May 30, 2019

Adam Boehler
Deputy Administrator
Director of the Center for Medicare & Medicaid Innovation
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Recommendations on Direct Contracting—Professional and Global Population-Based Payment Model Options

Dear Deputy Administrator Boehler:

The National Association of ACOs (NAACOS) thanks the Center for Medicare and Medicaid Innovation (Innovation Center) for its efforts to change the way health care is paid for and delivered by implementing alternative payment models including the new Direct Contracting Model, released on April 22, 2019.[1] The model's three options represent another accountable care option for those ready for capitation and high levels of risk and reward. As the largest association of accountable care organizations (ACOs), representing more than 6 million beneficiary lives through more than 330 Medicare Shared Savings Program (MSSP), Next Generation Model, and commercial ACOs, NAACOS and its members are deeply committed to the transition to value-based care. NAACOS is an ACO member-led and member-owned non-profit organization that works on behalf of ACOs across the nation to improve the quality of Medicare delivery, population health and outcomes, and healthcare efficiency.

ACOs, the origins of which date back to the George W. Bush Administration, have been instrumental in the shift to value-based care. ACOs focus on providing high-quality health care while controlling costs, and many ACOs are embracing value and preparing to assume greater accountability. Importantly, the ACO model also maintains patient choice of clinicians and other providers.

NAACOS responded to the Innovation Center's Request for Information on the Geographic Population-Based Payment (PBP) Model Option but wanted to take the opportunity provide feedback on the Professional and Global PBP Options. Each represent a new path forward for ACOs to deepen their commitment in Medicare Alternative Payment Models (APMs) and improve care coordination for an important segment of patients. The Innovation Center's work in this area is admirable and appreciated. We support these being voluntary models and are very pleased these options are designed to qualify as Advanced APMs.

[1] https://innovation.cms.gov/Files/x/dc-geographicpbp-rfi.pdf

The Direct Contracting Model builds off of existing ACO models and includes many ACO principles and themes such as empowering local physicians, hospitals, and other providers to work together and take responsibility for improving quality, enhancing patient experience, and reducing waste. In exchange for taking accountability for a group of patients, Direct Contracting Entities (DCEs) can share in savings generated and are offered tools to improve care for patients. The Direct Contracting Model, like existing Medicare ACO programs, seeks to improve the quality of care for fee-for-service (FFS) Medicare beneficiaries.

The Next Gen model and other ACO programs are proving to save Medicare money while improving quality, at a time when healthcare spending continues to outpace the growth of the overall economy. An independent analysis released in December showed the MSSP saved Medicare $2.7 billion between 2013 and 2016.[2] CMS estimated that the overall impact of MSSP ACOs, including "spillover effects" on Medicare spending outside of the ACO program, lowered spending by $1.8 – $4.2 billion (0.5 – 1.2 percent) in 2016 alone.[3] The first-year evaluation of Next Gen ACOs shows they reduced Medicare spending in 2016 by $100 million and $62 million after accounting for shared savings and losses.[4] Initial analysis of second-year results show Next Gen ACOs netted at least $165 million to Medicare in 2017.

Meanwhile, ACOs continue to show they deliver high-quality care. In 2017, MSSP ACOs subject to pay-for-performance measures earned an average quality score of 90.5 percent out of 100 percent.[5] In the Next Gen program, quality in the program's first year was improved in the form of fewer acute care hospital stays and more annual wellness visits.[6] Other Innovation Center ACOs demonstrated high quality with the Pioneer ACO Model having and average quality score of 93 percent.[7]

The Innovation Center should take note of the success of Medicare ACOs and seek to replicate that in Direct Contracting Model options. NAACOS urges CMS to respect ACOs' current participation status and even expand options by making the Next Gen model a permanent Medicare program. DCEs should be given necessary fraud-and-abuse waivers, and utilization management tools should be expanded to allow entities to better manage their assigned populations. The Innovation Center should also apply lessons learned from current and past models when crafting risk adjustment and benchmarking policies.

Our below recommendations on Global PBP and Professional PBP Model Options of Direct Contracting reflect our desire to see Medicare achieve long-term sustainability, enhance care coordination for millions of beneficiaries, lower the growth rate of healthcare spending, and improve the quality of care. ACOs play a critical role in achieving these goals.

