



Getting Medicare right

September 16, 2019

VIA ELECTRONIC SUBMISSION

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8013

Re: Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures [CMS-5527-P]

Dear Administrator Verma:

The Medicare Rights Center (Medicare Rights) appreciates the opportunity to comment on the proposed rule, "Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures." Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Each year, Medicare Rights provides services and resources to over three million people with Medicare, family caregivers, and professionals.

General Comments

We are supportive of efforts to reduce Medicare program spending while improving quality of care, and quality of life, for Medicare beneficiaries. We also agree that mandatory models are in some cases needed in order to truly test whether a payment system is feasible and appropriate. As such, we are generally supportive of the two proposed mandatory models: (1) the Radiation Oncology (RO) Model and (2) the ESRD Treatment Choices (ETC) Model.

The RO Model moves a set number of participating providers toward episodic payment for radiation treatment for certain cancers. This may eliminate financial incentives to extend treatment or to provide treatment in ways that are more expensive without a clinical gain.

The ETC Model is meant to provide financial incentives to providers to promote appropriate home dialysis and renal transplant. Both goals have the potential to drive down costs while increasing the quality of life and improving health outcomes for patients. Both home dialysis

and renal transplant are less used than in the United States compared with other developed countries, and CMS identifies several causes for this relative disuse, including insufficient education and incentives for providers and a lack of information and support for patients.

I. Executive Summary

B. Summary of the Major Proposed Provisions

2. Model Overview – Proposed Radiation Oncology Model

A. SUMMARY OF MAJOR PROVISIONS

(3) Overlap with Other CMS Programs and Models

The Centers for Medicare & Medicaid Services (CMS) notes that in addition to the models under consideration here, a Medicare beneficiary may be assigned, aligned, or attributed to another model or program with similar cost and care goals. Given this potential overlap, notices to beneficiaries about their participation in such initiatives must clearly explain what models mean for beneficiaries and how they may work together. CMS must provide this information in a simple, comprehensive way that will make beneficiary participation in one or multiple models clear.

(4) Episodes and Episode Pricing Methodology

CMS proposes that the payments for the episodes be adjusted for beneficiary experience starting in Performance Year 3. We support having the beneficiaries' experiences included as a measure of quality of the care.

(7) Beneficiary Protections

CMS proposes requiring participants in the RO Model to notify beneficiaries of their inclusion in this model through a standardized written notice. To ensure this standardization, CMS proposes making a notification template available to participating providers, which they could personalize with contact information and logos, but not otherwise change. We strongly support the creation of this template notice and encourage CMS to do consumer testing of all model notices to ensure they are easily comprehended, clear, and complete. As referenced above in I.B.2.A.(3), CMS should also consider how to convey information to beneficiaries about their participation in multiple models.

3. Model Overview – Proposed ESRD Treatment Choices (ETC) Model

a. Summary of Major Provisions

(1) Proposed ETC Model Overview

CMS identifies dialyzing at home or receiving a kidney transplant as potentially better options than in-center dialysis for more beneficiaries than currently use them. CMS proposes to incentivize participating providers to assist ESRD beneficiaries to choose the best course of treatment for their disease. We support encouraging providers to work more closely with beneficiaries and to explore treatment options, especially those that are likely to lead to better outcomes, lower costs, and higher quality of life. We have some concern that the underlying assumption that beneficiaries are currently choosing their treatments may be overlooking the profound role that providers currently play. If beneficiaries are not currently the real drivers of these choices, they may also not be the real drivers of future choices.

(2) Model Scope

CMS's proposed ETC Model would focus on encouraging greater use of home dialysis and kidney transplants for ESRD beneficiaries. While we strongly support the availability of home dialysis for beneficiaries who would choose and be appropriate candidates for this modality of treatment, it is vital that beneficiaries not be pressured into home dialysis. For some, this option may not be practical or desired, and providers must not be incentivized to unwisely promote home dialysis.

(6) Medicare Payment Waivers

CMS proposes to waive certain educational requirements regarding the provision of the Kidney Disease Education benefit, including the limitations on that benefit for beneficiaries solely in Stage IV. The waivers would allow ETC participating providers to furnish these educational services to beneficiaries in later stages of kidney disease and allow the content benefit to be tailored to each beneficiary's needs. We support this waiver to allow greater access to these educational supports. However, CMS must ensure that the flexibility of content does not permit providers to give these beneficiaries incomplete information.

