



February 2, 2017

Nevin Laib, PPG, SEP
c/o Adam Obest
Center for Medicare and Medicaid Innovation
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1628-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

Dear Mr. Laib:

The Alliance for Home Dialysis appreciates the time you and your colleagues took to meet with our members on Thursday, January 5, 2017. We found the conversation very productive and thank you for your willingness to continue to engage with us.

Below, we have detailed the follow-up items CMMI staff requested during our meeting. We look forward to continuing the conversation around these issues.

1. Home dialysis data collection and release: ESCO cohort 1 data and round 1 of the Health Care Innovation Awards

The Alliance appreciates the work CMMI has done to further data collection on home dialysis uptake, both through the ESCO model and through its Health Care Innovation Awards (HCIA) grant program. We eagerly await the release of the data from the first cohort of ESCOs in the next few months, and are encouraged that CMMI recognizes the many benefits of having home dialysis data to assess the impact of the ESCO model in facilitating the uptake of home therapy where appropriate.

As we noted, we have also been disappointed in the lack of information available 18 months after the completion of the first HCIA telemedicine pilot project (July 2012-July 2015) on peritoneal dialysis at the George Washington (GW) University. The Alliance appreciates CMMI staff members' efforts to connect us with the Project Officer for this project following our meeting, however the Project Officer has not yet responded to the Alliance's introductory communications. Anything you can do to help us make this connection and secure the needed information would be greatly appreciated.

2. Telehealth waiver under the Comprehensive ESRD Care Initiative

The Alliance is encouraged by CMMI's forward thinking on opportunities for telehealth to expand access to home dialysis, and we appreciate the opportunity to provide additional information on telehealth, including options for a potential telehealth waiver under the CEC program.

We appreciate the point that CMMI staff made, that many waivers in the CEC initiative must be granted by law enforcement. However, the Alliance believes that CMMI could test expanded utilization of telehealth (including remote patient monitoring) with respect to ESRD beneficiaries on home dialysis - without needing law enforcement approval - inasmuch as this fits squarely within the aim of the CEC initiative to improve the care of ESRD beneficiaries. As you are aware, Section 1115A(d)(1) of the Social Security Act provides the Secretary with broad authority to waive the statutory requirements titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing CMMI models.¹

To allow expanded utilization of telehealth in the CEC model for ESRD beneficiaries on home dialysis – we hope that CMMI will consider waiving the following specific portions of section 1834(m) of the Act:

- The “originating site” requirements at section 1834(m)(4)(C)(i) concerning the geographic limitations, and section 1834(m)(4)(C)(ii) which limits the term “originating site” to those listed in the statute.
- The “facility fee” at section 1834(m)(2)(B) of the Act, with respect to cases where the originating site is the beneficiary's home.

For purposes of the CEC model, we would urge that CMS also specify that telehealth services encompass “remote patient monitoring and management” services currently not on CMS' telehealth list (though they were pilot tested in previous CMMI demonstrations).

In implementing these waivers, CMMI would evaluate, through the collection and analysis of data, the hypothesis that revising the current telehealth framework to allow for telehealth for home dialysis ESRD beneficiaries leads to both higher quality and more affordable care for Medicare enrollees and reduced Medicare expenditures.

3. Inclusion of home dialysis patients in patient experience surveys; potential for expanding usage of DSS

During the meeting, we discussed the Alliance's support for inclusion of home dialysis patients on quality of life and patient experience surveys used in the ESCOs. As you know, the ICH-CAHPS survey excludes home dialysis patients from responding, and therefore, important data

¹ Section 1115A(d)(1) of the Social Security Act (The Secretary may waive such requirements of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b).)

on home patient satisfaction is missing from the overall picture coming out of the ESCOs. Although the Alliance is appreciative of CMMI's efforts to include home patients in the KDQOL survey, we still believe that there must be a survey mechanism to elicit and gauge home patient responses.

Currently, we are aware of six dialysis facilities that use a survey tool created by DSS Research to measure home patients' experiences. This survey was created approximately two years ago and was modeled on the ICH CAHPS questionnaire, using some of the same questions, scales, and demographics. This survey is given by the six facilities that use it as a supplement to the in-center survey.

The Alliance believes that this survey could effectively be expanded to cover all ESCOs to better capture home patient experience and satisfaction. The DSS survey is attached as an appendix to this letter for your review, and the Alliance would be happy to continue the conversation as to how it could be validated, expanded, and used more broadly. Alternatively, since our member at Northwest Kidney Centers is a participant in the Northwest Kidney Care Alliance ESCO and also uses this DSS Research tool for home patients, you may prefer to work with them directly to further assess the viability of making this (or a similar) tool available to all ESCOs.

4. Assistance with the Learning Collaborative

As discussed during our meeting, the Alliance would like to serve as a resource as CMMI considers new topics for use in the Learning Collaborative initiative. Among other things, the Alliance could connect CMMI staff members to participant ESCOs to discuss how home dialysis could be featured as a Learning Collaborative topic. Please do not hesitate to reach out to Alliance members or staff – or to work directly with Northwest Kidney Centers, an ESCO participant and the organization which recommended this approach in our meeting - to discuss how we can work together.

The Alliance very much appreciated the opportunity to meet with CMMI staff members to discuss how home dialysis can be incentivized through the CEC initiative. We look forward to continuing to work with CMMI on policies that advance utilization of home dialysis in the future as new cohorts of participants are added each year. Please contact Michelle Seger at michelle@homedialysisalliance.org or 202-466-8700 if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Stephanie Silverman". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Stephanie Silverman
Executive Director