May 25, 2018

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

Re: Request for Information on Direct Provider Contracting Models

Dear Administrator Verma:

The National Association of ACOs (NAACOS) appreciates the opportunity to submit comments in response to the Request for Information (RFI) on Direct Provider Contracting (DPC) Models, released by the Center for Medicare and Medicaid Innovation (Innovation Center) on April 23, 2018. As the largest association of ACOs representing more than 5 million beneficiary lives through more than 330 Medicare Shared Savings Program (MSSP), Next Generation, and commercial ACOs, NAACOS and its members are deeply committed to the transition to value-based care. NAACOS is an ACO member-led and member-owned non-profit organization that works on behalf of ACOs across the nation to improve the quality of Medicare delivery, population health and outcomes, and health care cost efficiency.

This RFI puts forward a new alternative payment model (APM) concept and poses many questions for the agency to consider if it decides to move forward with one or more DPC Models. In the RFI, the Innovation Center outlines four goals for a DPC Model(s): 1) reducing expenditures while preserving or enhancing quality of care by testing models with voluntary enrollment by patients; 2) enhancing patient access to physicians' (and potentially others') services; 3) reducing administrative burden on providers and suppliers; and/or 4) developing a revenue stream that allows providers and suppliers additional flexibility in how and where they provide care for their patients.

In addition to asking for feedback on specific DPC concepts, the RFI specifically solicits stakeholder input on how direct provider contracting would interact with, enhance, and/or refine current ACO initiatives, such as the MSSP. NAACOS views the DPC concept as one worthy of limited testing. As detailed in the recommendations below, we request that a primary care DPC model be embedded in a broader ACO model (in markets where ACOs are operating) to accomplish the goal of transforming primary care while at the same time continuing to engage providers in a model that emphasizes total cost of care and quality for a beneficiary population.

Comments on DPC Model Framework

Question 1: How can a DPC Model be designed to attract a wide variety of practices, including small, independent practices, and/or physicians? Specifically, is it feasible or desirable for practices to be able to participate independently or, instead, through a convening organization such as an ACO, physician network, or other arrangement?

NAACOS response: The RFI explains that through a DPC Model, providers would have accountability for certain costs and quality of a specific patient population. While numerous DPC Models could be implemented, at least some would have a primary care focus. NAACOS generally supports the Innovation Center implementing DPC Models, but we emphasize that the initial opportunity should be focused exclusively on primary care and, as discussed in response to questions 21 and 22, should work in concert with ACOs. Given the complexity and unique design of DPC Models, we recommend implementation initially be on a small scale to test the concept and make necessary refinements to the model before potentially rolling it out on a larger scale. Implementation in an iterative manner would allow program changes based on early DPC experiences, thus benefiting the program and its participants.

We emphasize our request that CMS start initially with a primary care DPC and not offer specialty DPC Models. Primary care is more appropriate for this type of model, and specialty DPC Models would be too similar to bundled payment programs. Further, it would be much more complicated to structure per beneficiary per month (PBPM) payments for specialty care which is typically more complex and can include episodes of care with greater variation in clinical conditions, treatment protocols and related costs. Starting with one primary care focused DPC would allow the Innovation Center to test the concept while focusing on beneficiary protections without having to pursue more complex specialty-focused DPC models. For purposes of beginning a DPC Model test, CMS would contract directly with primary care practices to establish the practice as the main source of primary care for services. As with other models, a DPC Model should be voluntary.

We would strongly oppose implementing DPC models that exclude ACO practices from participating. This would represent a step backward in the overall transition towards accountable care by removing practices from a broader ACO model, and this must be avoided. We do not need to move from siloed fee-for-service (FFS) to siloed APMs, and providers need to be incentivized to look at the cost and quality of care that patients receive from other providers as well. Many ACOs are interested in testing the DPC concept in a subset of their primary care practices, which would set up a natural experiment within an ACO to see which payment mechanism, FFS or PBPM, is more effective in supporting primary care and achieving the ACO's broader goals related to overall cost and quality for its patient population.