(8) Beneficiary Protections

Under this proposal, CMS explicitly confirms that beneficiaries would retain their rights to choose between participating and non-participating providers and to have access to medically necessary services, but beneficiaries would be unable to opt out of the ETC Model if they received care from a participating provider. We understand why this prohibition is in place.

In addition, CMS proposes that ETC participating providers must prominently display informational materials about the model in facilities and offices where beneficiaries receive care, and that such materials must not be materially inaccurate or misleading. We support these proposals and applaud CMS for reiterating that beneficiaries retain their rights to care and choice of providers.

D. Beneficiary Protections

1. Beneficiary Freedom of Choice

CMS reiterates that neither model participants nor downstream participants may restrict a Medicare Fee-for-Service (FFS) beneficiary's ability to choose his or her providers or suppliers and must not commit any act or omission, nor adopt any policy that inhibits beneficiaries from exercising their freedom to choose to receive care from their choice of provider. CMS proposes to allow these providers to communicate the benefits of receiving care under the model with the model participants. We appreciate these reiterations of beneficiary rights and urge CMS to ensure that any provider-beneficiary communications about the model are fully truthful and accurate.

2. Availability of Services

CMS proposes that model and downstream participants would be required to continue to make medically necessary covered services available to beneficiaries to the extent required by law. We agree that this requirement is a necessary component of all Medicare models and should also include to the extent required by professional best practice.

CMS also proposes that model beneficiaries would retain their rights to appeal Medicare claims. We agree that model beneficiaries and their assignees should not lose the right to appeal claims for Medicare items and services furnished to them solely because the beneficiary's provider or supplier is participating in an Innovation Center model.

CMS proposes to prohibit model participants and downstream participants from taking any action to avoid treating beneficiaries based on their income levels or based on factors that would render a beneficiary an "at-risk beneficiary" which they call "lemon dropping." They identify such a prohibition as a necessary precaution to counter incentives created by the proposed Innovation Center models for model participants to avoid treating potentially high-cost beneficiaries who are most in need of quality care. CMS also proposes to prohibit the corollary "cherry picking" in which model participants selectively target or engage beneficiaries who are relatively healthy or otherwise expected to improve the model participant's or downstream participant's financial or quality performance. We support prohibitions against these and all types of beneficiary discrimination, and urge CMS to engage in rigorous oversight to ensure that prohibited behaviors have been prevented or eliminated. We encourage CMS to investigate whenever anomalous demographic information arises from any model that may suggest such cherry picking or lemon dropping is occurring.

3. Descriptive Model Materials and Activities

CMS proposes to prohibit model participants and their downstream participants from using or distributing descriptive model materials and activities that are materially inaccurate or misleading. We strongly support this proposal.

CMS also proposes, in lieu of preclearance, to reserve the right to review provider-developed descriptive model materials and activities to determine whether the content is materially inaccurate or misleading, and to require providers to retain copies of these resources. We urge

CMS to reconsider using preclearance in general and especially if evidence arises that suggests cherry picking or other discriminatory practices are occurring.

In addition, CMS proposes requiring that such materials include a disclaimer that states the documents are not speaking on the agency's behalf, and that lists contact information for reporting suspected inaccuracies to CMS. We support the requirement for such a disclaimer and urge CMS to use consumer testing to ensure that beneficiaries understand all aspects of the disclaimer.

F. Audits and Record Retention

CMS identifies a particular need for CMS to audit, inspect, investigate, and evaluate the records and materials of participating providers to ensure they are in no way denying or limiting the coverage or provision of benefits to participating beneficiaries. We support rigorous oversight of model participants to protect the rights and health care of Medicare beneficiaries and to ensure beneficiaries are not subject to steering or other discriminatory behaviors.

H. Monitoring and Compliance

CMS proposes that enhanced compliance review and monitoring of model participants is necessary and appropriate to ensure the model's integrity. We appreciate and encourage rigorous oversight and monitoring of model participants and urge CMS to include monitoring for anomalous beneficiary demographics that could suggest patient steering or discrimination.

