-mail

Mr. David Wright, Director
CMS Survey and Certification Group
Department of Health and Human Services
Attention: CMS-1656
PO Box 8013
Baltimore, MD 21244-1850

Re: Proposed Revisions to the Revised Interpretive Guidelines for the CMS Conditions of Participation for Transplant Centers

Dear Mr. Wright:

Thank you very much for the opportunity to provide comment on the proposed revisions to the revised Interpretive Guidelines for the CMS Conditions of Participation for Transplant Centers. We appreciate the changes that the Survey and Certification Group has made in response to our comments from last year and the opportunity to review this revised document.

While these guidelines are significantly improved, they continue in several places to exceed authority under the Final Rule and to place 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. In many instances, the review and implementation of new interpretive guidelines takes at least 1000 hours or more of work by QA staff. That does not include the time and effort by other departments. and all other transplant program staff. Maintenance of existing interpretive guidelines, policy updated, and staff education is at least another 1000 hours per year. As such, any additional burden would require request to the OMB OIRA process for additional burden. And any aspects that differ from the Final Rule must be promulgated through the rulemaking process, not interpretive guidance. We will note specific sections below which meet either or both of these concerns.

In several places, the proposed IGs reference center responsibility for ensuring that patients understand various things. It is not reasonable to expect centers to attest to a patient's understanding. We would revise these to require documentation that the patient verbalized understanding, or similar.

Definitions:
The transplant phases proposed differs from the Final Rule. The Transplant Phase has been artificially extended backward to the beginning of the evaluation. The Final Rule plainly envisioned pre-transplant, transplant, and discharge phases. In response to public comment, the requirements for a multidisciplinary care plan, for instance, were removed from the pre-transplant phase. Redefining the transplant phase now to include the pre-transplant phase clearly conflicts with the discussion on page 15228 of the Federal Register Vol. 72 No. 61 published March 3, 2007. It would

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also add burden to transplant centers not covered by the existing OMB ICR. We request restoration of the phases in the Final Rule with definitions that eliminate confusion/overlap between the phases. For instance:

Transplant Recipient Phases:
-Pre-Transplant Phase: Begins with evaluation for transplant, through decision to list, and if listed, includes time spent on the waiting list until removal or admission for transplant.
-Transplant Phase: Begins with the admission for transplant and ends after the recipient leaves the OR following the completion of the transplant procedure.
-Discharge Phase: Begins when the recipient leaves the OR following the completion of the transplant procedure and ends upon discharge from that inpatient hospital stay.

Living Donor Care Phases:
-Evaluation Phase: Begins with the first presentation by the potential donor to the transplant program and continues until the donor is admitted to the hospital for donation.
-Donation Phase: Begins with the admission for donation and ends after the donor leaves the OR following the completion of the donation procedure.
-Discharge Phase: Begins when the donor leaves the OR following the completion of the donation procedure and ends upon discharge from that inpatient hospital stay.

Tag X-051
The addition of the words “hospital approved” to the first sentence risks misinterpretation by surveyors to require approval outside the transplant program without adding anything. We suggest removing those words: by definition, a center’s selection criteria are “hospital approved”. The final sentence would require the selection criteria follow the same process as policies which is not required by the Final Rule and would add additional burden. We suggest re-writing it as:

“Transplant programs must have policies that describe the process for creating and modifying written selection criteria.”

The requirement to “define all the factors that are considered…” is too prescriptive. There are always rare factors that come into play, and a policy needs flexibility.

Tag X-052
The statement that “the decision to place a candidate on the waitlist must be reached by a multidisciplinary review and decision”, while common practice, is not required by the Final Rule and may not be added by interpretive guidance. Indeed, the Federal Register makes clear the exclusion of the multidisciplinary care team from the pre-transplant phase for recipients. This should be removed and, if CMS has concern that centers are not using multidisciplinary teams to make selection decisions, put forward through the rulemaking process.

Tag X-055
The statements that “the multidisciplinary team considered” and “confirm multidisciplinary agreement on the decision”, are not required by the Final Rule and may not be added by interpretive guidance. Indeed, the Federal Register makes clear the exclusion of the multidisciplinary care team from the pre-transplant phase for recipients. This should be removed and, if CMS has concern that centers are not using multidisciplinary teams to make selection decisions, put forward through the rulemaking process.

Tag X-056
We would not suggest prompting patients with questions about whether they requested written selection criteria and received them. In practice, few ask. If they bring it up or there is a complaint, we suggest review; otherwise, we would limit this to review of the medical record.

Tag X-058
The final bullet appears suited to recipients, not donors. Suggest rephrasing along the lines of "Mental health history, including substance and alcohol use or abuse and how it may affect the recovery from donation."

Tag X-060
See comment on patient understanding from introduction.

