



International Association of Coroners & Medical Examiners

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Dedicated to the promotion of excellence in medicolegal death investigation through collaboration, education and accreditation.

November 2, 2020

The Honorable Alex Azar II
Secretary
US Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Mr. Azar,

Please allow this letter to express our concerns regarding CMS's proposed revisions to the outcome measure requirements for OPOs. Specifically, we are concerned CMS wants to use data derived from death certificates to calculate the donation rates for OPOs. CMS has proposed the numerator for the new OPO donation rate should be the number of deceased donors in the donation service area who had at least one organ transplanted, while the denominator should be the number of total inpatient deaths within the donation service area among patients 75 years or younger with a cause of death that would not bar organ donation. Death certificate data would be used to calculate the denominator. We are intimately familiar with the inherent problems with the accuracy of death certification therefore, using death certificates as a means to calculate the donation rates for OPOs at its foundation would be flawed. The widespread inaccuracy of death certificates is a well-recognized problem. Studies show that between 30% and 60% of death certificates inaccurately report the cause of a person's death. The pervasive inaccuracy of death certificate information can largely be attributed to varying levels of expertise of those who fill out the forms. In most cases, when a patient dies, the attending physician is responsible for determining the cause of death. Unfortunately, most doctors receive very little if any formal training on how to properly complete a death certificate. In addition to a lack of training, the CDC last updated its guidelines for doctors on determining death in 2003. Aside from inadequate training for accurate completion of a death certificate, the underlying cause of death that is required on death certificates, can be difficult to determine. This is especially true if doctors are unfamiliar with a patient's medical history. Accuracy of these documents is a long-standing concern in the medicolegal community. When a coroner, medical examiner, or physician sign a death certificate, we are attesting our best opinion, the individual died from the reported cause and manner of death. Ideally, we would be able to provide a clear description of the process that led to an individual's death. Realistically, describing the process is can be challenging. Death certificates are intended to focus on the immediate cause of death and do not and cannot document a person's entire medical history. This failure to document secondary conditions that are unrelated to the cause of death yet can make an individual ineligible for donation is why death certificates do not accurately reflect whether a deceased individual was eligible to be an



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organ donor. A more accurate denominator for the OPO donation rate is inpatient ventilated deaths which can be reported directly to CMS. In addition to being free of most infectious diseases, a patient must be placed on a ventilator in a hospital for organ donation to occur. Failure to account for this variable will result in an inaccurate measurement of the true donor pool.

Thank you for your time and consideration in the extremely important matter. We are sure everyone involved in this process want to accurately and fairly, accumulate data points which will provide a full picture of each patient's total ability to provide the legacy of donation. Please feel free to contact us should you have any questions, comments or concerns about the information we have provided.

Respectfully,

IACME Executive Committee