Federation of American Hospitals®

Charles N. Kahn III
President and CEO

May 30, 2019

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

Re: Center for Medicare and Medicaid Innovation; Request for Information on Direct Contracting---Geographic Population-Based Payment Model Option

Submitted electronically to DPC@cms.hhs.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 include teaching and non-teaching full-service community hospitals in urban and rural parts of the United States, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. The FAH welcomes the opportunity to respond to the Centers for Medicare & Medicaid Services (CMS) regarding the Request for Information (RFI) on Direct Contracting--Geographic Population-Based Payment Model Option, as posted electronically on April 22, 2019 (https://innovation.cms.gov/initiatives/direct-contracting-model-options/).

The FAH recognizes the sustained commitment of resources by CMS (including its Innovation Center) to design, test, and evaluate a variety of innovative health care delivery models as a pathway to improving quality and value for Medicare beneficiaries. The Direct Contracting Geographic Population-Based Payment Model option (the DC *Geographic* option) is one of five components of the Agency's new, voluntary Primary Care First Initiative. The Initiative represents a wide-ranging, multifaceted effort by CMS to test whether various configurations of primary care delivery and direct contracting relationships can bring value-based care to more fee-for-service (FFS) beneficiaries. The DC *Geographic* option in particular appears to seek participants beyond provider-based organizations, such as insurers or health plans, to accept full risk for total cost of care (TCOC) furnished to a geographically-defined FFS beneficiary population. Participants in this option would be

known as Direct Contracting Entities (*Geographic* DCEs), and they would be given flexibilities, such as paying downstream providers at variable discounts from FFS rates, that are often associated with the Medicare Advantage (MA) program (Medicare Part C).

The FAH shares the Agency's interest in value-based care models, as reflected by our members' ongoing participation in multiple CMS models, including the Medicare Shared Savings Program (MSSP), the Bundled Payments for Care Improvement Advanced (BPCI-A) model, and the Next Generation Accountable Care Organization Model (NGACO). Given our substantial experience with these and other models, we have reviewed the RFI with interest and provide the following comments.

Our comments will utilize the RFI's major topic categories:

Questions Related to General Model Design

General Comments

CMS indicates that the designs of the DC payment model options (*Professional, Global,* and *Geographic*) were heavily influenced by the Agency's existing programs and responses received for the Direct Provider Contracting RFI (DPC-RFI) issued in 2018. Links from existing programs, as well as the iterative testing of progressively larger DC models as described in last year's DPC-RFI, to the newly-developed *Professional* and *Global* options are readily evident. The DC *Geographic* option, however, appears to draw features primarily from the MA program and represents a sizeable leap rather than an iterative step from the testing plan in the DPC-RFI. CMS also plans for the *Geographic* option, the least-defined and most expansive DC option iteration, to begin full operations on the same January 1, 2021, start date as the better-defined and more incrementally progressive DC *Professional* and *Global* options.

We are concerned that CMS intends to launch a model for which structural and operational details are largely incomplete, on a compressed timeline that will not allow for application of lessons to be learned from the more straightforward DC *Professional* and *Global* options. We also are extremely concerned about developing and rolling out the DC *Geographic* option just as the CMS launches BPCI-A Model Year 3, the MSSP implements a major redesign, higher incentive payment thresholds and steeper penalties take effect in the Quality Payment Program (QPP), and the MA program begins offering new supplemental benefits. CMS resources are finite, and we would not want to see consequences to popular, existing models such as degradation of data timeliness and delayed high-priority updates arise from diversion of resources to new model deployment. **The FAH recommends that CMS lengthen the timeline and delay the launch date of the DC *Geographic* option**, allowing for thoughtful consideration of the DC RFI responses, unpressured model development, and learning from challenges encountered during DC *Professional* and *Global* option implementation. **We further recommend that the fully-developed DC *Geographic* option be posted for public comment and that time be allotted for making further revisions if needed** prior to the start of the model's first performance year. Finally, we encourage CMS to consider if, where, and how various direct contracting provisions might be added to existing models.

Responses to Specific Questions

1. CMS has carefully constructed evaluation plans for their models and the RFI seeks input about "special evaluation considerations" that might apply to the DC *Geographic* option. The FAH acknowledges that factors such as DCE size may present evaluation challenges (e.g., appropriate comparison group construction). However, **the FAH strongly recommends that the evaluation plan be at least as rigorous as those for prior models, particularly with regards to the scalability of the DC *Geographic* model option across the FFS population.**

Questions Related to Selection of Target Regions

Responses to Specific Questions

1. CMS invites input into the criteria for selecting the "target regions" in which the DC *Geographic* option will be tested. The FAH believes that proper target region selection is of paramount importance in testing this option, given the size of the DCEs (e.g., number of aligned beneficiaries, geographic footprint) and their resulting inherent ability to disrupt regional market dynamics. We agree with CMS that a target region should be sufficiently large to readily sustain the presence of at least 2 DCEs in order to encourage competition and support beneficiary choice.

