AMERICA'S PHYSICIAN GROUPS
Taking Responsibility for America's Health

May 17, 2019

Mr. Adam Boehler
Deputy Administrator for Innovation and Quality
Director, Center for Medicare & Medicaid Innovation
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Deputy Administrator Boehler,

We, America's Physician Groups (APG), write in response to the Request for Information (RFI) regarding the Geographic PBP model. APG welcomes the opportunity to provide feedback based on our members' expertise and success in pioneering payment and delivery models across a variety of federal payers including Medicare, Medicare Advantage (MA), and Medicaid. This RFI underscores your commitment to improving the Medicare delivery system by embracing new value-based models that improve on quality and control cost. We applaud this important step aimed at improving care for our nation's seniors.

APG represents over 300 physician organizations across 44 states, Washington, D.C., and Puerto Rico. Our members participate in value-based programs across all payer types, including the Medicare Shared Savings Programs (MSSP), CPC Plus, and the Next Generation Accountable Care Organization (ACO) program, and accept capitated payments from both MA and commercial plans. Many APG members have successfully operated under full risk-based models for over two decades and have developed the necessary infrastructure and expertise to be successful in innovative risk bearing models across a wide variety of socioeconomic and geographic areas.

APG members are truly taking responsibility for America's health by holding themselves accountable for patient outcomes by providing the patients and communities they serve with access to the best possible healthcare. Our preferred model of capitated, coordinated care avoids incentives for high utilization associated with fee-for-service (FFS) reimbursement. Instead, we believe that capitated models align incentives for physicians to provide the best care in the right setting to improve the health of entire populations, particularly chronically ill individuals. These capitated payment arrangements create incentives for (1) a team-based approach that emphasizes primary care and disease prevention; (2) greater access to new and innovative medical

technologies and treatments and, most importantly; (3) the achievement of better outcomes in both cost and quality of care.

We are pleased to offer ourselves and our members to you as a resource to aid your work at CMMI as you develop and implement new ways of delivering and paying for health care services through the Medicare system.

The Geographic Direct Contracting model is the most advanced and innovative TCOC (Total Cost of Care) model released by CMMI. Within the current models proposed parameters, DCEs (Direct Contracting Entities) will be at full risk for a designated targeted region. They (healthcare organizations, plans, or technology companies) will be paid on a capitated basis with an option of paying contracted providers directly or they could have an option of CMS continuing to pay claims while the DCEs remain totally responsible for the costs. The benchmark will be a designated discount (3%-5%) off of Medicare FFS per capita Part A and B for the region's assignable beneficiaries. It is anticipated that during the first year, only four target regions will be selected with a possible eight DCEs.

APG's response to specific questions in the RFI are as follows:

Questions Related to General Model Design:

1. ***What is your reaction of the Geographic Direct Contracting model?***

   We support that CMS would contract directly with DCEs, which may be existing physician organizations or other unique newly formed entities. It is important for methods to be developed to enable independent practices to participate in the Geographic DC model.

   To participate in this model, DCEs should meet below requirements, similar to those required for existing Medicare FFS ACO participants:

   - A formal legal structure that allows the organization to receive capitated payment and pay contracted or employed providers;
   - Adherence to State Laws in definition of risk bearing;
   - Successful experience in risk bearing contracts;
   - Primary care professionals under contract sufficient to provide care for the defined population;
   - Systems in place to identify and provide care for high risk and complex patients;
   - The ability to stratify the population (identifying patients with multiple complex chronic conditions and to provide (or subcontract) care management programs to the patient population);
   - Demonstrated experience (or have contracted arrangements with providers who have experience) in quality performance programs

It is essential that all DCE's have access to the tools, education, and practical experience necessary to successfully move the region providers from FFS reimbursement to appropriate APMs that reward and incent providers for improved patient outcomes. A significant "on-ramp" may be necessary for DCE's to gain the skills they need to be successful.

2. ***How might DCEs in the Geographic PBP model option address beneficiary needs related to social determinants of health (such as food, housing, and transportation) with particular attention to whether the geographic scale contemplated under the payment model option creates new opportunities for success in terms of community-based initiatives?***

   DCEs in the model should develop and implement systematic efforts to leverage currently available community outreach organizations and to use the capitated funding to provide focused SDOH interventions that will have the greatest impact based on the local knowledge of the DCE.

   The DCEs must have the freedom to assess and make determinations about what types of SDOH are warranted and what should be covered. For example, in addition to food, housing, and transportation, employing individuals to visit seniors' homes to perform safety checks and certain tasks such as nailing down carpets and replacing AC units could also help address beneficiary needs.

