To: The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services

From: Dr. Emily Blumberg, President

Date: July 18, 2019

RE: CMS Transplant Program Survey Activity Transition (March 29, 2019 memo)

On behalf of the American Society of Transplantation (AST), representing a majority of medical professionals engaged in the field of solid organ transplantation, we applaud your leadership and continuous efforts to improve the nation's healthcare delivery system. I write on behalf of the Society to ask CMS to address concerns we have with new Transplant Center interpretive guidelines. The CMS Center for Clinical Standards and Quality/Quality, Safety & Oversight Group has issued guidance to state surveyors, who as of January 1, 2019, have been designated responsibility for surveying participating transplant centers on the Conditions of Participation for Transplant Centers. The March 29, 2019 memorandum has reference number QSO-19-11-Transplant.

Our specific concerns are detailed below. As a high-level summary, the AST believes that, in many places, these interpretive guidelines exceed interpretation and instead constitute the establishment or expansion of new policy. First, regulations only can be changed by publishing proposed rules in the Federal Register and soliciting public comment. To our knowledge, this was not done with these guidelines. Second, these guidelines place significant additional burden on transplant centers. Compliance with the Paperwork Reduction Act requires that additional burden be estimated and submitted for review by the White House Office of Management and Budget. To our knowledge, that was not done for these regulations. Finally, as these constitute new regulations, they are required to have two offset reductions in regulation, as well as assessment on cost neutrality, as required by Executive Order 13771. To our knowledge, no offsets were made nor were additional costs approved.

We believe the public comment and burden review process exists to ensure regulations are vetted by those people who are affected by them, which in turn assures they are well-crafted to best protect patients and direct limited healthcare resources where they will do the most good. While we are sure these new IGs are well-intended, in many places they run counter to the interests of patients, and they create substantial new costs to transplant centers absent any evidence such costs will have any return on investment in favor of quality and safety. We urge CMS to roll back the changes listed below to ones consistent with the final rule and current best practice. If CMS believes any of the regulations need to be changed, we would be eager to collaborate with you to propose evidence-based rule changes that make sense for patients and that will be received favorably through a public comment and burden analysis process.

We would be happy to provide further feedback or clarification on our specific comments in writing or at a mutually convenient call or meeting. Thank you for your attention to this, and your partnership in achieving the right regulations for our field.

Specific Comments:

TPQR Report
The interpretive guidelines make reference to information obtained from OPTN/SRTR in advance of survey which the center is not permitted to challenge. To our knowledge, centers are not able to see these reports in advance, and so if there are errors, that would be a surprise to the center at time of survey. We would request that CMS ask the OPTN/SRTR to make these reports available on demand or periodically via their secure web site.

Definitions and Clarifications, Transplant Phases
These phase definitions do not align with actual practice, conflict with each other, and differ from the explicit intent of the Final Rule. Specifically, the discussion in the Federal Register makes it very clear that the evaluation/pre-transplant phase was excluded from many of the regulations for transplant candidates/recipients. This is why living donation has three phases and recipients only two. CMS is attempting to reverse this rulemaking decision by redefining the transplant phase to include a phase the Final Rule explicitly intended to exclude. It also does not align with any understanding of the transplant phase. We would suggest rewriting as follows:

Definitions and Clarifications
Transplantation/Donation Phases—
Transplant Recipient Phases:
• Transplant Phase: Begins when the potential candidate is admitted to the transplant hospital for transplantation and continues through the completion of the transplantation surgery and inpatient post-operative recovery from surgery.
• Discharge Phase: Begins once the multidisciplinary team initiates discharge planning and continues through to the discharge from the inpatient stay that includes the transplant procedure.