   The FAH strongly recommends that regional penetration of CMS' Advanced Alternative Payment Models (AAPMs) be considered in target region selection. The BPCI-A and the MSSP are of particular note, as they will continue through much or all of the DC *Geographic* option's planned test period (CY 2021 through CY 2025). The BPCI-A initiative has had wide uptake by providers and properly the model should not be jeopardized by the introduction of DC *Geographic* option DCEs into their catchment areas. Additionally, CMS is launching major changes to the MSSP as embodied in Pathways to Success. As with BPCI-A, the implementation of this new model should not jeopardize the potential success of the Pathways to Success program. Attention should also be paid to the presence of Other Payer AAPMs in a region, as these entities will be recognized under Medicare's QPP beginning with QPP payment year 2021.

2. CMS poses questions about testing the DC *Geographic* option in target regions with embedded rural areas. We agree with CMS that multiple market forces are unique to or disproportionately affect rural areas, such as out-migration and critical access hospital regulations. We also note the tenuous current fiscal status of many rural hospitals along with worsening practitioner shortages. If CMS elects to include target regions with embedded rural areas, DCE applicants selecting those regions should be required to submit a robust analysis of the DCE's potential market impact for the rural and adjacent urban components of its region along with a detailed plan to mitigate possible negative consequences for rural beneficiaries.

Questions Related to DCE Eligibility and Selection

Responses to Specific Questions

1. CMS invites comments on 13 criteria potentially applicable to DCE eligibility and their relative importance in selecting applicants for participation as DC *Geographic* option DCEs. While all of the described criteria have merit, we will focus on those we perceive to be of greatest import. Numbering of our comments matches the order in which the DCE eligibility criteria are presented in the RFI.
    a. Historical regional presence of the DCE applicant

    The FAH believes this is an extremely important DCE eligibility and selection criterion, and that market share of the applicant in and adjacent to a target region should be examined in detail. While a historical presence in a target region is intuitively appealing, we are concerned about the potential for a major, well-financed, non-provider market player to leverage being a *Geographic* DCE into establishing new or expanded market dominance relative to organizations with long-standing track records of furnishing services to the region's beneficiaries and making regional health care infrastructure investment. Our concern is amplified by the fact that applicants will define their own target regions.

    The FAH is further troubled by the examples provided by which applicants would demonstrate their historical presence; the examples seem much more relevant to health plans and insurers than to the provider-based organizations that form the backbone of existing CMS models. Health plans and insurers already have nationwide access to Medicare beneficiaries through MA as beneficiaries age into the program and through open enrollment periods, so we are unsure why a model that seems to replicate much of MA would be important to beneficiaries who already have chosen FFS Medicare coverage.

    The FAH agrees that historical presence of a DCE applicant in or adjacent to its proposed target region is an extremely important DCE eligibility and selection criterion. We recommend its use as a means of reducing opportunities for DCEs to inappropriately create or expand market dominance in a way that degrades beneficiary choice of providers in the region in which the beneficiary resides.

    b. Sophistication of data systems and data analytic capabilities

    In order to succeed, all value-based care models depend heavily on data acquisition and analysis to monitor outcomes. The size and complexity of *Geographic* option DCEs will amplify their data dependence. Based upon our members' ongoing data challenges as participants in multiple other models, the FAH is very concerned about the ability of CMS to provide accurate, timely, sufficient, and interpretable data to meet *Geographic* option DCE needs. We are further concerned that making changes to meet DCE data needs will dilute CMS's already constrained health IT resources and further impair data provision under existing models.

