

May 25, 2018

The Honorable Alexander Azar
Secretary of Health and Human Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: Request for Information on Direct Provider Contracting Models

Dear Secretary Azar,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Centers for Medicare and Medicaid Innovation's (CMMI's) Request for Information on Direct Provider Contracting (DPC) Models. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 152,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

ACP commends the administration in its desire to develop new innovative payment models and appreciates this opportunity to offer feedback on a DPC model. We emphasize the importance of a flexible model design with varying levels of voluntary financial risk, relief from administratively burdensome billing and quality requirements, and frequent sharing of performance data to attract and retain a diverse pool of participants, including small, rural and independent practices. We believe the overall concept of a physician-focused DPC model that would pay participating physicians a fixed, risk-adjusted PBPM payment to cover a predefined set of services in addition to opportunities to earn performance-based incentive payments offers an opportunity to improve care delivery and control costs while lifting burden on physician practices, reducing physician fatigue, and improving the physician-patient relationship.

Before the Centers for Medicare & Medicaid Services (CMS) moves forward with any such model, it is critical the agency further study and refine patient attribution, financial benchmarking and risk adjustment methodologies before holding practices financially accountable. Equally if not more important, CMS must consider any adverse impact the model could have on participation in existing Alternative Payment Models (APMs), such as the Comprehensive Primary Care Plus (CPC+) Program, or patient access to care issues that could result from patient cost sharing for new services or PBPM fees, particularly for low income or otherwise vulnerable patient populations.

Importantly, we also urge CMS to reconsider referring to the model as "DPC," which is used to refer to Direct Primary Care and has generated mass confusion among physicians and patients. Additionally, the term "direct provider contracting" traditionally refers to individual contracts that practices sign with Medicare Advantage plans, so using this term to describe a new Medicare direct provider contracting model will likely create additional confusion.

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?

ACP appreciates this question and believes it is vitally important to the success of any model to attract a wide range of participating practices. There is a widespread desire across the physician community to participate in APMs because they incentivize cost and quality improvement while offering some relief from one-size-fits all reporting criteria and burdensome billing requirements. It is important CMS leverage this flexibility by developing a diverse range of APMs that offer varying levels of risk to appeal to a wide range of practices of varying specialties, sizes and locations. We offer the following considerations and recommendations for the agency to consider as it looks to develop models in the DPC realm and look forward to elaborating on these concepts in future discussions with the agency.

CMS needs to devote the necessary time and resources to studying and improving risk adjustment, financial benchmarking and quality measurement, which are contingent to the failure or success of both individual APM entities, and models as a whole. ACP stands ready to support CMS as it works to develop, test and eventually implement new models and underscores the importance of transparency and frequent collaboration from the physician and patient communities to the future success of these models.

Flexibility in model design is paramount to attracting a diverse range of participants. CMS should deploy a diverse range of DPC models with varying levels of risk, including some models with zero or very limited downside risk. It is vital to engage small, rural and independent practices, many of which treat underserved communities that often have the most to gain from innovative new patient-centered care delivery strategies. These practices have the desire to join innovative new payment models and improve the delivery of care for their communities, but as small businesses they often lack the resources and financial capital to bear higher levels of financial risk. CMS should create risk models that offer more manageable risk levels and

support all participants, but particularly small, rural and independent practices, with up-front financial investments.

CMS needs to appropriately incentivize and reward practices that take on financial risk and test innovative new care delivery models. At a minimum, CMS should recognize participants of innovative new payment models with credit towards their MIPS score, such as full credit toward the Improvement Activities category score. Higher-risk DPC models should meet the appropriate criteria and qualify as Advanced APMs. CMS should also look to develop a separate Advanced APM risk standard for small and rural practices, which it solicited comments on in last year's proposed rule with updates to the Quality Payment Program (CMS-5522-P), but ultimately did not finalize. Importantly, creating a multitude of models with varying levels of risk will also serve as a glide path to help practices gradually ramp up to higher levels of risk and will ultimately result in more practices electing to participate.

As elaborated on more fully in Question 9, accurately adjusting for patient health status is vital to mitigating risk, particularly for smaller patient populations, and is therefore critical to encouraging more widespread interest and participation in new DPC models, particularly by small, rural, and independent practices.

As it deploys new APMs, CMS should leverage these opportunities to increase flexibility and reduce administrative burden for practices. By virtue of participating in an APM, practices and clinicians are held accountable for cost and quality. Requiring practices to engage in duplicative documentation and reporting is an unnecessary drain on time and resources, both for model participants and for CMS staff. Freeing clinicians from check-the-box billing requirements will allow practices to redirect time and resources toward patient care and to test and deploy new innovative strategies to drive care improvement.

ACP calls on CMS to respond to several outstanding recommended proposals by the Physician-Focused Payment Model Technical Advisory Committee (PTAC), several of which have a DPC-based design. These models were developed by specialty societies and other industry experts representing various factions of the health care spectrum and have a demonstrated pool of interested participants from a variety of specialties and sub-specialties. Implementing these models would be an easy strategy to immediately engage a diverse range of clinicians and practices in DPC and other types of new APMs, which are in short supply. We urge CMS to make greater use of this valuable asset by acting on outstanding PTAC recommendations and setting a formal process and timeline in place to review future model proposals.

As is the case with the CPC+ and Next Generation Accountable Care Organization ("Next Gen") Models, CMS should allow practices or physicians to participate on an individual National Clinician Identifier (NPI) or split-Tax ID Number (TIN) basis. From a logistical standpoint this makes the most sense, considering not all clinicians in a given organization will necessarily be directly involved in the line of care or condition that the model is focused around. Secondly, it ensures that all clinicians participating in the model are fully invested in the goals and outcomes of the model, which gives practices more confidence to enter into risk bearing payment arrangements and would lead to more widespread participation in the model.

