



May 25, 2018

The Honorable Seema Verma,
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

We would like to thank you and the Centers for Medicare and Medicaid Services (CMS) for seeking input through a Request for Information (RFI) on market-driven reforms and innovations to improve patient-centered care, released, April 23, 2018. Such input from stakeholders, like Direct Primary Care practices is essential for meeting the agency's goal of establishing a new direction for the CMS Innovation Center focused on reforms that enhance care and provider greater value to the Medicare program. We are happy to provide general comments from the Direct Primary Care Coalition in this letter. In the submission attached we will provide specific answers to many of the issues addressed in the RFI.

First, we respectfully request that CMS change the name of the program, which the RFI calls "Direct Provider Contracting"—using the acronym "DPC," to something more reflective of the broader nature of the range of programs envisioned. This rationale for this goes much deeper than simple semantics. There are now about 900 Direct Primary Care (DPC)¹ practices in 48 states and the District of Columbia. Confusion over programs that might have the same name, yet be very different in nature is assured with the name currently suggested. Moreover, twenty-five states have enacted legislation defining DPC as Direct Primary Care, and legally defining DPC agreements as contracts between patient and doctor for primary care services outside of the scope of state insurance regulation. Likewise, Sec. 1301 (a) (3) of the ACA has favorable regulatory treatment defining DPC Medical Homes as a delivery reform providing value based primary care services outside of traditional fee for service (FFS) health insurance. A DPC brand has been established and CMS should not attempt to fundamentally change that brand. Recent experience with ACA-mandated healthcare "CO-OPs" found a similar problematic experience in confusing ACA Consumer Operated and Oriented Plans with cooperatives (coops), many of which, unlike the ACA CO-OPs, provided valuable health services or benefits.

The DPC model has evolved over the course of the last decade and has experienced rapid growth in the last few years. Offered directly to individual patients and families, through employers, who often self-insure for their employee health benefits, through union plans, and working in conjunction with Medicare Advantage (MA) plans, DPC arrangements have become very popular with patients and physicians alike. Today, DPC practices all over the US provide peerless access to great primary care to an estimated 330,000 American patients. We estimate around one third of these patients may be Medicare beneficiaries.

¹ In this letter and the comments which follow, "DPC" will refer to Direct Primary Care only.

We note enthusiastically that the RFI anticipates Direct Primary Care (DPC) to be one of a range of models to be tested, and the Coalition is happy that CMS is investigating how a pure DPC model might relate to Medicare. It's important to understand that many Medicare beneficiaries already participate in DPC, but only using their own dollars out of pocket. Most DPC physicians have opted out of Medicare to legally participate in such arrangements, but DPC doctors are also very deeply committed to treating Medicare patients. The requirement to opt out is one of the key reforms CMMI will need to address to ensure participation from anyone currently practicing DPC. It's also important that CMS preserve the special nature of this doctor patient relationship as it rolls out a CMMI program suitable for evaluation. Simply put; it's critical to get this right. And the DPC Coalition stands ready to help.

We view this as a two-step dynamic learning process. We recommend the CMMI pilot proceed in a first phase utilizing existing DPC practices to prove the downstream savings that can be achieved. In the second phase, newly transitioned and larger practices attempting to rapidly scale DPC can participate. It would be expedient for CMS to focus first on practices presently doing DPC and Medicare beneficiaries who are utilizing these DPC practices or would like to. We also understand CMS may look at other models in direct contracting as well.

We propose that a DPC CMMI demonstration provide a per beneficiary per month amount (PBPM) into a medical savings account (MSA) utilized by the Medicare beneficiary to pay all or a portion of their monthly DPC membership fees directly to their chosen physician. The patient may join, depart or change DPC practices at any time. Medicare would continue to provide regular FFS payments for services outside the DPC arrangement such as specialty care and hospitalization. In this manner, the patient will self-select an environment in which they are receiving satisfactory care.