3. ***What barriers might prevent DCEs from addressing these social determinants of health?***

   Certainly, the high cost of providing certain benefits that are designed to address social determinants of health might be a deterrent for DCEs. The DCEs need to receive waivers for providing SDOH benefits and additionally receive SDOH payments that are included in the capitation. SDOH being incorporated within the risk adjustment should incentivize DCEs to provide more of these benefits. The DCEs must be able to determine the optimal method to pay for these services (FFS, Sub capitation, Pay for Performance, or discount off of retail). Additionally, DCEs should reward beneficiaries to utilize the service when a need is identified.

Questions Related to Selection of Target Regions:

4. ***What criteria should be considered for selecting the target regions where the Geographic PBP model option would be implemented?***

   When selecting target regions, we suggest avoiding large areas and wide locations due to the difficulty DCEs would have in managing multiple areas. When determining the size of the area, the outer limits of towns or potentially small cities that are adjacent to a specific location would be acceptable boundaries of the geographic region. It would be expensive to have care management infrastructure in multiple areas, and we believe that

adjacent towns and cities would create geographic areas that are reasonably manageable for DCEs.

While the size of the region should be considered in the selection, the number of assignable Medicare FFS beneficiaries that DCEs would have access to in a region should also be considered. Target region selection should consider the percent of beneficiaries in an area that are enrolled in MA. If the percent of beneficiaries enrolled in MA is high, there may not be enough Medicare FFS patients to spread the risk over two DCEs.

Notably, the target region size and location could impact the extent to which evaluation results would be representative of the broader Medicare population. The target region must be broad enough so that the results of the evaluation would be able to be accurately extrapolated to represent the general U.S. Medicare population.

Lastly, as mentioned in the RFI, preference should be given to geographic areas with more than two DCEs, but we believe that most rural areas will not have two DCEs thus perhaps in some regions one DCE should be permitted.

5. ***Are there attributes of target regions, such as low penetration of advanced alternative payment models or higher healthcare costs than the national average, which CMS should consider in selecting target regions for the Geographic PBP model option?***

   We believe that it would be in CMS's best interest to choose target regions that have demonstrated to have above average healthcare costs. The cost in these regions could potentially be high due to hospital monopoly or shortage of primary care. In areas with hospitals that have little or no competition, regardless of the amount of savings that a DCE obtains, these savings may be diminished by the ability to negotiate a lower hospital rate. If CMS were to target these areas with a hospital monopoly, we would suggest factoring into the geographic DCE model the amount of discount required for participants in those areas to only pay 90 percent of DRG. Additionally, DCE's should have waivers available to incent beneficiaries to lower site of services.

   There are several reasons that an area may have low penetration of alternative payment models which will impact the success of a Geographic DC launch in that area. Lack of primary care resources, dominance of a single hospital or commercial payer, or restrictive state laws on provider risk arrangements would be variables difficult to overcome. Absence of the above reasons for the low uptake of APMs would generate a conducive atmosphere for DCEs success.

<u>Questions Related to DCE Eligibility:</u>

6. ***What other selection criteria and core competencies should CMS consider requiring applicants to address? Please describe the benefits of including such additional***

selection criteria. What criteria are of the greatest importance and therefore should receive the greatest weight in our selection decisions?

We also believe that it is wise to include demonstrated ability to manage care on a global or professional basis, or at least in a contract with 10 percent downside risk, in the DCE selection criteria because it increases the odds of success for CMS. We also believe that CMS should suggest a DCE reserve requirement in order to ensure that the DCE does not end up in financial trouble.

The requirements below represent the seven domains that APG has identified as key to success in risk-based contracts. DCEs must be able to provide these either through subcontracts or their own experiences:

- Identify and stratify patient populations
- Caring for high risk and complex patients
- Commitment to advanced primary care capabilities
- Reduce unnecessary hospital admissions and readmissions
- Robust participation in quality and resource use measurement programs
- Defining the allocation of financial risk between medical group and payer
- Responsibility for downstream payments to contracted physicians

The ability to identify high risk beneficiaries and manage their care transitions should be given the greatest weight since this area has the greatest risk for adverse effects for the beneficiaries.