In considering how to attract physician and practice participants, it is vital that in establishing new programs, CMS does not adversely impact similar CMS initiatives already underway and yielding promising results, including the CPC+ and Next Gen Models. ACP has expressed its strong support for the CPC+ Model which is the only medical home model that is specifically identified in the Quality Payment Program/MACRA as an advanced APM. This model offers the potential of greatly strengthening the ability of internists and other primary care clinicians, in thousands of practices nationwide, to deliver high value, high performing, effective, patientcentered, and accessible primary care to millions of their patients. CPC+ participants have demonstrated meaningful strides in care delivery transformation and the program should continue to be fully funded and robustly evaluated. Next Gen ACOs also show promise on cost and quality metrics. In 2016, all 18 Next Gen ACOs achieved 100% across 33 quality measures and the majority qualified for shared savings payments. In total, the program saved Medicare \$48.3 million that year.² Both programs feature prospective payment options and would likely entail some similar design elements as a new Medicare DPC model. ACP is confident there is space for new DPC models to coexist alongside existing models. However, CMS should carefully consider potential adverse consequences to these and other current APMs as it looks to develop new models and the agency should make every attempt to avoid possible attrition and overlap issues. CMS could help to mitigate overlap between new and existing models by ensuring new models include distinct design features, such as a new risk options, and creating models that satisfy needs that are unmet by existing models.

2. What features should CMS require practices to demonstrate in order for practices to be able to participate in a DPC model (e.g., use of certified EHR technology, certain organizational structure requirements, certain safeguards to ensure beneficiaries receive high quality and necessary care, minimum percent of revenue in similar arrangements, experience with patient enrollment, staffing and staff competencies, level of risk assumption, repayment/reserve requirements)? Should these features or requirements vary for those practices that are already part of similar arrangements with other payers versus those that are new to such arrangements? If so, please provide specific examples of features or requirements CMS should include in a DPC model and, if applicable, for which practice types.

Voluntary participation and a gradual approach to implementation will achieve long-term buyin from clinicians and avoid imposing unnecessary burden on practices, as mandatory models do. If the model offers substantive incentives to join, including relief from burdensome billing documentation, quality reporting, and fraud and abuse requirements in addition to financial incentives for positive performance, a substantive number of practices will inherently want to join and will be invested in the program's goals.

As with any new payment model, CMS should not alienate potential participants by imposing unnecessarily restrictive criteria. The agency should avoid the use of "control groups." While we appreciate CMS' interest in collecting data to evaluate the success of the program, this could also be achieved by using Medicare enrollment data and administrative claims to identify other TINs that meet the criteria to participate but are still operating on a fee-for-service (FFS) basis

¹ "CPC+ 2017 Year in Review." CMS.

² "Next Generation ACO Model Financial and Quality Results Performance Year 1." CMS.

without restricting willing, eligible practices from the benefits of participating in the model. The practice of establishing control groups not only reduces participation by 50% outright, it diminishes morale among potential future applicants if they know they have only a 50% chance of being accepted. A lot of work occurs in advance of submitting an application, including negotiating possible contract details with willing subspecialists and securing a repayment funding source, etc.

One important consideration for high risk tracks will be to align model requirements with those for Advanced APMs, including use of Certified EHR Technology (CEHRT), quality measurement and taking on a minimum level of risk. However, it is important that CMS offer lower risk tracks that are not held to such restrictive standards in order to offer reasonable participation options for smaller, rural, and independent practices. As an example, the Comprehensive Care for Joint Replacement Model features two distinct tracks, one which requires CEHRT and qualifies as an Advanced APM, and another that does not, knowing that CEHRT is often prohibitively expensive and requiring it would alienate many small and independent practices from participating.

CMS could also consider granting Patient-Centered Medical Homes (PCMHs) and Patient-Centered Specialty Practices (PCSPs) "deemed status" in the DPC program, or at a minimum, permitting reduced demonstration requirements. These practices have already met a rigorous set of quality standards and honoring this recognition would reduce duplicative paperwork and begin to align private and public sector value-based initiatives which will be increasingly important as the number of APMs continues to grow.

3. What support would physicians and/or practices need CMS from CMS to participate in a DPC model (e.g., technical assistance around health IT implementation, administrative workflow support)? What types of data (e.g., claims data for items and services furnished by non-DPC practice clinicians and suppliers, financial feedback reports for DPC practices) would physicians and/or practices need and with what frequency, and to support which specific activities? What types of support would practices need to effectively understand and utilize this data? How should CMS consider and/or address the initial upfront investment that physicians and practices bear when joining a new initiative?

As with any model, CMS' support is critical, thorough educational resources, webinars and answering technical questions through the CMS Help Desk. It is critically important that Help Desk staff be well-versed in the technical details of the model so that they can respond to questions with affirmative, consistent information. The College would be glad to partner with CMS to host educational opportunities for ACP members. In addition to education for participating practices and providers, it is vital CMS target marketing efforts and educational materials toward patients, caregivers, and the general public about what the model would mean for patients.

