

**Proposed Questions for Stakeholder Engagement Meeting
Dialysis Service and Organ Transplant Center Regulations
To be Held 10/10/2019**

Dialysis Service

1. When the current dialysis regulations were written, chronic dialysis clinics were not widely available and most patients received chronic dialysis in the hospital. Now, most outpatient end stage renal disease patients receive their routine chronic dialysis treatments in a chronic dialysis clinic. What are the advantages and disadvantages of amending the dialysis service regulations to focus primarily on the needs of inpatients who require acute dialysis instead of on the provision of chronic dialysis?
2. What is the hospital's standard procedure for managing ESRD patients who come to the emergency department because they require dialysis treatment?
3. Do inpatients on peritoneal dialysis require assistance from a dialysis nurse or can a trained floor nurse under the direction of a nephrologist manage their needs?
4. What special infection control concerns apply to dialysis inpatients, and what kind of experts should participate in developing policies and procedures to address those concerns?
5. Current regulations require a hospital with a dialysis service to provide for or arrange for a number of resources. Which of the following resources should be kept or removed? Should any be added? Please provide the rationale for addition or deletion.
 - (a) Respiratory therapy
 - (b) 24-hour lab services
 - (c) Chronic dialysis on an outpatient basis
 - (d) Angiography
 - (e) Immunofluorescence studies
 - (f) Electron microscopy
 - (g) Microbiological studies for rickettsiae, fungi, bacteria and viruses
 - (h) Tissue culture
 - (i) Outpatient services
 - (j) Self-dialysis training program
 - (k) Home dialysis training program
 - (l) Transplantation evaluation of patients with end stage renal disease
 - (m) Renal transplantation
 - (n) Nuclear medicine service

6. Current regulations require a hospital with a dialysis service to provide for or arrange for evaluation and consultation by several kinds of specialists. Which of the following specialists should be kept or removed? Should any be added? Please provide the rationale for addition or deletion.
 - (a) Cardiology, endocrinology, infectious disease or hematology
 - (b) Neurology
 - (c) Psychiatry
 - (d) Orthopedic surgery
 - (e) Pathology
 - (f) Urology
7. What kind of behavioral health and social service resources should a dialysis service provide for dialysis patients?
8. What responsibilities do dialysis technicians have in a hospital dialysis service and how should the technicians be supervised?
9. Do you have any additional suggestions or comments about the dialysis service regulations?

Organ Transplant Center

Note: For the purpose of the following questions, “organ transplant center” means “An organ-specific transplant program within a transplant hospital.” (42 Code of Federal Regulations section 482.70.)

1. Current licensing regulations only apply to renal transplant centers. As the Department updates the regulations the goal is to align with the Organ Procurement and Transplantation Network (OPTN) and with the Centers for Medicare and Medicaid Services (CMS) by including all types of solid organ transplant centers. The OPTN has policies and guidelines that address vascularized composite allografts (VCAs). Should the organ transplant center licensing regulations include VCA centers, and if so, do VCA programs have special considerations that other kinds of organ transplant programs do not?
2. At what point in the evaluation process does a patient become a transplant patient under the care of the transplant center?
3. CMS requires a multi-disciplinary transplant team that includes a primary transplant surgeon, a primary transplant physician, and a clinical transplant coordinator. What minimum training and qualifications should these providers have?
4. What transplant-specific topics should be included in training for transplant nurses?
5. When a living donor donates organs, an independent advocate represents the interests of the donor. What should the minimum qualifications be for an independent living donor advocate, and what is the scope of the independent living donor advocate’s duties?
6. Does the informed consent process for transplant patients differ from the informed consent process for other surgical patients? If so, how?
7. In 2010, an educational pamphlet for providing transplant patients with basic information about organ trafficking was published by an international group of medical experts and endorsed by over eighty leading professional transplant associations and groups from the United States and abroad. Should the Department require organ transplant patient education programs to routinely include information about the potential consequences of purchasing an organ? Please explain the rationale for your recommendation.

8. The current California regulations for renal transplant centers and the CMS regulations for organ transplant centers have different requirements for the types of resources and medical expertise that must be available. Which of the following should be available, either for all transplant centers or for a specific type of transplant center? (Please note that this is not a complete list of the requirements from both sets of regulations.)
- (a) Internal medicine
 - (b) Immunology
 - (c) Cardiology
 - (d) Endocrinology
 - (e) Neurology
 - (f) Psychiatry
 - (g) Orthopedic surgery
 - (h) Urology
 - (i) Dialysis service
 - (j) Respiratory therapy
 - (k) Angiography
 - (l) Electron microscopy
 - (m) Nuclear medicine service
 - (n) Other
9. Current regulations say that, “Children (13 years of age or under) receiving transplant services shall be under the care of a [pediatrician].” The OPTN defines a pediatric transplant center as a center that serves patients under the age of 18. Should all transplant patients under age 18 be under the care of a pediatrician? If not, what should the age limit be and why?
10. Should the transfer plan for patient who is transitioning from pediatric to an adult transplant center include a plan for coordination between the pediatric center, the patient, and the adult center to minimize gaps in the patient’s care?
11. Current regulations require renal transplant centers to perform enough transplants per year to maintain sufficient performance and recommends 15 transplants per year to, “...demonstrate a capability to perform with high quality.” CMS and the OPTN have different measures to ensure clinical experience and acceptable outcomes. What should the minimum clinical experience and/or outcome requirements be for licensing regulations for renal and other kinds of organ transplant centers?
12. Do you have any additional suggestions or comments about the organ transplant center regulations?