NEXTGEN
ACO COALITION

May 30, 2019

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Centers for Medicare & Medicaid Services
US Department of Health & Human Services
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Submitted Electronically to DPC@cms.hhs.gov

Re: Direct Contracting Model

Deputy Administrator Boehler:

The Next Generation (Next Gen) Accountable Care Organization Coalition represents 21 of the existing Next Gen ACOs. We appreciate the opportunity to weigh in as you continue to design and implement the future portfolio of performance-based risk models.

The Next Generation ACO model has demonstrated that organizations can be successful in taking two-sided financial risk. The evaluation of the first performance year of Next Gen resulted in an estimated $63 million in net savings or a 1.1 percent decline in Medicare spending while maintaining quality for patients.

Next Gens have successfully implemented care management programs that are improving care for seniors in traditional Medicare. For example, Next Gens have engaged beneficiaries in transitions of care programs, disease management, social work and health enhancement programs, as well as strengthening relationships with primary care providers. As a result of these care redesign initiatives, Next Gens have achieved reduced readmissions rates, reduced non-emergent use of the emergency department; and improved quality for beneficiaries.

The Coalition is enthusiastic about the development of additional Direct Contracting models that can offer a capitated payment option for Next Gens that seek additional forms of payment and flexibility for downstream contracting arrangements. As the earliest adopters of two-sided performance based risk, we hope to serve as a resource for you as you design all tracks of Direct Contracting – professional, global and geographic. Valuable lessons learned in the Next Gen model can be instructive for Direct Contracting.

We urge you to codify the success of the Next Gen model into a regulatory full-risk offering in Pathways for Success. As we have seen, the Next Gen model, having the opportunity for 100

percent risk/reward for participants and the federal government, can be a meaningful driver to reduce costs and improve care. Next Gen offers 100 percent risk/reward opportunity for participants and the federal government. It should continue to be an option for provider organizations in the Medicare Shared Savings Program (MSSP) that are prepared to advance to the highest level of risk and reward. We believe that a full-risk offering in MSSP can operate in harmony with these new Direct Contract offerings, creating multiple options for Next Gen ACOs and others that want to take full risk for their patient populations.

Coalition members have been committed to advancing performance based risk for years – participating in the Pioneer ACO program, Comprehensive Primary Care Plus, and bundled payments. We look forward to this newest iteration of risk contracting and to working with you to continue to advance the health care delivery and payment system. As you develop this model we offer the following guiding principles:

- **Recognizing the investment of early adopters of performance-based risk**. Next Gen ACOs have been the agency's committed partners in the adoption of two-sided risk arrangements. Some Next Gens have participated in risk contracts with CMMI from the earliest opportunity. The investment and early adoption of these organizations should be recognized in the development of new models and they should not be disadvantaged as the Direct Contracting options are brought online.
- **Alignment with Medicare Advantage**. CMS should seek to create consistency across programs with alignment toward Medicare Advantage. Model design elements, such as risk adjustment, should be modeled after the Medicare Advantage program. In addition, CMS should consider additional opportunities to create parity between the Medicare Advantage program and traditional Medicare models, such as ensuring rates are sufficient to account for administrative costs (discussed below). Overall, the development of the Direct Contracting payment tracks presents an opportunity to alleviate conflicting requirements on provider organizations and to create symmetry across risk contracts.
- **Incentivizing the move to full-risk arrangements**. The agency should continue to identify new ways to encourage the adoption of full risk. This may include adopting new waivers, strong incentives and flexibilities to engage the beneficiary population, and providing more regular and complete data feeds (i.e., full paid claims for all attributed beneficiaries, including substance abuse and behavioral health) to provider organizations participating in full-risk arrangements, and by allowing organizations currently taking full risk to more easily aggregate lives under management.
- **Promoting transparency, stability and fairness across the Innovation Center portfolio**. As provider organizations move into full-risk and capitated payment arrangements in particular, it will become even more important that the agency provide transparency into its payment models. We reiterate our call for the agency to eliminate mandatory mid-year changes to model agreements and to adopt a more transparent and stable approach to its contracting with entities in full-risk arrangements. We recognize CMMI's desire for flexibility to modify payment model tests over time. However, we ask that they notify participants of major changes with plenty of time prior to the start of the applicable performance year.

Our specific feedback on the RFI is provided below.

NEXTGEN ACO COALITION

RESPONSE TO RFI QUESTIONS

Questions Related to General Model Design

1. How might DCEs in the geographic model address beneficiary needs related to social determinants of health?

We believe that all participants in performance-based risk models, including Next Gen and Direct Contracting professional and global, have strong incentives to manage population health and control costs, including addressing social determinants. Consistent with this shared goal, we welcome the opportunity to work with CMS and CMMI to develop waivers specific to two-sided risk bearing ACOs and DCEs that could assist participants in addressing the social determinants of health (SDOH).