Tag X-073
The requirement for verification in the operating room exceeds the Final Rule, which only requires verification after the organ arrives at the hospital. Requiring the surgeon to remember time of verification is unrealistic. We suggest the other licensed professional document the time, and surgeon be allowed to attest to the sequence of events without recalling the time. We appreciate the clarification of "other vital data".

We suggest removing sexist language referring to surgeon as "his".

Tag X-074
The statement "Verification of correct organ for the correct recipient and verification that the blood type and other vital data are compatible with the potential recipient must occur immediately before the removal of the living donor organ(s)." is confusing following the interpretive guidance above it. This seems to assume that that "immediately before organ removal" and "induction of anesthesia: are the same time points. That guidance is intended to cover that requirement. If it isn't, then it all needs to be removed- as it would constitute a second verification, not interpretation of the immediately before verification. We recommend that this language be reviewed for consistency in all ABO section.

The "after arrival in the OR" requirement is not present in Final Rule, and cannot be added through interpretive guidance.

We suggest using recovery surgeon for donor procedure to differentiate from recipient surgeon.

Tag X-081
See comment from definitions regarding phases.

The requirements related to living donors at a different center differ from prior CMS guidance under S&C Memo 11-40-Transplant. We suggest using the language from that memo here.

As we have noted, these prescriptive requirements around the multidisciplinary care team exceed the Final Rule. Quoting the Federal Register:

"We believe the multidisciplinary patient care planning provision proposed at § 482.94(c)(4) is <u>flexible and general in nature</u>. We believe the requirements will allow a transplant center to assemble a multidisciplinary patient care team using in-house hospital staff, which should create little or no extra burden."
p. 15228 Federal Register. Vol. 72, No. 61 (underline added)

Although multidisciplinary care is mandated by the Final Rule, these requirements are overly prescriptive and not consistent with the "flexible and general" language in the comments of the Final Rule authors in the Federal Registry. Furthermore, there is no requirement that each discipline personally see each patient. It is explicit that they be available to all inpatients and nothing more. Any additional requirement would require rulemaking, and the significant additional burden placed on centers would need to be submitted through the OMB OIRA process for public regulatory burden.

Transplant Centers must develop their own policies of how the multidisciplinary team functions and how care is planned but they should be free to specify how and when the disciplines contribute to this care. Again, quoting the Federal Register:

"Under the final rule and as we proposed, transplant centers are responsible for making social services furnished by a qualified social worker available to all transplant patients, living donors, and their families while a transplant patient or living donor is hospitalized."
p. 15231 Federal Register. Vol. 72, No. 61 (underline added)

"This final rule requires transplant centers to provide nutrition services to transplant recipients and living donors only during their inpatient stay. For example, a transplant recipient may need to be counseled on the modification of his or her dietary regimen after organ transplant or a living donor may need to be counseled for his or her temporary adjustment in nutritional intake after living organ donation.

"Although living donors are usually healthy individuals, we believe they should receive the same care provided to transplant recipients. Under the final rule and as proposed, transplant centers are responsible for making nutritional assessment and dietary counseling services furnished by a qualified dietitian available to all living donors while they are hospitalized for organ donation."
p. 15232 Federal Register. Vol. 72, No. 61

Any requirements regarding number of visits and manner of documentation exceed Final Rule authority and require new rulemaking and burden justification. Furthermore, the differentiation found in the Final Rule between living donors and recipients is not explicit in these revisions. Multidisciplinary care IS mandated in the donor evaluation. The form and documentation of each disciplines' contribution to care in the donor evaluation should be specified in transplant center policy.

Tag X-081
The language around a re-listing is confusing. Suggest leaving to OPTN.

Tag X-091
See prior comments on the excessively prescriptive rules around multidisciplinary care team. The discharge requirements are also excessively prescriptive and should be left to the centers and their professionals.

Tag X-092 and X-093
Please note the prior comments on phases where the multidisciplinary team is required to be involved and revise to limit to the transplant and discharge phases for recipients.

Tag X-099
The language around coordination of transplant and hospital QAPI programs exceeds any Final Rule regulations and should be removed. If the center demonstrates a QAPI program that meets these requirements, and the hospital maintains a compliant hospital QAPI program, the regulations are satisfied.

The language is extremely all-encompassing with its repeated use of the word “all”. Transplantation is complex, and centers must use discretion in what to track and where to target improvements. It is inaccurate to suggest these QAPI regulations added virtually no burden to transplant centers when in fact most have had to hire additional staff just to comply. The original Final Rule stated that compliance with the COPs would cost centers “less than $56,000 the first year and less than $21,000 in subsequent years.” Some large transplant programs now have 5-7 professionals working in the QAPI section of transplant programs. We are wary of any further broadening without OMB ICR review.

