



November 20, 2017

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Centers for Medicare and Medicaid Services: Innovation Center New Direction Request for Information

Dear Administrator Verma:

NAACOS is pleased to submit our comments in response to the agency's request for information (RFI) on the future direction of the Innovation Center. NAACOS is the largest association of ACOs, representing more than 3.7 million beneficiary lives through 250 Medicare Shared Savings Program (MSSP) ACOs, Next Generation, and commercial ACOs. 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 health care cost efficiency. NAACOS and its members are committed to transforming the way healthcare is delivered and paid for. Our members are at the forefront of this transformation effort and have invested significant time and resources to their success, which will ultimately improve care for Medicare beneficiaries and reduce costs for CMS.

The Innovation Center has played a significant role in testing various innovative strategies ACOs can deploy to further their mission of reducing health care costs, improving quality, and focusing on population health and outcomes. The Next Generation and Track 1+ ACO Models were established by the Innovation Center and have been instrumental in allowing ACOs to take on risk while allowing the freedom to test new strategies to effectively and efficiently manage care, such as waivers of payment rules like the Skilled Nursing Facility (SNF) Three-day Stay Rule and more flexibility and therefore greater access to telehealth services for the patients ACOs serve. This Innovation Center has also created initiatives to test the ACO model for Medicaid patients. Many of these innovations have aligned with the guiding principles outlined in this request for information, such as providing choice and competition in the marketplace while also giving providers choices as to the best model for their participation given their size, local healthcare market and ability to take on risk and we support these efforts.

Future Direction of the Innovation Center and Guiding Principles

As the Innovation Center considers its future direction, NAACOS urges the Innovation Center to look to ACOs as a national laboratory to test innovative care models and novel strategies within the ACO model. Our comments below provide a list of areas we recommend the Innovation Center test within the current ACO programs, including those operated through the Innovation Center and through the MSSP, to

determine which strategies will have the largest impact on improving patient care and cost efficiency. By providing ACOs with this added regulatory flexibility, ACOs will be provided with the tools they need to furnish high quality and cost-efficient care for their patients. Taking this approach with ACOs will allow for small scale testing that the Innovation Center seeks to achieve while focusing on specific payment and/or delivery interventions. It will also allow for a true study of the effectiveness of such models by allowing a limited number of ACOs to voluntarily elect such strategies to further their efforts to improve care for their patients.

Expanded Opportunities for Participation in Advanced APMs

NAACOS is looking forward to working with the Innovation Center to expand and improve the ACO model. However, we must also raise an important issue that, if not addressed, stands to significantly erode the model's effectiveness. Over the past several years, the Innovation Center has released numerous competing programs in rapid succession, imposing unintended consequences on existing program operations and goals, including those of the Medicare ACO programs. The increasing complexity surrounding how the agency operationalizes the overlap of these competing programs is growing at an alarming rate, causing troubling confusion and uncertainty for providers. In this request for information, the Innovation Center also calls for increasing the availability of specialty physician models to engage specialty physicians in alternative payment models (APMs). While we support the engagement of specialists in health care delivery and payment reform efforts, we also urge the Innovation Center to resolve the numerous operational challenges that currently exist when multiple, sometimes competing payment models intersect.

As detailed in a recent [letter](#) to the agency, we are also deeply concerned with the CMS's lack of strategic planning and direction in addressing APM overlap issues. It appears to date, CMS has attempted to deal with overlap on a per-program basis rather than taking a coordinated and strategic approach. It is essential that the agency develop a more thoughtful approach to program overlap issues, particularly as CMS moves forward with implementation of the Medicare Access and CHIP Reauthorization Act (MACRA). By the agency's estimates, the number of providers participating in APMs will grow dramatically in the coming years, compounding this problem. For example, CMS estimates the number of providers qualifying for Advanced APM bonuses will roughly double in the second year of the Quality Payment Program (QPP) to total 185,000 to 250,000 for the 2020 payment year corresponding to 2018 performance. Therefore, it is critical that CMS and the Innovation Center address this issue now before the operational challenges grow exponentially and ultimately undermine the progress made to date by APMs currently in existence. This is in alignment with the guiding principles outlined in this request for information which emphasizes transparent model design and evaluation. We assert that the current efforts have been lacking in this transparency.