It is vital CMS communicate information critical to participation decisions and cost and quality evaluation to participants with adequate advance notice. Last December, CMS introduced a risk adjustment factor that effectively reduced risk scores by 4.82% for Next Gen ACOs with less than three weeks' notice before the cuts took effect. Several participants who later exited the program cited this and other major program policy changes with little advance notice as a

major contributing factor for their decision.³ CMS should do everything it can to support practices that voluntarily participate in CMS models. Surprising practices with last minute rule changes that have a direct, adverse impact on their performance undercuts confidence in the model and makes practices less willing to participate in Medicare sponsored APMs, particularly in two-sided risk models where a significant portion of their payment is at risk. Any information directly related to changes in evaluation methodologies should be clearly communicated to model participants and the public well in advance through a transparent process that solicits engagement from participants and industry stakeholders.

Data is also a critical element of support CMS can offer practices. First and foremost, timely feedback on cost and quality performance is vital to practices' ability to learn from their past performance and channel that into process improvements that enhance patient outcomes and lower costs. Instead of waiting nearly an entire year after a performance year has ended to release financial and quality performance data in massive datasets, CMS should issue more frequent, targeted feedback to individual APM entities about their ongoing performance throughout the performance year so they can make more frequent adjustments to value-based care initiatives and more effectively drive improvements in patient care.

Releasing claims data would help to improve the transparency and accountability of the program, as well as empower stakeholder organizations and industry leaders to study and test improvements to risk adjustment, quality measurement, and benchmarking methodologies. ACP is willing to work with CMS to improve APMs and offer more technical refinements, but without access to claims data, we are hamstrung in our ability to offer tangible feedback. We commend CMS for making Medicare Advantage claims data available for the first time and hope the agency considers following suit with claims data for traditional Medicare.

In terms of quality reporting, CMS can support vendors and practices by providing adequate notice of new measures and requirements before holding practices financially accountable. It takes time to program systems, field test new functionalities, and train staff each time a new measure is added or criteria is changed. This cannot reasonably take place within a few months' time. Before the administration moves forward with any punitive element of new requirements that are based on third party vendor technologies, it should first conduct robust reviews of current commercial products to ensure there is a substantive inventory of reliable products that meet new requirements.

Finally, CMS can support practices through financial resources. This includes providing up-front investments so that practices can invest in new staff, technologies, and infrastructure that are inherent to starting or joining an APM. EHRs, Qualified Clinical Data Registries (QCDRs), and other products can also be expensive and present another barrier to participating in APMs, particularly for small, rural, and independent practices. CMS could offset the cost of products for certain types of practices, or consider creating a government sponsored product or website that fulfills the basic data collection and reporting functionalities mandatory to participating in the model at a reduced or free charge. This type of support would be particularly impactful for

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 $^{^3}$ "Seven ACOs Exit Next Generation Model, Blaming CMS for "Unilateral" Changes." American Journal of Managed Care. May 2018.

small and rural practices whose lack of liquid capital often hinders their ability to join APMs despite a real thirst to drive innovation and improve the quality of care in their communities.

5. CMS is also interested in understanding the experience of physicians and practices that are currently entirely dedicated to direct primary care and/or DPC-type arrangements. For purposes of this question, direct primary care arrangements may include those arrangements where physicians or practices contract directly with patients for primary care services, arrangements where practices contract with a payer for a fixed primary care payment, or other arrangements. Please share information about: how your practice defines direct primary care; whether your practice ever participated in Medicare; whether your practice ever participated in any fee-for-service payment arrangements with third party payers; how you made the transition to solely direct contracting arrangements (if applicable); and key lessons learned in moving away from fee-for-service entirely (if applicable).

We appreciate CMS' interest in seeking input from clinicians currently participating in DPC arrangements. In addition to the comments provided below, we would be happy to connect CMS with ACP members participating in such arrangements upon request.

The growth of direct patient contracting practices (DPCPs) in recent years⁴ is evidence of the promising benefits these types of models can offer, including relief from physician burnout caused by frustration with paperwork and other administrative burdens, more stable reimbursement in an era of increasing unpredictability and cuts, and improvements to the overall patient experience by expanding access to more services and increasing the amount of face time with physicians.

As the agency moves forward with considering such a model, we caution CMS to further study and consider several important potential unintended consequences, including exacerbating racial, ethnic, and socioeconomic disparities in health care and imposing too high a cost burden on some lower-income patients. We urge the agency to conduct further independent study into factors contributing to the growth of existing DPCPs and their impact on workforce, cost, and patient access to care, especially for vulnerable patient populations.

With regard to consumer-directed models including those that allow beneficiaries to contract directly with clinicians such as direct patient care models, as outlined in ACP's paper titled, "Assessing the Patient Care Implications of 'Concierge' and Other Direct Patient Contracting Practices: A Policy Position Paper From the American College of Physicians," the College supports physician and patient choice of practice and delivery models that are accessible, ethical, and viable and that strengthen the patient–physician relationship. ACP believes that physicians in all types of practices, including DPCPs, must:

⁴ "<u>Assessing the Patient Care Implications of "Concierge" and Other Direct Patient Contracting Practices.</u>" Annals of Internal Medicine. ACP. December 2015.

⁵ "Assessing the Patient Care Implications of "Concierge" and Other Direct Patient Contracting Practices." Annals of Internal Medicine. ACP. December 2015.

- Honor their professional obligation to provide nondiscriminatory care, serve all classes
 of patients who are in need of medical care, and seek specific opportunities to observe
 their professional obligation to care for the poor;
- Be transparent with patients and offer details of financial obligations, services available at the practice, and the typical fees charged for services;
- Consider the effect that downsizing a patient panel for any reason could have on the local community, including patients' access to care;
- Ensure that monthly administrative fees, retainer fees, or other patient cost sharing does not create barriers to care, particularly for low-income or vulnerable patient populations; and
- Consider ways to reduce any barriers to care for lower-income patients that may result from PBPM fees, noting that this problem could be mitigated if CMS does not require patient copays for such fees.