As CMS considers adding additional programs to its portfolio, the FAH suggests that CMS improve its data delivery by including program assignment to individual beneficiaries, so program participants have a clear understanding of the association between beneficiary and respective APM.

c. Discount percentage provided to CMS

CMS suggests that the discount percentage (upfront savings) provided to CMS by a DCE be used for DCE eligibility and selection and has mentioned a range of 3-5%. The substantially increased size and geographic footprint of *Geographic* DCEs should allow for economies of scale unachievable by participants under smaller-sized CMS models. **The FAH recommends that CMS maintain a discount percentage that is appropriate for the size and scope of the model which, for this model, we believe would be at the higher end of that described by CMS.**

d. Target region and population sizes

The FAH strongly agrees that the size and population of the target region have merit as criteria for DCE applicant eligibility and selection and we have addressed them more specifically in our comments in other sections. **We recommend that the composition of the region's FFS population (e.g., Medicare entitlement source, demographics, SODH) and Medicaid population also be considered.**

e. Leveraging current CMS models in the target region

As described earlier, the FAH is gravely concerned about the potential of the DC *Geographic* option to facilitate regional market dominance by DCEs and jeopardize the continued success of existing CMS models. We strongly recommend that CMS consider the strength of the applicant's strategy for avoiding negative impacts on other CMS models underway in the target region. Specific questions for applicants could include how model overlap would be addressed and how beneficiaries eligible for attribution to more than one model would be identified and managed.

f. Quality measure and goal selection

The FAH strongly endorses a comprehensive assessment of the DCE applicant's quality measures and goals as an important criterion for use in DCE eligibility and selection. We are concerned, however, that identification of quality measures and goals appears to be left to the discretion of the applicant. We applaud CMS' Meaningful Measures initiative along with harmonization of measures and goals across CMS' various quality programs (e.g., QPP for practitioners and the Hospital Inpatient Quality Reporting program for acute care hospitals) as an appropriate approach for reducing unnecessary reporting burden. We firmly believe, however, that the goals and priorities of CMS's quality reporting programs, including that for the DC *Geographic* option, should be guided by CMS rather than through *de novo*, unstructured design by the DCE. **The FAH strongly recommends that CMS require a core set of**

goals and measures for all *Geographic* option DCEs and that the DCE quality criterion be revised to measure the degree to which the applicant's quality improvement plan will facilitate achievement of the required goals and benchmark measure performances.

2. CMS requests input on participation by groups or organizations in the *DC Geographic* option who have not regularly participated in other CMS value-base care programs and any conflicts of interest that might arise with their inclusion as DCEs. As we have noted above, CMS appears keenly interested in health plans and insurers serving as *Geographic* option DCEs, and we have expressed our serious concerns about the potential risks of regional market instability, harm to existing CMS models and their participants, and limitation of beneficiary choice.

   Assuming that CMS successfully attracts health plans and other insurers as *Geographic* option DCEs, the FAH is very concerned about conflicts of interest that might arise. Examples might include:

   - The DCE offers an MA plan that overlaps with some or all of the DCE's target region.
   - Another division of the DCE plan's corporate parent offers a Medicare supplement or Part D coverage in the target region.
   - The DCE has significant FFS and/or MA market share in one or more service areas adjacent to the DCE target region.
   - The DCE administers a Medicaid Managed Care Organization (MCO) for the state that includes some or all of the DCE's target region.
   - The DCE provides Medicare-Medicaid benefits coordination under contract to a state Medicaid program.

   The FAH very strongly recommends that robust boundaries and limitations be put in place to avoid conflicts of interest such as those described above. We also strongly recommend that CMS consider issues that could result should a single DCE gain control over a very large percentage of the covered Medicare lives in the DCE's target region.

Questions Related to Beneficiary Alignment

<u>General Comments</u>

The questions posed by CMS in this (Beneficiary Alignment) and the following section (Beneficiary Protections) address topics that are inherently linked; for example, beneficiary alignment may be influenced by beneficiary incentives while those same incentives may generate the need for beneficiary protections. Although we have divided our comments on these two sections to follow the structure of the RFI, our comments will be best understood by considering them together.

CMS has indicated that all of the DC payment model options (*Professional, Global,* and *Geographic*) will emphasize voluntary beneficiary alignment while retaining claims-based attribution to facilitate DCEs reaching their required minimum numbers of aligned beneficiaries. We believe that for all of these models, alignment should be voluntary and not based on primary Evaluation & Management (E&M) code. Voluntary alignment in other

CMS value-based initiatives has required that a beneficiary specify (via the beneficiary portal MyMedicare.gov) a primary clinician or "main doctor". A beneficiary cannot directly align him/herself directly to an ACO, but instead aligns to an ACO clinician. For DC *Geographic* option target regions with 2 or more DCEs, CMS is considering allowing direct alignment to the DCE as well as randomized alignment of the region's beneficiaries across the available DCEs. Additionally, in discussing the DC payment options elsewhere, CMS has mentioned "enhanced" voluntary alignment and "Prospective Plus" alignment without defining the terms further.

