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October 5, 2020

The Honorable Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, Southwest
Washington, D.C. 20201

Dear Secretary Azar:

I write to address potential problems with the Centers for Medicare & Medicaid Services (CMS) proposed rule titled: "Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations."

The Organ Procurement Organization (OPO) that is responsible for serving many states in the northeast shared several problematic outcomes with my office. Specifically, they are concerned about how the rule integrates data compiled from death certificates, the metrics used to measure OPO performance, and the decertification process for underperforming OPOs.


As you know, the proposed rule calculates the total number of organs available for transplant in an OPO's service area by using federal death records of patients 75 years old and younger that die from a condition that does not exclude them from the donation process. I have been told that this dataset can be misleading and imprecise due to the potential for death certificates to omit medical conditions and other diagnoses that prevent donation.

Executives also mentioned that many OPOs could be penalized if they fail to meet CMS's recommended performance metrics. The rule says that OPOs can be decertified if they do not at least match the transplant and donation rates of the top 25 percent of OPOs. Some studies estimate that this could cause 37 of 58 OPOs in the U.S. to close. The experts who I have spoken to in New England believe that this threshold is uncompromising. They recommend revising the benchmarks to deviate from the mean – rather than the top 25 percent – to more accurately define an OPO's success.

Finally, I have heard that there is uncertainty about CMS's OPO decertification process. It is important that CMS provide clear guidelines that demonstrate how and when an OPO could be decertified and options that encourage OPOs to improve their performance. This will help ensure that OPOs work with CMS to retain a network of successful procurement and transplant groups.

Thank you for reviewing these concerns.

Sincerely,



JIM HIMES
Member of Congress