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Adam Boehler
Deputy Administrator for Quality and Innovation
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Room 310G-04
Washington, DC 20201

Subject: Request For Information

Dear Deputy Administrator Boehler:

On behalf of the physician and medical student members of the American Medical Association (AMA), I want to commend the Center for Medicare and Medicaid Innovation (CMMI) for considering the development of Direct Provider Contracting models, and for soliciting input from the AMA and other stakeholders on how to best structure this approach. Physician-focused alternative payment models (APMs) have significant potential to enable physicians to improve the quality of their patients' care, and we strongly urge CMMI to greatly increase the number of available APMs in order to make them a viable option for most physicians and have a meaningful impact on spending and quality of care for patients.

We recommend that the CMMI develop a family of Direct Provider Contracting models for physicians to pilot. This family of models should allow a broad array of physicians to participate, including both primary care and specialty physicians and other health professionals. Many specialty societies and practices have already been working to develop APMs that could be implemented using Direct Provider Contracting, and the Physician-focused Payment Model Technical Advisory Committee has recommended 10 models that are all amenable to being tested using a Direct Provider Contracting model.

In addition, we propose that CMMI structure Direct Provider Contracting models similarly to the approach it is using in the Comprehensive Primary Care Plus (CPC+) initiative, by providing risk-stratified monthly payments to practices based on the type of patients a practice sees. We urge CMMI to only hold physician practices responsible for costs that they can reasonably influence. The AMA does not believe that any physician practice should be held accountable for the total cost of care of a patient population. The CMMI should prioritize models that allow small, independent practices to participate without the need to join or contract with a larger organization, such as models that do not require substantial financial risk or major new capital investments to succeed.

Direct Provider Contracting models should remove barriers in the current payment systems. These barriers can include lack of payment or inadequate payment for high-value services or financial losses for improving health and eliminating unnecessary services. There are also administrative barriers faced by physicians such as prior authorization or lack of access to necessary data.

Finally, we recommend that CMMI work with interested specialties and practices on methods for

assessing quality performance in Direct Provider Contracting APMs. We also urge CMMI to use its waiver authority to provide Direct Provider Contracting models with appropriate fraud and abuse waivers.

We recommend CMMI to work collaboratively with the specialty societies and practices that have already put significant work into designing APMs as it further develops its plans for a Direct Provider Contracting model. The AMA would be happy to facilitate a listening session for you with physician leaders among these groups in order for CMMI to gather additional feedback. Thank you for the opportunity to comment. We have included more detailed answers to each question in the Request for Information attached. If you have questions, please contact Sandy Marks, Assistant Director, Federal Affairs, at sandy.marks@ama-assn.org or 202-789-4585.

Sincerely,

James L. Madara, MD

**Response to CMMI Request for Information (RFI)
on Direct Provider Contracting (DPC) Models**

Questions Related to Provider/State Participation

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 Accountable Care Organization (ACO), physician network, or other arrangement?**

We commend CMMI for considering the development of new alternative payment models and for seeking broad input on how to best structure these models. Although it is important to create a Direct Provider Contracting model in which primary care physicians can successfully participate, it is also important to provide Direct Provider Contracting models for specialists. Many patients have one health condition that dominates their medical concerns and drives most of the health care services they receive. Frequently, a specialist manages this condition, not a primary care physician, and any significant opportunities to reduce spending will be under the control of the specialist. CMMI will not be able to control spending and improve quality for the majority of patients unless it creates better ways of paying all physicians. The current Medicare payment system can be as problematic for a specialist as for a primary care physician who is trying to care for a patient with one or more conditions that do not require intensive management by a specialist. As a result, there is considerable interest in alternative payment models among both specialists and primary care physicians, and a well-designed Direct Provider Contracting approach is likely to be of interest to a wide range of physicians.

A Direct Provider Contracting model will attract participation from a broad array of physician practices and their patients if key aspects of the model—particularly payment amounts, risk adjustment methods, and quality measures—can be customized to the specific types of patients and health problems that physician practices treat. It is obvious that different specialists treat different types of patients and conditions. However, different primary care practices also treat different types of patients and conditions, depending on the types of patients who live in their community and the availability of specialists. Consequently, there is unlikely to be any one-size-fits-all payment model that will work for all physicians or physician practices. We recommend that CMMI implement a family of Direct Provider Contracting models that can be successfully used by as broad a range of physicians as possible.

