Federation of American Hospitals®

Charles N. Kahn III
President and CEO

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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

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

Submitted electronically to www.regulations.gov

Dear Administrator Verma,

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members are diverse, including teaching and non-teaching, short-stay, rehabilitation, long-term acute care, psychiatric, and cancer hospitals in urban and rural America, and they provide a wide range of acute, post-acute, and ambulatory services. The FAH appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the referenced Notice of Proposed Rulemaking entitled Medicare Programs; Specialty Care Models to Improve Quality of Care and Reduce Expenditures.

CMS Should Implement Models on a Voluntary Basis

The FAH strongly believes that all Center for Medicare &Medicaid Innovation (CMMI) models should only be implemented on a voluntary basis as the **statute does not authorize CMS to mandate provider participation in any CMMI models.**

The FAH has repeatedly expressed significant legal and policy concerns over any proposal to implement a CMMI model under which provider and supplier participation would be mandatory. We believe that CMS has incorrectly interpreted that it may require mandatory participation of providers in a CMMI demonstration. The FAH disagrees that §1115A of the

Social Security Act (SSA) provides CMS with the authority to mandate provider and supplier participation in CMMI models. Such mandatory provider and supplier participation runs counter to both the letter and spirit of the law that established the CMMI and the scope of its authority to test models under section 1115A and make recommendations to Congress for permanent or mandatory changes to the Medicare program.

The purpose of the CMMI is to test innovative payment and service delivery models to maintain or reduce program expenditures while preserving or enhancing quality of care, with an emphasis on models that improve coordination, quality, and efficiency of health care furnished to Medicare and Medicaid beneficiaries (§1115A(a)(1) of the SSA). The statute directs the Secretary to select "from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures" (§1115A(b)(1)(A) of the SSA). The law further directs CMS to evaluate each Phase I CMMI model, and only after taking into account this evaluation, if appropriate, the model may continue to be tested in Phase II to expand "the scope and duration," provided certain requirements are met (§1115A(c) of the SSA), including a requirement for a separate notice and comment rulemaking for any expansion. CMS is required to report periodically to Congress on CMMI models and make proposals for legislative action on models it deems appropriate (§1115A(g) of the SSA).

The language, structure, and requirements of section 1115A of the SSA clearly indicate that Congress did not delegate its lawmaking authority to CMS. Under section 1115A, any permanent or mandatory changes to Medicare payment systems must be enacted by Congress after taking into account results of models that have been tested. Congress is the branch of the Federal government responsible for enacting changes to Medicare payment systems through legislation; CMS is granted limited authority under specific provisions of law to make specific changes to those payment systems or to test new models. There is no language in the statute or any legislative history that supports the interpretation that Congress delegated its authority to make permanent changes to the program to the Secretary through the CMMI. In fact, the limited legislative history on this provision indicates the exact opposite. Notably, nowhere does the law expressly state that CMS can make models mandatory.

Because delegations of lawmaking authority to the agencies may be constitutionally suspect, Congress would have had to include specific statements in the legislation indicating that it both intended to and actually was delegating its lawmaking role to the Agency. Any such delegation would have had to include clear standards for the administration of duties to limit the scope of Agency discretion as well as procedural safeguards from arbitrariness or abuses. In other words, Congress would have had to specifically permit CMS to require participation of providers of services and suppliers in a model tested by the CMMI in the language of the authorizing statute. CMS may not impute that Congress granted the Agency this authority.

Any Agency interpretation that the statute permits mandatory models raises issues of impermissible delegation of lawmaking authority where none was intended. This is especially true because Congress precluded administrative or judicial review of a substantial number of matters of CMMI demonstration authority under section 1115A(d)(2) of the SSA to permit the testing of models. The waivers of administrative or judicial review require that the scope of delegation to the Agency be read in the narrowest terms, meaning that the Agency may not infer additional grants of authority absent specific language in the statute. An Agency

determination allowing mandatory participation of providers of services and/or suppliers is an overreach in interpretation that contradicts the statutory mandate and raises concerns about impermissible delegation of lawmaking authority to the executive branch. **Absent specific language in section 1115A authorizing the mandatory participation of providers of suppliers, we do not believe CMS may implement a policy that requires such mandatory participation. We urge CMS to ensure that all CMMS models are voluntary, including the proposed Radiation Oncology (RO) model.**

CMS has successfully demonstrated that it is fully capable of testing models under section 1115A solely through providers of services and suppliers that volunteer to participate in those models. Experience with the Bundled Payments for Care Improvement (BPCI) Initiative shows a substantial number and range of providers and suppliers willing to participate in carefully crafted models. Encouraging voluntary participation by providers and suppliers was the intent of Congress in enacting section 1115A and is the proper and appropriate use of legislatively granted demonstration authority. It was the manner in which previous demonstrations were conducted pursuant to section 402(a) of the Social Security Amendments of 1967 (P.L. 90–248), as amended by section 222(a) of the Social Security Amendments of 1972 (P.L. 92-603).