Tag X-102
The phrase “*Transplant patient deaths and graft failures are considered to be adverse events*” should be removed. With this statement, CMS is suggesting that every single death and graft failure, whenever it occurs, constitutes an adverse event. We are deeply troubled by this. Organs have various expected life spans, and 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 enormous burden this creates (and the inevitable dilution of the strength of adverse event analysis 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), 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. In essence, the decision to treat a patient death or graft failure as an adverse event should be triggered when events surrounding a patient’s death or graft failure meets CMS’s definition of an adverse event.

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.

The Final Bullet is confusing. We would re-write as “Reporting any suspected or confirmed donor-derived disease transmission as required by OPTN policy.”

Tag X-103
The final two bullets belong under X-104.

Tag X-112

The evidence of coordination section is overly prescriptive, in excess of current practice (as such creating new burden which must be vetted through the OMB OIRA process), and not desirable. The hospital and the director are correctly allowed by the Final Rule to determine the method of this coordination, which often – and quite appropriately – involves delegation.

Tag X-114
We defer to the ASTS on this requirement, but note it is more prescriptive than the Final Rule requires, and differs from the practice at some centers, which would require additional burden analysis. The cost of requiring additional physical presence by a highly compensated transplant surgeon is significant and must be justified to the OMB.

Tag X-116
This guidance is new and does not seem to clearly address any likely concern. Suggest letting this tag speak for itself, or saying instead “Surgical services may be provided via consultation by other surgeons.”

Tag X-117
We appreciate this clarifying guidance.

Tag X-119
While we generally agree with this, the final sentence is problematic as it requires prior experience with transplant patients. Centers should continue to be allowed to use preceptorships and other orientation practices to introduce coordinators with good experience and knowledge outside transplant to the specifics of transplantation. Most centers have provisions for orienting coordinators without transplant experience, and so requiring only transplant-experienced coordinators creates substantial burden which would need to be justified to the OMB.

Tag X-120
The prescriptive requirements for the manner of coordination with dialysis centers exceeds the intent of the Final Rule, as described in the federal register. This should be left to center policy and practice, and the ESRD network. See the discussion on pages 15229 and 15230 of the Federal Register Vol. 72 No. 61.

Tag X-121
The requirement for ILDA/ILDAT interview prior to initiation of evaluation is an invented requirement consistent neither with the Final Rule nor current practice. As such, it would require rulemaking and OMB ICR submission.

Tag X-122
The extremely restrictive interpretation differs with current practice, prior guidance from CMS, and the plain-language meaning of “routine”. Making this change is not necessary to protect donors, and it would require both rulemaking and OMB submission. The further requirement that they not be part of the transplant program is an entirely new rule, and not a desirable one as the ILDA/ILDAT necessarily need to work closely with the transplant team to protect and counsel the donor effectively.

Tag X-123
This tag pertains to the knowledge and understanding of the ILDA/ILDAT, not the information provided to each potential donor. The review of this tag should be constrained to review of training materials, policies and procedures, job descriptions, and ILDA/ILDAT interview. X-124

specifies what the ILDA/ILDAT must do. Indeed, these requirements conflict with your guidance in X-124 that preclude discussion of recipient outcomes (as likely does HIPAA).

Tag X-124
We disagree with the statement that ILDA/ILDAT not advise on the donor's decision. While they cannot decide for the donor, they certainly are advising the donor in order for that donor to make an informed decision.

We disagree with the requirement the discussion may not address the needs of the recipient. It is impossible to assess motivation for donation without discussing the needs of the recipient. While the donor must be primary, none of this would be happening absent a needy recipient and a donor motivated to address that need.

Tag X-125
We strongly disagree with this revision to the interpretive guidelines. Transplant patients have uniquely complex pharmacological needs. Pharmacists require extensive post-doctoral training to develop the expertise necessary to serve this patient population. While many physicians, advanced nurse practitioners, and physician assistants certainly understand basic principles of pharmacology, transplant patients have greater pharmacotherapy needs which demand the skills of a transplant pharmacist who has undergone specialized training. Pharmacists provide knowledge of pharmacology, optimal dosing, appropriate monitoring, management of drug interactions, and management of medication side effects while contributing to program-wide initiatives and clinical program developments. Transplant pharmacists are best positioned to "translate" an ideal theoretical medication regimen into one that is practical (i.e. scheduling medications for optimal outcomes considering drug interactions and pharmacology, medication adjustments per insurance/hospital formulary or affordability) and provide the corresponding medication education and training for the patient to prevent rejection and readmission.

It has been well demonstrated that the work of transplant pharmacists increase adherence rates and improve transplant outcomes.[1,2,3,4,5] The transplant pharmacist's highly specialized training, designed to maximize patient outcomes in this unique patient population, cannot be replicated by other professions on the multidisciplinary team. A transplant multidisciplinary team without the contributions of a pharmacist's specialized training and expertise would result in suboptimal outcomes. We respectfully implore you to reconsider the proposed changes.