In addition to waiver flexibility, we would like to work with CMS and CMMI to determine whether there is a mechanism to include SDOH in the risk adjustment model for ACOs and DCEs across model types.

Questions Related to Selection of Target Regions

1. What criteria should be considered for selecting target regions where the geographic model would be implemented?

Next Gens have focused on improving care management and coordination for Medicare beneficiaries, including coordinating care across providers and settings, managing care transitions and improving beneficiary engagement. Many Next Gens have built care management and infrastructure and have made significant investments in redesigning care delivery for their patients. Direct Contracting geographic regions should be selected in a manner that allows this innovation to flourish and without causing significant disruption in areas where performance-based risk is already underway.

2. What are the considerations for implementing the geographic model in rural areas?

Rural markets create unique challenges for performance-based risk contracting. Our experience in these markets has shown that there are challenges specific to cost-based reimbursement in the formation of baselines, particularly as they relate to critical access hospitals (CAHs).

For example, under the structure contemplated by the agency in the case of direct contracting models, the DCE would take a discount on its provider population. However, the CAHs continue to be paid cost-based reimbursement. This payment model structure disincentivizes that CAH from contracting with the DCE and makes it difficult to engage rural providers in DCE or ACO type arrangements.

To implement any DCE model in rural areas, CMS will have to develop a strategy that specifically encourages the participation of rural providers with a cost-based reimbursement methodology.

Questions Related to DCE Eligibility

1. What selection criteria and core competencies should CMS consider requiring of applicants?

Entities participating in the geographic Direct Contracting model should meet, at a minimum, the same criteria required of participants in existing CMS and CMMI risk-bearing programs. For example, Next Generation ACOs are required to establish a legal entity authorized to conduct business in each state in which it operates for the purposes of receiving and distributing shared savings; repaying losses; establishing, reporting and ensuring compliance with quality criteria and performance standards; and fulfilling the model's participation agreement. Next Gens are required to have an identifiable governing body with sole and exclusive authority to execute functions and make decisions on behalf of the ACO. The program lays out specific requirements for the composition, control and responsibilities of the governing body including the important role of participating providers who are invested in the success of the clinical delivery model.

The Next Gens are also required to have a leadership and management structure that meets certain criteria, including having clinical management and oversight managed by a senior-level medical director who is a model participant, physically present on a regular basis at any clinic, office or other location participating in the ACO, and board-certified and licensed in a state in which the ACO operates. Next Gens are also required to demonstrate compliance with applicable state licensure requirements governing risk-bearing entities, unless it has a specific exemption from such state laws.

CMS should require organizations participating in the Direct Contracting geographic model to have experience with coordinating and managing care and demonstrated success with risk contracting and population health.

In addition, CMS should require that geographic DCEs contract with primary care providers in their region for these physicians become participating providers in the geographic DCE. A formal participating provider agreement would be required for the geographic DCE to attribute beneficiaries. CMS should require that these participating provider agreements be specific to geographic DCE and the region in which the geographic DCE is approved to operate.

Finally, CMS should not allow Medicare Administrative Contractors, or related parties, to participate in geographic DCEs in regions in which the MAC operates.

2. What types of entities might participate in the geographic model that have not participated in other models? What conflicts of interest might arise and how should CMS or the DCE address them?

We agree that this model will attract entities that have not participated in CMS Innovation Center models or other Advanced Alternative Payment Models in the past. We encourage the agency to design the model in a way that creates a level playing field across participant types, including plans, providers and health information technology companies.

We see that conflicts may arise where a geographic DCE enters a market with an existing Next Gen ACO or other performance-based risk participant. In these markets, CMMI will need to develop an approach to attribution that resolves conflicts that may arise between the geographic DCE and other DCEs or performance-based risk ACOs in the market. These conflicts can largely be addressed through the design of the beneficiary alignment methodology (described below) and maintaining a level playing field for other rules across programs.

Questions Related to Beneficiary Alignment

1. How should CMS think about attribution for geographic DCEs?

Attribution for geographic DCEs should be done through an approach similar to that for existing ACO programs and the newly announced Direct Contracting professional and global options – using a combination of claims-based alignment and voluntary alignment.

We also encourage the Innovation Center to carefully consider how Direct Contracting geographic alignment will interact with alignment in existing models, including Medicare ACO models and Direct Contracting global and professional risk models. In particular, we call on the agency to adopt a tiered approach to attribution that creates a preference for models where the entity is taking two-sided risk for total cost of care, followed by primary care models and specialty models.