As NAACOS has [noted](#) previously, the overlap of bundled and episode payment programs with ACOs creates conflicts when patients attributed to an ACO are also evaluated under a bundled payment program. Under current CMS policy, a bundled payment participant maintains financial responsibility for the bundled payment episode of care, and any gains or losses during that episode are linked to the bundled payment participant and removed from ACO results following the close of the performance year. While CMS planned to test an alternative policy by excluding Next Generation and Track 3 ACO beneficiaries from certain episodes, this exclusion would not apply to Track 1 or Track 2 beneficiaries, which comprise the majority of ACO beneficiaries, and ultimately this experiment was later cancelled by the agency. The problem is exacerbated by the fact that ACOs are not permitted to participate as bundlers in current bundled payment programs. Should CMS and the Innovation Center continue to include ACO patients in bundles, we urge CMS and the Innovation Center at a minimum to allow ACOs to participate as formal bundlers, specifically permitting gainsharing for ACOs with bundlers. ACOs focus on and make considerable investments in care coordination and improving care transitions to manage post-acute care effectively. Many successful ACOs

credit these efforts for allowing them to achieve shared savings. Therefore, when appropriate based on the bundle and care provided by the ACO, we believe ACOs should be permitted to participate directly as bundlers in such payment models so they are afforded the opportunity to benefit from the care coordination activities with which they are already engaged.

Innovative ACO Strategies Recommended for Further Testing

Allowing for expanded use of payment rule waivers across ACO models by permitting waivers related to the SNF Three--Day Stay Rule, telehealth, home health and primary care co-payments to all ACOs

We support the Innovation Center's desire to provide further payment waivers to assist health care providers in innovating care delivery as part of model tests. We encourage CMS to provide as much flexibility as possible when creating new payment waivers to encourage broad use of the waiver. We also recommend an ongoing feedback loop with providers as new payment waivers are implemented to continually improve processes and reduce unnecessary burdens on providers using the waivers. For example, when first implemented, there were many challenges with the SNF Three-day Stay Rule waiver. The agency should continually solicit feedback from the providers using these waivers to improve on the processes and to enhance provider experience with the waiver to broaden use of the waiver.

Currently CMS affords certain ACOs relief from a number of cumbersome payment rules that actually prohibit care coordination and can increase costs. We urge CMS to expand the use of these payment rule waivers to extend to all ACOs. This includes the SNF three-day Rule. Eliminating the requirement of a three-day inpatient stay prior to SNF (or swing-bed Critical Access Hospital admission) admittance will allow ACOs to provide the right care for the patient in the most appropriate location. We also request that CMS waive certain telehealth billing restrictions to increase the use of these services by all ACOs. Specifically, elimination of the geographic components of the originating site requirements will allow all ACOs to have the ability to provide needed telehealth services in areas other than those classified as rural areas by CMS (currently defined as a rural Health Professional Shortage Area [HPSA] located either outside of a Metropolitan Statistical Area [MSA] or in a rural census tract). We also request that CMS allow beneficiaries to receive telehealth services from their place of residence.

Additionally, we urge CMS to waive certain post-discharge home visit supervision requirements to allow for broader use of these services by ACOs when clinically appropriate. We ask that CMS allow physicians to contract with licensed clinicians to provide these home visit services using general instead of direct supervision requirements specified at 42 CFR § 410.32(b)(3). This will provide all ACOs with needed flexibility during the critical post-discharge time period. Finally, we ask CMS to afford all ACOs with the ability to provide waived co-payments for primary care services provided by the ACO's providers to encourage patients' use of these critical services. CMS should afford all ACOs with every opportunity for success in reducing costs for its patients by allowing ACOs to use these high value services, and we request that these waivers apply to all ACO models.

Providing ACOs Upfront Funding for Transportation Services

Lack of transportation is often cited as a barrier to healthcare access and can lead to missed appointments, delayed care, and ultimately poorer health outcomes. This issue is especially important for effectively managing patients with chronic diseases, which require more appointments and timely healthcare interventions as well as ongoing medication management. A literature [review](#) of research on this issue found that patients with a lower socioeconomic status had higher rates of transportation barriers to

ongoing health care access than those with a higher socioeconomic status.¹ This is a critical issue that, if addressed, could help to improve health outcomes, particularly for the patients that most need ongoing care. Therefore, we recommend that the Innovation Center test the effect of providing funding for ACOs to provide transportation services to allow beneficiaries to seek the treatment they need. This could be provided as an upfront payment or as a defined member benefit. The transportation benefit could be billed by the health care provider, for example, providing eight trips for the patient and thereby giving transportation to and from the office for four visits for the patient. Other payers currently utilize this approach such as Humana and Providence Health Plan and could be used as models.

Allowing ACOs to Establish Post-Acute Care Networks

CMS does not currently allow ACOs to incentivize beneficiaries to seek treatment from the providers the ACO has identified as most efficient and high quality. Unlike the Medicare Advantage (MA) program, ACOs are unable to provide incentives for beneficiary engagement with the ACO's most efficient providers. This in turn creates challenges for the ACO in communicating with beneficiaries regarding their preferred providers for treatment. These are the providers engaged with the ACO and focused on providing coordinated, high quality care. NAACOS recommends the Innovation Center test the effect of allowing ACOs the same opportunities that are currently provided to MA plans to increase beneficiary engagement through incentives for beneficiaries choosing high quality, efficient providers that work collaboratively with the ACO, particularly for post-acute care providers to ensure ACO patients receive the highest quality care. In order to facilitate this request, CMS must also provide more transparency around post-acute care admissions and quality metrics for post-acute care providers.