Beneficiary Involvement

Question 16: CMS wants to ensure that beneficiaries receive necessary care of high quality in a DPC model and that stinting on needed care does not occur. What safeguards can be put in place to help ensure this? What monitoring methods can CMS employ to determine if beneficiaries are receiving the care that they need at the right time?

Question 17: What safeguards can CMS use to ensure that beneficiaries are not unduly influenced to enroll with a particular DPC practice?

Question 18: CMS wants to ensure that all beneficiaries have an equal opportunity to enroll with a practice participating in a DPC model. How can CMS ensure that a DPC-participating practice does not engage in activities that would attract primarily healthy beneficiaries ("cherry picking") or discourage enrollment by beneficiaries that have complex medical needs or would otherwise be considered high risk ("lemon dropping")? What additional beneficiary protections may be needed under a DPC model?

NAACOS response: The RFI explains that requiring beneficiaries to select a primary care practice and actively enroll with a participating organization is a key model component. Given the unique design of the DPC model, which moves away from traditional FFS Medicare payments and allows more variation in provider-patient relationships and payment, it is essential that strong beneficiary protections be put in place for this model. Requiring beneficiaries to actively engage in selecting a primary care practice and enrolling with a participating organization will be important so that beneficiaries understand what they are signing up for and are not surprised later when their benefits or cost-sharing changes. Beneficiaries should be required to review and agree in writing to participate in a DPC model.

The RFI notes that under this model, there would be PBPM payments, but it is unclear how those would be adjusted for patients with varying health status or risk. CMS must adequately adjust payments to prevent beneficiary cherry picking, because without doing so there may be incentives to avoid beneficiaries with complex clinical and social needs. In fact, concierge medicine often appeals to healthier patients, but this should not be a goal of the program and all patients should be equally served. However, the agency should consider how it handles risk adjustment in other programs such as the MSSP and not make DPC risk adjustment more favorable, thus attracting provider groups from the MSSP to DPC models, should they both be available.

We also urge the Innovation Center to provide full transparency of what is included in monthly PBPM payments. It is also essential that CMS clarify rules around balance billing, under which a provider bills a patient for the difference between what an insurer doesn't pay for a patient's care and what the provider chooses to charge. The agency should prohibit balance billing and Medicare APMs should be designed for fully participating providers, which represent the vast majority of providers. CMS must guarantee beneficiaries are not taken advantage of, and there must be meaningful oversight of DPC providers to ensure compliance with program rules.

Question 6: Medicare FFS beneficiaries have freedom of choice of any Medicare provider or supplier, including under all current Innovation Center models. Given this, should there be limits under a DPC model on when a beneficiary can enroll or disenroll with a practice for the purposes of the model (while still retaining freedom of choice of provider or supplier even while enrolled in the DPC practice), or how frequently beneficiaries can change practices for the purposes of adjusting PBPM payments under the DPC model?

NAACOS response: There should be limits in place regarding when a beneficiary can enroll in various Medicare programs, including a new DPC model. CMS should align enrollment timeframes across Medicare, including with Medicare Advantage, so that beneficiaries are not confused about when they can move into different programs.

Question 3: What support would physicians and/or practices need from CMS to participate in a DPC model (e.g., technical assistance around health IT implementation, administrative workflow support)? … How should CMS consider and/or address the initial upfront investment that physicians and practices bear when joining a new initiative?

NAACOS response: There are a number of supports necessary for CMS to properly implement any particular APM, including supports related to data necessary to properly manage care and to provide ongoing and timely feedback of program performance and education for providers participating in the APM. The latter is an area in which CMS could improve, and many providers are confused and frustrated about the complexity of various APMs and how they interact with one another. CMS must provide more clear guidance and step-by-step instructions and information on all APMs and how they interact with one another.