The College has also called for independent research on direct patient contracting practices (DPCP) that addresses the following:

- The number of physicians in a DPCP;
- Where DPCPs are located;
- Growth projections for the number of DPCPs;
- The number of patients receiving care from DPCPs;
- Factors that undermine the patient-physician relationship absent a DPC arrangement;
- Drivers of professional burnout that incentivize physicians to join DPCPs;
- Impact on ability to care for underserved populations;
- Effect of DPCPs on the health care workforce;
- Impact of DPCPs on patients' out-of-pocket costs;
- Impact of DPCPs on overall health system costs; and
- Patients' overall experience with the quality of care and clinical outcomes in DPCPs.

6. Medicare FFS beneficiaries have freedom of choice of any Medicare clinician 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 dis-enroll with a practice for the purposes of the model (while still retaining freedom of choice of clinician 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? If the practice is accountable for all or a portion of the total cost of care for a beneficiary, should there be a minimum enrollment period for a beneficiary? Under what circumstances, if any, should a clinician or supplier be able to refuse to enroll or choose to dis-enroll a beneficiary?

Patients participating in a DPC model should retain their right to seek care from a clinician or practice of his or her choosing. However, participating practices entering into a risk-bearing DPC arrangement also deserve protection against costs or services that are out of their control. Therefore, we recommend patients have freedom to receive services from any clinician. However, the DPC model must be structured to offer clear patient benefits that would encourage patients to stay within the model. Advantages under the DPC model could include

waiving cost-sharing for certain high-value and/or preventative services, access to a dedicated care team, and a more flexible range of supplemental services not covered by traditional Medicare, such as transportation to appointments. We are confident this will create incentives for many beneficiaries to seek services by the DPC-participating practices, particularly as health costs continue to rise and an increasing number of patients have expensive, high-deductible plans. However, any services outside of that pre-defined set, or administered by an outside clinician or practice should not be counted against the DPC model participant.

A minimum enrollment period is likely appropriate for a DPC-type model. The duration of such an agreement would be contingent on the types of services that are covered by the model. For acute conditions, a shorter period such as 90 days may be appropriate. For models focused on managing chronic conditions or a certain service line, a longer period of time such as one year may be more appropriate to collect the necessary amount of data.

The College supports physician and patient choice of practice and delivery models that are accessible, ethical, and viable and that strengthen the patient—physician relationship. The DPC model must be structured in a manner that does not encourage cherry picking of patients.

7. What support do practices need to conduct outreach to their patients and enroll them under a DPC model? How much time would practices need to "ramp up" and how can CMS best facilitate the process? How should beneficiaries be incentivized to enroll? Is active enrollment sufficient to ensure beneficiary engagement? Should beneficiaries who have chosen to enroll in a practice under a DPC model be required to enter into an agreement with their DPC-participating health care clinician, and, if so, would this provide a useful or sufficient mechanism for active beneficiary engagement, or should DPC clinicians be permitted to use additional beneficiary engagement incentives (e.g., nominal cash incentives, gift cards)? What other tools would be helpful for beneficiaries to become more engaged and active consumers of health care services together with their family members and caregivers (e.g., tools to access to their health information, mechanisms to provide feedback on patient experience)?

Voluntary patient assignment is the most effective and least intrusive way to assign patients to a clinician, and should be considered the preferred method. However, in order for the model to work successfully, the beneficiary population size must be large enough that the risk can be distributed. Therefore, we recommend a tiered approach to patient assignment similar to the CPC+, Next Gen, and Medicare Shared Savings Program (MSSP) models in which voluntary assignment is considered the preferred mode of assignment, but there is a secondary level of assignment based on plurality of allowed charges and if necessary, a determination based on the most recent eligible claim billed. We would like to reiterate that patient enrollment in any new DPC model should not jeopardize enrollment in CPC+.

Patient open enrollment periods should be aligned with the minimum enrollment period. If the minimum enrollment period is one year, then enrollment should be conducted on an annual basis. If the enrollment period for a particular acute condition model is shorter, beneficiary enrollment should occur more frequently so that the model can expand more quickly.

Patients that live between multiple states during the course of the enrollment period should be allowed to transfer their enrollment between clinicians, similar to enrollment in the chronic care management program. Whenever possible, this should be discussed prior to enrollment and reflected in their participation agreement with all clinicians and practices involved. Patient relationship categories and codes could also be used to facilitate the attribution of patients and care episodes to clinicians serving different roles over the course of a patient's treatment.

8. The Medicare program, specifically Medicare Part B, has certain beneficiary cost-sharing requirements, including Part B premiums, a Part B deductible, and 20 percent coinsurance for most Part B services once the deductible is met. CMS understands that existing DPC arrangements outside the Medicare FFS program may include parameters such as no coinsurance or deductible for getting services from the DPC-participating practice or a fixed fee paid to the practice for primary care services. Given the existing structure of Medicare FFS, are these types of incentives necessary to test a DPC initiative? If so, how would they interact with Medicare supplemental (Medigap) or other supplemental coverage? Are there any other payment considerations or arrangements CMS should take into account?

