May 24, 2018

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

Submitted via email at DPC@cms.hhs.gov

Re: Center for Medicare and Medicaid Innovation Request for Information on Direct Provider Contracting

Dear Deputy Administrator Boehler:

The Medical Group Management Association (MGMA) appreciates this opportunity to provide feedback regarding the draft direct provider contracting (DPC) model. We support the Center for Medicare and Medicaid Innovation's goal of increasing participation in Advanced Alternative Payment Models (APMs) by creating additional opportunities that encourage provider flexibility and choice and reduce burdensome regulations and one-size-fits-all requirements. MGMA commends the Innovation Center for seeking stakeholder input at the outset of DPC model development, and we look forward to an ongoing, constructive dialogue as model details are refined.

Since 1926, MGMA has been the premier association for professionals who lead medical practices. With a membership of more than 40,000 medical practice administrators, executives, and leaders, MGMA represents more than 12,500 organizations of all sizes, types, structures, and specialties that deliver almost half of the healthcare in the United States.

Before commenting specifically on the proposed DPC model, the Association wishes to emphasize our support for the Innovation Center's recent actions to reduce or eliminate mandatory participation requirements in several bundled payment models and to develop the voluntary Bundled Payments for Care Improvement (BPCI) Advanced APM. Despite general support for APMs, a large majority of physician group practices oppose government-mandated participation due to a lack of evidence that joining an APM leads directly to more efficiently delivered care and better patient outcomes, significant diversity among group practices, and the potential negative impact on practice innovation. Physician group practices overwhelmingly prefer flexibility and financial incentives over mandates when considering participation in an Advanced APM. While offering Advanced APM opportunities on a voluntary basis may lead to self-selection by participants that expect to do well on performance metrics, these industry leaders can establish the value proposition and thereby encourage other organizations to move to Advanced APMs.

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MGMA continues to support the clear objective of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) of incentivizing physician group practices to embrace alternatives to fee-for-service and to incur greater performance risk for clinical outcomes and the cost of care. Unfortunately, physician group practices have limited opportunities to move into an Advanced APM. Current regulations establish a restrictive risk standard and the Innovation Center previously took a top-down, government driven approach to testing APMs. According to estimates in the 2018 Quality Payment Program final rule, less than 71,000 clinicians are expected to participate in Advanced APMs, compared to 621,700 clinicians who will participate in the Merit-based Incentive Payment System (MIPS) in 2018.

The proposed DPC model, if implemented appropriately, could be a catalyst to increasing opportunities for physician group practices to participate in Advanced APMs by recognizing innovative care delivery and payment reforms happening in the marketplace today and encouraging physician-led, value-based transformation. We are encouraged by the potential of this model to support specialty and independent physician group practices that currently have few APM opportunities. MGMA seeks assurances regarding the Innovation Center's commitment to involving physician group practices of all sizes and specialties through attainable benchmarks, robust incentives, upfront investment support, data sharing, and tools for patient engagement. Without this commitment, the DPC model could drive further consolidation among healthcare providers while forcing independent practices out of business–actions which restrict patients' access to care.

MGMA urges the Innovation Center to consider the following principles for encouraging physician practice participation and allowing for their success in a DPC model:

- Patients over paperwork – Burden reduction must be a priority for the Innovation Center when implementing the DPC model. Collecting and reporting quality metrics remain technically challenging, data intensive, and administratively burdensome. Bureaucratic barriers to care, including prior authorization and appropriate use criteria, are at odds with care delivery and financial models in which participants are accountable for care outcomes.

- Alignment of patient incentives – DPC participants should be provided the authority to revise beneficiary cost-sharing and other out-of-pocket expenses to encourage Medicare beneficiaries to actively engage in their care and seek high-value care providers.