CMS Should Delay Implementation of the RO Model

The FAH strongly believes that the start date of the RO model demonstration project should be delayed beyond the January 1, 2020 start date to at least April 1, 2020. The proposed January 1, 2020 start date is a hurried and unrealistic implementation timeline that is likely to negatively impact the chances of a successful implementation. CMS should also consider how an unrealistic implementation schedule may impact patient care as providers included in the model manage the transition. The Proposed Rule's comment deadline closes on September 16th, so a final rule cannot reasonably be expected before early November. We believe it is unrealistic to expect hospitals to move forward with a complete planning process until a final rule is issued, and 60 days or less will be insufficient to implement the necessary infrastructure.

Providers require the necessary time to build the clinical, legal, financial and quality infrastructure, and analyze data to successfully launch the RO model. There is considerable administrative burden and time necessary to operationalize the model. Hospitals need sufficient time to conduct preparatory market analyses, understand the clinical and financial risk of their patient populations, and establish the needed organizational capabilities to manage payment bundles. This is not an easy exercise that can be accomplished on a short time line, and we do not believe it is appropriate to ask hospitals to move forward in earnest until a final rule has been issued and the playing field set.

Timely Availability of Accurate Data Needed to Properly Manage Care and Monitor Performance

It is **critical that model participants receive relevant and timely data, be permitted enough time to analyze the data, and take appropriate action with participant partners on a timely basis. The data must be provided prior to the start of any new model, and at regular intervals (*e.g.*, monthly) throughout the model.**

To successfully manage risk, participating providers must have sufficient time and data to analyze and understand the composition, characteristics, and needs of their patient population. As indicated by experience with the BPCI models and our members experience with CJR, comprehensive management and analysis of data is the foundation for hospitals to redesign and coordinate care and establish the necessary organizational and technological infrastructure.

Given our member hospital experience in receiving data from CMS under current models, we have concerns about the timeliness of the data received and its quality, including data that has been revised after model participants have relied on it for model implementation. Too often, our members do not find the provided data helpful, as it has been produced in a format that is difficult for our smaller hospitals to analyze. Those hospitals that have the capability to analyze the provided data have found it to be incomplete in many cases and not consistent with the hospital's own data.

CMS's Discount Factor is Overly Aggressive

The imposition of a four percent discount factor for the Professional Component (PC) and five percent for the Technical Component (TC) of the model is historically large and will impede provider success in the model.

The proposal clearly departs from other similar episode payment models developed and implemented by CMMI. For instance, under the Bundled Payment for Care Improvement (BPCI) Advanced model, CMS dictates a 3 percent discount. Similarly, the Comprehensive Care for Joint Replacement (CJR) model also incorporates a 3 percent discount factor. And while it has since been canceled, the proposed Episode Payment (EP) model also included a 3 percent discount factor.

The RO model is a mandatory program that we know from the experience of our member hospitals will require significant and costly up-front investment to develop the legal, clinical, financial and quality infrastructure needed to achieve RO model goals, including technology and data analyses. Further, these models will apply to many hospitals with little experience with episode-based payments, and there could be a great degree of variation in episode spending outside the control of the hospital, which is not adequately addressed through risk adjustment. **CMS should appreciate these factors and reduce the discount factor accordingly.**

CMS's Payment Withhold Targets Will Reduce Model Success

Taken together, the discount factor and the withhold targets mean that participating providers will see significant upfront reduction in payment. While participants will have the opportunity to earn these payment reductions back based on episode completion, quality and patient experience, in practical terms, it means that providers will be forced to find the needed upfront investment costs for successful participation in the model.

As CMS's experience should show, investment costs for providers participating in CMMI models are substantial. CMS's proposal will hinder the successful implementation of the model through unnecessary withhold amounts. **Provider success would be better supported by a more rational withhold scheme.**

Proposed Incorrect Payment Withhold

CMS proposes to withhold 2 percent of the total episode payment for both the PC and TC of each cancer type. CMS notes that the withhold would reserve money to address overpayments that may result from two situations: (1) duplicate RT services and (2) incomplete episodes.

Given CMS's own data showing that duplicate RT services and incomplete services are uncommon (2 and 6 percent, respectively), CMS should reconsider the withhold all together. As CMS notes, the likelihood of duplicate RT services and incomplete services is rare, so the protection provided to CMS by the withhold is unnecessary and unwarranted. Those withheld funds are more valuable to the providers enacting the model and to the model's success than they are to protect CMS from situations which, by CMS's own data, rarely occur.