7. ***What types of entities might participate in the Geographic PBP model option that have not participated in CMS Innovation Center models or other Advanced Alternative Payment Models offered by CMS, such as the Medicare Shared Savings Program, to date? What conflicts of interest issues might arise and how should CMS and/or the DCE address them?***

   Encouraging nontraditional participants such as technology companies to apply as DCEs has a potential to introduce new ideas within the industry; however, CMS needs to ensure that their motivations are not to monetize beneficiaries in other ways like mining their data for other businesses uses. While data mining is of concern to us, our bigger concerns are the DCEs' capability and the ability to manage care through primary care providers rather than through digital algorithms. We suggest that DCEs have to satisfy CMS that they have, through subcontract, the basic essentials of delivering care, especially to the frail, elderly, and complex.

<u>Questions Related to Beneficiary Alignment:</u>

8. ***CMS currently plans to select target regions with at least two DCEs to encourage competition. In the event that there are two or more DCEs in a given target region, we are considering either randomly aligning beneficiaries in the target region to one of the DCEs or allowing beneficiaries in the target region to voluntarily align themselves***

to a specific DCE. One potential benefit of a random alignment approach is that it could help to reduce reliance on risk adjustment, which is intended to account for differences in health risk in a given population. Where risk is taken on a large population basis, such as in the Geographic PBP model option, we would expect risk to be evenly distributed, making risk adjustment less necessary to account for differences, particularly if beneficiaries are aligned on a randomized basis as between DCEs operating in the same target region. Notwithstanding this interest, we seek information on what alternative alignment methodologies CMS might consider and the relative pros and cons of alternative approaches for beneficiaries and for DCEs operating in the same target region.

Some of our APG members believe that it would be in the best interest of the DCEs to have random alignment of beneficiaries. In the case of voluntary alignment, DCEs would have to market themselves to beneficiaries, resulting in marketing costs for which the DCEs would not likely be reimbursed. Though, we are concerned that if beneficiaries were to be randomly aligned, they would be more likely to opt out of the DCE they were assigned to. To prevent this, we suggest that CMS add beneficiaries' waivers in this model to allow incentives to stay in the network to be developed. Lastly, given that random alignment of beneficiaries would not necessarily avoid skewing, beneficiaries should also have some opportunity for risk adjustment.

Other APG members would prefer active enrollment to facilitate beneficiary engagement which is the cornerstone of their models. Additionally, active enrollment allows providers with geographic limits (particularly in areas with large numbers of square miles) to focus on locations that are aligned with their providers. With voluntary alignment, it is essential to have individual risk scores incorporating SDOH variables since the risk for adverse selection is too high.

9. ***Are there hybrid approaches to consider? For example, would stratified randomization of the beneficiary's residence be a preferable approach to complete randomization? What implications would either stratified randomization or allowing for voluntary alignment have on risk adjustment considerations?***

   CMS could possibly do micro geographic assignment as a hybrid model. In other words, you randomly assign patients to DCEs which would decide to be market "wide" or "narrow". The random assignment can be either a tight assignment (around zip code groupings) or broad (MSA). Each micro geography area could be given a risk score based upon SDOH and average FFS spend of the area.

10. ***Are there transparency/notification requirements, in addition to or in lieu of the requirements described above, that CMS should consider to protect beneficiary freedom of choice of any Medicare provider or supplier for beneficiaries aligned to a DCE participating in the Geographic PBP model option?***

    Experience has taught us that active and intentional enrollment by an engaged and informed beneficiary is vastly superior to passive claim attribution models used in

traditional Medicare ACOs. CMS should issue guidance with all DPE contracts that explicitly outlines permissible marketing and communication standards similar to what is annually released by CMS for the MA program. Further, CMS should increase investment and training for State Health Insurance Assistance Program (SHIP) staff to ensure they are able to assist beneficiaries in navigating the various options available to them under the Medicare program.

To facilitate beneficiary selection of a DCE, quality and service information would be made available to the beneficiary. Marketing materials which include information on the providers within the DCE need to be developed by the DCE, approved by CMS, and then disseminated by both CMS and the DCE to allow consumers to make fully informed choices about their care.

Beneficiaries would be empowered with information regarding the quality, cost, and scope of services available under each of FFS, MA, and the DCE, including additional care management programs or benefits. For example, CMS could develop a patient-facing dashboard (or an app) that would contain quality metrics, similar to the Quality Measures and Performance Standards in the ACO program reported at the DCE level. Patients could then compare the performance of their selected DCE directly.