- Access to data – Data sharing will be of the utmost importance for participants in a DPC model. The Innovation Center should devote significant resources to providing timely and actionable analyses of patient care trends, including gaps in care and cost drivers, to DPC participants. To the extent possible, these reports should be customized according to the specific DPC arrangement and regularly updated, preferably in real time.

- Choice of payment models – Physician group practices of all specialties, practice settings, and geographic areas should have the opportunity to participate in a DPC model, based on what best accommodates their practice and the needs of their patients. We encourage CMS to adopt physician-led APMs recommended by the Physician-Focused Payment Model Technical Advisory committee (PTAC) that are based on the DPC approach by using different types of payment during different phases of care and stratifying the risk based on a physician's patients and their medical conditions.

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- Upfront investment support – The Innovation Center should account for investment risk in the DPC model and assist interested physician group practices through direct investment support. Success in risk-bearing payment models requires practices to make significant infrastructure investments, furnish uncompensated care, and forego guaranteed performance-based payments if the clinical transformation efforts are not sufficient to reduce waste or improve outcomes.

- Evolution of risk – The Innovation Center should explore multiple tracks for DPC arrangements with physician group practices based on their experience in pay-for-performance programs and value-based models. We recommend the Innovation Center appropriately qualify risk for group practices based on the care and costs within their control.

- Care coordination – Modernization of fraud and abuse rules is needed to better support care coordination in innovative payment arrangements, such as the DPC. Working in concert with the relevant federal agencies, CMS should develop a standard waiver of certain otherwise applicable Medicare fee-for-service rules to allow DPC participants to effectively coordinate and assume accountability for beneficiary care.

In addition, MGMA urges CMS to consider our specific feedback that follows. Because there remain many unanswered questions about the proposed DPC model, we urge the agency to develop the model as transparently as possible so that potential participants can make fully informed decisions about participation. CMS should release detailed model information and seek comments about the model refinements prior to accepting model applications.

Provider/State Participation *[questions 1-5]*

CMS: 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?

The Innovation Center should devote significant resources to providing timely and actionable analyses of patient care trends, such as gaps in care and cost drivers, to DPC participants. To the extent possible, these reports should be customized according to the specific DPC arrangement and regularly updated, preferably in real time. Timely feedback of data on assigned beneficiaries would enable DPC participants to more effectively evaluate the impact of specific clinical interventions and revise them as needed.

In addition to ensuring timely data sharing, the Innovation Center should make actionable performance feedback available to individual participating physicians and group practices in a model–not just at the level of the organizing entities. The trickling down of information in models that are facilitated by organizations other than physician group practices, such as accountable care organizations (ACOs) or hospitals initiating bundled payment models, is not effective. To avoid communication gaps between the Innovation Center and physicians who are providing care directly to patients, all DPC participating practices should receive feedback regarding their assigned patient population. We also urge the Innovation Center to provide education and technical assistance, including a direct line of communication with government subject-matter experts, to participating physician group practices who need assistance interpreting their reports.

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Regarding the content of performance feedback, MGMA recommends the Innovation Center work closely with DPC participants to ensure their reports contain specific, actionable information that allows practices to estimate their current performance and understand potential areas for improvement. We urge the Innovation Center to include high-level summaries that provide practices with a helpful snapshot of their performance, how their performance compares to benchmarks according to practice size or specialty, and identifiable areas for improvement. The feedback should also allow practice staff to drill down to more detailed, patient-specific information to facilitate targeted improvements. For instance, if a physician group practice offers evening and weekend office visits, yet identifies a trend in emergency department visits by assigned patients during those time frames, the practice may intervene to increase patient awareness regarding extended hours, reduced costs and potentially faster physician access with an office visit.

CMS: How should CMS consider and/or address the initial upfront investment that physicians and practices bear when joining a new initiative?