NAACOS has previously expressed concerns about the agency's perceived lack of strategic planning and direction in addressing APM overlap issues. In many instances, CMS has attempted to deal with overlap on a per-program basis rather than taking a coordinated and strategic approach. It is essential that the agency develop a more thoughtful approach to program overlap issues, particularly as CMS moves forward with implementation of the Medicare Access and CHIP Reauthorization Act (MACRA). By the agency's estimates, the number of providers participating in APMs will grow dramatically in the coming years, compounding this problem. For example, CMS estimates the number of providers qualifying for Advanced APM bonuses will roughly double in the second year of the Quality Payment Program to total 180,000 to 245,000 for the 2020 payment year corresponding to 2018 performance. Therefore, it is critical that CMS address this issue now before the operational challenges grow exponentially and ultimately undermine the progress made to date by APMs currently in existence. CMS needs to create a centralized office or team dedicated to understanding how programs interact with others and educating providers on this overlap.

The Administration, Secretary Azar, and Administrator Verma have been emphasizing the importance of interoperability and have announced efforts to improve interoperability, promote the exchange of medical data, and give patients greater access to control over their health data. We appreciate these efforts and the continued commitment to implementing policies focused on health information exchange, which is an important component of patient care. Advancing interoperability is essential to all APMs and is a program support that should be addressed in a DPC model and more broadly. We urge CMS to move forward with its work on interoperability to benefit providers in this and other APMs as well as providers outside of APMs, and we look forward to submitting more detailed feedback on this issue in the near future.

In response to the question about how CMS should consider initial upfront investments that physicians and practices bear when joining a new initiative, this is an important question and we urge the agency to evaluate initial upfront investments for APMs, including ACOs. As previously advocated by NAACOS, we urge CMS to account for the significant investments ACOs make in start-up and ongoing costs and include these costs as part of the definition and calculation of risk under MACRA. Current CMS policy disregards these investments based on the agency's claims that it couldn't objectively and accurately assess these investments without exceptional administrative burden on CMS and those participating in APMs to quantify and verify such expenditures. However, if CMS carefully defined simple, clear standards for qualifying investments and required documentation and attestation from APM participants along with adequate audits, the agency could surely create a method to account for these investments. These investments are often significant and should be recognized by CMS as such.

Risk Levels and Accountability

Question 11: Should practices be at risk financially ("upside and downside risk") for all or a portion of the total cost of care for Medicare beneficiaries enrolled in their practice, including for services beyond those covered under the monthly PBPM payment? If so, what services should be included and how should the level of risk be determined? What are the potential mechanisms for and amount of savings in total cost of care that practices anticipate in a DPC model? In addition, should a DPC model offer graduated levels of risk for smaller or newer practices?

NAACOS response: The RFI notes that a primary care focused DPC model could include arrangements with primary care practices under which CMS would pay them a fixed PBPM payment to cover the primary care services the practice would be expected to furnish under the model and practices could also have the opportunity to earn performance-based incentives for total cost of care and quality. The levels of risk are unclear, as are the details regarding what costs and quality measures DPC models would be accountable for. Risk issues are further exacerbated by potential concerns over beneficiary cherry picking. It is imperative that CMS calibrate model details like risk and accountability appropriately in order for this to be a success and to not detract from other existing models, such as ACOs. DPC risk levels need to be sufficient enough to engage providers in meaningful ways and accountability should be a focus of the DPC program. That said, risk should not necessarily be required at the onset and limited relative performance two-sided APMs shows that many providers are not prepared to assume significant levels of risk. However, if risk levels are set too low, that could incentivize providers to leave other APMs, like ACOs, that are increasingly required to transition to two-sided models. The Innovation Center needs to be careful not to set up another competing primary care program that has lower risk levels and more generous upfront and ongoing funding, which would significantly undercut ACOs or other APMs. An important way to address these concerns is to embed a primary care DPC model within a broader model focused on responsibility and accountability for total cost of care and overall quality.