Tag X-150
The assignment of responsibility for informed consent to the transplant physician is not found in the Final Rule. The center's responsibility is for achieving informed consent, and it may do so using the individuals it considers most appropriate and qualified to do so.

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1 Chisholm MA, et al. Impact of clinical pharmacy services on renal transplant patients' compliance with immunosuppressive medications. Clin Transplant 2001; 15: 330-6.
2 Chisholm-Burns MA, et al. Impact of clinical pharmacy services on renal transplant recipients' adherence and outcomes. Patient Prefer Adherence 2008; 2: 287-92.
3 Stemer G, et al. Clinical pharmacy services and solid organ transplantation: a literature review. Pharm World Sci 2010; 32: 7-18.
4 Alloway RR, et al. Evolution of the role of the transplant pharmacist on the multidisciplinary transplant team. Am J Transplant 2011; 11: 1576-83.
5 Trofe-Clark J, et al. Value of solid organ transplant-trained pharmacists in transplant infectious diseases. Curr Infect Dis Rep 2015; 17: 475.

Tag X-152
The assignment of responsibility for informed consent related to the surgical procedure to the transplant surgeon is not found in the Final Rule. The center's responsibility is for achieving informed consent, and it may do so using the individuals it considers most appropriate and qualified to do so.

Tag X-153
There is no requirement – nor is it standard practice nor even desirable – to complete this consent element prior to evaluation. Indeed, it is typically provided as part of the evaluation process, which is fully compliant with the Final Rule.

Tag X-154
There is no requirement – nor is it standard practice nor even desirable – to complete this consent element prior to evaluation. Indeed, it is typically provided as part of the evaluation process, which is fully compliant with the Final Rule.

Tag X-155
There is no requirement – nor is it standard practice nor even desirable – to complete this consent element prior to evaluation. Indeed, it is typically provided as part of the evaluation process, which is fully compliant with the Final Rule.

The specific website-related requirements are not supported by the Final Rule, and they ignore patients who lack the Internet-access and/or facility with technology to get information from the SRTR site. Each center should decide how best to provide this information to its patients.

Tag X-156
There is no requirement – nor is it standard practice nor even desirable – to complete this consent element prior to evaluation. Indeed, it is typically provided as part of the evaluation process, which is fully compliant with the Final Rule.

Tag X-159
The assignment of responsibility for informed consent to the physician is not found in the Final Rule. The center's responsibility is for achieving informed consent, and it may do so using the individuals it considers most appropriate and qualified to do so.

Tag X-161
As noted elsewhere and in general comments, a process cannot ensure understanding. It can mandate informing and documenting verbalization of understanding.
The second paragraph is out of place – it relates to selection, not informed consent.

Tag X-162
The assignment of responsibility for informed consent related to the surgical procedure to the transplant surgeon is not found in the Final Rule. The center's responsibility is for achieving informed consent, and it may do so using the individuals it considers most appropriate and qualified to do so.

The two bullet points related to the recipient should be removed as they constitute HIPAA violations (as noted in the reverse elsewhere), unless they are made general to typical recipients. Further, providing recipient length of stay is an extremely strange requirement unlikely to be relevant to donor consent.

Tag X-163
IGs should make clear this information must be general, not recipient-specific unless authorized by the recipient. Otherwise it would violate HIPAA.

Tag X-164
This should be re-written to focus on donor risks, not transplant risk.
There is no requirement – nor is it standard practice nor even desirable – to complete this consent element prior to evaluation. Indeed, it is typically provided as part of the evaluation process, which is fully compliant with the Final Rule.

Tag X-165
There is no requirement – nor is it standard practice nor even desirable – to complete this consent element prior to evaluation. Indeed, it is typically provided as part of the evaluation process, which is fully compliant with the Final Rule.
The specific website-related requirements are not supported by the Final Rule, and they ignore patients who lack the Internet-access and/or facility with technology to get information from the SRTR site. Each center should decide how best to provide this information to its patients.

Tag X-170
We suggest specifying that this only applies to centers with a single surgeon and/or physician.

Tag X-186
The prescriptive requirements for the manner of coordination with dialysis centers exceeds the intent of the Final Rule, as described in the federal register. This should be left to center policy and practice, and the ESRD network. See the discussion on pages 15229 and 15230 of the Federal Register Vol. 72 No. 61.

We thank you for the opportunity to provide comment and your collaboration in making transplant as available, safe, and effective as possible for as many people as possible. We look forward to working with you in this area in the future. Please let us know if you have any questions or would like to discuss any transplant-related issues further.

Sincerely,

Ronald G. Gill
President