Waiving of beneficiary cost-sharing is a powerful incentive for participation and helps to encourage use of certain high-value and preventative services, which can help to better manage symptoms and reduce costs in the long-term. For instance, patients are presently discouraged from taking advantage of valuable Chronic Care Management (CCM) services due to the required patient copay. ACP recommends CMS collect data from patients regarding which services that are eligible for cost-sharing would be most meaningful. As an example, waiving of cost sharing for transportation or telehealth services may be an effective way to strengthen the patient physician relationships, particularly in rural service areas, while for other patients waiving of copays for regular check-up appointments may be more beneficial, particularly those managing a chronic condition.

9. To ensure a consistent and predictable cash flow mechanism to practices, CMS is considering paying a PBPM payment to practices participating in a potential DPC model test. Which currently covered Medicare services, supplies, tests or procedures should be included in the monthly PBPM payment? (CMS would appreciate specific Current Procedural Terminology (CPT®1)/Healthcare Common Procedure Coding System (HCPCS) codes as examples, as well as ICD-10-CM diagnosis codes and/or ICD-10-PCS procedure codes, if applicable.) Should items and services furnished by clinicians and suppliers other than the DPC-participating practice be included? Should monthly payments to DPC-participating practices be risk adjusted and/or geographically adjusted, and, if so, how? What adjustments, such as risk adjustment approaches for patient characteristics, should be considered for calculating the PBPM payment?

It is critical to the program's success that practices not be held accountable for costs outside of their control, including services outside of the pre-defined list of services included in the model or delivered by clinicians not participating in the DPC arrangement. The range of covered services will depend on the scope of the DPC model. ACP would be pleased to offer more specific comments regarding specific procedure codes once more information is made available pertaining to the types of conditions and service lines CMS plans to consider. Importantly, tests,

drugs or other supplies that involve significant out-of-pocket variable costs, such as drug infusions, should be separately reimbursed to help mitigate large, unpredictable upticks in cost. CMS should also avoid evaluating DPC model participants on total cost of care measures or community-based measures, such the Institute of Medicine's "vital signs" core measures. If practices and clinicians do not feel as though they have control over quality measures for which they are being held financially accountable, they will be far less inclined to participate in voluntary risk-bearing APMs.

Payments should be appropriately adjusted for geographic location, as well as patient risk status. The Hierarchical Condition Categories (HCC) methodology, which is used for several other APMs, was originally developed for health plans. It does not offer a level of specificity that is necessary to adequately risk adjust for a single APM entities, which have much smaller patient populations over which to spread risk. HCC scoring is flawed in several ways and fails to account for several important factors including degree of severity for a particular condition, managing patients with comorbidities, and social determinants of health. Patient relationship codes would allow CMS to gather more specific data around a doctor's role with each patient, but in deploying any new codes CMS should always look to fold new codes into existing clinical workflows and minimize administrative burden to the greatest extent possible.

In a recent paper⁷ on addressing social determinants to improve patient care and promote health equity, the College indicates its support for collaborative models that encourage a teambased approach for treating patients at risk to be negatively affected by social determinants of health. It is critically important that this DPC model and all future APMs actively work to improve care for disadvantaged populations, which includes properly risk adjusting for characteristics proven to lead to health disparities so that disadvantaged populations do not suffer from adverse selection issues. Longer term, models like this show promise as vehicles to enhance communication and coordination between clinicians involved in a patient's treatment, collecting and studying data to establish patterns of social determinants of health, and developing and testing innovative solutions to help bridge these gaps.

10. How could CMS structure the PBPM payment such that practices of varying sizes would be able to participate? What, if any, financial safeguards or protections should be offered to practices in cases where DPC-enrolled beneficiaries use a greater than anticipated intensity or volume of services either furnished by the practice itself or furnished by other health care clinicians?

CMS should establish a range of risk options, including zero or low-risk options that would be particularly appealing to small and independent practices where the PBPM payment is one element of reimbursement and does not fully replace traditional FFS. Adding guardrails similar to the MSSP's loss sharing limit would also help to alleviate the risk of financial catastrophe

⁶ Vital Signs Initiative. National Academy of Medicine.

⁷ "<u>Addressing Social Determinants to Improve Patient Care and Promote Health Equity</u>." Annals of Internal Medicine. ACP. April 2018.

should higher than anticipated spending occur, and would thus encourage more practices, particularly those that are small, independent, and rural, to participate in the model.

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?

A DPC model can work with a range of differing levels of risk that will be appropriate for different types of practices, similar to the Next Gen and CPC+ programs which each offer multiple tracks of varying risk ranging from traditional FFS plus an additional PBPM payment, up to full capitation. The model could have risk scaled on a percentage basis to offer several risk options for FFS reductions of varying degrees that would be implemented into a prospective, PBPM payment. However, the overall model design and structure would be kept consistent to minimize unnecessary complexity. A one-sided risk model may be more appropriate for smaller and rural practices and also offers an on-ramp to test the model, gain experience, and eventually foray that into higher risk bearing models. Meanwhile, practices that are larger and have the means to take on downside risk or those that have more experience will be enticed by the higher levels of reward that two-sided risk models offer. It is important that at least one of these higher risk models, if not multiple, meet the minimum risk standards to qualify as an Advanced APM. The College recommends a prospective payment structure consisting of one up-front lump sum payment comprised of expected spending, administrative expenses, and additional funding to invest in value-based initiatives, which would be adjusted for patient risk, national and regional spending trends, and other variables. That amount would then be retroactively reconciled against true spending according to the level of risk and adjusted for quality performance.

Performance data from other APMs that feature retroactive reconciliation against a financial benchmark have identified areas that require further study and refinement, including appropriately weighting regional verses national spending so as not to adversely impact practices in low spending areas, as well as not allowing past improvements in quality and cost performance to count against practices in future performance years. One possible way to correct for this latter issue is to not rely solely on a practice's own historic performance and to account for an APM participant's cost and quality performance relative to non-APM participants in the same performance year so that participants can continue to be rewarded for consistently positive performance on cost and quality metrics.

