



American Society of Transplant Surgeons

March 31, 2014

Marilyn Tavenner

Administrator

Centers for Medicare and Medicaid Services

Department of Health and Human Services

Hubert H. Humphrey Building

200 Independence Avenue, SW - Room 445-G

Washington, DC 20201

**Re: Medicare and Medicaid Programs; Emergency Preparedness
Requirements for Medicare and Medicaid Participating Providers
(CMS 3178-P)**

Dear Ms. Tavenner:

The American Society of Transplant Surgeons (ASTS) appreciates this opportunity to comment on the specific part of the proposal that would revise the transplant center conditions of participation to include emergency preparedness requirements. ASTS is an organization composed of more than 1800 transplant professionals dedicated to excellence in transplantation surgery through education and research with respect to all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure. ASTS supports the overall intent of the proposed rule to ensure that patient access to life-saving organ transplantation and related services is not interrupted in the event of an emergency.

Under the proposed rule, every transplant center would be required to make arrangements with one or more Medicare-approved transplant centers to provide transplantation services and other care to patients during an emergency. A written agreement would be required that would have to set forth, at a minimum, (1) the circumstances under which the agreement would be activated and (2) the types of services that would be provided during an emergency. While ASTS agrees with the overall intent of this proposed rule, we believe the proposed rule would impose additional regulatory burdens on transplant centers with little or no offsetting benefit.

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Organ transplantation is highly integrated with and interdependent on other portions of our healthcare system and not amenable to simple solutions. How a transplant center should respond to an emergency will depend on many factors, including the nature of the emergency; whether it is local, regional, or national; and the type of patients likely to be impacted. These variables may combine in unpredictable ways. A plan such as transferring patients to another transplant center may simply be unworkable depending on the nature of the emergency and the needs of the patients. Requiring transplant centers to commit, in advance, to a specific course of action could actually impede a transplant center's ability to avail itself of all available alternatives.

In this regard, we point out that organ transplantation is already highly regulated through the Organ Procurement and Transplantation Network (OPTN). Under contract with the Health Resources and Services Administration (HRSA), OPTN develops and enforces policy requirements for transplant centers within the United States. Current OPTN policies include procedures that transplant centers must follow in the event of regional or national emergencies to ensure the safety of transplant patients and the appropriate matching of transplant candidates with available donors. In addition, transplant centers are required to notify the OPTN if they make any alternate arrangements for transplant care in response to an emergency. Furthermore, transplant centers are located within larger hospital entities and thus would be subject to general hospital emergency preparedness requirements. We believe that patient safety and the continuation of appropriate transplant care during an emergency can best be maintained by coordinating with the OPTN and the hospital administration.

In summary, for the reasons set forth above, we do not believe the proposed transplant center conditions of participation related to emergency preparedness are necessary to ensure patient safety and continuation of transplant care given the existence of OPTN emergency policies and CMS rules applicable to hospitals generally. Thank you for considering ASTS' comments. If you have questions or require further information, please contact ASTS Executive Director Kim Gifford at kim.gifford@asts.org or 703-414-7870.

Sincerely yours,

A handwritten signature in black ink that reads "Alan Langnas". The signature is written in a cursive, flowing style.

Alan N. Langnas, D.O.
President