Specifically, beneficiaries that are attributed to Next Generation ACOs or Direct Contracting professional or global models, should not be attributable to Direct Contracting geographic model participants. In cases where model participants are already assuming two-sided risk for total cost of care for an attributed beneficiaries, those beneficiaries should be afforded the same status as Medicare Advantage beneficiaries, and therefore not be aligned to a new geographic DCE in the market. Without this key feature, Next Gen infrastructure our organization invested in for sustainability may no longer be viable.

In addition, we ask that the agency consider outlining a structure for all Direct Contracting model participants that speaks to nesting new models within existing population-based payment models, similar to the way Medicare Advantage risk contracts operate. Once an organization is taking risk in a Next Generation ACO or Direct Contracting global or professional risk arrangement, it should retain the flexibility to incorporate bundled payments, specialty models or medical home models for its contracted network, at its discretion and without disruption to its population-based payment model.

2. Are there transparency/notification requirements that CMS should consider to protect beneficiary freedom of choice of provider in the geographic model?

CMS should require clear communication to beneficiaries about the geographic model and what it means for a beneficiary to be aligned to a geographic DCE and how they maintain alignment to their existing ACO entity when that is their preference. These documents and other materials communicating freedom of choice should be tested with focus groups to ensure that they are achieving the desired result and not creating additional confusion for beneficiaries. There has

been significant experience with focus grouping and testing CMS communications in the Medicare ACO participant cohorts, and we encourage the agency to incorporate that feedback as it designs beneficiary communications.

3. How might DCEs inform beneficiaries of payment model options (and thus care management support available to them and their physicians) and engage them in their care? What barriers would DCEs face in engaging with beneficiaries in their target region?

DCEs in the geographic model should be subject to the same types of requirements for informing beneficiaries about payment model options as the Direct Contracting global and professional risk participants. Again, lessons learned from existing models should inform the types of communications that are most effective.

In addition, we encourage the agency to provide additional clarity around the conversations that DCEs in all models (geographic, global and professional) may have with their patients about their model options, including Medicare Advantage and including remaining aligned to their existing ACO, CIN or PCP. The agency should consider whether additional waiver flexibility is needed to assess the best program options for beneficiaries and to have conversations with beneficiaries about which model presents the best choice for the beneficiary's financial and clinical needs.

Questions Related to Program Integrity and Beneficiary Protections

1. What regulatory flexibilities or operational activities would be needed to promote DCE success and how might such flexibilities affect program integrity in Medicare?

We encourage the agency to continue to think about tools for beneficiary engagement for the geographic DCEs and more broadly for the Medicare accountable care model portfolio. For many ACOs, the openness of the Medicare network has posed a challenge to coordinating care and managing population health.

Reduced cost sharing and other incentives for in-network care continue to be critical features for building successful performance based risk models in traditional Medicare, as will delegated authority for DCEs to perform utilization management functions. We remain hopeful that forthcoming regulations to address the Anti-Kickback Statute and beneficiary inducement prohibitions for performance-based risk models may provide additional tools in this regard.

We also understand that there are limits on the tools that are available in traditional Medicare. One challenge that we have highlighted in the past is that many Medicare beneficiaries have supplemental coverage policies that cover all of the beneficiary's cost sharing. In a fee-for-service environment, these policies create barriers to driving value-based decision making. We note that other stakeholders have recommended reforms to Medigap that could assist with beneficiary engagement in traditional Medicare. We would be pleased to discuss how these changes could support the move to value in the future. We also understand that such changes could implicate congressional involvement.

Finally, we recommend the inclusion of additional waivers in the Direct Contracting models, including professional, global and geographic tracks:

- Regulatory or other approval pathway for an ACO to bring to market a wraparound Medigap plan;
- Waiver of cost share when treatment is provided during an annual wellness visit (AWV). Current rules require providers to bill an E&M in addition to the AWV, so would be looking for waiver of that cost share for the E&M, with the ability to limit this to beneficiaries who do not have Medigap coverage;
- Coverage for labs or other incidentals provided during an AWV, and waiver of any applicable cost share for those services, with ability to limit this to beneficiaries without Medigap coverage;
- Transportation – beyond existing nominal value carve out from the beneficiary inducements statute, we request fraud and abuse flexibility and clarity to allow transportation for beneficiaries;
- Home Health Aide – as a stand-alone service outside of a certified episode, especially for beneficiaries with dementia;
- Paramedic/EMT visit – future compatibility with ET3, allowing the ACO to send a paramedic to the home (could be an expansion of home visit waiver to include EMTs or paramedics);
- Waiving site of care – broadly, there are certain services that can only be provided in a facility, but can be clinically cared for in an outpatient or home setting.
    - "Hospital at Home" or "Observation at home" – episode that meet level 1 acuity and Observation level of care, but can be adequately cared for with intensive hospital-at-home program.
    - Drug infusion – Drugs that are currently only covered under Part A (so only billable in the inpatient or SNF setting) that can be infused in the home.
- Waiving copays for medications that are used to treat chronic conditions, when the beneficiary does not have coverage for those through Medigap or Part D; and
- Expanded use of prior authorization/pre-claim review for low-value services – along the lines of this review, aligned with ReviewChoice demo for Home Health and DMEPOS for DME.