In terms of DPC model accountability, in addition to an emphasis on primary care there should be a focus on total cost of care, which is the only way to effectively bend the cost curve. Primary care represents a small portion of overall spending. Skilled primary care focuses on enhanced care coordination, preventing adverse complications and avoiding more serious episodes, which often are reflected in care and costs outside of primary care, such as specialty care, hospitalizations, or post-acute care. Therefore, a primary care DPC model should retain accountability for some level of total cost of care and overall quality. Total cost of care accountability reinforces the incentives and need for advanced primary care, which creates the right incentives to best serve beneficiaries. However, when accountability only focuses on the care delivered by a particular provider or type of care such as primary care services, this situation can skew incentives and will likely not result in overall savings to the Medicare Trust Fund. Evidence to support this can be found in research such as this study published in the *Journal of the American Medical Association,* which found that a medical home pilot was not associated with reductions in utilization of hospital, emergency department, or ambulatory care services or total costs of care over three years. By embedding a DPC model in a broader total cost of care model, such as an ACO, CMS would support the transformation of primary care but do so in a way that continues to focus on accountability for overall cost and quality for a beneficiary population.

Question 15: Are there ways in which CMS could restructure and/or modify any current initiatives to meet the objectives of a DPC model?
Please see our response to Question 21 below.

Questions Related to Existing ACO Initiatives

Question 21: For stakeholders that have experience working with CMS as a participant in one of our ACO initiatives, how can we strengthen such initiatives to potentially attract more physician practices and/or enable a greater proportion of practices to accept two-sided financial risk? What additional waivers would be necessary (e.g., to facilitate more coordinated care in the right setting for a given patient or as a means of providing regulatory relief necessary for purposes of testing the model)? Are there refinements and/or additional provisions that CMS should consider adding to existing initiatives to address some of the goals of DPC, as described above?

NAACOS response: We greatly appreciate CMS using this RFI to consider ways to strengthen existing ACO models. It is critical to continue refining and investing in the development and success of ACOs, which represent a leading Medicare APM. The ACO concept is a longstanding, bipartisan solution to reform healthcare delivery and payment, and ACOs have heavily invested in clinical and operational transformations to deliver efficient, high quality care to their beneficiaries. ACOs have faced a challenging initial learning curve, but we are seeing increasing positive results from ACO performance. For example, according to CMS information MSSP ACOs that earned shared savings in 2016 had a significant decline in inpatient hospital expenditures and utilization as well as decreased home health, Skilled Nursing Facility (SNF) and imaging expenditures and ACOs participating over a longer period of time show greater improvement in financial performance (e.g.,. 42 percent of MSSP ACOs that started the program in 2012 earned savings in PY 2016 versus 18 percent of those that began in 2016).

That said, success in the Medicare ACO programs, primarily the MSSP and Next Generation Model, has been challenging and a number of program reforms are needed to improve the performance of ACOs which would in turn attract more practices to participate in ACOs. NAACOS has been advocating for a number of DPC model elements for ACOs, such as increased beneficiary engagement tools, flexibility from onerous regulations and administrative burdens, and new opportunities for payment mechanisms other than FFS.

Specifically, to improve the ACO program and retain and attract participants, CMS should:

- **Fix flaws with financial benchmarking formulas.** CMS should allow ACOs the option to move more quickly to regional benchmarks, remove ACO beneficiaries from regional populations used to determine the regional component of rebased benchmarks, and add ACO savings back to benchmarks to prevent continually decreasing benchmarks.
- **Address risk adjustment limitations.** CMS should allow risk scores for continuously assigned beneficiaries to increase over time without use of an arbitrary cap and should instead apply renormalization to address coding and intensity changes. This approach is consistent with Medicare Advantage and should be applied to ACOs.
- **Provide more timely care coordination data:** CMS should develop a mechanism to share more robust health data, including that from the HIPAA Eligibility Transaction System (HETS), with ACOs in real time to enhance care coordination, improve outcomes and reduce costs.
- **Exclude ACO beneficiaries from bundled payment programs.** As discussed earlier in this letter, the complexity and confusion from overlapping APMs is very concerning and leads to negative unintended consequences that undermine ACOs. CMS should address the problematic

interactions between the ACOs and other CMS/Innovation Center programs by excluding all ACO patients from bundled payment programs unless a collaborative agreement is in place between the bundler and ACO.