A Direct Provider Contracting model will attract considerable interest from many physicians if it eliminates or mitigates barriers they currently face in delivering good care to patients and reduces unnecessary administrative burdens they currently experience. For example, a rapidly growing number of physicians are expressing severe frustration with prior authorization requirements for medications and tests that are being used by Medicare Part D plans, Medicaid and Medicare managed care, and commercial health plans. We recommend that if a specialty society has developed an evidence-based guideline or pathway for drugs or tests, and if a physician practice participating in a Direct Provider Contracting model agrees to adhere to that guideline/pathway, CMMI should require that the practice and its patients be exempt from any prior authorization programs under Part D for the drugs and tests covered by the guideline/pathway and CMMI should encourage other payers to establish similar exemptions.

In addition, CMMI should give priority to designing and implementing payment models in which small, independent physician practices can successfully participate without the need to join or form a larger provider organization and without being forced to rely on a third party. In many of the CMMI alternative

payment models implemented to date, high levels of financial risk and significant administrative burdens have made it difficult or impossible for small physician practices to participate without relying on such organizations. This is inappropriate. Structuring Direct Provider Contracting models similar to the way the Comprehensive Primary Care Plus initiative is designed (i.e., providing risk-stratified monthly payments to practices based on the types of patients they see, and focusing accountability on the aspects of cost and quality that physicians can reasonably expect to influence) will make it much more likely that Direct Provider Contracting Models will be successful.

Many specialty societies and medical practices have been working to develop alternative payment models that are based on an approach similar to what is described in the RFI and that would enable participation by small and large practices. We would be happy to help convene these groups to help you develop the details of Direct Provider Contracting models that could attract participation from a large number of practices in a wide range of specialties. The Physician-Focused Payment Model Technical Advisory Committee (PTAC) has recommended testing or implementation of 10 different physician-focused payment models, all of which could be structured as Direct Provider Contracting 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.**

We believe the most important question to ask first is "what barriers in current Centers for Medicare & Medicaid (CMS) payment systems and regulations need to be removed so that practices can deliver high-quality care to their patients at a lower cost?" Many physician practices that are involved in current CMS value-based payment models and CMMI alternative payment models find the requirements so burdensome that they are spending less time with their patients and are incurring financial losses even in the so-called "upside only" models. Indeed, many primary care physicians have moved to a direct primary care model in order to escape burdensome requirements imposed by CMS and other payers that make it difficult and unprofitable for the physicians to deliver the care that patients need.

An overarching principle guiding the development of any new payment models should be avoiding unnecessary, burdensome requirements. We urge that CMS not include any administrative requirements in a Direct Provider Contracting model unless it can be shown that the requirements are essential to good quality care. Before any administrative requirement is imposed, CMS should justify why it is needed and what other options were examined, and potential participants should be given the opportunity to suggest less burdensome approaches to achieving the same goal. In addition, if potential participants in the model identify regulatory barriers to success, CMMI should use its waiver authority to modify or eliminate these barriers.

For example, to date, CMS has required the use of certified electronic health record technology (CEHRT) by APMs. However, many physicians have found that instead of helping them to deliver higher-quality, more coordinated care, CEHRT is reducing the time they can spend with patients and increasing their administrative costs. CMS should only require physicians and other providers to use CEHRT as part of

APMs if CMS has verified that CEHRT can, in fact, deliver the information needed by participants in the APM efficiently, effectively, and at an affordable cost. APMs should be encouraged to leverage technology to support the goals of the APM and help participants improve communication, patient engagement, collaboration, diagnosis, treatment planning and quality. Any CEHRT requirement must also provide sufficient flexibility as to recognize custom functionality that "builds on" CEHRT—a concept taken directly from one of CMS' priorities for Promoting Interoperability measures in the Quality Payment Program. Often, these additional enhancements are layered on top of CEHRT—creating a new and improved experience for patients and their care team—and is a greater return on investment than the original purchase of the EHR. Going forward, CMS and Office of the National Coordinator for Health Information Technology should take greater responsibility for proactively ensuring that CEHRT includes the capabilities physicians need to enter, retrieve, share, and analyze clinical data in APMs.

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?**

Similar to the recommendation above, if it appears that physician practices will need technical assistance or support in order to comply with the requirements of one of the Direct Provider Contracting models CMS is developing, we recommend re-examining those requirements to determine whether they can be eliminated or simplified. Once that has been done, participants in the model should receive adequate payments to cover the costs of implementing any administrative requirements imposed by CMS and of obtaining any technical assistance they need in order to comply.

One of the greatest barriers physicians face in designing and implementing new approaches to care delivery and payment is their inability to obtain data on the full range of services their patients are receiving today. Most of the savings from improved care delivery come from lower spending on services such as hospital admissions and post-acute care that are not delivered directly by physicians. Some of the biggest opportunities for improved care coordination come from avoiding duplication and conflicts with services delivered by other providers; the problems occur because physicians do not know what other providers have done, and vice versa. Physicians need access to information about the other services their patients are receiving that would enable them to identify and quantify opportunities for savings or take action to achieve these savings. CMS needs to create more effective and user-friendly mechanisms through which physicians can access and analyze CMS claims data, and CMS needs to provide financial support to physicians to help them gather and analyze relevant clinical data that is not contained within claims data.

