

May 23, 2019

Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

***RE: Request for Information on Direct Contracting—Geographic Population-Based Payment Model Option***

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) request for information (RFI) on the Geographic Population-Based Payment (PBP) model option of the Primary Cares Initiative.

Our members are deeply engaged in redesigning their delivery systems to increase value, better serve patients and support the evolution of risk-sharing arrangements as a means to advance this work. As such, the AHA supports the development of models that improve beneficiaries' access to care and providers' ability to provide high-quality care that best meets their patients' needs. Given that many of our members provide primary care and many more interface with primary care providers in their delivery of coordinated care for patients, we look forward to learning more about CMS's strategy to redesign primary care as a pathway to drive broader delivery system reform. We hope our comments are helpful in developing that pathway.

As described in the RFI, the Geographic PBP model option would require participants to assume risk for the total cost of care (TCOC) for Medicare fee-for-service (FFS) beneficiaries in one of four defined target regions. Participants – referred to as direct contracting entities (DCEs) – would have formal relationships with Medicare enrolled providers or suppliers in the target region, including provider organizations, health plans and others. CMS would pay DCEs on a capitated basis and offer them the choice



between contracting with and paying downstream providers or having CMS retain claims payment and reconciliation responsibility (while the DCE would remain at full financial risk).

The RFI raises important questions about the parameters and implementation of the Geographic PBP model option. However, the lack of detail makes it difficult for providers to conduct well-informed analyses in response to the questions. Accordingly, we urge CMS to develop the model as transparently as possible so that potential applicants can make fully-informed decisions about applying for participation. More specifically, we recommend CMS consider our stakeholder feedback and continue to release additional information about its plans for the Geographic PBP model option.

## GENERAL MODEL DESIGN

In the RFI, CMS solicits input on how DCEs in the Geographic PBP model option could address social determinants of health (SDOH). We appreciate CMS's recognition of the importance of SDOH and the key role they play in improving the overall health and well-being of patients and communities. **To that end, we urge CMS to ensure the PBP amount in this model option is sufficient to provide participants with adequate resources to address both the medical and non-medical needs of community members.** In fact, because many providers and other entities do not currently have the resources or ability to address SDOH with their own funds, or are restricted from doing so due to legal and regulatory barriers, spending on SDOH may not be reflected in the historical TCOC. Therefore, if CMS wishes to encourage DCEs to address SDOH, it should, at least initially, provide a PBP that may exceed DCEs' historical spending. **CMS also should ensure, through the use of waivers or otherwise, that there are clear legal and regulatory bases for DCEs to provide services that address SDOH.**

**In addition, if CMS intends for providers themselves to be able to participate in the model as DCEs, we recommend creating a pathway to risk that can prepare these participants for TCOC risk.** Such a pathway is essential for providers and other entities with varying degrees of experience with risk-sharing arrangements to transition to value-based care, especially given the significant risk that CMS would require of participants in the Geographic PBP model option. This also is particularly important for the primary care providers that the Primary Cares Initiative aims to target, as they generally already face significant barriers to earning adequate reimbursement for the care they provide.

## PAYMENT

Part D Drug Costs. Accounting for Part D drug costs in DCEs' benchmarks could provide several opportunities for and challenges to participation in the Geographic PBP model option. With participants accountable for TCOC, they may attempt to increase generic and biosimilar drug utilization, which would help lower the overall prescription

drug spend. Similarly, if TCOC capitation better incentivizes providers to prescribe lower cost drugs where available, this may play a role in incentivizing brand manufacturers to increase pricing competition, which would ideally help drive down the overall cost of prescription drugs.

However, accounting for Part D costs also could present challenges to participants' success under this model. In particular, certain patient populations have significant utilization of high cost Part D drugs – without appropriate risk adjustment for those patients, participants could quickly burn through their capitated payments. For example, Sovaldi, which offered significant advancements in safe and effective treatment of hepatitis C for millions of seniors, launched at a price of \$1,000 per pill, equating to \$84,000 for a total course of treatment. Despite the vital treatment that drugs like Sovaldi provide, managing the cost of these extraordinarily expensive drugs, especially if they are new and not immediately reflected in the benchmark, is likely to present serious financial challenges for participants.