We urge CMS to start by keeping it simple; test a DPC model that we know already works, using a defined contribution rather than a defined benefit. Of all the potential models listed in the RFI, we feel it would be easiest and most expedient for CMS to focus *first* on a DPC model that provides people in Medicare who are already in a relationship with an existing DPC practice paid for by a direct per-beneficiary-per-month (PBPM) payment. This would be used to pay the practice for a set of primary care services agreed upon between patient, doctor and CMS. Medicare could modify existing Medicare Medical Savings Accounts (MSAs) to enable the PBPB model. CMS would deposit payment into the account for primary care services from their existing DPC physicians. Medicare would continue to provide regular FFS payments for services outside the DPC arrangement such as specialty care and hospitalizations. Using CMMI demonstration authority, Medicare has an opportunity promote unfettered access to a high functioning primary care model working in the marketplace today—not by providing a defined benefit, but by providing a defined contribution to an MSA in appropriate amounts for Medicare patients participating in DPC practices. Participating DPC Practices would be able to add new Medicare beneficiaries to their practices, working with CMS to market the program to new participants to help add scale to the demonstration.

Outcomes in the demonstration would largely be measured by CMS using downstream claims data from care provided in other parts of the system. DPC should reduce number and size of these claims if permitted to function properly. This evaluation model reflects current practice in DPC arrangements with many employers today. CMS and patients should have the ability to share data with DPC physicians on utilization of care outside of DPC, potentially using the Blue Button program. Using such data, a reasonable set of annual reports on enrollment, patient encounters and patient satisfaction would be all the reporting a DPC practice should be required to participate with CMS. DPC practices should be able to utilize their existing EHR technology or the ONC Direct Project to report this minimal level of data without additional burden. This methodology should be tested over a minimum three-year period and compared to other advanced payment models. Claims data from employers using DPC arrangements for

their employees has shown that it improves care and reduced the overall cost of care by up to 20% using a similar data methodology.

The Hallmark of DPC is the restoration of a true personal relationship between patient and physician. People look to this simple model as one that has great potential to create a better functioning health system. DPC brings truly valuable, improved primary care to patients, reduces burden for doctors and cuts unnecessary administrative expenses by eliminating third party FFS primary care claims. It enables a true care delivery system for primary care, not a reimbursement system.

We believe that Americans of all ages and incomes should have access to high functioning, affordable, comprehensive, accessible, personal primary care. We look forward to working with you to give America's seniors, the disabled, and low income patients access to the best care America has to offer with Direct Primary Care.

Sincerely,

Jay Keese

A handwritten signature in black ink, appearing to read "J. Keese".

Executive Director

Direct Primary Care Coalition

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General Comments on RFI Questions: The comments of the Direct Primary Care Coalition will use the acronym DPC to refer to Direct Primary Care. The RFI states “CMS could enter into arrangements with primary care practices under which CMS would pay these participating practices a fixed per beneficiary per month (PBPM) payment to cover the primary care services the practice would be expected to furnish under the model, which may include office visits, certain office-based procedures.” Small independent DPC practices succeed in large part because of a mutually selected marriage between the patient and the physician. To preserve this selected marriage quality CMS should test a model that avoid the old “arranged marriage” problems associated with capitation. We feel that CMS will get the most traction from physicians currently engaged in DPC if they attempt to reflect the current state of the market.

The fact is that of the more than 800 DPC practices, most are populated by patients who pay a monthly fee individually. This is a reflection of the marketplace that CMS should use CMMI authority to test. There are a growing number of employer arrangements which provide a direct contribution to the DPC physician. We will address some of the attributes of these practices in the answers to your questions below. While some larger DPC practices may have an appetite for a direct payment from CMS to the provider, CMS is likely to attract larger numbers of smaller independent DPC practices with a PBPM payment that comes directly from the beneficiary. There are many cultural and legal reasons for this. Most DPC physicians have “opted out” of Medicare specifically to see Medicare patients under private contract. These terms would need to be changed if these physicians were now “accepting” payments from Medicare again. DPC physicians also want to avoid complicated False Claims Act liability (tied to payment).

Specific RFI Questions:

- 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?

Generally ACOs and other large networks are not necessary for the success of independent DPC practices. Many ACOs lack price transparency, a core tenant of DPC. DPC practices require a contract directly between the practice and the patient. This is not a feature of ACOs.