In current CMS APMs, the upfront investments needed have been higher than necessary. The upfront investments include the high cost of the technology and services physician practices have had to acquire in order to submit data to CMS and analyze the data they receive from CMS, and the high fees associated vendors charge to install customizations necessary to implement APMs. It would be far less expensive overall if CMS made the investments needed to create more efficient and user-friendly systems for data submission and feedback.

Furthermore, with the initial upfront investment, CMS and the Office of Inspector General (OIG) should provide fraud and abuse waivers for the items, services, or goods that are used to create or develop a Direct Provider Contracting model. Such waivers should cover a broad array of arrangements, including infrastructure creation, care coordination mechanisms, clinical management systems, quality improvement mechanisms, care utilization management, hiring of new staff, information technology, consultant and other support, and training.

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?**

The Medicaid Managed Care Regulations issued by CMS in 2016 (81 FR 27498 et seq.), particularly the requirements under CFR §438.6(c), have made it difficult for states with managed care structures to implement desirable alternative payment models. We urge that CMS revise its regulations and processes so that state Medicaid programs:

- have the authority to require Medicaid managed care plans to offer physicians and other providers the option of being paid for care of Medicaid patients through the same methods used in Medicare alternative payment models;
- have the ability to provide additional payments to participating physicians and providers outside of MCO capitation rates; and
- can receive approval from CMS to do these things expeditiously.

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 commend CMS for seeking input from physicians who are currently participating in direct primary care arrangements, but it seems unlikely that the most effective way to get this input is through written responses to a CMS RFI. Instead, we encourage CMS staff to visit these physicians in their practices to better understand how they deliver care differently with a different payment model. The AMA would be pleased to assist CMS in arranging such visits.

Questions Related to Beneficiary Participation

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?**

If a physician practice is going to receive per-beneficiary-per-month (PBPM) payments to support the services that patients need for effective care of one or more health conditions during the month, then it makes sense for patients to agree to only receive services from that practice for that condition or conditions during that month. This is similar to the requirement CMS uses today for the Chronic Care Management codes. However:

- Patients should not be required to receive all services from the practice, only the types of services that the practice has agreed to deliver in return for the monthly payment.
- Patients should retain the ability to receive care through standard fee-for-service payments, either from the participating physician practice (if the practice wishes to offer services under either payment arrangement), or from a different practice that is not participating in the monthly payment system.
- Physician practices should have the option of asking patients to agree to enroll for longer periods of time and to refuse to enroll patients who are unwilling to agree, but patients who do enroll should retain the right to choose a different practice at the end of any month if they wish to do so.

Physician practices should not be required to take accountability for the total cost of care of a patient population. Physicians are willing to be accountable for aspects of utilization and spending that they can influence or control if they have adequate resources, flexibility, and information needed to do so.

CMS should create Direct Provider Contracting models that would allow a team of physicians and other health professionals (such as a primary care physician, one or more specialists, and one or more other health professionals) or a team of physicians and other types of providers (such as primary care physicians, specialists, and hospitals) to be paid jointly to deliver a coordinated set of services for all of the treatment needed for an acute condition or management of a chronic condition. Patients who select that team would agree to receive all of the services related to the condition from the members of the team, and to pay a single, pre-defined cost-sharing amount for those services. If patients chose to receive a portion of their services from providers that are not on the team, the patients could pay a higher cost-sharing amount for those services and the team would not be held accountable for Medicare spending on those services.

It will be important for a practice or team to spend adequate time with each patient to explain the advantages of receiving services from the practice or team and how the patient can access the services the practice and team have to offer. For example, practices participating in a Direct Provider Contracting

model may offer access to more timely appointment scheduling, after-hours and between visit phone call or email consultations, improved communication and coordination with other professionals and providers such as emergency departments, and services like remote patient monitoring and home visits. Practices or teams should receive a higher payment during the initial month of care for a new patient in order to support effective patient education about how to most effectively participate with the practice in the model. CMS and the OIG should also provide any needed waivers to improve the effectiveness of innovative patient engagement strategies.

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)?**

Practices should be given the flexibility to phase in the enrollment of their patients over a period of time. The biggest "incentive" for patients to enroll will likely be the opportunity to receive additional services from the practice and to receive existing services in more flexible ways. For example, a flexible monthly payment to a physician practice would enable the practice to respond to patient needs in whatever way is most convenient and effective for the patient, including phone calls and emails as well as face-to-face visits. This would likely be very attractive for many patients, but they will need to be educated about the ability to receive these services and the advantages of doing so.

