

June 26, 2017

David R. Wright  
Director  
Survey and Certification Group  
Center for Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop C2-21-16  
Baltimore, MD 21244-1850

Dear Mr. Wright:

On behalf of the American Society of Nephrology (ASN), thank you for your leadership of the End-Stage Renal Disease (ESRD) Survey and Certification Group.

Representing nearly 17,000 nephrology health professionals, ASN is a not-for-profit organization dedicated to promoting excellence in kidney health and ensuring access to optimal patient-centered quality care, regardless of socioeconomic status, geographic location, or demographic characteristics. The society values the efforts of the Survey and Certification Group to ensure the highest health and safety standards within dialysis facilities. Your efforts are crucial to helping patients and health professionals in these healthcare environments.

I write today regarding the June 2, 2017, Survey and Certification Group memorandum concerning practices for filling saline syringes at the dialysis patient treatment station in dialysis facilities. The high rate of bloodstream infections in dialysis patients is a well-known concern for the kidney community, and any opportunities to reduce this rate should be seriously considered. In theory, pre-filled saline syringes could help prevent infection by simplifying procedures at the start and completion of a hemodialysis session, thereby potentially reducing the risk of contamination.

ASN is committed to the goal of ensuring patient safety. However, the society has several reservations regarding the recent policy. Although ASN does not have a formal position regarding the use of pre-filled saline syringes, concerns regarding the evidence base for, and the potential unintended consequences of, this protocol have been raised that the society believes warrant consideration. As a result, ASN encourages you to delay implementation of the policy (which is slated to start July 2, 2017) to allow more time for community discussion, including patient and health professional organizations, dialysis providers, and the Centers for Disease Control and Prevention (CDC).

In the past, such communication has resulted in implementation of beneficial policies with broad support. These discussions often generate information and advice that will best guide CMS policy. ASN recommends that this dialogue include the presentation of the data supporting this practice change, delineation of CMS's goals in implementing this policy, and information concerning the cost-effectiveness. For example, if the goal in promoting the use of pre-filled saline syringes is to adhere to CDC best practices and minimize infections, other alternatives that adhere to CDC guidance may already be used by some dialysis centers and may offer

advantages compared to pre-filled syringes. Additionally, concerns have been raised that implementing this practice will cost tens of millions of dollars nationally—funds that would be diverted from other endeavors to promote patient safety.

ASN believes public dialogue between CMS and the community will permit discussion of the pros and cons regarding the use of pre-filled saline syringes as well as understanding about the rationale for the policy and facilitate its acceptance. Public dialogue might also uncover and mitigate unintended consequences caused by the implementation of the changes described in this memorandum. ASN would be pleased to facilitate a community-wide conversation that includes all relevant stakeholders, either in-person in the Washington, DC, area or in a virtual forum.

I appreciate your consideration of the recommendation to delay implementation, and I look forward to hearing your thoughts regarding ASN's invitation to convene stakeholders for dialogue on this important topic. Please contact ASN Director of Policy and Government Affairs Rachel Meyer at [rmeyer@asn-online.org](mailto:rmeyer@asn-online.org) or 202-640-4659 with any questions or comments, or to discuss next steps.

Again, thank you.

Sincerely,

A handwritten signature in cursive script, appearing to read "Eleanor D. Lederer".

Eleanor D. Lederer, MD, FASN  
President