Attracting smaller DPC practices can be done by keeping things simple. Allow the patient to select and contract with a DPC practice with a periodic fee. CMS would reimburse the patient “directly” for all or a portion of the periodic fee. CMS will track downstream spending of all patients that are members of DPC practices and will report this data back to the practices (at the practice level) and in the aggregate when determining whether to expand the program. We assume that most DPC Practices will not be participants in existing ACOs. We encourage CMS to test a stand-alone DPC model. Initially, participation in the DPC model should be open to practices that are existing DPC practices, or those committed to transforming their practice. The greatest risk in combining an existing ACO practice with a new DPC practice, is that the practice may still see most of their patients in a fee for service fashion and not provide new DPC patients with the highest level of ongoing chronic care prevention and treatment available in current DPC practices. While there is room for a DPC model that may have some of the shared savings attributes of an ACO, the independent DPC model should be tested in a stand-alone manner to ensure a proper evaluation.

- 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.

The Coalition has adopted a simple three-part definition of Direct Primary Care, which has been described on [DPC Frontier](#) and in the Journal of Legal Medicine². To be defined as DPC, practices: 1) charge a periodic fee, 2) have an agreement with the patient which does not bill third parties any fees for services covered by that agreement, and 3) does not levy prohibitive per visit charges (more than the monthly equivalent of the periodic fee).

Another attribute of successful DPC practices is to employ a range of telephonic or smartphone technology to encourage interaction with patients outside of the setting of an office visit. CMS recently conducted research with DPC physicians around the country, in which the Coalition was happy to lend its assistance. That research found that most DPC providers gladly embraced technology, including EHRs. With the third-party fee for service visit out of the picture as the essential payment mechanism for primary care, physicians and patients are free to share information in any format they choose. As such, DPC encourages multiple modalities of communication and data sharing between patients and their physicians, including telemedicine, virtual visits, patient portals, and direct digital messaging. Most DPC physicians use EHRs to track clinical data, but not based on ICD or CPT claims, and since most certified EHRs are claims based, there may be other technological solutions employed by DPC practitioners that are more appropriate.

A key defining principle of DPC is that practices do not assume insurance risk and are by law or regulation clearly viewed as “outside of insurance” in the majority of states. Practices are not subject to reserve or escrow requirements like health plans. There are typically no enrollment periods. If a Medicare patient is unhappy with a DPC practice then they are free to seek care at a different practice. CMS could consider the notion of self-attestation that most revenues come from periodic fee (DPC) patients rather than third party fee for service patients. Limited panel size is another characteristic of most DPC practices. Attestation to a limited patient panel size per physician could be considered. Exceptions should be made for team-based care models which a growing number of DPC practices employ.

- 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)? What types of data (e.g., claims data for items and services furnished by non-DPC practice providers 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?

² Eskew P, Journal of Legal Medicine Vol. 37, Iss. 1-2, 2017.

One of the challenges of such a program is how to measure to ensure quality and the impact of the program for evaluation purposes. Data sharing with practices will be imperative for a successful demonstration, and a fair evaluation. DPC practices by nature operate in a claimless environment, where flat fees cover payment for primary care services. Claims-based CPT and ICD codes can create additional burden for DPC practices while often leading to very little value for the patient, or CMS. We believe that the overall health status of Medicare patients can and should be measured by CMS—not the provider—using claims data from care delivered by providers outside of the DPC agreement. If comprehensive primary care is being delivered through DPC this claims history should dramatically improve. It is important to remember that one of the goals of this pilot is to reduce the reporting burdens which currently keep physicians practicing in the third party FFS environment from spending necessary time with patients. As such, we believe that two-way data sharing is critical for the successful measurement of the DPC pilot being proposed. We suggest to the degree possible that data sharing between patient, DPC practice, and CMS be a key part of the demonstration. This could be accomplished simply by utilizing the data already available from the API in the CMS Blue Button 2.0 program which currently allows beneficiaries to securely download personal health information to a computer or other device to share with providers and keep in a computer-based personal health management tool. We are committed to working with CMS to achieve a balance which will meet the evaluation and quality goals set forth by CMS without adding undue burden to DPC practices.