A practice's ability to implement some new and different services will depend on how many patients agree to participate in the new payment model, because a minimum number of patients will be needed to make the service financially viable. Moreover, additional patients may enroll after hearing positive feedback from the initial enrollees. Consequently, it will be necessary to allow adequate time for patient enrollment and the practice's services to co-evolve. It seems likely that this will require at least one year for many patients, and potentially longer to enroll healthier patients because they seek care less frequently.

As noted above, it will be important for a practice or team to spend adequate time with each patient to explain the advantages of receiving services from the practice or team and how the patient can access the services the practice and team have to offer. Participating practices or teams should receive a higher payment during the initial month of care for a new patient in order to support effective patient education.

Many physician practices have found it helpful to have an agreement with patients that defines mutual responsibilities and expectations. CMS should indicate that such an agreement is *permissible*, but should not *require* such an agreement, nor attempt to specify the contents of agreements beyond identifying any prohibited elements.

Many patients face significant barriers in taking the actions needed to improve their health and reduce avoidable spending, such as: inability to travel to a physician's office and/or obtain transportation assistance during normal working hours; inability to afford the cost-sharing payments required for

medications and other treatments; difficulty in understanding instructions; and lack of access to affordable housing or fresh food. Rather than narrowly focusing on creating "incentives" for patients, CMS should work with physicians to overcome the *barriers* that patients face. Although the flexibility provided by monthly payments that are not tied to traditional office-based services will help address some of these barriers, it is important to ensure that payment amounts are adequate to cover practices' costs and that the payments are higher for patients who face the types of barriers that require additional or more expensive services.

To further facilitate patient engagement and overcome barriers that patients face, CMS should work with the OIG to create a fraud and abuse patient incentive waiver from the beneficiary inducement civil monetary penalty and the federal anti-kickback statute for services or incentives offered by Direct Provider Contracting practices to patients to encourage appropriate utilization practices and adherence to treatment plans.

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?**

It can be difficult or impossible for physicians to reduce health care spending when the services required to do so impose higher cost-sharing burdens on patients. For example, the ability to deliver care management services to patients can enable physicians to significantly reduce Medicare spending, but the requirement for patient cost-sharing deters many patients from agreeing to receive those services. Conversely, in the absence of any cost-sharing requirements, patients could request unnecessary services from a physician practice, making it more difficult for the practice to focus time and resources on the patients who need the most attention.

CMS should work with practices that are interested in a Direct Provider Contracting model to develop one or more "value-based" cost-sharing structures for patients, and work with the OIG to create an appropriate fraud and abuse waiver for any cost-sharing amounts that are waived. These structures might be based on the characteristics of patients and their health problems (e.g., eliminating cost-sharing for a home visit to a patient at high risk of hospitalization) and/or based on the community where the practice is located (e.g., higher payments and lower cost-sharing for home visits in a rural community where patients live long distances from practices and do not have access to public transportation services). Patients could also be allowed to pay more to receive services from a particular Direct Provider Contracting practice if they believe that practice will deliver better-quality care than other practices.

As noted earlier, we recommend that CMS create Direct Provider Contracting models that would allow a team of physicians—such as a primary care physician, one or more specialists, and other providers—to be paid jointly to deliver a coordinated set of services for all of the treatment needed for an acute condition or management of a chronic condition. Patients would be charged a single, pre-defined cost-sharing amount if they agree to receive all of the services related to the condition from the members of the team, and they could be charged higher amounts if they wish to obtain a portion of the services from physicians

or other providers who are not a member of the team.

Questions Related to Payment

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®)/Healthcare Common Procedure Coding System 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?**

The structure of a PBPM payment should be based on what is needed to give the physician practice the resources and flexibility to deliver good care to patients without putting the practice at risk for costs that it cannot control. Many physicians would prefer a monthly payment instead of Evaluation & Management (E/M) payments because of the problematic restrictions associated with E/M payments, particularly the limitation to face-to-face visits with the clinician, which prevents the physician from addressing a patient's need over the phone or via email and does not support proactive outreach to patients by practice staff.

Just as E/M payments are higher for new patients than for established patients, PBPM payments should also be higher for new patients in a Direct Provider Contracting model. During the initial month of care, a physician practice should be paid a sufficient amount to enable it to spend adequate time determining an accurate diagnosis (or verifying previously assigned diagnoses), developing a treatment plan based on the most current evidence, providing education and self-management support to patients to ensure they understand the treatment plan, and revising the treatment plan if it becomes clear that the patient cannot or will not adhere to the plan.