Allow Entities to Skip "Performance Year Zero"

While the Direct Contracting Model begins January 2020, this Performance Year Zero is only for beneficiary alignment purposes, with performance periods in the Professional and Global PBP Model Options beginning January 2021 (Performance Year One). It is critical for CMS to allow ACOs currently participating in the MSSP or the Next Gen program to continue their current participation through 2020 and be permitted to move seamlessly into Direct Contracting in 2021. CMS could provide this option by either allowing current participants to skip Performance Year Zero or by allowing them to participate in their current initiative and the Direct Contracting Model for 2020.

[2] https://www.naacos.com/mssp-savings-2012-2016-full-report
[3] https://www.govinfo.gov/content/pkg/FR-2018-08-17/pdf/2018-17101.pdf
[4] https://innovation.cms.gov/Files/reports/nextgenaco-fg-firstannrpt.pdf
[5] https://www.naacos.com/highlights-of-the-2017-medicare-shared-savings-program-results
[6] https://innovation.cms.gov/Files/reports/nextgenaco-fg-firstannrpt.pdf
[7] https://www.naacos.com/2016-medicare-aco-results--highlights

This would limit disruptions with current programs and would ACOs to continue improving their accountable care focus without a gap. It would also avoid forcing ACOs to sit on the sidelines for a year during which time they would have to comply with the Merit-based Incentive Payment System of the Quality Payment Program.

While CMS has said the agency will maintain 2020 participation in existing ACO programs as an option for Direct Contracting participation, we request the agency clarify its position through written guidance.

Allow Entities to Join in Subsequent Years if They Miss the 2020 Application

The Innovation Center in the past has offered multiple application periods for its models but has not stated if the agency will allow entities to apply to participate in Direct Contracting after this year's application cycle. Given the short turnaround between announcing this model, releasing details on the model's design, and having to make participation decisions, CMS should provide an opportunity for entities to apply in subsequent years. It is particularly important that CMS provide an opportunity for DCEs to begin participation in January 2021 as the Next Gen program will be ending in December 2020.

Address Model Overlap

The rollout of several APMs within a relatively short time frame often results in portions of the patient population qualifying for multiple models. The increasing number of APMs tested simultaneously by CMS elevates the need to ensure that models are complementary. Because model overlap impacts the financial performance of providers who participate in multiple models, CMS should give precedence to the total-cost-of-care models including Direct Contracting and ACO programs that may experience material financial harm in absence of protections. Specifically, CMS should:

- Provide attribution and financial reconciliation preference to longitudinal, total-cost-of-care models;
- Allow DCEs to choose if beneficiaries can also be aligned to other models, for example, if their beneficiaries can also be included in bundled payment APMs;
- CMS should explore options to reward providers who partner with the Innovation Center on multiple risk-based APMs (e.g., increased opportunity for shared savings in some models, additional flexibilities); and
- Study the impact of model overlap independently and as part of the evaluation of all Innovation Center models.

Keep Claims Processing as a Voluntary Option

CMS staff have stated that DCEs assuming full capitation in the Global PBP Option will be required to process FFS claims for participating providers. However, there have been additional conflicting comments about specifically which DCEs would be required to process claims, if any. We urge CMS to clarify in writing that claims processing remains voluntary.

Claims processing has been voluntary in the Next Gen Model (for the population-based payment mechanisms), and a minority of those ACOs elect to partake. In fact, very few ACOs have expressed an ability or desire to assume this task, especially considering CMS has not indicated extra funding would be provided for taking on this work. Medicare has a reputation as an efficient and reliable claims processor, and it would introduce considerable complexity, cost, and burden to shift this responsibility to providers.

Further, making claims processing voluntary in the Global PBP Option would be consistent with the Geographic PBP Option, where CMS plans to allow a DCE to elect to have CMS continue to process claims.

Additionally, assuming claims payment in some states would necessitate meeting new regulatory requirements at the state level. In some states, this could require obtaining a health insurance license and abiding by a host of new laws and regulations, adding additional costs that would be unnecessary if CMS continued to pay claims. Further, if processing claims is required for DCEs, that would likely have a detrimental effect on participation. Considering the costs and administrative burden associated with claims processing, we urge CMS not to require claims processing of any DCEs.