4) **Which Medicaid State Plan and other Medicaid authorities do States require to implement DPC arrangements in their Medicaid programs? What supports or technical assistance would States need from CMS to establish DPC arrangements in Medicaid?**

States have attempted Medicaid pilots. Ultimately, the same DPC models we propose for Medicare could be applied to Medicaid. However, we believe Medicare will provide a greater opportunity to test payment and delivery models first, and that lessons learned there will provide an appropriate roadmap for expanding DPC into Medicaid, which we all recognize presents some significant challenges in payment arrangements and basic population construct. The state of Michigan passed a provision in its 2017 budget to provide for a Medicaid DPC pilot ³ and we hope that CMS will work with the state to implement that pilot. There was a large scale DPC practice, Qliance, which provided DPC membership with Medicaid plan customers for Coordinated Care, a Centene Medicaid managed care organization (MCO) operating in Seattle, WA. At the height of the program in 2014, there were as many as 30,000 WA state Medicaid lives in DPC. The program had extremely high patient satisfaction scores, provided improved care for beneficiaries and reduced costs for the plan. However, the program was discontinued due to a series of disputes between the practice and plan, which ultimately led to the closure of Qliance. Learning from this, we believe that a balanced payer mix is critical for the success of DPC or any other delivery reform. Therefore, any Medicaid DPC program should focus on providers who can accept patients in Medicaid, but also have private patients and Medicare beneficiaries. Data sharing is also critical. In any agreement with an MCO, the direct agreement needs to be a contract between plan, state and provider on behalf of the patient. Performance data and patient data needs to be shared between plan and provider. In any circumstance there should be an agreement between the individual patient and the DPC practice defining the scope of services, expectations, and fees. If all or part of the fee is covered by an MCO then a separate agreement defining the payments owed and aggregated data to be exchanged should be drafted between the MCO and the practice. Finally, an appeals process involving the state Medicaid agency needs to be in place so that any disputes between plan and practice can be

³ section 1913 of Michigan Public Act 107 of 2017

resolved using regular channels. Crafting a Section 1115 waiver option that provides states with the flexibility to implement their own Medicaid DPC programs would be wise and a Medicare pilot could inform CMS and states about best practices.

- 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 think CMS should test a range of market based models that meet the three-part definition of DPC.⁴ The first among these would be the model described in question 1 aimed at existing DPC practices, in which beneficiaries already in a DPC relationship receive a direct PBPM to pay the practice primary care services outlined in a direct agreement between patient and clinic. Medicare would continue to provide regular FFS payments for services outside the DPC arrangement such as specialty care and hospitalization. Outcomes in the demonstration would largely be measured by CMS using downstream claims data from care provided in other parts of the system. DPC practices are diverse by nature and provide many different ranges of primary care services. Services provided by DPC providers are always outlined in a direct agreement, or contract between provider and patient, or payer on behalf of the patient. An attestation process would enable DPC practices to share that the majority of their patient panel is outside of the third-party fee for service system could be used by CMS. These practices would be evaluated based on downstream spending and outcomes for their DPC patients in an ongoing basis to determine whether their patients will continue to qualify for premium reductions or subsidies. Finally, in all these payment arrangements, the “opt out” issue needs to be addressed so that existing practices can appropriately inform the CMMI demonstration program.

- 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? 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 provider or supplier be able to refuse to enroll or choose to disenroll a beneficiary?

DPC practices typically have no enrollment restrictions. These open enrollments are enforced in state laws defining DPC in many cases. We envision this program to be voluntary for both physicians and patients. This a key part of the patient accountability mechanism for DPC. If the patient doesn't feel they are getting appropriate care, they can end their membership. We have some concerns around payment issues in the CMS payment to provider model that may keep beneficiaries from participating due to lack of clarity. CMS might attempt a capitated payment to DPC practices or a reimbursement program where CMS beneficiaries submit a monthly invoice to CMS. Our experience

⁴ seen in answer to Question 2.

with both of these options is that they create significant logistical administrative demands on behalf of CMS that would increase the cost of this program. We would like to reinforce that the most elegant payment modality for a DPC model is to provide the Medicare patient with a direct method to pay their desired DPC provider. A funded MSA would allow a beneficiary to join a practice with enrollment fees and supports the existing DPC movement which has a variety of pricing models. Residual MSA fees could also be used for out of pocket costs including medication, imaging, labs and co-pays with subspecialists etc.

There should not be “minimum enrollment periods.” Forcing a patient and physician to see each other when one party no longer wants to continue the relationship is called a capitated HMO – these arrangements fail for obvious reasons. Practices may choose how to select patients for their practice based on their scope of services, remaining bandwidth (full panels), etc. Practices shall not discriminate based on age, gender, or race. It is noteworthy that today DPC practices typically price services in age bands, as a simple form of risk adjustment. However, this may not be an appropriate risk adjuster for Medicare which is made up primarily of seniors.