MGMA is encouraged by CMS' recognition that APM participants take on considerable risk as they transition to payment arrangements that reward outcomes rather than volume. Success in risk-bearing payment models requires practices to make significant infrastructure investments, furnish uncompensated care, and forego guaranteed performance-based payments if the clinical transformation efforts are not sufficient to reduce waste or improve outcomes. Rather than account for investment risk on a model-by-model basis, MGMA urges CMS to amend the definition of Advanced APM financial risk to include the loss of guaranteed payments and investment risk. MGMA contends MACRA provides CMS with broad discretion to define "financial risk for monetary losses under such APM that are in excess of a nominal amount."

To account for investment risk, CMS should first count the loss of guaranteed payments as financial risk, allowing APM participants to treat repayment or withholds of performance-based payments as financial risk. Because investments in health information technology (HIT) or care coordination staff and training do not guarantee shared savings or performance-based payments, APM participants take on significant risk that may not be compensated through performance-based payments. Second, CMS should include business and investment risk in the definition of financial risk. These investments include start-up and operating costs to help fund critical APM activities designed to improve beneficiary care, enhance care coordination, and reduce unnecessary spending and hospitalizations. Business risk involves extending hours, hiring new staff, and furnishing uncompensated services that are the lynchpin of care coordination, such as patient education and consultations with other specialists to ensure seamless care transitions.

A 2016 study by the National Association of ACOs (NAACOS) found ACOs spend, on average, $1,622,032 in operating costs to participate in the Medicare Shared Savings Program.[1] Respondents factored in the costs related to clinical care, HIT, ACO management, and other operating expenses. As these results demonstrate, the costs of redesigning care delivery to improve beneficiary health are significant, but not unknown. The $1.6 million estimate aligns with CMS' previous estimates. In the November 2011 Final ACO Rule, CMS stated, "Our cost estimates for purposes of this final rule reflect an average estimate of $0.58 million for the start-up investment costs and $1.27 million

[1] NAACOS, "ACO Cost and MACRA Implementation Survey," May 2016 https://naacos.memberclicks.net/assets/docs/news/naacos-costandmacra-survey-5.24.2016_final.pdf.

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in ongoing annual operating costs for an ACO participant in the Shared Savings Program."[2]

CMS based these estimates in part on those related to the Physician Group Practice (PGP) Demonstration, a precursor to the Medicare Shared Savings Program (MSSP) that ended in 2010. According to the Government Accountability Office, participants in the PGP demonstration invested, on average, $489,354 at the outset of the program.[3] While the majority of expenses were labor costs for care managers, expenses related to physician and staff education programs, physician feedback systems, and data collection processes also contributed to their significant upfront costs.

In addition to accounting for investment risk in the Advanced APM risk standard, the Innovation Center should assist physician group practices interested in the DPC through direct investment support. The Advance Payment (AP) ACO and ACO Investment Model initiatives may serve as examples of innovative care delivery models that utilize upfront financial support to generate greater participation among physician group practices. These models specifically target small and rural practices, as well as those who serve vulnerable patient populations. According to the final evaluation report, "the AP ACO model enabled physician practices to invest in resources to coordinate care, analyze patient data, become more aware of costs and utilization, and enhance communication within the practice and with providers outside of the ACO."[4] Additionally, AP ACOs that used claims or EHR data to identify patients for care management tended to have lower-than-expected spending. As discussed throughout this comment letter, access to data about assigned patients should be greatly enhanced for DPC participants.

Beneficiary Participation *[questions 6-8]*

CMS: 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)?

The Innovation Center should provide DPC participants broad authority to waive patient copays to prioritize high-value services to drive better health outcomes and lower costs. We have heard from our members that when it comes to Chronic Care Management (CCM) services, for instance, patients, who are often on a fixed income, are discouraged from taking advantage of this high-value service due to the copay requirement. DPC participants should have the authority to waive patient copays for CCM and other high-value services. The DPC model design should both reward providers for actively engaging patients in decision making about their care and appropriately incentivize patients to consider cost when it comes to their treatment options.