In addition to differentiating the first month of care from subsequent months, it is important to vary the monthly amounts for different types of patients. A monthly payment that is adequate for a practice with relatively healthy patients could be completely inadequate for a practice that has many patients who have multiple or advanced conditions and who need to be seen frequently. Consequently, it is essential to risk-stratify the monthly payments based on patient needs. The Hierarchical Condition Categories (HCC) risk adjustment system that is routinely used by CMS would be inappropriate for this purpose, for several reasons, including:

- HCCs only consider patient diagnoses, not other patient characteristics that can affect the patient's need for services, such as functional status and access to transportation;
- HCCs are based on chronic condition diagnoses recorded in prior years and fail to consider new acute and chronic conditions which a practice is addressing; and
- The weighting in the HCC system is based on predicting total Medicare spending for a large population of patients, not for determining the resources that a physician practice will need to spend on the patients enrolled.

CMS should work with physicians to develop better methods of stratifying patients based on needs relevant to their care, instead of continuing to use the flawed HCC system for new APMs. New risk stratification systems should be implemented by creating new billing codes for the risk-stratified patient categories, and several specialty societies have developed APMs that use this approach.

The decision as to what other services to include in the monthly payment should be based on the nature of the costs associated with those services and the ability of the practice (or a team of providers) to deliver the services. In some practices, physicians perform procedures themselves, whereas in other practices, patients are referred elsewhere for those procedures. A practice's ability to perform a procedure efficiently and effectively and the cost of doing so will depend on how frequently it is performed, which in turn depends on the types of patients the practice is treating. Consequently, it would be inappropriate to pay the same monthly amount to every practice and expect it to cover the same set of services. Finally, procedures that involve significant out-of-pocket variable costs for the practice (e.g., vaccinations or drug infusions) should not be included in a monthly payment because it would financially penalize a practice for doing more of the procedures when patients needed them.

For treatment of acute conditions, it will likely be more appropriate to use a bundled episode payment than a PBPM payment for a Direct Provider Contracting model, since the goal of services should be to resolve the condition as quickly and effectively as possible. Just as with PBPM payments, though, the decision as to what services should be included in a bundled episode payment will depend on the types of services that the physician practice or provider team can control, and episode payment amounts should be risk-stratified to ensure they are adequate to cover the costs of different numbers and types of services needed by different patients.

In many cases, it will be desirable to provide two different options for the number and types of services that are included in either a PBPM payment or an episode payment, e.g., one option with a narrower range of services and one option with a broader range of services. For example, many medical specialty societies have developed payment models that have one option for a PBPM payment as a supplement to current E/M and other payments (similar to the CMS CPC+ model), and a second option that bundles current payments into a PBPM payment (similar to the primary care model proposed by the American Academy of Family Physicians that has been recommended for testing by PTAC). Providing multiple levels of bundling will not only facilitate participation by practices in different communities that have differing abilities to control certain kinds of services, it could also provide an easier "on ramp" for practices that have the potential to control a wide range of services but do not have the capacity to begin doing so all at once.

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?

A PBPM payment should be designed to be adequate to cover the costs that would be incurred by a solo physician in delivering care to a patient panel of a size that a solo physician could reasonably be expected to manage, considering the time needed to deliver all recommended services to those patients. The payment should also be adequate to cover the costs involved in complying with any administrative requirements imposed by CMS. CMS should work with interested physicians to estimate these costs in order to set the initial payment amounts, and CMS should then revise those initial payment amounts based

on a study of the actual costs practices incur during the initial implementation years after they have the ability to redesign the way they deliver care. The payments should not be based on current CMS payments to the practice without verifying that these payments are adequate to cover the costs of the services that the practice would need to provide and the administrative costs of participation.

The financial safeguards and protections for practices should include:

- Resource/risk-stratification of payment amounts, so that practices receive higher payments for patients who will likely require more services or more expensive services. The variables and weightings used for stratification of payments should be based on the characteristics of patients that affect the use of practice resources as well as any other services the practice will be accountable for, not just diagnosis codes for conditions that existed in prior years.
- Higher payments for new patients and for patients with newly-diagnosed conditions, to enable the practice to spend adequate time in diagnosis, treatment planning, and patient education.
- Exclusion of services or aspects of services that are not delivered by the practice and that cannot reasonably be controlled by the practice.
- Supplemental "outlier" payments for large out-of-pocket costs incurred by the practice for services to individual patients.

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?