CMS also proposes that the agency could perform unannounced site visits to investigate concerns related to the health or safety of beneficiaries or other patients or other program integrity issues. We support this proposal.

III. Proposed Radiation Oncology Model

C. RO Model Proposed Regulations

3. Proposed Participants

d. Proposed Geographic Unit of Selection

4. Proposed Beneficiary Population

CMS explains that beneficiaries maintain the right to choose to receive services in a geographic area not included in the RO Model. We appreciate this explicit clarification of beneficiary rights.

6. Proposed Pricing Methodology

i. Proposal to Apply Coinsurance

CMS proposes that beneficiaries in the RO Model would pay 20 percent of each of the bundled payments for their cancer type, regardless of what their total coinsurance payment amount would have been under the FFS payment system. CMS notes that the coinsurance payment

amount of the bundled rate may occasionally be higher than what a beneficiary or secondary insurer would otherwise pay under Medicare FFS. We urge CMS to hold beneficiaries harmless in the event the coinsurance exceeds what they would have paid under Medicare FFS.

Because of the way payments would be combined under the model, CMS notes that a single provider visit may be more costly than it would have been otherwise. CMS encourages participating providers to collect coinsurance for services furnished under the RO Model in multiple installments via a payment plan, provided the RO participants inform patients of the installment plan's availability only during the course of the actual billing process. We support the availability of payment plans under circumstances where beneficiaries covered by Medicare FFS would otherwise have faced a lower cost per visit. We reiterate our exhortation to CMS that beneficiaries be held harmless when the total cost of the episodic coinsurance exceeds that of the total cost of the coinsurance under Medicare FFS.

13. Proposed Data Sharing

f. Access to Share Beneficiary Identifiable Data

CMS proposes monitoring model outcomes to ensure to the greatest extent possible that the RO Model is successfully lowering costs while model beneficiaries continue to receive high-quality and medically appropriate care. CMS notes this monitoring may include longer-term analytic strategies to confirm ongoing analyses and detect more subtle or hard-to-determine changes in care delivery and beneficiary outcomes. We support such longer-term study, especially if anomalous demographic information is present that suggests discrimination, patient steering, or cherry picking is occurring.

a. Proposed Monitoring for Utilization/Costs and Quality of Care

CMS proposes to monitor participants in order to detect attempts to maximize revenue by engaging in inappropriate patient recruitment or billing practices, and to identify issues with beneficiary experience of care, access to care, or quality of care. CMS also seeks to monitor the Medicare claims system for potentially adverse changes in referral, practice, or treatment delivery patterns. We support this monitoring. Discriminatory practices as well as other attempts to game the system must be prevented and eliminated.

b. Proposed Monitoring for Model Compliance

CMS proposes to require that all participants document in the beneficiary's medical record pre-treatment discussions about, among other things, the goals of care under the model; whether the treatment intent is curative or palliative; and the beneficiary's inclusion in, and cost-sharing responsibilities under, the RO Model. We support this required documentation and urge CMS to develop and consumer test language for providers to use in discussing these complex issues.

15. Beneficiary Protections

CMS proposes requiring RO Model providers to inform beneficiaries in writing about their participation in the model, as well as about their cost-sharing responsibilities and right to refuse having their data shared. As noted above, we support the provision of a CMS template for this notice and we appreciate the inclusion of information explaining the beneficiary's right to refuse data sharing. We urge CMS to conduct consumer testing on any notices to ensure beneficiaries understand this information when it is presented to them. We also applaud CMS's acknowledgement that templates limit the potential for fraud and abuse, including patient steering.

CMS notes that beneficiaries may contact CMS or their local Beneficiary and Family Centered Care-Quality Improvement Organizations (BFCC-QIOs) (local BFCC-QIO) with any questions. In order to support beneficiaries in models and to ensure the models protect beneficiaries while meeting their health care needs, we again urge CMS to create the Alternative Payment Models Beneficiary Ombudsman first promised in 2017.