Additionally, several public and private sector APMs are built on the strategy of incentivizing providers to reduce costs by allowing them to share in a portion of the savings they generate. Interestingly, some private payers have begun extending this strategy to patients, and we encourage the Innovation Center to emulate this approach in the DPC model. Offering patients an opportunity to share in savings for choosing a less expensive treatment plan may generate greater

[2] Final ACO Rule, 76 Fed. Reg. 212, November 2, 2011.
[3] Government Accountability Office, "Care Coordination Programs Used in Demonstration Show Promise, but Wider Use of Payment Approach May Be Limited," Feb. 2008, https://www.gao.gov/new.items/d0865.pdf.
[4] L&M Policy Research, "Evaluation of CMMI Accountable Care Organization Initiatives: Advanced Payment ACO Final Report," Nov. 2016, https://innovation.cms.gov/Files/reports/advpayaco-fnevalrpt.pdf.

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model savings. The Innovation Center should simultaneously explore safeguards that would ensure patients are not incentivized to select less effective treatment plans.

Payment *[questions 9-12]*

CMS: 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?

The Innovation Center should explore multiple tracks for DPC arrangements with physician group practices based on their experience in pay-for-performance programs and value-based models. At least one DPC model option should include sufficient risk to qualify as an Advanced APM. Similarly, we urge CMS to ensure the fixed and incentive payments in any DPC model are sufficiently high to attract a range of providers whose patients may have a variety of medical conditions. Accordingly, the model payments must be adequately risk adjusted to reflect any such conditions. DPC participants should be accountable only for the care and costs within their control.

To avoid inventing DPC models from scratch while industry leaders test innovative financial and care delivery alternatives to fee-for-service, CMS should adopt APMs recommended by PTAC that are based on the DPC approach by using different types of payment during different phases of care and stratifying the risk based on a physician's patients and their medical conditions.

General Model Design *[questions 13-15]*

CMS: 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?

To encourage participation and allow for success in innovative payment models such as DPC, CMS must modernize its regulatory framework to create appropriate flexibility for physician group practices to effectively manage costs and assume accountability for beneficiary care. The existing fraud and abuse framework has become an impediment to the quality-driven payment models that CMS, Congress, and the healthcare industry have promoted. One of the hallmarks of these payment models is economic incentives to foster cooperative behaviors among physicians. However, such payments may be classified as improper referral fees under the Physician Self-Referral (Stark) Law's physician compensation provisions. Consequently, there is confusion within the physician community about how to participate in a payment model that may be inconsistent with existing law.

In addition to limiting incentive-based physician compensation, the current legal framework inhibits physician group practices from using appropriate patient incentives to help achieve better clinical outcomes for Medicare beneficiaries. For example, in an effort to deliver high quality patient care, a physician providing a glucose monitoring device and test strips for a patient with diabetes participating in a chronic disease management program invites scrutiny under the beneficiary

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inducement provisions of the Anti-Kickback Statute and Civil Monetary Penalties law, which limit the ability to provide in-kind items or services to beneficiaries to advance clinical goals.

CMS has recognized the tension between outdated fraud and abuse laws and innovative payment models and has issued regulatory waivers pursuant to its authority in section 1115A(d)(1) of the Social Security Act. This waiver authority is one of the most powerful tools in helping APM participants achieve their goal of delivering value-based care without fear of running into legal or regulatory liability concerns. MGMA encourages CMS to work with the HHS Office of the Inspector General to identify appropriate physician compensation and beneficiary inducement waivers that would better allow DPC-participating providers to coordinate with other physicians and appropriately engage patients in their care.

Finally, MGMA urges the agency to move away from the current piecemeal approach to fraud and abuse waivers and instead develop a single, overarching waiver that automatically exempts qualified DPC participants from redundant Medicare billing and fraud and abuse requirements. CMS should then extend this template waiver to current and future Innovation Center models to further streamline and simplify the waiver process and mitigate confusion across the provider community. Particularly as these models may overlap and all center on a common premise of incentivizing care communication and taking financial accountability for a patient or episode of care, participating group practices would benefit from the same waiver.