Living Donor Care Phases:
• Evaluation Phase: Begins when the potential donor consents to undergo evaluation for donation and continues until the time the donor is admitted to the transplant hospital for donation.
• Donation Phase: Begins when the potential candidate is admitted to the transplant hospital for donation and continues through the completion of the donation surgery and inpatient post-operative recovery from surgery.
• Discharge Phase: Begins once the multidisciplinary team initiates discharge planning and continues through to the discharge from the inpatient stay that includes the donation procedure.

Guideline §482.90
This guideline requires selection criteria to include “all the factors that are considered”, which is not possible. Variation in human biology inevitably creates situations in which transplant centers must exercise judgment beyond written criteria which cannot anticipate every theoretically possible combination of factors. Additionally, the requirement that the selection criteria follow hospital policy approval process exceeds any Final Rule requirement and is inconsistent with practice in that selection criteria do not have the force of policy at all hospitals. Finally, requiring the written criteria to include justification is not a requirement of the Final Rule and as such constitutes additional rulemaking and burden. We suggest re-writing as follows:

Transplant programs are required to develop their own selection criteria to determine suitability for organ transplantation and living donation. There must be evidence that the written selection criteria are followed for the selection of transplant candidates to be placed on the transplant waitlist and, if applicable, potential living donors. Any changes to the written selection criteria must be approved according to a process defined in the center’s policies and procedures.

Guideline 482.90(a)(4)
While we agree that if any patient or dialysis facility has requested the written criteria CMS may verify that they received them, in practice very few patients or facilities make such requests, and random phone calls, especially to patients, are unlikely to yield meaningful assessment but are likely to confuse patients. We would suggest review of this tag be limited to assuring a center's policies and procedures require provision of written selection criteria upon request, as well as investigation of any complaints and any records in which surveyors observe documentation of such a request.

Guideline §482.90(b)(3)
It is not possible for a hospital to determine that a donor understands risks, only that they are able to articulate understanding. We propose re-writing as:

"Informed consent" means the individual participates in his or her health care decision-making through a process which:
a) provides the living donor with information about the decision to donate and the procedures, alternatives, risks, benefits and other pertinent information;
b) is provided to the living donor in a manner suitable for comprehension;
c) includes documentation by the hospital that the potential living donor can articulate his/her understanding of the information above; and
d) ensures voluntary consent by the living donor.

Guideline §482.92(b)
The requirements of timing related to the arrival in the OR and induction of anesthesia are additions to the Final Rule requirements and as such would require rulemaking and burden analysis. Additionally, we would appreciate an interpretive clarification that "transplanting surgeon" in the case of a living donor refers to the recovering surgeon as otherwise paired exchange with other hospitals would be impossible. We also would appreciate clarification that OR refers to the OR suite to allow for cases in which anesthesia is initiated in a pre-operative holding area such that if a center wishes to have the patient participate in the verification it can do so without running afoul of the regulations.

Guideline §482.94
Please see our comments regarding definitions/clarifications regarding phases.

The requirement that a transplant center take responsibility for living donors at other centers is unsupported by the Final Rule and directly conflicts with prior CMS guidance (specifically a memorandum with Ref: S&C-12-19-Transplant issues March 9, 2012) regarding paired exchange. It also is not realistic, best practice, nor beneficial. So long as living donor recovery takes place at a CMS-approved transplant hospital, that hospital has under this regulation, and should retain, responsibility for the donor and all related compliance. A center should only take on responsibility for compliance related to the living donor if it does so through an arrangement with a hospital that is *not* a CMS-approved transplant center.

Guideline §482.94(c)(3)
The guidance related to the start of evaluation clearly conflicts with the Final Rule regarding phases (see our prior comments), and this tag itself which explicitly refers to patients admitted for transplant. New rulemaking and burden analysis would be required for this guidance to be enforceable. We suggest revising as follows:

A multidisciplinary care plan includes ongoing assessments to identify any new patient needs and/or to determine if any currently identified patient's needs have changed. A multidisciplinary team must be identified for each patient at the time of admission to the transplant hospital for transplantation. This

multidisciplinary team participates in the patient care planning from admission through discharge. The methods for assuring involvement and documentation should be defined in a transplant center's policies and procedures.

