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VIA ELECTRONIC MAIL

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Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Re: CMMI Model Evaluation and Certification Recommendations

Dear Director Fowler:

The Health Care Transformation Task Force (HCTTF or Task Force) writes to offer recommendations for improving the Center for Medicare and Medicaid Innovation (CMMI) model evaluation and certification process. These recommendations are based on feedback from our members in response to the results of a series of convenings we organized in 2021 with a panel of outside experts, the director of the CMS Office of the Actuary, and the former director of the CMMI Rapid Research and Evaluation Group. The convenings centered on discussing opportunities to improve the model evaluation and certification process. We offer these comments with the goal of supporting CMMIs efforts to expand successful models and fully leverage the knowledge gained from existing models to improve the design of future reform efforts.

Founded in 2014, the Task Force is an industry consortium representing a diverse set of health care stakeholders – including providers, payers, purchasers, and patient advocacy organizations – all committed to adopting payment reforms that encourage health care organizations to move from a system that incentivizes the volume of services to one that rewards the value of care delivered. HCTTF member organizations strive to provide a critical mass of policy, operational, and technical support that, when combined with the work being done by the Centers for Medicare and Medicaid Services (CMS) and others, can increase the pace of delivery system transformation.

Our members have experience with CMS-designed alternative payment models (APMs) and believe these models are critical for both improving quality and reducing health care expenditures. HCTTF members have consistently supported CMS's efforts to develop more

advanced risk models that promote accountability for spending and outcomes for Medicare beneficiaries. The comments offered reflect a desire to support CMMI's ongoing efforts to transform our health care system.

The challenges with model evaluation and certification not only impact the ability of CMS to scale innovations, but they also present headwinds for building and maintaining momentum with model participants. Evaluation limitations combined with model participant confusion over the difference between the within-model performance data that CMMI publishes for some models versus the formal model evaluations where participant performance is judged against an external comparison group have caused stakeholders to question the accuracy of evaluations. Skepticism about evaluations in conjunction with the low rate of model certification leave early adopters of CMMI models feeling stuck in endless test cycles and presents a clear risk for discouraging new participants from joining models. Improving the evaluation and certification methodologies and offering greater transparency regarding the process should be seen as critical components of CMS's larger effort to transform the health care system.

Model Evaluation Recommendations

The Task Force acknowledges and appreciates the challenging task facing CMMI in conducting rigorous model evaluations in an ever-shifting health care environment. We believe that CMMI has done an admirable job working to meet its evaluation mandate given the complexity of the models under review. We also note the fact that model evaluators have faced numerous, often recurring, challenges and limitations in evaluating models. These include determining the right counterfactual and appropriate comparison groups, achieving sufficient sample sizes to power evaluations (especially in voluntary models), accounting for spillover effects and model overlaps, accessing data on activities in the private sector, and measuring the long-term impact of models beyond the testing period. These challenges have made it difficult to fully quantify the impacts of models and translate evaluation findings into broader policy actions.

As CMS works to implement its strategic refresh, strengthening CMMI evaluations should be a top priority. Evaluations offer crucial data for model certification, inform the design of new models, and provide stakeholders across the health care system with insight into which concepts are worth further refinement. Furthermore, if CMS is going to advance efforts to improve health equity it will need to revisit CMMI model evaluation approaches to ensure that it is capturing the necessary data to identify equity impacts. Specifically, model evaluations will need better race and ethnicity data capture and sub-group analyses while maintaining sufficient statistical power to detect the differential impacts of models.

I. Evaluation Focus Areas

The Task Force recognizes and supports the need for CMMI to employ rigorous and statistically sound methodologies to evaluate models. As CMMI works to align with the priorities in the CMMI strategy refresh, we believe that the Center would be well served to focus on

evaluation strategies that seek to determine the extent to which a model's outcomes are driven by the following four factors:

1. **The underlying model concept**: Does the theory of change and logic model at the core of the innovation center investment proposal hold up to real word testing, where core concepts of the model changed during the performance period.
2. **The execution of the model:** How did CMS and its contractors manage the model roll-out and ongoing operations, were there any challenges encountered that impacted participation, were they due to human error or technical/systems limitations.
3. **The characteristics of the model beneficiaries, participants, regions, and markets:** Do model impacts vary based on beneficiary characteristics and does that variation have implications for health equity, does model performance vary in significant ways across participants, could the features of successful model participants be scaled and spread to other providers, does the observed variation provide evidence that a model could be more or less effective if limited to specific beneficiaries/regions/markets.
4. **The design of the evaluation and its ability to detect an effect:** Was the evaluation designed and sufficiently powered to detect an effect, did the evaluators encounter challenges or limitations that impact the ability to draw conclusions about the models.