IV. End-Stage Renal Disease (ESRD) Treatment Choices Model

C. Provisions of the Proposed Regulation

1. Proposal to Implement the ETC Model

CMS recognizes that the appropriateness of home dialysis as a treatment option varies among patients according to demographic and clinical characteristics, as well as personal choice. While we support the greater availability of home dialysis, we urge CMS to carefully analyze patient outcomes to ensure this option is not inappropriately pushed on patients.

4. Home Dialysis Payment Adjustment

b. Facility HDPAs; c. Clinician HDPAs

CMS proposes that the Facility HDPAs and the Clinician HDPAs would not affect beneficiary cost sharing. Under the model, beneficiary cost sharing would instead be based on the amount that would have been paid under the ESRD Prospective Payment System. This is intended to avoid a perverse incentive in which beneficiaries would benefit from the model's failure to improve rates of home dialysis. We agree that this proposal is needed to avoid incentivizing a failure to meet the model's goals.

7. Medicare Program Waivers

a. Medicare Payment Waivers

As above, CMS proposes that payment adjustments made under the model would not impact beneficiary cost sharing. We agree with this proposal.

9. Beneficiary Protections

CMS reiterates that participating beneficiaries would retain their freedom to choose a dialysis services provider or supplier. The agency also explicitly prohibits ETC model participants from restricting beneficiary freedom of choice or access to medically necessary covered services; from using or distributing descriptive model materials and activities that are materially inaccurate or misleading; and from offering or paying any remuneration to influence a beneficiary's choice of dialysis. We agree with and appreciate these prohibitions.

CMS proposes to hold beneficiaries harmless from any model-specific payment adjustments made to Medicare payments under this Model. We reiterate our support for this proposal.

CMS proposes to require model participants to prominently display informational materials about the model in each of their offices or facility locations. We reiterate our support for this proposal.

CMS proposes to provide a template for such materials to model participants which would identify required content that the participant must not change as well as places where the participant may insert its own original content. This template would include information for beneficiaries about how to contact the ESRD Network Organizations with any questions or concerns regarding the ETC Model. All participant-beneficiary communications that are descriptive model materials and activities would be prohibited from being materially inaccurate or misleading. We support these proposals.

10. Monitoring

a. Monitoring Activities

CMS proposes to closely monitor the implementation and outcomes of the ETC Model throughout its duration to ensure it is administered safely and appropriately. We support such close monitoring and encourage CMS to note anomalous demographic information that may indicate the presence of discrimination or patient steering.

CMS proposes to monitor providers for inappropriate encouragement or recommendations for home dialysis, including instances of coercion. We support this particular emphasis on inappropriate encouragement and coercion. As we note throughout, we are concerned that patients could be swayed or even forced into accepting home dialysis through provider exhortation or failure to identify red flags. Patient safety and quality of care could be at risk if the movement toward home dialysis is too forceful or aggressive.

CMS additionally proposes to employ longer-term analytic strategies to detect more subtle changes in care delivery and beneficiary outcomes. We support this approach. Certain forms of discriminatory or steering behavior may not be readily apparent but identifiable through longer-term trends or subtle patterns of care.

CMS also proposes to examine the extent of any unintended consequences, including any increase in adverse clinical events, steering, market changes, out-of-market referrals, and unsafe referrals for home dialysis. Again, we applaud this proposal for rigorous oversight.

CMS proposes to continue stakeholder engagement and communications regarding these models, including relationships with beneficiary advocates, and to closely monitor patient surveys to uncover any unintended consequences. We applaud this focus on patients and their advocates in order to unearth details about the model's effect on individuals and populations. We again urge CMS to create a dedicated Alternative Payment Models Beneficiary Ombudsman to cast a wide net for beneficiary issues.

12. Learning System

CMS proposes to operate a voluntary learning system focused on increasing the availability of deceased donor kidneys for transplantation. We support the creation of this learning system to spread best practices in kidney transplantation and ESRD care.

Conclusion

Thank you for the opportunity to provide comments on these mandatory models. For additional information, please contact Lindsey Copeland, Federal Policy Director, at 202-637-0961 or lcopeland@medicarerights.org or Julie Carter, Senior Federal Policy Associate, at 202-637-0962 or jcarter@medicarerights.org.

Sincerely,



Frederic Riccardi
President
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