- 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 provider, and, if so, would this provide a useful or sufficient mechanism for active beneficiary engagement, or should DPC providers 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)?

CMS should undertake a campaign to make new Medicare beneficiaries aware of this option. The Coalition stands ready to work with CMS to reach out to both physicians and potential patients to support and take a lead in such efforts. Medicare beneficiaries should sign a DPC patient contract with the practice upon their enrollment in that practice. CMS could provide feedback to both the patient and the practice about the patient’s spending by categories over time (meds, labs, radiology, other office visits, inpatient visits) etc. Simply displaying these prices can make a big difference.

- 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?

A simple mechanism could be employed with a reduction in Medicare beneficiaries’ part B premium. The patient will continue to pay the DPC practice “directly.” Whether the patient chooses to purchase other supplemental plans is an individualized decision and this should not have any effect on their ability to participate or not participate in the DPC pilot.

- 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 providers 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?

See responses to questions 3 and 14. We estimate that 80% or more of the DPC practices across the country do not engage in any CPT or ICD coding. This level of measurement within DPC practices in the private sector is simply unnecessary.

- 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 providers?

Overutilization should not be a concern for CMS. We want beneficiaries to “over utilize” primary care to avoid more costly alternatives. If the patient “uses” the DPC practice more than anticipated then this could actually be a benefit to CMS. It is, however a concern for the patient and the practice. Use is often high when the patient first joins, due to uncontrolled chronic conditions neglected by the third party system. Experience shows that this almost always decreases over time as patients realize the physician is genuinely available to them and offers alternative ways of delivering care outside of traditional office visits, such as the use of telemedicine. If practices of all sizes are to be able to participate in a DPC demonstration CMS should then avoid placing new rules on the practice. See additional thoughts in our responses to questions 2 or below in question 11.

- 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?

There are some larger DPC practices which would have an appetite for a direct PBPM payment from CMS. There could be two distinct payment methodologies in such a direct contracting arrangement. Track 1 would be a flat monthly per member per month (PMPM) fee model, and Track 2 a risk sharing model, in which a portion of the PMPM fee is at-risk based on the total cost care for the provider’s Medicare beneficiaries. Some DPC practices also provide employer based benefits and MA contracts at almost full risk. These are the exceptions, not the rule. It is important to note that we see both models in DPC as being at full risk for fees. Physicians in DPC accept monthly fees for all primary care services. If patients are not satisfied with care or treatments, patients are free to leave the practice at any time. We view this as a very high level of financial and performance risk associated with APMs as defined in MACRA (PL 114-10). Hospital systems have expressed interest similar risk sharing or capitated models. Such systems should be required to adopt DPC best practices about low panel size and ability to refer to services offered outside the system. If such a DPC practice has a scope that is too narrow, hours that are too restrictive, and appointments that are too short –patients will tend to self-police by leaving the practice and choosing a better DPC

option that will let them decrease their use of the rest of the health care system. DPC practices today are free to focus a significant amount of time providing services to patients that impact the costs outside of the care provided in the DPC agreements. Practices act as guides throughout other parts of the healthcare system to control costs, many of which are out of pocket in private markets today. They also offer access to deeply discounted transparent prices for labs, imaging, most drugs, and other ancillary services which could reduce expenses in Parts A and D further reducing financial risk for CMS.

12) What additional payment structures could be used that would benefit both physicians and beneficiaries?