Assessing how these four factors influence the findings of a model evaluation would add much needed clarity for model participants and make it clear for CMS which concepts are not worth further investment (the underlying theory of change is incorrect, or the operation of a model is not feasable) versus those that warrant further refinement (correctable errors in design/implementation, potential to focus on particular providers/beneficiaries, changes to evaluation methods to determine impacts).

II. Evaluation Methodologies

To date, several CMMI model evaluations have relied on the use of difference-in-difference (DiD) trend analysis to determine model impacts. While this is a well-accepted evaluation methodology, it has important limitations that impact its utility for CMMI models. The primary limitation from our perspective is the challenge of controlling for variables like the effect of prior participation in APMs, overlap between models, and the impacts of spillover effects from CMMI models into the broader market. While CMMI models can have systemic impacts on provider practice patterns across all patients (regardless of attribution to a model) and that the behavior of providers in a model can impact those outsides of the model, current CMMI model evaluations often treat the trends seen in the comparison group as independent of the model intervention group.

The federal government, through the many models launched by CMS and legislation like The Medicare Access and CHIP Reauthorization Act of 2015, has been engaged in a decade long effort to encourage a shift away from fee-for-service (FFS). It is reasonable to hypothesize that the slowing trends for national health expenditure growth rates may be at least partially be the result of the efforts to drive Alternative Payment Model (APM) adoption. If this is the case, current evaluation approaches may make APMs a victim of their own success.

To address this issue, we urge CMMI to prioritize efforts to implement evaluation strategies that more effectively isolate the effects of specific models while controlling for variables like model overlaps, spillover effects, and participant factors such as participation in prior models. The panel of participating experts in our 2021 convenings recommend that CMMI reexamine the use of stepped-wedge evaluation design methodologies and consider implementing randomized control trials (when feasible) to better isolate the impact of a specific model interventions.

III. Leveraging Model Design to Aid Evaluation

We recommend CMMI leverage its model design process alongside existing models and CMS programs to develop stronger comparison groups to support evaluation. To this end, the Task Force has previously submitted a letter with recommendations for leveraging the Medicare Shared Savings Program (MSSP) as a platform for CMMI to test Accountable Care Model innovations. That letter expressed our belief that aligning new ACO concepts developed within CMMI with MSSP would be advantageous for both CMS and model participants.

As a permanent program, MSSP offers the benefit of providing ACO participants permanent participation tracks that they can continue in or transition to in the event a specific innovation fails. It also would simplify the model portfolio for ACOs by aligning all ACO participation options to a single application timeline with a predictable update schedule and opportunity for public comment on proposed changes. The permanence of the MSSP program also offers a natural long-term comparison group for CMMI model evaluations allowing for faster, more efficient, and more robust impact analyses. CMS could design and test a range of model concepts within the existing MSSP program in a manner that would allow evaluators to clearly compare impacts across well-defined participant groups. Our letter recommended testing the following concepts:

- **New Payment Arrangements**: A full-risk participation option with a discount, primary care capitation, per member per month funding mechanism for services like care management and behavioral health. CMS should also consider reinstating the ACO Investment Model (AIM) or make available similar upfront cash flow mechanisms with long repayment periods targeted toward organizations that might need more capacity-building support, which would be critically important in engaging safety net and rural providers.
- **Methodologies for Promoting Equity**: Incentivizing a focus on health equity using financial methodologies designed to reward increasing the total number of primary care relationships and outreach to currently unassignable or historically underserved beneficiaries.
- **Improving Beneficiary Affordability**: Testing a waiver of all cost sharing liability for the services that Medicare beneficiaries – aligned to an ACO participating in a total cost of care arrangement – receive from providers within the ACO network. This could also help to reduce churn and improve care coordination and beneficiary engagement.