CMS: How can CMS foster alignment between requirements for a DPC model and commercial payer arrangements to reduce burden for practices?

A common theme we have heard from our own membership is the importance of engaging multiple payers in a single model. A larger patient population in multi-payer models means APM participants are less vulnerable to the influence of external variables on their patient health outcomes and would be evaluated more accurately on their performance. Aligning monetary incentives across payers would also provide greater financial means for practices to invest in services not reimbursed under the fee-for-service contracts to ensure success in the model. With all payers sharing the common goals of decreasing costs and delivering high-value care, there is a clear incentive to work together and partner with providers to achieve these goals. As an example of cooperation among payers, the multi-payer Comprehensive Primary Care Plus model has generated positive feedback.

For these reasons, we urge the Innovation Center to create a multi-payer DPC option. To facilitate multi-payer DPC arrangements, CMS should adopt PTAC-recommended models that have been tested and proven effective in private payer arrangements, as they have built-in appeal for private payer involvement. We also suggest CMS establish a council or workgroup consisting of private payers, government officials, and physician group practices to discuss how private sector models may be adopted or adapted by the Innovation Center and to explore additional cooperative models.

Program Integrity and Beneficiary Protections *[questions 16-20]*

CMS: 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?

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MGMA appreciates CMS' focus on patient choice within the DPC model and believes that patient safety, outcomes, and experience must be at the forefront of care delivery reform. A fundamental goal of existing Innovation Center models and value-based care in general is not just cost reduction, but also improvement of clinical outcomes. This dual focus protects against stinting care or substituting cheaper or lower quality services for the care that is needed. By rewarding quality achievement and appropriately adjusting for patients' medical and socioeconomic risk factors, the DPC model would incentivize improved patient outcomes while preserving the necessary flexibility that enables physicians to put their medical expertise to work when developing high-value care strategies for each unique patient.

While we recognize some monitoring activity may be necessary, we recommend CMS pursue opportunities to streamline program integrity efforts across all programs and keep paperwork to a minimum. In announcing new initiatives related to "Meaningful Measures" and "Patients Over Paperwork," CMS acknowledged the challenges associated with administrative tasks and committed to "removing regulatory obstacles that get in the way of providers pending time with patients."[5] CMS should utilize this same approach–mitigating the misdirection of resources and promoting value over volume–in its strategies for future payment reform.

Existing ACO Initiatives *[questions 21-22]*

CMS: 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?

One of the biggest barriers physicians participating in ACOs have faced is that there are no changes to the way they are paid in the MSSP. 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 APMs are needed for physicians participating in ACOs as well as for physicians who are not participating in ACOs, and so well-designed DPC models could complement ACO initiatives and enable them to be more successful. As the agency refines the DPC model, we urge careful consideration of how it will interact with existing APMs, including ACOs, to ensure aligned incentives across the delivery system and consistent approaches to measure cost and quality performance.

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. Rather than 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.

[5] CMS, "'Patients over Paperwork' Newsletter," Dec. 2017 https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/PoPDecember2017Newsletter.pdf.

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CMS: 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 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 physicians and other providers to support higher-value approaches to care.

Conclusion

MGMA members facilitate day-to-day operations of new payment models and bring valuable perspectives to the development of APMs. Thank you for this opportunity to offer comments on the development of a DPC model. We strongly encourage CMS to publish detailed information about a DPC demonstration and seek additional comments before calling for model applications.

We are happy to serve as an ongoing resource in future discussions about the DPC model. Please contact Jennifer McLaughlin at 202.293.3450 or jmclaughlin@mgma.org with any questions.

Sincerely,

/s/

Anders Gilberg, MGA
Senior Vice President, Government Affairs
Medical Group Management Association

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