March 31, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
ATTN: CMS–1599–P
7500 Security Blvd.
Baltimore, MD  21244-8013

Dear Ms. Tavenner:


The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services’ (CMS or the Agency’s) proposed rule entitled “Medicare and Medicaid Program; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers” 78 Fed. Reg. 249 (December 27, 2013). The AAMC represents all 141 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 82,000 medical students, and 110,000 resident physicians who collectively deliver over one-fifth of all clinical care in the nation. This letter will focus on a set of proposals for transplant centers as these are particularly germane to AAMC members.

This proposed rule would amend the Conditions of Participation (CoPs) or Conditions for Coverage (CfCs) for 17 Medicaid and Medicare provider and supplier sectors. The AAMC appreciates CMS’ desire “for a more consistent regulatory approach that would ensure that providers and suppliers nationwide are required to plan for and respond to emergencies and disasters.” However, there must be a reasonable need for imposing new requirements. As discussed below, the AAMC is concerned that the proposed addition of two CoPs governing transplant centers, and an additional requirement on hospitals and the Organ Procurement Organization (OPO) are not needed and may be unduly burdensome.

Additional Transplant Center Conditions of Participation (CoPs) are Unnecessary

Under the proposed rule, CMS would require all transplant centers to have an agreement with at least one other Medicare-approved transplant center in order to provide transplantation services and other care for its patients in an emergency. This agreement would need to address two issues:

- The circumstances under which the agreement would be activated, and
- The types of services that would be provided during an emergency.

In addition, CMS also proposes a new requirement for transplant centers and the OPO. Current regulations require transplant centers to ensure that the hospital in which it operates has a written agreement with the OPO that identifies specific responsibilities for the hospital and the OPO relating to organ recovery and allocation.
CMS proposes that transplant centers ensure that this written agreement also addresses duties and responsibilities of hospitals and the OPO during an emergency.

The AAMC strongly believes that the proposed CoPs are unnecessary given the close cooperation of transplant centers throughout the United States. Transplant centers, most of which are located in academic medical centers, have a long history of operating collegially and efficiently, particularly during natural or man-made disasters. We have not heard of any accounts by our members, or from CMS, regarding transplant centers failing to properly ensure the appropriate care for these patients during an emergency.

Moreover, the addition of new transplant center CoPs is redundant with current requirements and could result in substantial cost and time burden for these providers. The Joint Commission and other accreditation bodies already require centers to have disaster contingency plans in place which fulfill the spirit of the requirements proposed in the rule. The Association has received feedback from a member institution that estimated the total time burden to comply with these specific proposals to exceed 100 hours. This is much longer than the 15 hours estimated by CMS, and would result in a much greater total cost than the estimated $1,388 per transplant center.

AAMC member have raised a number of concerns about the CMS proposal to have in place “an agreement with at least one other Medicare-approved transplant center to provide transplantation services and other care for its patients during an emergency.” Among the difficulties with this proposed requirement are the following:

- For larger multi-transplant program centers, it would be necessary to have an agreement with multiple transplant hospitals.
- In cities that have multiple transplant centers, a natural disaster would likely affect all centers equally and there would be nowhere to transfer patients.
- The transfer agreement requirement for transplant patients could have the unintentional result of giving those patients preferential treatment, which is inconsistent with the missions of these hospitals.

If CMS is concerned that transplant centers are not preparing adequate contingency plans for disasters, then AAMC believes that consideration should be given to working with the Organ Procurement and Transplantation Network (OPTN), a public private entity consisting of stakeholders in the organ donation and transplantation system, to develop a rule governing the appropriate requirements for transferring patients during such a crisis. It would be especially useful for OPTN to allow transplant centers to accept each other’s patients without the need for a specific contract in the case of a disaster.

Finally, if CMS finalizes the proposal the AAMC urges the Agency to work with stakeholders to develop Interpretive Guidance to ensure that additional burden is not placed on transplant centers. More broadly, this type of collaborative effort should be employed whenever Interpretive Guidance is written.

Thank you for your consideration of the above comments. If you have questions or require further information, please contact Scott Wetzel at swetzel@aamc.org or 202-828-0495.

Sincerely,

Joanne M. Conroy, M.D.
Chief Health Care Officer

Cc: Ivy Baer, AAMC
Scott Wetzel, AAMC