- **Improving Implementation and Operations**: Establishing a defined implementation period for new organizations to build capacity to take on risk as an ACO.
- **Enhanced Waiver Options**: Expanded waivers based on lessons learned from other models such as the Next Generation ACO model waivers for post discharge home visits, care management home visits, and telehealth.
- **Promoting Alignment Across Models and Provider Types**: Integrated primary care and specialist models into ACOs by aligning episode-based payments for specific specialties with financial methodologies designed to support and promote primary care under accountable care arrangements.

IV. Public Input on Evaluations

The Task Force recognizes that there are many talented researchers, model participants, and other members of the public that have valuable insight into strategies for improving model evaluations. Thus, **we recommend CMMI issue a Request for Information (RFI) seeking public input on: (1) strategies for improving model evaluations, and (2) approaches for maximizing the value of lessons learned from models that do not meet the criteria for certification. Furthermore, to improve transparency around the model evaluation process we recommend that CMMI provide a written summary of RFI feedback to stakeholders.**

V. Transparency in Model Design and Evaluation

Transparency both in model design and evaluations is critical to advancing efforts to identify and scale promising models. Currently, model stakeholders and outside researchers have insufficient information to fully understand the theory of change underlying model designs or to replicate the evaluation results. **The Task Force recommends that CMMI publish the logic models for all APMs to aid outside researchers' efforts to understand the thinking supporting specific model designs.** Furthermore, **we recommend that CMMI leverage existing pathways such as the Research Data Assistance Center and the CMS Virtual Research Data Center to make future model evaluation data available to researchers** to support outside evaluation efforts that would contribute to the knowledge base to advance model design.

Model Certification Recommendations

The model certification process presents distinct but related challenges for CMS efforts to drive health care transformation. During our 2021 convenings organized to discuss model evaluations and certification, it became clear that the statutory requirement for the Chief Actuary of CMS to certify that a model under consideration for expansion "would reduce (or would not result in any increase in) net program spending…" was not a routine or well-defined process or standard. Congress did not define the level of evidence or degree of certainty needed for certification in the statute and there are no committee notes to offer insight into discussions leading to this requirement. Consequently, CMS was tasked with interpreting the statutory language and establishing a standard for the level of evidence necessary for certifying a model.

The resulting certification standard CMS adopted is 95 percent or greater certainty of savings as stated by CMS officials. This is a very high bar, so high in fact that some researchers have noted that CMS is likely missing out on opportunities to expand models that would drive systemic health system changes and long-term savings to the Medicare Trust Fund. Additionally, using this high threshold of certainty to define success for a model overall means that CMS is missing out on chances to identify and spread model concepts that would work well if applied to specific types of participant organizations, services, and conditions.

I. Reevaluating the Certification Standard

The Task Force urges CMS to reevaluate the degree of certainty required to certify CMMI models in light of the limitations of prospectively forecasting savings. As part of this reevaluation, CMS should consider a model's individual potential to generate savings as well as the potential for a model to contribute to broader health system transformation that would result in long-term gains in efficiency, efficacy, equity, quality, and outcomes.

To inform this effort, **we recommend that CMS issue an RFI requesting public comment on standards for actuarial certification that a model "would save money" if expanded.** This RFI should also request feedback on potential approaches that CMS could use to leverage promising models that fail to meet certification thresholds but may still make meaningful contributions to advancing broad health system transformation and reduce long-term CMS spending. We believe the governing statute affords discretion to CMMI to follow a more policy-outcomes driven approach over an overly stringent actuarial determination.

II. Transparency in Model Certification

Currently, the public has no insight into which models CMS is considering for certification by the Office of the Actuary or the results of the reviews. Transparency regarding which models make it to certification and the results of the reviews would benefit CMMI stakeholder engagement efforts and provide greater clarity on the potential of specific model concepts. **The Task Force recommends that CMS publish an annual public facing report identifying the model's considered for certification and the actuarial determination for any model reviewed for certification regardless of approval for expansion.**

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The HCTTF is eager to work with CMS to achieve sustainable change in value-based payment and care delivery, a goal that requires alignment between the private and public sectors and engagement with payers, providers, purchasers, and patients. Please contact Joshua Traylor (Joshua.Traylor@hcttf.org | 202.556.0339) with any questions or comments on this letter.

Sincerely,

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