Thus, as CMS determines the payment parameters for the Geographic PBP model option, we urge the agency to examine options that would provide flexibility to participants with respect to Part D Plan requirements in order to avoid simply shifting the risk of the Part D program to providers participating in the model. We recommend CMS consider provisions like the allowance of therapeutic interchange for certain drugs to encourage the increased use of lower cost, generic drugs at the pharmacy counter.

Setting and Risk Adjusting the Benchmark. CMS explains in the RFI that it would calculate DCEs' benchmarks based on the historical Medicare Parts A and B per capita spending in a given target region. While we understand why CMS would look only to a target region's TCOC spending to determine the benchmark for that region, we are concerned that such an approach will be untenable for low-cost regions. In areas where DCE applicants already have achieved significant cost savings for Medicare, finding ways to save even more would be extremely difficult if such applicants are compared only to their own past performance. **We urge CMS to consider a national/historical or regional/historical blended benchmark to ensure it incentivizes low spending organizations to apply for participation in the Geographic PBP model option.**

**We also urge CMS to apply a robust risk adjustment methodology to DCEs' benchmarks to ensure this model option does not inappropriately penalize participants treating the sickest, most complicated and most vulnerable patients.** By accepting full risk for beneficiaries' TCOC, DCEs would be held responsible for all spending by any provider for beneficiaries' health care needs over the course of a year. This degree of risk could expose DCEs to extreme fluctuations in beneficiary spending based on changes to a beneficiary's health status, including those over which they have no control. This would be especially difficult for a DCE that operates across a variety of populations and/or counties that have extremely varied health statuses. Several of our members have expressed how important the presence of adequate risk adjustment is to

their decision as to whether to apply for the Geographic PBP model option; to that end, we urge CMS to release information about risk adjustment as soon as possible.

**To further encourage application, we also suggest CMS risk adjust DCEs' benchmarks on an annual basis so as to reflect the changing health status of the beneficiaries in a target region.** Doing so is essential for ensuring DCEs do not struggle against an outdated risk score. Such a situation could create a level of risk some DCEs and/or providers do not wish to bear, deterring them from applying to the Geographic PBP model option. In addition, CMS routinely applies shorter-term caps on risk and price adjustments: the agency capped trend factor variation in the Bundled Payments for Care Improvements program on a quarter-over-quarter basis and risk scores in the Next Generation accountable care organization (ACO) program at 3 percent over two years. The Medicare Advantage (MA) program also utilizes annual premium adjustments based on beneficiaries' HCC risk scores. CMS should look to MA and the experience of ACOs in other programs to ensure risk scores are sufficiently flexible.

**With respect to selecting a discount amount to apply to DCEs' benchmarks, we urge CMS to make 3 percent the maximum discount to which a DCE could be subject.** Specifically, CMS would determine the Geographic PBP benchmark by calculating DCEs' historical Medicare Part A and B per capita spending for aligned beneficiaries during a baseline period; trending these historical expenditures forward to the performance year; applying a geographic adjustment factor; and discounting the benchmark. But in order to succeed under this model, DCEs need a fair opportunity to achieve meaningful savings. Setting a discount of 4 or 5 percent in the first year of participation – not to mention future years when target spending amounts will be reduced – would risk turning the Geographic PBP model option into a straight payment cut, preventing it from achieving CMS's goals and putting patient care at risk.

Additionally, to fundamentally shift the total cost of care and total care experience for all beneficiaries in a large region, DCEs would need to make significant investments in infrastructure to close gaps in care transitions and coordination and in data analysis and reporting systems to better target care to beneficiaries' needs. At the outset of the Medicare Shared Savings Program, we conducted research that found it would cost a large, multi-hospital ACO approximately \$12 million in initial investments to launch the ACO and an additional \$14.1 million annually to run it. We would expect the investment costs to be even higher in the Geographic PBP model option due to the significantly higher degree of risk envisioned and the larger number of providers and other entities across which each DCE would need to operate. As such, in order for DCEs to make their participation in this model option financially viable, they would need to achieve cost savings well beyond their discounted benchmarks in order to cover their investments. They also would need to account for new administrative and processing functions entailed by the transition from a FFS model to a capitation model, even if CMS retained most of the claims processing functions it currently performs. We urge CMS to take

these challenges into consideration when setting DCEs' benchmarks and to consider support for the upfront investment and administrative functioning DCEs would have to undertake to participate in this model option.