Responses to Specific Questions

1. The FAH is concerned that the alignment options available to beneficiaries under the DC *Geographic* option have not been clearly specified, hampering our and others' responses to alignment questions posed by CMS. We are also concerned by the potential for beneficiary incentives and beneficiary engagement/outreach efforts to unduly influence beneficiaries as they consider their alignment options. This last concern is amplified by the possibility that a *Geographic* option DCE might be a large, well-known health plan or a subsidiary plan of a well-known corporate parent. As such, we believe that CMS should not allow MA plans to use MA funds or rebates to finance DCE beneficiary alignment or engagement. We also note that voluntary alignment and primary clinician designation have proven to be challenging concepts for many FFS beneficiaries. Finally, we are significantly concerned by the implication that beneficiaries could be aligned to a DCE without their express consent through "randomized alignment". We are also concerned that a plan could also propose using its provider network for alignment purposes – a proposal we would oppose. **In order to put beneficiary interests first, we recommend that only voluntary alignment to a DCE clinician should be permitted under the DC *Geographic* option.** Additionally, we suggest that beneficiaries should have the opportunity to adjust or appeal their alignment should their circumstances change such as changing physicians or moving out of a geographic area. Should the alignment terminology and options be clarified at some future date, we would consider modifying our recommendation provided robust beneficiary protections were also put it place to prohibit undue influence by DCEs.

   CMS asserts in the RFI that the need for risk adjustment could be mitigated by randomized beneficiary alignment provided the beneficiary pool is sufficiently large. CMS also offers stratification of randomized alignment by beneficiary place of residence. The FAH is concerned that this question in the RFI is the only mention of risk adjustment in the entire document when a fuller discussion of risk mitigation, including the use of risk corridors, is warranted. While consensus about proper risk adjustment is not always reached by health policymakers, risk adjustment in CMS programs has been trending towards more robust rather than diminished risk adjustment strategies. We would be interested in seeing the evidence CMS is using to support that a randomly-aligned, total covered population of 75,000 FFS beneficiaries is sufficient statistically to minimize or discard risk-adjustment in calculating expenditures and scoring quality measures under the DC *Geographic* option. Lacking such evidence at present, **the FAH cannot support randomized alignment of beneficiaries to *Geographic* option DCEs.**

2. CMS seeks input on transparency through required beneficiary notifications as a means of protecting beneficiary freedom-of-choice, since FFS beneficiaries aligned to *Geographic* option DCEs retain all of their Original Medicare benefits and may choose Medicare-enrolled providers/suppliers from within or outside of the DCE. CMS asserts that DCEs would be required to notify their beneficiaries when they have been aligned to the DCE, what alignment means in terms of the care that they will receive, and how to opt-out of CMS sharing of certain individually-identifiable information about them with the DCE. **The FAH supports full transparency between DCEs and beneficiaries about alignment, including annual notifications as listed above, as is required of CMS ACOs.**

3. Transparency about payment model options available to beneficiaries and alignment to the models' entities, however, should not be transformed into a pseudo-marketing opportunity, such as monthly alignment status "updates" by telephone, electronic mail, or hard copy mail sent by DCEs to beneficiaries. Transparency must be balanced against information overload and unwanted, excess communication as CMS appreciates given its requirements under MA open enrollment periods. FFS beneficiaries, having already selected Original Medicare benefits over a capitated, managed care model, should not feel pressured into alignment with a DCE. **The FAH believes that transparency balance is applicable to all FFS payment models, including ACOs and DCEs, and that transparency requirements and communications boundaries for DCEs should be at least as rigorous as those for CMS ACOs.** DCEs should not be allowed the marketing and communication opportunities that are available to MA plans, unless such opportunities are to be extended to other CMS ACOs.

   The FAH also recommends that notification of a DCE's availability to FFS beneficiaries within the DCE's target region should follow a CMS template that has been tested on beneficiary focus groups for clarity and appropriate tone. CMS should remind FFS beneficiaries annually during open enrollment of their freedom-of-choice when selecting providers/suppliers. Finally, but critically important, is that in the case of involuntary alignment (e.g., randomized within a DCE) CMS should require the beneficiary to be notified at least annually of his/her right to opt-out and provided with a clear explanation of how opting out can be accomplished.