Physician practices should not be held accountable for the total cost of patient care because no physician practice can control all of the major factors that drive health care spending. Physicians are willing to be accountable for aspects of utilization and spending that they can control if they have adequate resources, flexibility, and information needed to do so. If one physician practice delivers a broader range of services than other practices, or if a practice believes that it has or can develop the ability to manage more aspects of spending than other practices, the practice should have the option to take accountability for additional aspects of spending. However, no physician practice should be placed at financial risk for costs it cannot control or be given financial rewards for withholding care that patients need.

If a Direct Provider Contracting model places physician practices at financial risk for services they do not actually deliver, the practices could be subject to state health insurance regulations requiring financial reserves and other patient protections. In this case, it would likely only be feasible for physician practices, particularly small practices, to participate in the payment model if CMS increased payments sufficiently to enable the practices to build adequate financial reserve and to incur the compliance costs associated with insurance regulations. This problem would be unlikely to arise with a PBPM payment designed only to provide more flexible payment for the services delivered by the physician practice itself; in fact, some states have enacted laws specifically exempting direct primary care and similar payment models from state insurance regulation because the payments and services do not involve insurance risk.

We recommend that Direct Provider Contracting models build on the approach CMS is currently using in the Comprehensive Primary Care Plus initiative, i.e., providing the practice with both a PBPM payment

and a performance-based payment based on the specific aspects of cost and quality that the practice can control. Many physicians are aware of opportunities to reduce spending without harming patients, but they have been unable to pursue these opportunities due to one or more barriers in current Medicare payment systems. A number of physician groups and medical societies have developed payment models to overcome these barriers, and we believe that several of these models should be implemented by CMS as part of an overall Direct Provider Contracting initiative.

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

It is rare that any patient will receive all of their care from one physician or even one physician practice. Even if the patient's primary care physician is participating in a Direct Primary Care or other Direct Provider Contracting model, that physician may only be able to have a limited impact on spending and quality if all of the other physicians and providers involved in the patient's care continue to be paid under a fee-for-service system that penalizes them when the patient is healthier or receives fewer services. While a Direct Provider Contracting model could provide the flexibility primary care physicians need to coordinate with specialists, this flexibility will have limited benefit if the specialists are not being paid in a complementary way.

A good starting point would be for CMS to implement the physician-designed payment models that have been recommended by the Physician-Focused Payment Model Technical Advisory Committee over the past year. PTAC has recommended testing or implementation of 10 physician-focused payment models that would enable primary care physicians and specialists to deliver better care at a lower cost to many types of patients. For example:

- **Hospital at Home.** Two proposals recommended by PTAC would enable many patients who would otherwise receive acute care in a hospital to receive the care in their own homes. Australia and other countries have used similar programs for many years to save money and improve patient outcomes.
- **Specialty Medical Homes.** PTAC recommended a payment model developed by the Illinois Gastroenterology Group (IGG) that reduced spending and improved outcomes for commercially-insured patients with Crohn's Disease. The same approach could be used by many other specialties for the chronic conditions they manage, with impacts on a significant portion of Medicare spending and helping many patients receive better care.
- **End-Stage Renal Disease.** PTAC recommended a payment model developed by the Renal Physicians Association to reduce costs and improve care for patients on dialysis. This model would enable CMS to expand the savings it is achieving in the Comprehensive ESRD Care Model beyond the 10percent of nephrologists who are currently able to participate in that program.
- **Palliative Care.** PTAC has recommended two palliative care services proposals that would help primary care physicians and specialists ensure their patients with advanced illnesses receive better, lower-cost care. The importance of these models was recently cited by former Senators Bill Frist and Tom Daschle in a column in The Hill.
- **Bundled Payments.** PTAC recommended a payment model in which bundled payments can be paid to teams of physicians managing a health problem, an episode of acute care, or a service

line, such as surgery, regardless of where the care is delivered, in contrast to current CMS bundled payments that are limited to patients who are admitted to a hospital.

- **Primary Care.** PTAC has already recommended an advanced primary care payment model that is very similar to Direct Primary Care models. Implementation could enable many more primary care practices to implement medical home programs for Medicare patients.

Questions Related to General Model Design

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?

As discussed earlier, we urge that CMS not include any data collection or other administrative requirements in a Direct Provider Contracting model unless it can be shown that the data are *essential*. Before any requirement to submit data is imposed, CMS should justify why the data are needed and what other options for obtaining the information were examined. Potential participants also should have opportunities to suggest less burdensome approaches.

In general, physicians already collect all clinical information that is relevant to appropriate and effective diagnosis and management of patient care. CMS should make every effort to use the types of data that are already collected. It is unclear to us why CMS would need any clinical information that physicians are not already collecting as part of their patient care responsibility. If CMS needs such information, CMS should explore whether it could gather that information directly rather than requiring physicians to do so. If physicians agree that additional information would help them deliver better care to patients, but it has been financially infeasible for them to collect the information, then CMS should work with physicians to overcome whatever barriers exist to obtaining additional useful data.