- **Reinstate advanced funding opportunities.** CMS previously offered programs to help fund ACOs up front, with those payments later recouped via shared savings. These programs, such as the Advanced Investment Model or similar ones, should be reinstated to help ACOs fund activities and transformations early on in ACOs' development.
- **Reduce quality reporting burdens.** ACO quality reporting burdens should be minimized so ACOs are not responsible for more than 30 quality measures and instead can focus on fewer measures that are more meaningful for meeting their goals, especially those that are outcomes-based rather than process measures.
- **Make Track 1+ a permanent part of the MSSP and allow indefinite participation.** Track 1+ was launched in 2018 with a strong initial class of 55 participants. The attraction of Track 1+ is the more reasonable risk level. We urge CMS to make Track 1+ a permanent part of the MSSP and allow indefinite participation that meets two-sided requirements without requiring more risk. We also urge the shared savings rate be raised to at least 60 percent so it is greater than that of Track 1.
- **Provide additional flexibility for ACOs with certain fraud, waste and abuse laws, including the physician self-referral law.** Specifically, there should be increased Stark Law protection for ACOs, especially as it pertains to addressing the uncertainty about acceptable arrangements with parties outside of the ACO and for patients beyond traditional Medicare.

In the context of question 21, CMS asks how the agency can attract more ACOs to participate in two-sided models. This presumes that one key way overall ACO program success is measured is based on the portion of ACOs in two-sided models. We reject that notion: program success should not be measured by how many ACOs are accepting two-sided financial risk. Instead of measuring success by how many ACOs are in two-sided risk models, CMS should measure success by how overall Medicare spending is changing, what the spillover effects are on other parts of Medicare, and the extent to which patients are receiving high quality care that maintains or improves their health and quality of life. Therefore, we request a program modification to allow extended Track 1 participation beyond the six year limit for ACOs that meet specific cost or quality criteria detailed in this recent letter to CMS signed by NAACOS, American College of Physicians, American Medical Association, Association of American Medical Colleges, Medical Group Management Association, and Premier Healthcare Alliance.

The DPC model aims to enhance beneficiary engagement, which we fully support. We also feel ACOs should have new ways to enhance their relationships with beneficiaries. In order for ACOs to effectively manage cost and quality as well as to assume accountability for beneficiary care across a range of providers, ACOs need to be able to incentivize beneficiaries to receive optimal care consistent with the quality and the goals of the ACO. Therefore, we recommend ACOs be able to offer discounts, waive co-payments and provide other incentives to beneficiaries for using ACOs' preferred providers. Many ACOs are currently reluctant to assume financial risk for a patient population without the ability to effectively manage care and implementing beneficiary incentives would help address this concern. Further, this is an important tool to better engage beneficiaries and increase their awareness of properly coordinated care. Beneficiaries play a critical role and their choices can have a considerable effect on the quality and cost of their care. CMS should also improve the use of ACO voluntary beneficiary alignment, in which beneficiaries designate their primary care provider and are attributed to an ACO based on that selection. While available starting with PY 2018, this important tool could be improved and more widely used.

In addition to the advanced funding opportunities discussed above, NAACOS urges CMS to consider new opportunities for payment mechanisms other than FFS. This would address challenges ACOs face from relying on FFS payments without other cash flow mechanisms from Medicare. ACOs also have to wait approximately nine months after the close of the performance year to receive shared savings payments, and this considerable delay further exacerbate ACOs' ability to invest in its ongoing clinical and operational transformations. Many other APMs, such as Comprehensive Primary Care Plus, provide up front and ongoing payments that can be used for organizational transformation. Therefore, a primary care DPC model would be an effective way to move away from FFS payments, and if incorporated into a broader ACO model, the incentives to enhance primary care would be aligned with the ACO's broader goals of reducing unnecessary utilization and improving outcomes through keeping patients healthy and preventing costly and unpleasant adverse health episodes and outcomes. Introducing a partial capitation option to MSSP is also supported by statute. Section 1899 of the Social Security Act addresses the MSSP, and specifically 1899(i)(2)(A) addresses the Secretary of Health and Human Services introducing a partial capitation model to certain ACOs. Therefore, we urge CMS to allow ACO practices to participate in a primary care DPC model, which will provide a test for moving away from FFS payments and could be built upon in the future.