We appreciate CMS's desire to test market based reforms to the healthcare system. Permitting the use of the Medicare MSAs for the purposes of a PBPM payment to the DPC practice would be ideal. The MSA is a little-used but existing vehicle which could be greatly expanded under a market based program such as a DPC pilot. We support the notion of a Medicare HSA, outlined in the 2018 HHS Budget in Brief. The DPC marketplace should be preserved. Medicare can participate in the marketplace not by providing a defined benefit, but by providing a defined contribution to an MSA in higher amounts for Medicare patients participating in DPC practices. While we would expect CMS to test other models, this new market based model could provide a smooth transition for the growing number of beneficiaries entering into the program who already have HSAs paired with high deductible health plans. It is unclear to us whether CMMI authority would allow for such changes which may also require changes in the Tax Code. Medicare has another existing potential vehicle to facilitate a direct beneficiary PBPM payment. Medicare [Form 1490S](#) is currently used by Medicare recipients when they seek reimbursement for care that was not paid for by Medicare (such as when traveling abroad). Developing a similar reimbursement form for DPC purposes that is agnostic to the physician's status (Participating, Nonparticipating, or Opted Out) would be a simple first step that would be welcomed by most DPC physicians. An alternative mechanism might be reducing the Medicare recipient's part B premiums by a certain amount when the patient becomes a member of a DPC practice. If anticipated savings are not realized, then Medicare could reserve the right to increase the part B premiums in part or in whole back toward the original amount in the next year.

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?

We applaud CMS's desire to remove administrative burdens. As more DPC practices are established there is more open competition. Areas of the country with a high prevalence of DPC such as Denver, Seattle, and Phoenix are the most competitive. Competing more openly on quality and range of services will expand over time and Medicare can help provide scale for this level of competition. In a more competitive environment, DPC practices will be incentivized to aggregate and publish certain outcomes data to help recruit patients. Consistency in commercial payer contracts would also be helpful to permit patients to privately contract for covered services at any time upon their choosing. Easing restrictions placed on providers by some commercial payer arrangements would allow

physicians to begin transforming to DPC by avoiding the 90 or 180-day termination clause in most contracts with dominant health plans.

- 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?

Performance should be tracked with objective measures outside of the DPC practice as noted in our response to question 3. We understand CMS may need to require practices to submit patient enrollment data. Given that DPC operates in a claimless environment by nature, we would suggest the following data sets, generally kept by physicians as a part of good clinical practice could be collected and shared with CMS on a periodic basis to assist in the measurement and evaluation of the program:

The Practice Will Collect

- Enrollment Details– list of Medicare patients enrolled in the DPC practice
- Attestation of at least one interaction with the patient in the past twelve months
- ONC Direct Standard (PDF file of chart without duplicate data entry)

CMS Will Collect

- Patient satisfaction surveys such as CG-CAHPS
- Preventive Testing Data (such as mammograms and colonoscopies)
- Downstream Spending by Category: (may be accomplished using Blue Button API)
 - Labs
 - Medications
 - Radiology
 - ER Visits
 - Specialty Visits
 - Hospitalizations

We urge CMS to use the authority CMMI gives the agency to scale any delivery reform program that is certified by the CMS Actuary as improving outcomes without increasing costs.

- 15) What other DPC models should CMS consider? Are there other direct contracting arrangements in the commercial sector and/or with Medicare Advantage plans that CMS should consider testing in FFS Medicare and/or Medicaid? Are there particular considerations for Medicaid, or for dually eligible beneficiaries, that CMS should factor in to designing incentives for beneficiaries and health care providers, eligibility requirements, and/or payment structure? Are there ways in which CMS could restructure and/or modify any current initiatives to meet the objectives of a DPC model?

Iora Health has a successful Medicare Advantage model which could be scaled and replicated, and perhaps adjusted with the experience from the demonstration. Plans should be encouraged to use the same attributes and best practices, which we assume will prove successful in the CMMI demo, e.g. data sharing, use of downstream claims data. This will prevent the MA models from becoming static. CMS might consider making small changes designed to achieve wider adoption of the PACE program, has many attributes of DPC. DPC could prove ideal for Dual eligible patients in Medicare

who tend to be the highest utilizers of care. CMS would need to decide how a portion of the monthly fee would be covered in conjunction with state Medicaid programs. Again, lessons from an initial demo involving existing Medicare-only patients would prove invaluable for informing the process of scaling DPC to duals.

- 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?

Any CMS DPC demonstration model must be required to place a significant emphasis on the execution of high quality care. Claims outside primary care should be closely monitored by CMS. In a three-year demonstration, a DPC practice should show significant improvement in quality in the first two years of the demonstration. If by year three a practice cannot contain or reduce costs among a patient population patients will no longer receive an MSA contribution if they remain with the same practice. Given DPC's ability to reduce both administrative expenses and the use of advanced care/hospitalization such improvements should be seen by year three. If quality improvements and CMS cost reductions continue after year three, we would suggest CMMI use its authority to make the DPC payment model permanent for practices by meeting the CMS Actuary's cost reduction assessment in ACA Sec. 3021. This is where data sharing is critical. If the physician and/or the patient does a poor job managing chronic conditions, then CMS should have the data to inform both parties, requesting corrective measures. These could include removing a portion or all the DPC subsidy (or part B premium discount) to the patient. CMS should monitor downstream spending outside the DPC practice and share this data with patients and physicians in as real-time a fashion as possible.