If data that physicians already collect would be useful to CMS, then CMS should identify the most efficient way of obtaining that data, and compensate practices for any costs they incur for submission. In general, it seems likely that the most efficient way for physicians to submit additional data would be through systems they already use—billing systems, EHRs, and clinical data registries—so CMS should look for ways to encourage or require vendors to provide the additional data, and, if necessary, increase payments to practices by amounts needed to cover any additional vendor charges.

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?

Many of the quality measures used in current CMS alternative payment models are problematic, and CMS should not continue using them in additional models. For example, many of the measures are statistically unreliable for the small numbers of patients in individual physician practices; some are based on performance targets that are appropriate only for a subset of the patients to whom they are being applied, thereby penalizing physicians for delivering the most appropriate care to their patients; and many measures and benchmarks fail to adjust for patient characteristics that could affect performance but are beyond the control of physicians. There are no measures at all for many kinds of acute and chronic conditions, and there are no measures specifically designed for patients with multiple conditions that need to be managed in a coordinated way.

We recommend that CMS work with interested practices to identify ways of evaluating aspects of quality that are relevant to a Direct Provider Contracting model but do not have the types of problems that current quality measures do. This will likely involve modifying current measures in some way or developing new measures. For most aspects of quality, the most effective way of doing this will be using data collected through Qualified Clinical Data Registries. One major barrier to developing better quality measures and implementing clinical data registries has been the lack of payments to support collection of the necessary data; another major barrier has been the lack of payments to support the delivery of the services needed for high performance on those measures. A properly designed Direct Provider Contracting model could overcome both of these barriers.

In addition, the lack of functionality within EHRs has prevented the advancement of quality measurement. Another major barrier is the lack of interoperability between EHRs and registries and the fees EHR vendors charge physicians to connect to registries.

As noted earlier, we do not believe that any physician practice should be held accountable for the total cost of care. Not only can no physician practice control all of the major factors that drive health care spending, it is impossible to measure all of the aspects of quality that could potentially be harmed by efforts to place physician practices at financial risk for things they cannot control. On the other hand, giving individual physician practices the resources they need to provide high-value services to patients would enable them to reduce costs and improve quality for the types of services they do control. By giving the majority of physician practices the opportunity to participate in well-designed alternative payment models that are focused on the needs of their patients and the aspects of spending they can control, CMS will have the best opportunity to control the total cost of care in Medicare.

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?

As noted earlier, there is no single payment model that will work well for all patients and all physician practices. Many specialty societies and practices have developed alternative payment models that use approaches similar to what is described in the RFI, but they use different payments in different phases of care and stratify patients based on characteristics that are relevant to the specific condition being managed. Some of these models have already been reviewed and recommended by the Physician-Focused Payment Model Technical Advisory Committee, including the proposal from the Illinois Gastroenterology Group and Project SONAR, the proposal from the American Academy of Hospice and Palliative Medicine, and the proposal from the American Academy of Family Physicians.

CMS should give priority to designing and implementing payment models in which small physician practices, practices in rural areas, and practices serving low-income populations can successfully participate. The more financial risk that is imposed and the greater the administrative burdens, the less likely small practices will be able to participate.

Questions Related to Program Integrity and Beneficiary Protections

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 best way to avoid stinting on care is to: (a) ensure that physician practices are paid an adequate amount to deliver the services that patients need; (b) avoid placing the practices at financial risk for services and costs they cannot control (which could force them to underspend on services they can control); and (c) allow physicians to follow evidence-based guidelines for patients when those guidelines are applicable and to deviate from them when they are not applicable for individual patients. Rather than requiring burdensome and expensive data collection and submission, CMS should rely on physician practices to maintain appropriate documentation for treatment plans and decisions about which services to deliver, just as it relies on practices to maintain appropriate documentation for the claims they file for payment.

Well-designed quality measures that are directly related to the care that patients would receive in a Direct Provider Contracting model would help patients choose high-performing practices and enable CMS to ensure that only high-quality practices are participating.