If the financial success or failure of an individual APM entity, as well as the model as a whole is measured against a spending benchmark, it is paramount that various benchmark methodologies be studied, field tested, and modified as necessary *before* practices' payments are at risk. It is equally important that practices field testing new benchmarking methodologies be rewarded for assisting in these efforts, rather than penalized on their cost or quality performance in the QPP. As more models are developed, accurate financial benchmarking will

become increasingly important and sophisticated. CMS needs to dedicate the necessary resources to getting that methodology right sooner rather than later.

Different DPC models may target different conditions and service lines, so the included services may differ by model. What is consistent across all models is that these services should be clearly defined and understood in advance. Equally important, practices should not be held accountable for services outside of that pre-defined list or administered by a practice or clinician not participating in the DPC model. CMS should partner with ACP and other clinician societies to develop a list of included services in later stages of model development.

As noted earlier, CMS should reward small and rural practices to join innovative payment models with substantive credit toward the Quality Payment Program. At a minimum, participating practices should receive substantial credit toward their MIPS score, including but not limited to full credit towards their Improvement Activities category score. In addition, CMS should consider establishing a separate, lower Advanced APM nominal amount standard for small and rural APMs that would be no greater than the Medical Home Model standard.

13. As part of the Agency's guiding principles in considering new models, CMS is committed to reducing burdensome requirements. However, there are certain aspects of any model for which CMS may need practice and/or beneficiary data, including for purposes of calculating coinsurance/deductible amounts, obtaining encounter data and other information for risk adjustment, assessing quality performance, monitoring practices for compliance and program integrity, and conducting an independent evaluation. How can CMS best gather this necessary data while limiting burden to model participants? Are there specific data collection mechanisms, or existing tools that could be leveraged that would make this less burdensome to physicians, practices, and beneficiaries? How can CMS foster alignment between requirements for a DPC model and commercial payer arrangements to reduce burden for practices?

One of the advantages of value-based payment arrangements is that practices are inherently held accountable for cost and quality outcomes. Accordingly, CMS should look to eliminate administrative requirements for participating clinicians and practices, including prior authorizations, appropriate use criteria, evaluation and management documentation guidelines, prior authorization, and duplicative quality reporting measures. CMS should exert broad use of its waiver authority to exclude DPC participants from redundant billing requirements including but not limited to hospital discharge, skilled nursing facility three-day rule, home health, home visits, and telehealth requirements, as well as grant model participants the ability to waive patient cost sharing or provide other direct patient benefits. CMS should also use its waiver authority to lift DPC-model participants from the threat of fraud and abuse restrictions that needlessly interfere with the very types of incentive-based compensation relationships that drive improved quality and reduce cost and threaten APM development. Alleviating burdens caused by these outdated and burdensome requirements will also serve as an added incentive for clinicians and practices to join the model. As always, CMS

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⁸ "Assessing the Patient Care Implications of "Concierge" and Other Direct Patient Contracting Practices." Annals of Internal Medicine. ACP. December 2015.

should work with key stakeholders, including private payers, health information technology vendors, and frontline clinicians, to harmonize and streamline administrative tasks and reporting requirements in order to reduce administrative burden.

CMS has an opportunity to put its Meaningful Measures and Patients over Paperwork initiatives to action by minimizing and streamlining the number of quality reporting measures and reducing the overall administrative burden on practices. ACP has long identified reducing administrative tasks as an important objective, including developing the "Patients Before Paperwork" initiative in 2015, and publishing a position paper last year which introduced several recommendations to mitigate the negative impact of administrative tasks on physician practices. CMS should avoid imposing any new measures or documentation requirements at all costs. If the agency does choose to move forward with requiring new measures or data requirement, they should provide financial, time, and quality of care impact statements for public review and comment. If a new administrative task or requirement is deemed to have a negative effect on quality and patient care, unnecessarily question clinician judgment, or increase cost – it should be revised or removed entirely. Additionally, CMS should make a concerted effort to remove outdated measures, particularly as additional measures are added, so that participants are not increasingly burdened over time.

14. Should quality performance of DPC-participating practices be determined and benchmarked in a different way under a potential DPC model than it has been in ACO initiatives, the CPC+ Model, or other current CMS initiatives? How should performance on quality be factored into payment and/or determinations of performance-based incentives for total cost of care? What specific quality measures should be used or included?

Practices should be expected to meet a basic standard of quality, while high-performing practices should be rewarded for delivering high-quality care through additional performance-based quality bonuses, higher benchmarks, or some other reward mechanism.

Capturing a reasonable amount of quality data is important to ensure beneficiary protections and uphold program integrity standards. In particular, quality measurement can be a valuable tool in collecting new data to shed light on important issues, such as disparities in health outcomes based on several social determining factors. Coordinated care models like this one present an opportunity to collect data, understand patterns, and test solutions.

However, it is vitally important that CMS balance the benefit of collecting this data with administrative burden on practices, and always look to reduce reporting burden in other areas before introducing any new measures or burdens. Reasonable quality standards can be upheld while drastically streamlining and reducing the overall number of quality measures. CMS should look to establish a set of core measures across multiple APMs that establish a quality baseline, and then offer an additional menu of more model or specialty-specific measures. This would minimize burden on physician practices and allow for flexibility so that specialties and sub-

^{9 &}quot;Where We Stand: Patients Before Paperwork." ACP.