## SELECTION OF TARGET REGIONS

In describing how it would select target regions for participation in the Geographic PBP model option, CMS indicates it would “favor” target regions with at least two DCEs to encourage competition. However, the agency also indicates that DCEs selected for participation “would be at full risk for the TCOC for Medicare FFS beneficiaries in the target region.” Limiting eligible target regions to only those with two or more DCEs could exclude some of the entities best positioned to participate in this model option – those that have gained experience managing utilization for large swaths of their populations by holding most or all of the market share in their regions. **We request that CMS clarify how a DCE could be at full risk for the TCOC for all beneficiaries in a given region if there is more than one DCE in the region.** Would CMS permit more than one DCE to split responsibility for beneficiaries in a target region? If so, how would CMS attribute beneficiaries to the various DCEs?

We also request clarification of CMS's intention to allow DCEs to propose the geographic areas that would constitute their target regions. We are concerned this could allow a DCE to design a target area that excludes more severely ill populations. **We strongly urge CMS to establish safeguards against any such gaming of the target region design and any other manner in which DCEs could “cherry pick” only healthy patients, leaving vulnerable populations without access to care.**

Regarding implementation of the Geographic PBP model option in a rural area, we urge CMS to take thoughtful and targeted action to preserve access to and quality of care. Specifically, CMS should ensure that the capitated payment amount in the Geographic PBP model option is sufficiently risk adjusted to account for the health status of rural beneficiaries. Contrary to CMS's belief that risk is more evenly distributed when it is taken on a population basis as large as is contemplated by this model option, reducing the need for risk adjustment, rural populations tend to be sicker overall, and adequate risk adjustment therefore would be necessary in any target region that includes a rural area.

We also urge CMS to take thoughtful and deliberate action to preserve access to and quality of care for beneficiaries in rural areas. To do so, CMS should consider the challenges unique to rural and frontier communities, such as geographic isolation caused by mountain ranges or other physical barriers; weather events such as floods that are more common to these areas; disparate road conditions or lack of availability of paved roads; long travel times between patients and health care providers; and low populations and low patient volumes. **To ensure that DCEs adequately account for these challenges if they operate in rural or frontier areas, we recommend that**

**CMS issues clear provider network requirements to guarantee timely access to services.** We also encourage CMS to work with DCEs to assist them with integrating data and oversight across participating providers, especially in rural and frontier areas where providers may be more disparate and at a greater distance from one another.

## **DCE ELIGIBILITY**

Two of the DCE selection criteria that CMS lists in the RFI include whether the DCE applicant “has the ability to perform ongoing data collection, analysis and reporting to support quality improvement and decrease healthcare costs” and whether the applicant “has the capacity to provide strategic and operational direction and technical assistance to healthcare providers to support health care delivery transformation.” The importance of these two capabilities – data collection and the provision of technical assistance – to the implementation of an alternative payment model (APM) as far reaching as the Geographic PBP model option would be matched, if not exceeded, by the challenge in providing them. Thus, we urge CMS to work with DCEs to help ensure they are able to deliver these services to their downstream providers and other relevant entities.

In holding providers responsible for the TCOC, CMS must offer them the tools to understand their patient populations in a detailed way so they can recognize areas where changes in care could improve patient outcomes and reduce system costs. Once they understand potential levers for change, providers need guidance in how to pull those levers, especially given that many will be asked to practice medicine in new and unfamiliar ways. **To that end, we urge CMS to explore and dedicate resources to determine methods that would provide participants with complete, timely – ideally real-time – and understandable data and technical assistance.** By doing so, CMS would empower providers to maximize the effectiveness of any care redesign efforts they undertake as part of their participation in the Geographic PBP model option.

## **BENEFICIARY ALIGNMENT**

In the RFI questions, CMS describes the beneficiary alignment methodologies it is considering – presumably for use in target regions with two or more DCEs, if CMS proceeds with selecting such regions – including randomly aligning beneficiaries to a DCE or allowing beneficiaries to voluntarily align themselves. If CMS randomly assigns beneficiaries to DCEs without them having expressed interest in being assigned, it would essentially direct them to providers they have not selected, even if in reality they would not lose their ability to choose their own providers. We are concerned about CMS’s proposed random alignment, as it could be confusing to beneficiaries. We urge CMS to consider this possible confusion in selecting an alignment methodology.