In response to the RFI's question about what additional waivers would be necessary (e.g., to facilitate more coordinated care in the right setting for a given patient or as a means of providing regulatory relief necessary for purposes of testing the model), we are pleased to reiterate a number of suggestions for which we have repeatedly advocated. Currently CMS affords certain ACOs relief from a number of cumbersome payment rules that actually prohibit care coordination and can increase costs. We urge CMS to expand the use of these payment rule waivers to extend to all ACOs. This includes the SNF 3-day Rule. Eliminating the requirement of a 3-day inpatient stay prior to SNF (or swing-bed Critical Access Hospital admission) admittance will allow ACOs to provide the right care for the patient in the most appropriate location. We also request that CMS waive certain telehealth billing restrictions to increase the use of these services by all ACOs. Specifically, elimination of the geographic components of the originating site requirements will allow all ACOs to have the ability to provide needed telehealth services in areas other than those classified as rural areas by CMS (currently defined as a rural Health Professional Shortage Area [HPSA] located either outside of a Metropolitan Statistical Area [MSA] or in a rural census tract). We also request that CMS allow beneficiaries to receive telehealth services from their place of residence. These telehealth changes were recently made in the Balanced Budget Act of 2018 and are scheduled to go into effect in 2020 for two-sided ACOs, but we urge more expeditious implementation as well as providing this flexibility for *all* ACOs.

Additionally, we urge CMS to waive certain post-discharge home visit supervision requirements to allow for broader use of these services by ACOs when clinically appropriate. We ask that CMS allow physicians to contract with licensed clinicians to provide these home visit services using general instead of direct supervision requirements specified at 42 CFR § 410.32(b)(3). This will provide all ACOs with needed flexibility during the critical post-discharge time period. Finally, we ask CMS to afford all ACOs with the ability to provide waived co-payments for primary care services provided by the ACO's providers to encourage patients' use of these critical services.

Question 22: Different types of ACOs (e.g., hospital-led versus physician-led) may face different challenges and have shown different levels of success in ACO initiatives to date. Would a DPC model help address certain physician practice-specific needs or would physician practices prefer refinements to existing ACO initiatives to better accommodate physician-led ACOs?

NAACOS response: We acknowledge the challenges that various types of ACOs face which are based on a variety of factors, such as culture, local market dynamics, patient population, provider engagement and ownership, and organizational structure. As addressed in our response to question 21, we urge CMS to embed a primary care DPC model in a broader ACO model in markets where ACOs exist. Doing so will enhance the focus of primary care for all ACOs, thus reinforcing the core of the ACO. We also support a number of refinements to existing ACO initiatives, as detailed in our response to question 21, and we emphasize that creating a DPC model and refining the ACO model are not mutually exclusive. Both should be pursued, and these models should complement one another.

Conclusion

In closing, we appreciate CMS's efforts to further the transformation of Medicare to value-based payment models, by introducing a primary care DPC model as well as through improvements to existing models, such as ACOs. We believe the ACO model serves as an example of providing market-driven options for providers to collaborate to benefit patients, themselves and the Medicare Trust Fund. We urge CMS to consider the feedback included in this letter and thank you for your consideration of our comments. Should you want to further discuss any of our recommendations, please contact Allison Brennan, Vice President of Policy, at abrennan@naacos.com.

Sincerely,

Clif Gaus, Sc.D.
President and CEO
National Association of ACOs