Questions Related to Payment

1. CMS would calculate historical total cost of care for geographically aligned population to set a spending target for the DCE. What adjustments should we consider in calculating the benchmark for the performance year?

As you establish benchmarks for all models of direct contracting, we ask that you consider the following:

Sustainability over the long term. Many Next Gens have been participating in shared savings models in traditional Medicare since the introduction of the Pioneer ACO program. The savings achievements of those entities must be balanced with considerations about achieving fair

benchmarks for new entrants. New benchmarking approaches should recognize the need to encourage participation from a wide array of participants and should not disadvantage early adopters of accountable care programs. In addition, rolling benchmarks (continuous rebasing) disadvantages ACOs that lower cost trend. To increase sustainability of ACO models, CMS should consider phasing in recent experience over time.

Accounting for regional variation. Benchmarking strategies should account for circumstances at the regional level to the greatest extent possible, as opposed to national adjustments that do not accurately take into account the circumstances on the ground for participating organizations. Examples include the national coding intensity adjustment, which is a weak proxy for demographic changes at the local level and national trend factors that do not reflect expenditure growth in the regions in which ACOs operate. Entities with experience in two-sided risk models should have prior experience taken into account with respect to regional benchmark weighting, rather than having to restart with a low regional weight.

CMS should pay DCEs for newly assumed administrative costs. Under the new Direct Contracting models described by the Innovation Center, DCEs will be permitted to assume new functions, such as paying claims. As you continue to develop these models we encourage you to consider the administrative costs DCEs will assume if they elect to participate in models that incorporate these new features. DCEs should be appropriately compensated for taking on these new functions.

Continue on the path toward parity with MA by eliminating the cap on risk adjustment. The Next Gen program has a three percent upper cap on risk adjustment. When creating new models we recommend that you eliminate this cap on risk adjustment. Removal of the cap would be consistent with the approach to risk adjustment in Medicare Advantage and with our experience with non-Medicare contracts for senior populations. CMS should also employ a disciplined approach to calculating coding intensity adjustment actors. Current CMS methods attribute all growth in risk scores beyond demographic risk entirely to coding intensity, when in fact, populations may be increasingly chronically ill. We encourage CMS to examine coding patterns on a local/regional level and employ a more veracious approach to calculating coding intensity adjustment factors that considers increasing prevalence of chronic disease in a region. CMS should consider the market concentration of a DCE participant and back out the experience from the calculation of the regional reference point. Finally, we ask that risk adjustment policy be laid out clearly and in advance so that model participants know what coding policies apply.

2. Should DCEs benchmarks include accountability for Part D drug costs?

The ability to include Part D drug costs should be at the discretion of the DCE geographic participant. Pharmacy risk capabilities will largely depend on the specific organizational participant and the geographic area. We see this as a complex undertaking given the number and dynamic change with Part D plans and pharmacy benefit managers and therefore would not recommend that it be required, especially not in the early years of this program.

3. If DCEs enter downstream payment arrangements with providers, how should cost sharing amounts be determined and collected from beneficiaries?

The DCE should be responsible for creating an implementation plan for its downstream entities to implement any applicable cost sharing waivers. CMS should ensure that there is a level playing field when it comes to cost sharing amounts for beneficiaries – for example, the DC geographic model should not be advantaged in terms of beneficiary cost sharing waivers or tools as compared to the global or professional risk DC arrangements or Next Gen.

4. How should CMS address utilization of services and costs for beneficiaries aligned to a DCE that occur outside of the DCE's target region?

If a beneficiary receives care outside of the geographic area for the DCE, we recommend that CMS pay the fee-for-service claim for the outside entity. CMS should then hold the geographic DCE accountable for that out-of-area spend. How that is done specifically will depend on whether it is a fee-for-service payment arrangement or capitation.

This point underscores the need for tools to encourage beneficiaries to engage with the DCE and its contracted providers and to understand the significance of the DCE construct.

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We appreciate the opportunity to provide feedback on the development of Direct Contracting models. We look forward to working with you to implement this exciting new direction for performance-based risk contracting.

Sincerely,

Mara McDermott
Executive Director
Next Gen ACO Coalition