

September 16, 2019

Ms. Seema Verma  
Administrator, Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue SW, Room 445-G  
Washington, D.C. 20201

**RE: Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures (*Federal Register*, Vol. 84, No. 138, July 18, 2019)**

Dear Ms. Verma:

On behalf of our more than 200 member hospitals and nearly 50 health systems, the Illinois Health and Hospital Association (IHA) takes this opportunity to submit comments on the proposed rule establishing two new specialty care models specific to radiation oncology and end-stage renal disease (ESRD). We appreciate the Centers for Medicare & Medicaid Services' (CMS) commitment to pursuing improvements to the quality of care experienced by Medicare beneficiaries while being good stewards of taxpayer dollars. Additionally, we acknowledge the considerable time and effort CMS has put into both proposed models thus far. However, we have some concerns about both models, detailed below. Due to these concerns, **our overall comment is to respectfully request that CMS delay both models for at least one year to allow for additional research into the efficacy of these models, and to allow providers more time to prepare for the payment changes being proposed.**

**Radiation Oncology Model (RO Model)**

We agree with the motivation behind CMS' RO Model: to create a system that gives radiation oncologists greater predictability in payment and increased opportunity to clinically manage episodes of care. However, we respectfully request that CMS defer implementation for at least one year, allowing for more research and another round of comments prior to finalizing the model.

This delay is requested primarily because we have questions about the treatment modalities included in the RO Model. In particular, we request that CMS provide data on the comparative effectiveness between included and excluded modalities, similar to the evidence provided on proton beam therapy. We understand that CMS included the modalities most commonly used for the cancer types addressed by the RO Model, but we remain concerned that more effective, and potentially more expensive, treatment modalities were not included because they are not currently accessible by a larger cohort of Medicare

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beneficiaries. We base this comment on the growing body of evidence suggesting that identified disparities in cancer outcomes by race may be due to disparities in treatment options and utilization.<sup>1</sup> Further, recent data show gender disparities in treatment research<sup>2</sup> and utilization,<sup>3</sup> as well. Thus, we ask CMS to provide more data and analysis regarding the justification for the modalities they chose to include, and how it will use this model to address disparities in access to treatment across race/ethnicity and gender.

Additionally, we request CMS delay the implementation of the RO Model to allow providers more time to prepare for mandatory participation. IHA appreciates CMS' commitment to implementing a model that produces robust and nationally representative data for the purposes of evaluation. However, we are concerned that CMS has not yet selected the hospital outpatient departments and physician group practices that will be required to participate. Given CMS's current proposed timeline, participating providers would have five months to prepare for model participation, at best, should CMS chose to delay implementation until April 2020. Whether or not this would be sufficient depends largely on the resources available among chosen providers. IHA strongly feels that many of our member hospitals would require more time to successfully prepare for and participate in the RO Model. Therefore, we request that CMS notify the randomly selected core-based statistical areas (CBSAs) as soon as possible, and allow the providers in those CBSAs at least 12 months to prepare for model participation.

Finally, we ask CMS for more clarity around the proposed episode payment rates. First, we are unsure as to why CMS is including cancer type as a factor in determining the case-mix adjustment as there are separate base payment rates for each cancer type. These unique base rates would likely already account for differences in the cost of radiation therapy services across different types of cancer, making the inclusion of cancer type in the case-mix adjustment unnecessary. We request CMS to provide a rationale for including cancer type in the case-mix adjustment. Additionally, we find the proposed historical-experience adjustment inappropriate as it would reward historically inefficient providers and penalize historically efficient providers, paying them more and less than the base rate, respectively. This result appears to undermine the model's intent of reducing "program spending through enhanced financial accountability for model participants." Therefore, we suggest CMS forgoes the adoption of the historical-experience adjustment. Finally, we are concerned with the large proposed discount factors under the RO Model: specifically, a 4% discount factor to the professional component payment

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<sup>1</sup> Esnaola N and Ford M. Racial Differences and Disparities in Cancer Care and Outcomes: Where's the Rub? *Surg Oncol Clin N Am*. 2012 Jul; 21(3): 417-vii. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4180671/>.

<sup>2</sup> U.S. Food & Drug Administration, 2019, FDA in Brief: FDA Encourages Inclusion of Male Patients in Breast Cancer Clinical Trials. Available from: <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-encourages-inclusion-male-patients-breast-cancer-clinical-trials>.

<sup>3</sup> American Society of Clinical Oncology, 2018, Study Finds Gender Disparities in Head and Neck Cancer Treatment and Outcomes. Available from: <https://www.asco.org/about-asco/press-center/news-releases/study-finds-gender-disparities-head-and-neck-cancer-treatment>.

and a 5% discount factor to the technical component payment. These are very large discounts to apply to providers that are required to participate in a 100% provider-risk model that has not yet been tested. IHA urges CMS to significantly lower the discount rates and to phase them in over time.

### **ESRD Treatment Choice Model (ETC Model)**

Similar to the RO Model, we agree with CMS that increasing utilization of home dialysis and kidney or kidney/pancreas transplant among Medicare beneficiaries with ESRD are positive and worthwhile endeavors. However, we again respectfully request that CMS delay implementation for at least one year as we question whether the current payment incentive model is appropriate given the data driving this model. Additionally, we request that CMS inform providers in the selected hospital referral regions of their mandatory participation as soon as possible, maximizing the amount of time providers have to prepare for the program.

CMS explained that a major motivation for the ETC model is the fact that the U.S. lags behind other countries in its use of home dialysis and kidney transplantation. We examined the same data as CMS in the United States Renal Data System,<sup>4</sup> and we agree that the U.S. does utilize these treatment options at lower rates than other countries. However, these data indicate that only New Zealand and Australia use home dialysis for a significantly higher proportion of their dialysis patients (18.4% and 9.3%, respectively). Further, it appears that countries with high rates of transplantation have fewer patients per capita in need of transplantation. Specifically, the 10 countries with the highest rate of transplantation per 1,000 chronic dialysis patients have the lowest rates of chronic dialysis per million population. This suggests to us that the U.S.' low transplantation rate is likely exacerbated by population characteristics that differ in high-utilization countries. Without controlling for inherent differences between country populations, these comparisons are not as meaningful as they could be, and we respectfully request that CMS provide more data to support this model prior to implementation.

Additionally, CMS acknowledges that the utilization of home dialysis comes with challenges that are specific to the patient's overall health and home, as well as the current infrastructure of the U.S. health system. CMS indicates several times throughout the proposed rule, and more specifically on page 34537, that low-utilization rates of home dialysis and other non-in-center modalities are largely driven by a lack of: patient education, staff and space to provide education, training, clinic visits, and supervision of these alternative modalities. IHA respectfully requests that CMS explore a care model that focuses more on payment incentives related more specifically to these factors. In our opinion, the proposed outcomes driving provider payment under the ETC model, rates of home dialysis and kidney transplantation, involve too many factors outside the control of providers given the current systems. We are concerned that providers may experience significant financial burden if they are unable to improve these

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<sup>4</sup> United States Renal Data System, 2015. Available from: [https://www.usrds.org/2015/view/v2\\_13.aspx](https://www.usrds.org/2015/view/v2_13.aspx).

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outcomes during the life of the model, which may impact their ability to serve the Medicare population and provide access to much-needed services.

Ms. Verma, thank you again for the opportunity to comment.

Sincerely,

A.J. Wilhelmi  
President & CEO