Questions Related to Program Integrity and Beneficiary Protections

Responses to Specific Questions (please see related comments in the preceding section)

1. CMS requests input on how to avoid undue influence on beneficiary choices, including voluntary alignment, by incentives provided to them by DCEs. Undue influence has two components: the nature of the incentive and the communication about why the incentive was provided. The FAH recommends that DCEs should not be permitted to provide incentives to aligned beneficiaries that are greater than those allowed in other CMS ACO models and that CMS must closely review the nature of the incentive and the manner in which it is being conveyed to the beneficiary.

2. CMS appropriately requests recommendations about strategies to avoid blocking access to beneficiary care by DCEs. Despite having many similarities to MA plans, the *DC Geographic* option remains a FFS model available to beneficiaries who have chosen to

remain in Original Medicare rather than choosing capitated, managed care (MA). Care should be taken, therefore, not to add utilization management controls to the *DC Geographic* option, such as (unnecessary) pre-authorization of covered benefits. While care furnished by *Geographic* option DCE providers should appropriately incorporate consensus guidelines and best practices, guardrails should be established to preserve beneficiary choice. Similarly, for DCEs that also operate MA plans in the target region, CMS should monitor for evidence of wholesale adoption of the MA plan's provider network into the DCE as core or preferred providers. Screening for homogeneity of a DCE's provider list with nearby MA provider network lists should occur before the DCE begins to provide clinical care. Another potential provider-related issue is the risk of inappropriate pressure being exerted on non-associated providers by large regional DCEs to accept discounted payments without written agreements, as care of aligned beneficiaries by non-associated providers will be counted as an expenditure against the DCE at reconciliation. Any site visits that are conducted by CMS or its contractors to a DCE should include an effort to contact several non-associated providers about their interactions with the DCE.

An important first step to discourage stinting on care is a robust quality improvement program at the DCE whose results are made publicly available. We earlier voiced our concerns about the limited and unstructured quality program requirements suggested for inclusion by CMS as a DCE eligibility and selection criterion. We are further concerned that cost reduction is being prioritized over quality outcomes in the RFI; in fact, only one of the 13 suggested DCE eligibility and selection criteria addresses quality.

The FAH recommends that CMS require a core set of goals and measures for all *Geographic* option DCEs and that the DCE quality criterion be revised to measure the degree to which the applicant's quality improvement plan will facilitate achievement of the required goals and benchmark measure performances. Quality data should be extracted automatically from DCE data systems whenever feasible and reports made available on a rapid cycle basis.

Focused monitoring by CMS of certain metrics in near-real-time would also offer insight into potential stinting. CMS could monitor utilization data for selected high-cost interventions and advanced imaging studies (e.g., repeat total joint arthroplasty, PET scans) for sudden and significant shifts to be followed up by an in-depth look at outcomes and patient experience of care.

3. **In support of program integrity, the FAH strongly recommends that regulatory flexibilities granted by CMS "to promote DCE success" should not exceed those allowed in other CMS ACO models.** Usage rates of beneficiary enhancements such as the SNF 3-day rule waiver by *Geographic* option DCEs should be tracked by CMS and compared to those of other CMS models operating in the target regions.

Questions Related to Payment

Responses to Specific Questions

1. We strongly recommend that non-associated providers must always be able to bill CMS directly for services they furnish to aligned beneficiaries and that payments to those providers should not be affected by the model (i.e., should be paid at the rates applicable as if the model did not exist).

2. CMS poses questions about the upfront discount (CMS savings) that should be expected from DCEs. As noted previously, the FAH recommends that CMS maintain a discount percentage that is appropriate for the size and scope of the model which we believe, for this model, should be at the higher end of that described by CMS. Declining discounts have not been a feature of other CMS models and should not be incorporated into the DC *Geographic* option, particularly given the highly unstructured quality requirements set for DCEs compared to other ACO models and the risk that coding intensity might occur under the DC *Geographic* option given the model's similarities to MA.

3. CMS asks about ways to address service utilization and costs when aligned beneficiaries obtain care outside of a *Geographic* DCE's target region. Assuming that the population-based payments (capitation) to DCEs are not interrupted when beneficiaries spend time outside the DCE target region, the FAH recommends that the DCE should remain accountable for the out-of-region care. Exceptions might be considered for specific, highly-regionalized services such as solid organ transplantation. Relatedly, we also strongly recommend that non-associated providers must always be able to bill CMS directly for services they furnish to aligned beneficiaries and that payments to those providers should not be affected by the model (i.e., should be paid at the rates applicable as if the model did not exist).

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We appreciate the opportunity to comment on this proposed model. Please feel free to contact Paul Kidwell on my staff at (202) 624-1500 with any questions.

Sincerely,