Predictable and Accurate Benchmarks

Benchmarks establish the spending targets entities must meet to achieve shared savings. CMS initially used historical total-cost-of-care spending to set benchmarks in Medicare ACO programs. More recently, the agency has incorporated regional spending into benchmarks to avoid ACOs facing continuously diminishing benchmarks. The benchmarking methodology is critical to programmatic success and will drive or deter participation. To date, the agency has released few details on how benchmarks will be set in the Direct Contracting Model. NAACOS urges CMS to release these details expeditiously to provide applicants further information on which to base participation decisions.

CMS announced the Direct Contracting Model will use a blend of historical and regional expenditure data to calculate benchmarks, with the blend shifting over the life of the model. Relying heavily on historical expenditure data creates an unattainable situation where providers have decreased ability to beat ever-lowering benchmarks. Medicare ACO programs have faced challenges by comparing performance to providers' own historical spending. ACOs either in low-cost regions, who are the dominant provider in their region or have already created substantial savings through their own redesign efforts, face grave difficulty achieving savings and may leave the program over time as a result of benchmarks that are too low to achieve savings. NAACOS continues to believe that Medicare Advantage-like benchmarks are more predictable and sustainable for model participants. Greater reliance on regional adjustments would offer greater incentives for high-preforming providers to participate in Direct Contracting. Alternatively, we suggest that CMS use a tiered benchmarking methodology, where benchmarks are increased for low-cost regions and decreased for high-cost regions.

Additionally, removing an entity's beneficiaries from the regional reference population will minimize an ACO from being evaluated against itself. At the very least, CMS should exclude the entity from the region to prevent an otherwise tautological comparison that essentially double counts those assigned beneficiaries. This is important in areas where the entity has significant market saturation.

Finally, to address entities whose reference population falls below 5,000 after removing assigned beneficiaries, we recommend CMS use a modified approach to reach 5,000 beneficiaries. In one example, CMS could increase the weight of the counties that have a lower proportion of resident beneficiaries, and thus higher FFS population. Another option would be for CMS to expand the regional service area to include assignable beneficiaries in adjoining counties until a sufficient comparison group is reached. Yet another option, recommended by the Medicare Payment Advisory Commission in their March 11, 2016 comment letter to CMS, would increase the stability of the regional FFS spending calculations by increasing the number of years of data included in the calculation.[8] For example, use a five-year rolling average for county level spending estimates.

[8] http://www.medpac.gov/docs/default-source/comment-letters/medpac-comment-on-cms-s-proposed-rule-on-the-medicare-shared-savings-program.pdf?sfvrsn=0

Fair Risk Adjustment Methodology

As with benchmarking, CMS has promised more details will come on risk adjustment. NAACOS urges CMS to release these details expeditiously to provide applicants further information on which to base participation decisions. Meanwhile, lessons on risk adjustment can be learned from the Next Gen program. NAACOS urges CMS to use a risk adjustment approach similar to that in Medicare Advantage. ACOs should not face an unrealistic cap on risk score increases but should instead have risk scores adjusted annually through a Medicare Advantage-like process designed to address changes in coding practices. A coding-adjustment factor should be sufficient to address coding intensity concerns. Over time, the same risk adjustment approach should be used across Medicare, creating parity and emphasizing the need to come to consensus on the most appropriate methodology.

Utilize Reliable Assignment Methodology

CMS announced the Direct Contracting Model will use both claims-based assignment and voluntary alignment. We strongly support retaining a claims-based assignment approach, along with an improved voluntary alignment process. Many beneficiaries are not yet aware of voluntary alignment, and as such, it is critical for program success to include claims-based assignment, which focuses on providers who furnish the majority of primary care services.

The Innovation Center has noted new "Enhanced Voluntary Alignment" as an improved aspect of the Direct Contracting Model. Voluntary alignment has existed in the MSSP since 2018, and while NAACOS supports voluntary alignment and its benefits for ACOs, we have been disappointed by the lack of uptake by seniors. Beneficiaries need alternative options to electing primary clinicians outside of visiting MyMedicare.gov. These options should include allowing a beneficiary to align by calling 1-800-Medicare. Allowing more marketing and promotion of voluntary alignment would help encourage signups to the level that makes it meaningful. CMS needs to provide more guidance in what marketing materials are allowed or feedback on proposed outreach to provide more communication with beneficiaries than the template materials CMS provides currently.