We recognize the need to capture patient experience as it can provide valuable information about the services physicians are providing to patients, but we would encourage CMS to look outside of Consumer Assessment of Healthcare Providers and Systems (CAHPS). Specifically, CMS should look beyond Clinician and Group (CG)-CAHPS, which has been routinely utilized to measure patient experience

within existing CMMI models. CG-CAHPS is the primary care/internal medicine focused patient experience survey and is not relevant to surgical care. CG-CAHPS was also not designed for measuring practice improvement over time, but for public reporting. In general, the CAHPS consortium surveys are expensive to implement, receive low response rates, and often force practices to overemphasize or underemphasize certain areas of patient care to receive a high score. Small practices are particularly challenged when forced to implement CAHPS because of the size of their patient population and inability to produce a sufficient number of surveys to receive reliable results. If CMS insists on incorporating patient experience into DPC models then we recommend that CMMI tailor the patient experience requirements to each specific DPC model and work with specialty societies on the appropriate patient experience measures to collect. We are aware of some specialty societies that have developed and/or are in the process of developing patient experience measures related to their clinical area.

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

If a Direct Provider Contracting model is designed with clear goals and a payment model that physician practices feel is designed to enable success on those goals, then both CMS and the participating practices should be able to clearly and consistently communicate the reasons that patients would want to participate and why. If the payment amounts are designed properly, there would be no incentive for practices to try and enroll patients who would not benefit from the model. An additional safeguard could require that any rewards to patients be related to their medical care and be in-kind, as well as prohibiting cash payments.

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?

The best way to avoid cherry-picking and lemon-dropping is to identify the factors that affect how many services a patient will need and to ensure that payments to the practice are adjusted appropriately for those factors. If patients with specific characteristics will require more time or resources from the physician practice, the practice should receive a higher payment for those patients, so there is no financial incentive for the practice to avoid them. If payments and performance measures are effectively stratified or risk-adjusted based on the patient characteristics that have a significant effect on costs and outcomes, then there would be no financial advantage to a practice from excluding patients based on those characteristics. Indeed, the practice could actually benefit from serving the higher-cost, higher-risk patients because they may offer greater potential for savings on the aspects of costs that the physician can control.

Another way to avoid these types of selection problems is to include models within the Direct Provider Contracting family that are specifically designed for patients with advanced illnesses. Examples available to CMS include the palliative care and end stage renal disease models recommended by the PTAC.

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?**

As noted earlier, the most important "incentive" for patients to enroll should be the opportunity to receive additional services from the practice and to receive existing services in more flexible ways through a payment structure that is not limited by the rules of the current fee-for-service system. The "incentive" would result from the payments made to support the practice's services; it would not require separate payments to patients, nor would payments need to cover the costs of goods provided solely to encourage their participation. If patients face significant barriers in taking the actions needed to improve their health and reduce avoidable spending, then payments should be made to the physicians practice so it can help the patient overcome those barriers. Those payments would not increase spending because they would be offset by savings from reductions in avoidable spending. The ability for patients to overcome the barriers they face in improving their health would likely encourage the patients to seek care from a participating practice, and the savings resulting from the improvements in their health would create financial benefits for the patients, the physicians, and CMS. The Medicare program already has safeguards to prevent provision of medically unnecessary services, as this would be a false claim subject to serious penalties.

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

It is not clear why there would be any greater risks of identity theft in a Direct Provider Contracting model than in any other payment model.

Questions Related to Existing ACO Initiatives

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?**

One of the biggest barriers physicians participating in ACOs have faced is that there are no changes to the way they are paid under the Medicare Shared Savings Program. There are no upfront payments for high-value services that are not paid for under the Medicare Physician Fee Schedule, and there is no flexibility to deliver fewer or lower-cost services without incurring immediate losses of revenues. Good alternative payment models are needed for physicians participating in ACOs as well as for physicians who are not participating in ACOs, and so well-designed Direct Provider Contracting models could complement ACO initiatives and enable them to be more successful.

However, success should not be measured by how many physician practices or ACOs are accepting "two-sided financial risk." The ACOs that are currently accepting two-sided risk have higher spending per beneficiary than other ACOs, including ACOs that were judged by Medicare to have incurred "losses" because spending exceeded their benchmarks. In addition, average spending by two-sided ACOs is higher than national average Medicare spending per beneficiary, an indication that these ACOs have higher spending than many physician practices that are not participating in ACOs. Instead of measuring success by how many ACOs are in two-sided risk models, CMS should measure success by the extent to which patients are receiving high quality care that maintains or improves their health and quality of life.

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?

Because CMS ACO models make no changes in the way any providers are paid and rely on shared savings to serve as both an incentive to change care delivery and the only mechanism of paying differently for services, different types of providers will face very different incentives and challenges. For example, one of the biggest opportunities for reducing spending is reducing avoidable admissions to hospitals, but reductions in hospital admissions will have a very different financial impact on hospitals and on physicians who deliver hospital-based care than on primary care physicians and specialists who deliver services that can reduce hospital admissions. CMS should implement a family of DPC payment models that will enable all physicians, hospitals, and other providers to support higher-value approaches to care.