Regardless of the alignment methodology CMS chooses, it will be key to the success of the Geographic PBP model option to ensure participating providers have sufficient time to understand their assigned beneficiaries so as to redesign care to improve quality and

lower costs. If beneficiaries are able to switch at will between DCEs without consequence, it will be impossible for providers to gather reliable information about their patient populations and to design targeted interventions that meet those patients' needs. **Therefore, we urge CMS to consider incorporating into the Geographic PBP model option "open enrollment periods" during which beneficiaries could choose to enroll or disenroll from the DCEs they have selected or to which they are assigned.** Such enrollment limits will allow providers longitudinal access to patients, which is essential for making a meaningful impact on patient outcomes in the primary care setting, and will enable providers to make investments in patient care based upon a reasonable estimate of the payments they expect to receive.

We also are concerned about how CMS will align beneficiaries to DCEs who already are attributed to other APMs in a given target region, such as ACOs or bundled payment initiatives. There are several regions around the country where there are few remaining unattributed lives, such that the only way DCEs in those regions could gather 75,000 beneficiaries would be by re-assigning already attributed beneficiaries. If CMS plans to align these previously attributed lives to DCEs, it will cause significant disruption to the care for these beneficiaries, who already have and could lose their existing care teams. **In light of this potential disruption to patient care, we recommend that beneficiaries already attributed to a value-based payment arrangement not be attributed to a DCE.**

CMS also seeks input on the transparency/notification requirements it should impose on DCEs participating in the Geographic PBP model option. We recommend that CMS ensure any transparency/notification requirements do not create significant regulatory burdens for DCEs and participating providers. Doing so could cause them to divert important resources away from patient care. Instead, we urge CMS to consider how it could reduce complexity and burden by itself providing some of the necessary transparency and notice to beneficiaries aligned to DCEs participating in this model option.

## **PROGRAM INTEGRITY AND BENEFICIARY PROTECTIONS**

As CMS recognizes in the RFI, regulatory flexibilities will be key to promoting DCE success in the Geographic PBP model option by empowering participants to direct beneficiaries to the clinical settings that best serve their short- and long-term needs. **We therefore urge CMS to waive regulations related to the physician self-referral law and the Anti-kickback Statute relevant to financial arrangements formed by participating providers and that comply with model requirements.** CMS currently waives these regulations for ACOs to enable participants to form the financial arrangements necessary to succeed and should do so in this model option as well. **We also urge CMS to waive anti-trust laws that would prevent providers acting as or in conjunction with DCEs from entering into financial arrangements with their competitors.** Such arrangements would be necessary for a DCE to manage the TCOC

and entire care experience of patients under the Geographic PBP model option, and providers need assurances that any such arrangements would not run afoul of the law.

Additionally, the waiver of certain Medicare program regulations is essential to enabling providers to coordinate care and ensure that it is provided in the right place at the right time. To support this work, CMS should waive certain payment rules and offer to Geographic PBP model option participants the Skilled Nursing Facility (SNF) “3-Day Rule” waiver that it provides to ACOs. Waiving payment regulations such as certain hospital discharge planning requirements, telehealth requirements, the inpatient rehabilitation facility (IRF) “60% Rule,” the IRF “Three-hour Rule,” and the home health homebound rule also is essential, as these regulations frequently inhibit care coordination. These waivers would provide participants with valuable tools to increase quality and reduce unnecessary costs, commensurate with the level of risk and accountability that CMS is asking them to assume through this and other models as it shifts the burden of risk further away from the Medicare program onto providers. Because waivers of the fraud and abuse, anti-kickback, and payment laws and regulations mentioned here would be essential to participants’ success in the Geographic PBP model option, we urge CMS to announce the waivers it will offer before the application due date for this model option.

As mentioned above, we also urge CMS to implement beneficiary protections that would ensure that beneficiaries would not lose their existing care relationships. Requiring as proposed that DCEs have a historical presence in the target region is one such way to ensure new entrants do not pull patients away from their care teams, and we strongly support this requirement.

Thank you for your consideration of our comments. If you have any questions, please feel free to contact me or have a member of your team contact Shira Hollander, senior associate director of payment policy, at (202) 626-2329 or [shollander@aha.org](mailto:shollander@aha.org).

Sincerely,

/s/

Thomas P. Nickels  
Executive Vice President  
Government Relations and Public Policy