Guideline §482.98(a)(1)
This guideline well exceeds the Final Rule requirements and as such would require rulemaking and burden analysis. Moreover, it reflects a lack of understanding of nursing as a separate discipline from medicine in suggesting that a physician is qualified to assess the competency of a nurse. Nursing competency should be assessed by nursing leaders, not physicians. In addition to failing to recognize the discipline of nursing and exceeding authority under the Final Rule, this guidance is impractical under collective bargaining agreements and other arrangements at hospitals (as most transplant hospitals are) where the physicians and nurses are employed by different corporate entities. We would not propose an IG for this tag: we believe the text of the Final Rule sufficiently guides surveyors.

Guideline §482.98(a)(3)
We believe this guidance exceeds the Final Rule in the requirement that the attending surgeon be physically present for the entire operation. We base this on the fact that the OMB review of these regulations indicated they were covered by existing best practice. Had the intention been (or if it is now) to require the surgeon to spend this additional time in the Operating Suite, an assessment is necessary to ascertain the additional cost of surgeon time under this regulation, and such burden must be reviewed by OMB, and possible offset by reduction elsewhere. It is not standard practice that surgeons be present for the entire operation; the current standard of care requires the attending surgeon be present for key aspects of the procedure.

Guideline §482.98 (d)
The requirement to have ILDA interview potential donors prior to evaluation is obviously rulemaking and burden imposition. It is clearly outside the current standard of care. If CMS wishes to make this rule, it needs to do so through rulemaking. The AST, and we suspect other professional organizations, would oppose this as we have achieved extremely successful protection of living donor rights through an ILDA integrated in the process, not attempting to work with patients prior. In addition to a subsequent requirement that even further weakens the ILDA/ILDAT role, we believe this regulation would confuse patients and make it more challenging for transplant centers to support and educate living donors.

Guideline §482.98(d)(1)
This guidance obviously directly conflicts with the rule itself. Any plain reading of the rule's inclusion of "on a routine basis" can only reasonably be interpreted to mean that occasional involvement is permitted, otherwise the clause would have no meaning. This is supported by the discussion of the Final Rule in the Federal Register. Similarly, the requirement the ILDA/ILDAT not be associated with the transplant program in any capacity is an entirely fabricated new regulation that has gone neither through rulemaking nor burden assessment. It also makes compliance with the rest of the tags impossible as the transplant program cannot assure the training and competence of an ILDA/ILDAT if it is not permitted to be associated with that person or team. This guideline would have to be proposed as a rule, and if it were, we would strongly oppose it as not being in the interest of donors by removing the critical protections of centers' obligations to train, support, and provide excellent ILDA/ILDATs for their patients.

Guideline §482.98(e)
In this current iteration, the guidelines limit access to essential services and expertise provided by a transplant pharmacist as part of the multidisciplinary transplant team. We agree that pharmacology expertise can be shared by multiple members of the team, similarly to psychosocial and nutrition knowledge. However, CMS has reaffirmed this level of expertise needs to be provided by qualified social workers and dietitians to ensure the highest quality of patient care. The presence of a transplant

pharmacist's unique expertise in clinical pharmacology and pharmacovigilance yields significant value to solid organ transplant donors and recipients. Over the last 20 years, transplant pharmacists have established unique, integrated service models in transplantation that run in tandem and are supplemental to the expertise wielded by other providers. These services have been established and maintained with support from transplant providers as they stand unique and independent from their own clinical pharmacology knowledge.