11. ***How might DCEs inform beneficiaries of the payment model option and engage them in their care? What barriers would DCEs face in engaging with beneficiaries in their target region?***

    It is absolutely critical that beneficiaries have access to the information and education they need to make informed healthcare choices. CMS must ensure that geographic DCE participants clearly understand the model and what services are included under it. As this model relies on patient engagement to be successful, an informed and committed patient panel is essential.

    The geographic DCE model could include differential cost sharing that would induce beneficiaries to remain in-network with a lower or no co-pay to stay with in-network providers. Beneficiaries that wish to visit physicians not contracted with the DCE would be able to do so, but they would not benefit from the lower or no co-payments to stay within network. It would thus operate in a manner similar to existing and proven point-of-service models seen in commercial insurance.

    Waiving costs for services already in use that enhance health (e.g. gym memberships, nutrition services, and certain counseling services) would also be a desirable benefit to stay within network and comply with a treatment plan.

Questions Related to Program Integrity and Beneficiary Protections:

12. ***What monitoring methods can CMS employ to ensure beneficiary access to care is not compromised and that beneficiaries are receiving the appropriate level of care? What data or methods would be needed to support these efforts?***

The use of a quality and performance measure program, such as the MA Stars program, will prevent any stinting on services and will create further incentives for the delivery of high-quality care, both for individual beneficiaries and to the enrolled population. CMS should take steps to improve quality transparency including metrics on prior authorization denials and wait times. Further, the Agency should take steps to implement a public-facing patient feedback dashboard that is interoperable with CMS Blue Button and 1-800-Medicare. CMS must include quality metrics in its DCE contractual requirements that primarily focus on outcome measures and include patient- reported satisfaction metrics. The focus on "Beneficiary Voice", like number of complaints to CMS and wait times for services, are extremely important in addition to a handful of HEDIS measures that are already being collected by providers.

13. What regulatory flexibilities or operational activities would be needed to promote DCE success and how might such flexibilities affect program integrity of the Medicare program?

The implementation of the proposed Regulatory Sprint to Coordinated Care which focuses on changes to HIPPA, Stark, Civil Monetary Penalties, and Anti-Kickback would be sufficient.

APG has submitted comment letters for Stark with key areas detailed below:

<u>Stark Law: Regulatory Options for Modernization</u>

- APG notes that CMS has issued various exemptions for Medicare Shared Savings Program (MSSP) participants. CMS should expand these and issue additional safe harbors and Stark Law waivers for physician organizations participating in any alternative payment models (APM) that meet meets certain care coordination thresholds.

- Specifically, the Stark Law should **<u>not</u>** apply to referrals, or related collaborative actions, made by physicians, physician organizations, or transaction participants when:
    - The Medicare beneficiary/patient for whom payment is made is among the population covered by a financial risk bearing agreement;
    - The providers in the transaction are financially integrated, such financial integration to include, but not be limited to, capitated and other risk-based models where the sharing and/or capitated payment is at the physician group level
    - The physicians participating in the transaction all are subject to a quality measurement program equivalent to Medicare Star Ratings Data (Stars) or Medicare Shared Savings Program (MSSP) Accountable Care Organization (ACO) programs.

- A core set of waivers, including explanatory FAQs, should be developed for all alternative payment models being tested at CMS. Frequently, waiver implementation and tracking are being applied differently among the models which are causing

confusion for participants and beneficiaries. A core set of waivers (including tracking requirements) designated as a package would eliminate the unnecessary burden and confusion that participants currently experience. This confusion is leading to low adoption of many of the waivers due to concerns of noncompliance. The three-day SNF waiver is a prime example of low adoption due to concerns of regulatory noncompliance risks. The application of these waiver protections should extend to include any downstream entities participating in the model with the applicant. Tracking the implementation of the waivers needs to be streamlined to avoid the current burdensome process.

- A more streamlined working process between CMS and the OIG (Office of Inspector General) needs to be developed. Frequently, the posting of the waivers is delayed until just before the participation agreements are due. Additionally, since CMS is unable to comment on any fraud and abuse questions, many questions remain unanswered waiting for OIG opinions causing the updating of FAQs focused on Fraud and Abuse to be delayed.

- CMS should issue regulatory guidance on how to apply the volume or value of referrals standard including clarification on whether incentive payments or actions to improve quality, even if they partially reflect the volume or value of a provider's referrals, are permissible. Currently, under the Stark Law any incentive or compensation arrangement must be structured to distribute financial gains to physicians in a broad generic manner rather than rewarding individual providers for specific results and activities. Risk arrangements between managed care organizations and physicians are exempt, but this exception does not include the FFS Medicare alternative payment models. This guidance should also include any downstream partner entities that are participating in the models.