¹⁰ "Putting Patients First by Reducing Administrative Tasks in Health Care: A Position Paper of the American College of Physician." Annals of Internal Medicine. May 2017.

specialties still have sufficient, clinically relevant measures. At the same time, it would create more consistency in measures across various APMs that would allow for a more meaningful comparison of their impact on patient outcomes. Along these lines, CMS should look to align Medicare quality metrics with those used by the private sector wherever possible, including but not limited to PCMH and PCSP criteria. This holds practices to a proven, high standard of care while reducing burden on practices by not subjecting them to countless sets of requirements for each individual payer that all aim to measure high quality.

Overall, quality measurement must move toward becoming more relevant and accurate, which entails placing a greater emphasis on patient access, experience, and outcomes. CMS should also look to address current gaps in quality measurement, such as managing conditions for patients with comorbidities and/or social pre-determinants of health. The College strongly recommends CMS collaborate with specialty societies, frontline clinicians, patients, and EHR vendors in the development, testing, and implementation of measures with a focus on collecting more meaningful data while decreasing clinician burden by minimizing the overall number of measures and integrating quality reporting more seamlessly into clinical workflows.

ACP's Performance Measurement Committee (PMC) has reviewed and provided detailed recommendations on all MIPS performance measures relevant to internal medicine. The PMC recommendations are based upon a scientific review process that involves four domains: purpose and importance to measure, clinical evidence base, measure specifications, and measure implementation and applicability. ACP strongly encourages CMS to review these recommendations when considering measures for internal medicine specialists.

The Core Quality Measure Collaborative, which has been led by the America's Health Insurance Plans (AHIP) and its member plans' Chief Medical Officers, leaders from CMS and the National Quality Forum (NQF), as well as national physician organizations, employers and consumers, seeks to promote measures that are evidence-based and generate valuable information for quality improvement, decision-making, and value-based payment and purchasing. The core measure sets are designed to be meaningful to patients and consumers and to physicians, while maintaining parsimony and reducing the collection burden and cost.

The College recommends that any measures CMS proposes to use outside of the ACP recommendations and core sets identified by the Core Quality Measures Collaborative be those recommended by the Measure Application Partnership (MAP). ACP remains concerned that a majority of new measures added to MIPS for the 2018 reporting year have received only conditional support from the MAP, and the 2017 measures that remain on the list for the MIPS program were given a MAP recommendation to "encourage continued development." This MAP designation is reserved for measures that often lack strong feasibility and/or validity data. Therefore, measures given the "encourage continued development" recommendation should be resubmitted to the MAP once the suggested development occurs.

¹² "<u>Time Out — Charting a Path for Improving Performance Measurement.</u>" New England Journal of Medicine. May 2018.

¹¹ ACP Performance Measure Recommendations.

Additionally, ACP continues to believe that all measures, whenever possible and regardless of source, should go through a multi-stakeholder evaluation process—a role that is performed by the National Quality Forum (NQF). This process is important, as it involves measures being evaluated against four important criteria—importance to measure, scientifically acceptable, usable and relevant, and feasible to collect.

ACP recommends CMS take concrete actions to provide clear options for specialties and subspecialties that may be most impacted by reducing the number of measures, including creating a set of more focused "menu" measures in addition to the core measure set. CMS should look to QCDRs as valuable sources for clinically relevant specialty measures.

The agency should also support the development and testing of new specialty measures by offering practices rewards to test out new measures, such as credit in the MIPS improvement activities category, and not penalizing them for performance during initial testing periods for new measures. CMS should consider establishing safe harbors for entities that are taking on innovative approaches to quality measurement and improvement activities in DPC. The DPC model should provide clear protections for individual clinicians who participate in these types of activities by having the entities register certain measures as "test measures" where their performance on those particular measures would not count against them.

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? What data or methods would be needed to support these efforts?

The College remains committed to ensuring beneficiaries receive the highest quality of care in practices that engage in direct contracting. Reporting a reasonable number of quality measures centered on patient access, outcomes, and experience will help to ensure quality of patient care is being upheld, particularly for underserved patient populations. Reporting burden should be minimized by focusing on high impact, outcomes based, and patient-reported measures that also align with private sector quality measurement criteria, such as for PCMHs and PCSPs. Additionally, practices should be expected to adhere to clinical evidence-based guidelines and maintain appropriate, but not excessive, supporting documentation to support their care decisions.

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?

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¹³ "<u>Assessing the Patient Care Implications of "Concierge" and Other Direct Patient Contracting Practices.</u>" Annals of Internal Medicine. ACP. December 2015.

ACP has long advocated that new APMs, including any new DPC arrangements, not result in adverse patient selection or clinician availability issues for Medicare beneficiaries. DPC model participants have an opportunity to partner with CMS to learn more about and work to narrow current disparities by helping to collect demographic data about its patient population and partnering with CMS to implement new strategies to narrow disparities.

One key to not exacerbating social inequities is proper risk adjustment. If a patient's health status is properly accounted for in the risk adjustment methodology, there will be no incentive for any of these adverse types of selection issues to occur because physicians will be adequately compensated for treating sicker patients. As elaborated in question 9, the current HCC risk scoring used by several current APMs is inadequate in that it fails to take into account severity of condition, overlap of multiple conditions, and social determinants of health. Invaluable data can be gathered from the Patient Relationship Categories and Codes, using clinical data from medical, surgical, emergency, lab, pharmacy, radiology departments and coupling such data with claims data organizations can apply comparative and predictive analytics to build a comprehensive, real-time picture of patients' health risks. We reiterate the importance of rewarding, rather than penalizing practices that help to test new measures and methodologies. ACP looks forward to continuing to work with CMS to test and improve the accuracy of risk adjustment and address some of the current deficiencies of HCC coding, possibly through establishing new patient relationship codes.