Transplant pharmacists provide expertise in pharmacokinetic and pharmacodynamic principles that allow for optimal dosing, appropriate monitoring, accurate management of drug interactions, and mitigation of adverse effects. Additionally, transplant pharmacists possess the skill set to supply highly specialized pharmacotherapy services to potentially vulnerable populations, including low health literacy, limited social support, and pediatric recipients. Transplant pharmacist integration into multidisciplinary teams has decreased medication-associated adverse events and opportunistic infections. [1-3] Transplant pharmacist-led programs in the ambulatory setting have improved the management of chronic disease states and public health initiatives.[4-8] Additionally, transplant pharmacists apply their unique expertise in contributing to institutional initiatives drug therapy protocols, quality improvement, research and clinical program development.[9] The transplant pharmacist is the team member best positioned to "translate" a desired medication regimen into one that is practical, safe, and affordable. Transplant pharmacists provide medication education to patients and caregivers which is critical for preventing rejection, adverse drug effects, and readmissions.[10-11] The work of transplant pharmacists increases adherence rates, decreases mortality, and improves transplant outcomes.[9, 12-16] Transplant pharmacists provide pre-transplant evaluation, assessing for pharmacotherapeutic contraindications to transplantation and providing pre-emptive recommendations relating to post-transplant medication management.[17]

Among all of the transplant practitioners, pharmacists and pharmacologists have the greatest exposure to clinical pharmacology during their professional training. It is this pharmacy-specific training that allows for the above benefits; this training provides a depth and breadth of pharmacology knowledge that is not shared to the same degree among physicians, advanced nurse practitioners, nor physician assistants. As the demand for transplant pharmacy services has increased, the transplant pharmacist community has better defined their training opportunities and practice models as well as expanded the number of transplant pharmacy residencies to meet the demand.[9,18-19] Additionally, a newly developed Solid Organ Transplant Pharmacist Board Certification offers a novel opportunity for training and education for pharmacists working with transplant teams.[20]

Since the initial iteration, the use of "pharmacology" rather than "pharmacist" in CMS guidelines has been challenged.[21] We agree that a clinical pharmacologist would provide appropriate pharmacology expertise. A transplant multidisciplinary team without the contributions of a transplant pharmacist's specialized training and expertise would result in suboptimal outcomes and introduce quality and outcome disparities between centers that are able to provide transplant pharmacists expertise versus those that cannot or choose not to.

Guideline §482.102(a)(3)
The requirement to discuss alternatives should not be made prior to evaluation: it is necessary to evaluate the patient to understand the alternatives given the patient's specific situation.

Guideline §482.102(a)(5)
The guidance far exceeds the regulation. The regulation requires providing the data, not resources to understand it. That is a new rule and new burden that must go through the rulemaking and burden analysis process. Further, the SRTR website relies on advanced statistics. It is not possible for centers to explain those analyses to patients unless both the center staff and patient have training in statistical methods. The SRTR itself has both the contractual obligation and the competence to explain its reports to patients and shifting that burden to centers is not in the interest of patients, not permitted as a

requirement under any federal regulation, and has not been assessed by the OMB for cost burden placed on transplant centers.

Guideline §482.102(b)(3)
This contains multiple references to the recipient. We assume this is a cut-and-paste error. We suggest correcting to refer to the donor.

Guideline §482.102(b)(4)
It violates the HIPAA rule to discuss the specific alternatives for that recipient. We believe the regulation should be left as is and centers can discuss alternatives to living donor transplantation in general terms.

Guideline §482.102(b)(6)
See our comment on **Guideline §482.102(a)(5)** above.

Guideline §482.104(a)(cont'd)
This is overly prescriptive in suggesting what is "usually" included, which may be taken by state surveyors as a requirement. It also requires bi-directional communication, half of which is outside the control of the center. We believe this rule needs no interpretive guidance as it specifically leaves it to the center to develop a compliant policy and procedure.

Again, we appreciate the opportunity to comment on these interpretive guidelines and your continued support of our patients. Please let us know if you have questions or wish to discuss any of these points further.