The Pioneer ACO Model provided an option to fill out paper forms in an office, but that proved administratively burdensome. This has proven to be true with Next Gen ACOs as well. DCEs should be allowed to provide front-desk technology to assist seniors with completing voluntary alignment. Seniors are reluctant to visit websites on their own and are often intimidated or afraid that they will "do it wrong". Prohibiting the ACO from assisting with online voluntary alignment creates more concerns within the doctor-patient relationship than it avoids. Patients do not understand why offices are unwilling to be helpful. Without the ability to assist beneficiaries with voluntary alignment, it's more efficient for ACOs to use other tools to increase predictability in assigned populations like annual wellness visits or other in-office exams, which help align patients through claims-based assignment.

Allowing broader options for voluntary alignment will support consumer-driven health care and will allow DCEs to establish a stronger connection with their beneficiaries. Among other advantages, this connection will lead to less beneficiary churn, which is a major barrier to value-based care.

Allow Flexibility in Spending 7 Percent Primary Care Capitation

The Professional and Global PBP Options will offer a Primary Care Capitation equal to 7 percent of the total cost of care for primary care services (with an option for 100 percent capitation in Global PBP). While CMS has yet to offer details on how these payments will be calculated, we encourage the Innovation Center to allow practices creativity in distributing these payments to providers within their entities. The capitated payments should not be just another way to distribute FFS payments. For care transformation to be truly

meaningful, they need to encourage providers, especially primary care, to think about patient visits in ways other than 15-minute segments. To help, entities need flexibility in structuring payments to encourage spending time with patients to promote health and wellbeing. Accordingly, we would request a waiver from fraud-and-abuse rules, including antikickback and Stark Law, be made available for the distribution of capitation payments.

Utilization Management Tools

CMS should implement more aggressive utilization management tools and control mechanisms. For example, primary care providers should be alerted when assigned patients seek care outside their networks or are admitted to a hospital, and those same providers should be allowed a point of intervention to assure beneficiaries are made aware of existing benefit enhancements. This would be a way for entities to influence in a positive way the use of patient services, which would be necessary if DCEs taking on the significant levels of risk CMS is proposing. This empowered approach assures beneficiaries are able to make informed decisions about the right place and intensity of services most appropriate in managing their care.

DCEs need the utilization management tools allowed in Medicare Advantage or other tools that encourage patients to stay within their networks, tools which health plans frequently utilize today. Entities should be allowed to encourage patients to seek care within their ACO-like structure without limiting choice. CMS should allow the same or similar utilization management criteria present in Medicare Advantage to assure that unnecessary utilization does not occur, for example, through repeat advanced imaging, add on skilled-nursing-facility (SNF) days, and other medically unnecessary services. This is consistent with CMS-intended controls through requirements under the Protecting Access to Medicare Act of 2014, including appropriate use criteria.

Benefit Enhancements

Today's benefit enhancements, while welcomed and an improvement, aren't enough. Many ACOs, including those in the MSSP and the Next Gen Model, have expressed interest in or begun utilizing payment-rule waivers and other benefit enchantments. These include the waiver from CMS's requirement for a three-day inpatient stay before stay before admission to a SNF, waiving Medicare's geographic restrictions for use of telehealth, waivers to support post-discharge home visits, and waivers to permit financial incentives for beneficiaries receiving certain primary care services from ACO providers. CMS has required approval processes for some waivers, such as requiring application and approval for MSSP ACOs to use the 3-day SNF wavier, which is not a requirement in the Next Gen program. NAACOS recommends CMS provide broad use of waivers under the Direct Contracting Model with simplified or no approval processes and fewer administrative and compliance requirements. We also recommend that the Innovation Center reconsider the beneficiary coordinated care rewards for keeping care within the DCE structures. Doing so would assure that primary care provider alignment is consistently rewarded. Opportunities to discuss care with beneficiaries can take place during annual wellness visits and other primary care visits and are foundational to the health of the population.

NAACOS also encourages CMS to think outside the box on existing tools, for example, by broadly allowing care management home visits beyond two visits. Increased use of care management home visits, in conjunction with broad use of post-discharge home visits, would provide important tools to manage ongoing needs of high-risk beneficiaries in transitions of care. Currently, two criteria must be met to be considered homebound:

> (1) the beneficiary must need the assistance of a supportive device, special transportation, or another person to leave their residence; or have a condition that makes leaving his or her home medically contradicted; and

(2) there must be a normal inability to leave the home and leaving home must require a considerable and taxing effort.