14. ***Providing incentives to beneficiaries to positively influence their behavior and healthcare decision-making could implicate the fraud and abuse laws and potentially raise quality of care, program cost, or competition concerns, particularly if the incentives would cause beneficiaries to be aligned to one DCE over another entity participating in DC or another CMS initiative. What safeguards should CMS put in place to ensure that any beneficiary incentives provided do not negatively impact quality of care, program costs, or competition?***

If incentives move beneficiaries to DCEs with higher quality and lower cost, then the goal has been accomplished. The incentives must tie into improving health status as MA rules have maintained. The key is to ensure that DCEs are not cherry picking or lemon dropping with active enrollment or that adequate risk adjustment is being given to areas with random assignment. Allowing the DCEs to compete openly on quality (which includes incentives to enhance care) will allow relaxation of current market dynamics in order for true innovation to take place.

Questions Related to Payment:

15. ***Should DCEs' benchmarks include accountability for Part D drug costs? What opportunities and challenges might this provide to entities participating in the Geographic PBP model option?***

    We believe that it would be best to begin including accountability for Part D drug utilization in DCE benchmarks at a later phase, maybe in year three, giving DCEs time to adjust to the new model. Additionally, when creating the benchmarks including accountability for Part D drug costs, given the unlikeliness of a DCE signing a long-term contract with inflating rates, rates should be adjusted annually.

    In addition to comments already made on payment in this response, regarding the collection of cost assignments, we would suggest a daily feed for deductibles in order to pay claims.

16. ***CMS would calculate the historical TCOC for a geographically aligned population in order to set the spending target for the DCE, also known as the benchmark. We are interested in feedback regarding adjustments we should consider in calculating the benchmark for the performance year, such as the use of the U.S. Per Capita Cost national trend, other trend factors or specific geographic adjustments.***

    We would recommend that benchmarks are rebased every other year using the regional actual costs but using U.S. Per Capita Cost National Trend for the off non rebased years. This would allow a more accurate accounting of regional differences in age, health status, and expenditures. Benchmarks and discounts may need to account for the amount of out migration found in the region like snowbirds. A focus on costs of new Part B drugs must be analyzed as we anticipate that area to increase with biologicals.

17. ***Additionally, we envision applicants will propose a discount to the benchmark for the geographically aligned population. We seek comment on the range of discounts we might expect applicants to propose and why (e.g., by analogy or reference to other experiences). How might we think about requiring applicants to structure these proposed discounts over the life of the model?***

    We suggest that DCEs seek discounts that bring Medicare spending to CPI, but no lower. This should ensure savings for CMS and a profit for DCEs, which would strengthen the model and improve care.

18. ***We are interested in feedback on the payment methods available to DCEs in the Geographic PBP model option. In particular, we would like feedback on the "notional" account policy, described above, under which DCEs could select to have CMS continue to make FFS claims payments to all healthcare providers in the region. These FFS claims payments would be reconciled against the DCE's benchmark as part of final settlement.***

APG members are familiar with this as a "service fund" in MA in which a partial cap is paid up front and claims are reconciled later. This is essential for some DCEs that are new to the concept of processing claims or do not want to process all of the claims.

19. ***If DCEs were to enter into their own downstream payment arrangement with healthcare providers, how should cost sharing amounts be determined and collected from beneficiaries?***

    DCEs must attest that they have the competencies to adhere to state and federal regulations. This could be done by the DCE or by providers. DCEs could perhaps consider the use of an ASO or TPP.

20. ***How should CMS address utilization of services and costs for beneficiaries aligned to a DCE that occur outside of the DCE's target region*?**

    The beneficiary must commit to living in the area for at least 6 months to select active enrollment or be randomly assigned. CMS must also alert a DCE when a beneficiary has moved so the DCE can contact that beneficiary. If the beneficiary is not returning to the region within a reasonable time, the beneficiary will be dropped from the DCE's attributed population. Additionally, DCEs must be informed when transition of care (hospitalization admission/discharge) occurs so appropriate care coordination can be done.

Conclusion

Thank you again for your leadership and for the opportunity to provide input. We are excited about this opportunity to help CMS in its mission to improve care for America's seniors and strengthen the Medicare system overall. Please do not hesitate to contact the APG Federal Affairs staff (Valinda Rutledge, VP of Federal Affairs vrutledge@apg.org) with any questions you may have.

Sincerely,

Donald H. Crane
President & CEO
America's Physician Groups