1. Taber DJ, et al. Improved patient safety and outcomes with a comprehensive interdisciplinary improvement initiative in kidney transplant recipients. Am J Med Qual 2013; 28: 103-12.
2. Leape LL, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. JAMA 1999; 282: 267-70.
3. Henselr D, et al. Impact of electronic health record-based, pharmacist-driven valganciclovir dose optimization in solid organ transplant recipients. Transpl Infect Dis 2018; 20: e12849
4. Newland DM, et al. Positive impact of a pilot pharmacist-run diabetes pharmacotherapy clinic in solid organ transplant recipients. Diabetes Spectr 2018; 31: 167-76.
5. Chisholm MA, et al. Effect of clinical pharmacy services on the blood pressure of African-American renal transplant patients. Ethn Dis 2002; 12: 392-7.
6. Migliozzi DR, et al. Achieving blood pressure control among renal transplant recipients by integrating electronic health technology and clinical pharmacy services. Am J Health Syst Pharm 2015; 72: 1987-92.
7. Pinelli NR, et al. Pharmacist managed diabetes and cardiovascular risk reduction clinic in kidney transplant recipients: bridging the gap in care transition. Diabetes Res Clin Pract 2014; 106: e64-7.
8. Carthon C et al. Impact of a pharmacist-led vaccine recommendation program for pediatric kidney transplant candidates. Pediatr Transplant 2017; 21: e12989.
9. Alloway RR, et al. Evolution of the role of the transplant pharmacist on the multidisciplinary transplant team. Am J Transplant 2011; 11: 1576-83.
10. Musgrave CR, et al. Improving transplant patient safety through pharmacist discharge medication reconciliation. Am J Transplant 2013; 13: 796-801
11. Schnipper JL, et al. Role of pharmacist counseling in preventing adverse drug events after hospitalization. Arch Intern Med 2006; 166: 565-71.
12. Chisholm MA, et al. Impact of clinical pharmacy services on renal transplant patients' compliance with immunosuppressive medications. Clin Transplant 2001; 15: 330-6.
13. Chisholm-Burns MA, et al. Impact of clinical pharmacy services on renal transplant recipients' adherence and outcomes. Patient Prefer Adherence 2008; 2: 287-92.
14. Stemer G, et al. Clinical pharmacy services and solid organ transplantation: a literature review. Pharm World Sci 2010; 32: 7-18.
15. Trofe-Clark J, et al. Value of solid organ transplant-trained pharmacists in transplant infectious diseases. Curr Infect Dis Rep 2015; 17: 475.
16. Sam S, et al. Roles and impact of the transplant pharmacist: a systematic review. Can J Hosp Pharm 2018; 71: 324-37.
17. Maldonado AQ, et al. Assessing pharmacologic and nonpharmacologic risks in candidates for kidney transplantation. AM J Health Syst Pharm 2015;72:781-93.
18. *American Society of Health-System Pharmacists Guidelines on Pharmacy Services in Solid Organ Transplantation. https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/pharmacy-services-in-solid-organ-transplantation.ashx?la=en&hash=470429B2521E82665A477EA95443104BD43B16C9 (accessed 2019 June 19).*
19. *American Society of Health-System Pharmacists Required Competency Areas, Goals, and Objectives for Postgraduate Year Two (PGY2) Solid Organ Transplant Pharmacy Residencies.* https://www.ashp.org/-/media/assets/professional-_development/residencies/docs/pgy2-transplant-cago-2017.ashx?la=en&hash=1B1C07A56083EA715EDEBA0474D72D 45 FFC0B1DF *(accessed 2019 June 23).*
20. Board of Pharmacy Specialties. Solid Organ Transplantation Pharmacy Recognized as New Specialty. https://www.bpsweb.org/2018/08/22/solid-organ-transplantationpharmacy-recognized-as-new-specialty *(accessed 2019 June 5)*.
21. Centers for Medicare & Medicaid Services. Final Rule: Hospital Conditions of Participation:

Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants. March 30, 2007. Available at: www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Downloads/trancenterreg2007.pdf.