Beneficiaries should be not be denied the acute need for skilled homecare services at a level consistent with current home health standards simply because they are able to leave the home. There are many examples of patients forced into acute care stays, prolonged SNF stays, and other inpatient alternatives simply because they did not qualify as "homebound." We urge the Innovation Center to remove the homebound-status requirement and allow DCEs to more broadly use home health. Safeguards could be put in place similar to those used with the SNF three-day waiver, such as restricting the enhancement to home health agencies that achieve a three-star or above rating and/or have a provider of the DCE or preferred provider certify the episode. Additionally, recognizing the shift of care management to advanced practitioners, the home health benefit enhancement should allow advanced practitioners to certify the need for home health both with and without homebound status as long as the practitioner is part of the participant or preferred provider list.

More freedom to use skilled homecare services could help patients receive care in a setting they choose while aiding DCEs in controlling costs. For example, a patient needs follow-up care following an acute hospital stay. They could do well if discharged to the home, if support for a successful transition is in place, but current evidence-based guidelines dictate a brief SNF stay. The post-discharge home visits could be deployed in the first week to two weeks after the hospital stay, in order for medications to be monitored, home transition be safety assessed and resolved, transportation to the physician, or arrangements for house calls and physical therapy be resolved. The patient may opt to choose the least restrictive option of post-discharge home visit and return home with the supports provided by the benefit enhancement, rather than the institutional stay in a SNF.

Provided Fraud-and-Abuse Waivers

NAACOS strongly supports CMS's use of waivers from fraud-and-abuse rules, including the federal Anti-Kickback Statute and Physician Self-Referral Law (the Stark Law). These waivers have helped ACOs practice care coordination techniques necessary without fear of running afoul of rule that prevent fraud and abuse, which were designed for a predominately FFS payment system. We request clarification on what waivers will be available for Direct Contracting participants and if they're mirror those available to today's Medicare ACOs.

Give Entities Access to HIPAA Eligibility Transaction System Feeds

Health Insurance Portability and Accountability Act (HIPAA) Eligibility Transaction System (HETS) allows providers to check Medicare beneficiary eligibility in real-time using a secure connection. Anytime a Medicare beneficiary visits a medical provider, including the emergency department or inpatient hospital, DCEs could be made aware with access to this HETS feed. Such awareness would allow providers to communicate with treating providers at the hospital or elsewhere and work with the beneficiaries to ensure optimal treatment, medication adherence, and follow-up care.

But CMS has been unwilling to provide ACOs with access to this system. We request CMS allow a DCE to have access to HETS for their care coordination efforts. Limited testing would help address CMS's concerns to wider use, including technological hurdles and so-called false positives from events scheduled in advanced, while give an idea of the work needed by ACOs and CMS to broaden access to the HETS feeds.

Reward Entities for Higher Quality Performance

While not making details available yet, CMS promises a small set of core quality measures that focus more on outcomes and beneficiary experience rather than processes. Fewer, more outcomes-oriented measures would be appreciated as they make quality reporting more meaningful and less burdensome. NAACOS, however, encourages CMS to release more details on the measures under consideration and how performance will influence financial rewards. It is important to recognize high-quality performance compared to established measure thresholds as well as to recognize – and reward – quality improvement relative to providers' previous performance.

NAACOS requests that providers be rewarded for high quality performance, rather than only using performance to adjust downward for savings. Quality improvement should be a reward, which is a primary goal of CMS and its value-based payment programs. In today's ACO programs, unfortunately, providers that achieve high-quality performance are not rewarded through increased shared savings or higher benchmarks. In contrast, Medicare Advantage plans are rewarded with higher benchmarks for higher quality, which puts ACOs at a disadvantage. ACOs that make large investments to improve quality performance may be less able to keep spending below their benchmarks as a direct result of their increased investment in quality. For example, an ACO that does extensive patient outreach for cancer screening, such as colonoscopies, could expend considerable resources delivering these services, which may prevent the need for expensive late-stage cancer treatments for the screened patients.

Conclusion

NAACOS supports Innovation Center efforts to transform healthcare payment and delivery systems to reward value and incentivizes quality, well-coordinated care. We appreciate the opportunity to provide feedback on how to improve these new model options. Direct Contracting provides a chance to learn new lessons about accountable care that can be applied to the broader Medicare program. NAACOS and the Innovation Center share the goal of wanting these models to be successful, and we believe our above recommendations will create better model options. Thank you for your consideration of our comments.

Sincerely,

Clif Gaus, Sc.D.
President and CEO
National Association of ACOs