Model Should Account for New Technology Advancement

FAH members that provide radiation treatment (RT) strive to provide the best quality of care using the most appropriate technology to provide that care. CMS should consider how investments in new technologies may be impacted by the demonstration which could have consequences for patient care in the future.

New technologies being tested now, such as MR-linacs and adaptive radiotherapy, have the potential to improve clinical effectiveness and patient experience. However, as proposed, the RO model does not include a provision to account for the increased costs that these new technologies may require.

Accounting for the need to enhance payment for new technologies is a normal function of the Medicare program. Under the Medicare Inpatient Prospective Payment System, CMS does consider the need to enhance payments based on the introduction of a new medical service or technology. In the case of the RO model, CMS should consider the considerable investment required to acquire and utilize these new technologies by RT providers. **CMS should seek to avoid an outcome that forces cause RT providers to forgo acquisition of new technologies that enhance patient care due to financial strain caused by the RO model.**

Appropriate Quality Measurement

Measuring quality is an integral part of all CMMI models and is a key component of a potential expansion of a successful model. **It therefore is imperative that CMS carefully evaluate the quality measures proposed and used in each model to ensure that the measures selected fit the purpose of the demonstration. In particular, the FAH requests that measures proposed and adopted be National Quality Forum (NQF) endorsed.** In addition, the measures must appropriately capture accurate and relevant timely data directly related to the care provided to the patient. Any quality measurement program should recognize pre-established goals as well as quality improvement from one measurement period to the next.

In this case, the FAH is concerned that the measures selected are insufficient to measure the structural quality provided by RT providers and determine which are providing

the highest value care. As designed, the model does not account for variation in accreditation and equipment used for treatment. Such variables, not accounted for in traditional measurement, do have an impact on the quality of care provided by RT providers.

Additionally, the FAH is concerned that CMS does not delineate the clinical data elements that it has indicated it will require to be reported. Given CMS's aggressive proposed implementation schedule and the eventual need by providers to ensure their systems are extracting the correct data, it is imperative that CMS release those proposed data elements expeditiously. The lack of information on these data elements is an additional reason why CMS should delay the implementation of the model.

The FAH does not support the use of the *Treatment Summary Communication – Radiation Oncology* measure as it was withdrawn from NQF for consideration by the developer and not re-submitted for maintenance or endorsement.

Finally, the FAH does not support incorporation of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Cancer Care survey prior to NQF endorsement if it is to be used for performance measurement or linked to payment withholds. As it currently stands there is insufficient testing of the CAHPS Cancer Care survey to ensure comparability of the performance scores based on practice size and type, patient characteristics, and/or geographic regions. Further, the FAH questions the harmonization of the CAHPS Cancer Care survey with the CAHPS Hospice survey. Finally, the FAH recommends that prior to the incorporation of the CAHPS Cancer Care survey a coherent sampling strategy be specified to ensure patients and families are not over-burdened during this time of stress and anxiety and receive only the relevant survey.

Geographic Designations Likely to Result in Advantages for Non-RO Model Participants

Despite CMS's assertion otherwise, it is likely that the use of Core-Based Statistical Areas (CBSA) to determine model participation will result in patient overlap between RT providers that are required to participate in the model and those that are not participating in the model.

As noted above, given the model does not account for the funding required to invest in new clinical technology and proposes to withhold funding from providers, it is likely that model participants will be at a distinct disadvantage to those RT providers not required to participate in the model. For those non-participating providers, it is likely they will continue to have the financial resources required to invest in updated technology that will allow them to attract additional patients.

This overlap is likely to occur in areas where the CBSA's intersect in densely populated areas where it would not be unusual for patients to travel between counties for medical care. This is especially true as patients look for the most clinically appropriate treatment and are able to choose amongst providers that may be in and out of the model. **This is yet another reason, beyond the statutory limitations, why the model should be voluntary.**

Potential Model Overlap Rules Should be Clarified

The FAH has long encouraged CMS to be more deliberate in providing CMMI model participants with clear guidance on how scenarios in which CMMI models overlap will be treated. FAH members are engaged in a number of Innovation Center initiatives and the lack of clarity on model overlap continues to be an issue.

As CMS notes, there are a number of CMMI/CMS models which could interact should the RO model be finalized. Of these, CMS only defines the terms of a potential overlap for one model – the Oncology Care Model. Unfortunately, for models like BPCI-Advanced, the Medicare Shared Savings Program (MSSP), or other Accountable Care Organization (ACO) models, CMS does not provide clear guidance on how model overlap would be treated.

We continue to encourage CMS to be more deliberate and specific about how model overlap will be treated. Such clarity is not only beneficial for those providers that will be required to participate under the RO model but, importantly, for those providers participating in the other models identified by CMS in the proposed rule.

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Thank you for the opportunity to comment on the proposed RO model. Should you have any questions, please feel free to contact Paul Kidwell of the FAH staff at (202) 624-1500.

Sincerely,