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

This question implies that a practice is likely to be DPC in name only and will be offering incentives for patients to "enroll" with the practice even though the practice does not play to provide DPC-level care. CMS could avoid this problem by not attempting to pay the practice directly and providing additional funding in a patient's MSA by only a portion of the monthly fee (not by the amount of the entire fee).

- 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?

There are already patient antidiscrimination and abandonment laws at the state and federal level. DPC practices are ideal for patients with multiple chronic conditions and those who are typically high utilizers of care. See our response to Questions 6 and 10. We would anticipate that if patients select their own DPC physicians, these issues will be addressed on their own as the relationship with the physician develops. Typically, a new DPC patient has at least one uncontrolled chronic condition. DPC physicians are compensated appropriately to spend the time with patients needed to diagnose and treat these chronic conditions. A significant part of the incentive for the physician is to keep the patient engaged, healthy and satisfied and coming back to the practice rather than seeking care elsewhere.

- 19) Giving valuable incentives to beneficiaries to influence their enrollment with a particular DPC practice would raise quality of care, program cost, and competition concerns. Providers and suppliers may try to offset the cost of the incentives by providing medically unnecessary services or by substituting cheaper or lower quality services. Also, the ability to use incentives may favor larger health care providers with greater financial resources, putting smaller or rural providers at a competitive disadvantage. What safeguards should CMS put in place to ensure that any beneficiary incentives provided in a DPC model would not negatively impact quality of care, program costs, and competition?

Under a defined contribution model, if a DPC physician provides medical services that are unnecessary then he is wasting both his time and practice overhead dollars. Providing unnecessary services is a rampant problem in the third party FFS reimbursement setting resulting in higher costs for CMS. In a DPC practice there should not be any incentives to patients that join other than the prospect of increased access to care and easier communication with their personal physician. The scenario contemplated by the question is not a common practice for DPC physicians today.

- 20) How can CMS protect beneficiaries from potential risks, such as identity theft, that could arise in association with a potential DPC model?

Identity theft is a greater concern in traditional third party FFS practice settings that routinely share patient data to multiple entities associated with “payment” under HIPAA. In the independent DPC practice, records are much more secure because the “payment” sharing rationale no longer applies. The patient is paying for the care, so third parties cannot demand access to the information under the HIPAA “payment” exception. Personal details such as social security numbers, needed for insurance verification and claims purposes, are simply not needed in most cases. When this information is not gathered, it is obviously not at risk of being misused. Credit card information, names, birthdate, and addresses are typically stored in secure membership management payment platforms.

- 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?

DPC is a fundamentally different clinical model than an ACO. Some of our practices have experience working in the ACO setting. The Medicare Shared Savings model was incompatible with DPC; another excellent reason why CMS should move towards a new direction with a true DPC model. Financial incentives without true patient accountability have not been successful. That said, we know there are some ACOs operating at a high function in a culture of shared learning and mutual accountability and that they can achieve some improved levels of care. However, even models that have demonstrated improved clinical outcomes do not always reduce costs for CMS, since administrative and payment regimes around ACOs—relying on bonus payments to incentivize care—are inherently more complicated than straight third party FFS. Even when these models work as designed they add layers of complexity and expense. Most of our members with experience in these models have learned lessons which have led them further in the direction of DPC as a more advanced alternative payment model for primary care.

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?

Several of our members attempted to work with ACOs in the early years of CMMI. The rules of the Medicare Shared Savings Program are not compatible with DPC. Regardless of whether the ACOs were hospital or physician led, even DPC practices willing to take capitated fees were unable to participate because the level of upfront payment was not sufficient. Primary care delivered through DPC is a relationship-based service. Our overwhelming experience in ACO models has been that a relationship with a personal DPC physician achieves greater efficiency and accountability in primary care.