It is also vitally important that CMS structure patient cost-sharing in such a way that does not create new barriers to care, particularly for disadvantaged patient populations. For instance, patients are discouraged from taking advantage of valuable Chronic Care Management (CCM) services due to the required copay. CMS should strongly consider not requiring patient cost sharing for the PBPM payments and other high-value services. At a minimum, CMS should consider offering discounted rates or waiving certain copays for patients who cannot afford them. This will enhance patient participation in the program and avoid exacerbating current access to care issues due to a patient's ability to pay or other social predetermining factors.

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?

We appreciate the agency's demonstrated willingness to make adjustments to the benchmarking methodology and other design features since the inception of ACOs and look forward to continuing to partner with CMS to make further refinements to continue improving on the success of these programs. ACP has been actively engaged with a coalition of other industry stakeholders which has coalesced around several high-impact recommendations that

would enhance and improve the program.¹⁴ Chief among these is ensuring that the financial benchmarking and risk-adjustment methodologies are accurate. We ask that CMS immediately release claims data for ACOs so that we can more closely study the data and develop more specific recommendations in both of these areas. Additionally, while we commend CMS for incorporating regional spending into benchmarks, we ask that the agency expedite the process and allow ACOs to opt into that immediately, as opposed to waiting until the end of their three-year agreement period to do so. Risk adjustment should also be recalibrated annually, as opposed to every three years. Not only are ACOs' risk adjustment scores not adequately accounting for patients with worsening conditions, the impact is compounded by the fact that the regional trend factor against which ACOs are compared does adjust annually, so ACOs fare worse comparatively.

Similar to our recommendation for the DPC program, we recommend CMS reduce the current 31 quality measures required by ACOs and consider establishing a core set of mandatory measures, with a supplementary set of menu measures. In developing these measures, CMS should actively engage patient and provider organizations. CMS should also take advantage of the various specialty-focused measures QCDRs offer by giving ACOs more flexibility to report via other reporting mechanisms including QCDRs, as opposed to exclusively through the CMS Web Interface. ACOs are delivering high quality care with minimal reward in the form of a scaled sharing rate, but this only impacts ACOs if they surpass their minimum savings rate and qualify for shared savings. Therefore, we recommend CMS consider rewarding ACOs with superior quality performance by increasing their benchmark.

In terms of clinician participation and beneficiary alignment, we echo our recommendations for the DPC model that CMS allow ACOs more flexibility in defining participating clinicians by defining this at the NPI or a "split TIN" level so that large systems can more accurately select which clinicians are invested in the model. As noted earlier, ACP strongly supports voluntary patient assignment and urges the agency to work with ACOs to make voluntary patient assignment a more robust element of assignment for ACOs.

We appreciate CMS' goal of supporting ACOs and encouraging them to move to higher risk when they are ready. For this reason, we encourage CMS to allow ACOs to move up to higher risk tracks at any point throughout their three-year agreement period, as they did when Track 1+ was introduced. If CMS wants ACOs to advance to higher risk tracks, there is no reason to make an ACO wait until the end of their three-year agreement period when they feel they are ready after one or two years.

This said, ACOs that demonstrate savings to Medicare and/or meet high quality standards should not be forced to advance to a higher risk track. According to a recent study conducted by the National Association of ACOS, more than seven out of every 10 ACOs would be likely to leave the MSSP as a result of having to assume risk at the end of their second contract term. Value-based care strategies take time to materialize into quality improvement and savings, which is largely why ACOs in the program longer have historically performed better. Rather

¹⁴ MSSP Stakeholder Coalition Letter. February 2015.

¹⁵ "How likely is your Track 1 ACO to leave the MSSP as a result of having to assume risk?" NAACOS. May 2018.

¹⁶ 2016 Shared Savings Program ACO interactive dataset. CMS.

than prematurely force Track 1 ACOs out of a program that shows promise, CMS should continue working with stakeholders to refine and improve the program, particularly addressing current flaws in the benchmarking and risk adjustment methodologies. CMS could also consider allowing ACOs the option of distributing their risk over the course of their three year benchmark, rather than each year, as another way to distribute risk, particularly for smaller, independent ACOs.

Other important ways CMS can continue to attract and retain ACOs is by providing them with permanent advance payment opportunities, which are particularly critical for smaller, physician-lead ACOs with fewer assets. CMS should also look to offer ACO participants freedom from duplicative and burdensome administrative requirements by expanding its payment and fraud and abuse waiver authority, particularly to one-sided ACOs, and allowing ACOs more freedom to offer supplemental benefits, similar to that recently granted to MA plans.

III. Conclusion

ACP appreciates the opportunity to provide feedback on CMMI's DPC Model RFI. We hope the Innovation Center carefully considers our recommendations that creating an array of voluntary models with varying levels of risk is the most effective way to engage a variety of practices of different sizes, specialties, and backgrounds. We understand this is the beginning of an ongoing conversation and look forward to continuing to partner with you to provide feedback throughout the development of this and other APMs that will allow physicians to continue driving innovation and leading the transition to value-based care.

Thank you for considering our comments. Please contact Brian Outland by phone at 202-261-4544 or e-mail at boutland@acponline.org if you have questions or need additional information.

Sincerely,

Jacqueline W. Fincher, MD, MACP

Chair, Medical Practice and Quality Committee

American College of Physicians