Providing ACOs Upfront Funding for Social Services

There is increasing evidence that social determinants are a greater driver of cost and outcomes than genetics or clinical care. Currently there is little financial incentive or infrastructure to pay for social determinants of health (SDOH) work or to support community agencies that work on SDOH initiatives. Few ACOs have found ways to effectively connect their work to closure of SDOH gaps, but those that have, have been able to demonstrate significant cost reductions and shared savings while improving on quality of care. New models of care could align financial sustainability with not only coordination of social resources but also with the work of community partners that close social determinants gaps. Innovations then could come from not only the healthcare delivery side, such as building community networks, referral systems for social determinants gaps, and screening for SDOH gaps, but also from financing of community agencies. NAACOS recommends the Innovation Center conduct more research to test the effectiveness and value of providing upfront funding to pay for closure gaps.

Consumer-Directed Care & Market-Based Innovation Models

The RFI notes that the Innovation Center is currently considering testing allowing Medicare beneficiaries to contract directly with healthcare providers, having providers propose prices to inform beneficiary choices and transparency. NAACOS has serious concerns with this model. ACOs currently provide beneficiaries with choice, as the model does not restrict where a patient seeks their care. The ACO model is voluntary. Providers choose to participate and have a number of tracks and model choices to consider participation. Finally, the ACO program also promotes price transparency as the agency posts public use files (PUF) to allow the public unfettered access to ACO performance information on quality and cost. ACOs must also post their performance information on their organization websites to further promote transparency not

¹ "Traveling Towards Disease: Transportation Barriers to Health Care Access." Syed, S.T., Gerber, B.S. & Sharp, L.K. *Journal of Community Health* (2013) 38: 976. <https://doi.org/10.1007/s10900-013-9681-1>

only on costs but also performance on health outcomes and quality metrics. Lastly, ACOs are required to include a Medicare beneficiary on their board of directors, further engaging patients and giving them a say in the ACO's healthcare operations and activities. We urge the Innovation Center not to move forward with programs promoting direct contracting with providers which will undermine the consistency of pricing and benefits for beneficiaries and would increase complexity for patients, providers and Medicare as a payer.

Unlike Medicare Advantage, ACOs cannot restrict a beneficiary's choice of provider. Additionally, the patient attribution process is such that an ACO will not know which patients were attributed to the ACO until after the performance period has ended. Therefore, the ACO must employ strategies to coordinate the patient's care regardless of whether the patient may or may not be attributed to the ACO and despite the fact that the patient may ultimately choose a low-performing provider outside of the ACO's network to receive certain portions of their care. This makes the model one of the most consumer-directed population health models CMS deploys. Altering this process to require beneficiaries to actively elect an ACO would create insurmountable administrative complexities and would be confusing to beneficiaries. One of the unique aspects of the ACO program is that the organization must care for all patients in the same manner, not knowing who will ultimately be attributed to the ACO for the purposes of program calculations to determine quality and cost metrics for the ACO. This results in ACOs treating all patients as potentially included in their ACO and results in high quality, coordinated care for all beneficiaries. The current voluntary patient alignment option launched in 2017 has been fraught with problems and creates confusion among beneficiaries. Requiring patients to actively elect participation in an ACO would be detrimental to the program and would likely result in too few participants to implement the ACO model. Additionally, voluntary alignment does not limit a beneficiary's choice of provider, therefore there is little the patient gains from this process. For these reasons, we urge the Innovation Center to continue to make any patient alignment options voluntary.

Mental and Behavioral Health Models

The Innovation Center's request for information lists mental and behavioral health models as a priority area for testing. We support this mission and urge the Innovation Center to test several strategies in this category within the ACO model. There are a number of regulatory barriers ACOs face when trying to provide mental and behavioral health services to their patients. We believe the Innovation Center could test additional payment and regulatory rule waivers in this area to broaden access to these critical services. First, we urge the agency to provide ACO patients waivers of Medicare co-payments for behavioral health services. Removing this cost for the beneficiary will provide a high return on investment, ultimately allowing more beneficiaries to seek treatment. Further, we recommend the Innovation Center create a program to provide ACOs with upfront funding to invest in the integration of behavioral health and primary care services. Many ACOs currently engage in this work but are hamstrung by the lack of sufficient payment for behavioral health services. If provided with upfront payments, ACOs could employ case workers, psychiatry and other support staff to more appropriately integrate behavioral and primary health care.

The current payment rates for behavioral health services do not support the work needed to truly make a difference in this area. The Substance Abuse and Mental Health Services Administration's (SAMHSA's) Primary and Behavioral Health Care Integration (PBHCI) grants program showed some [success](#) in improving the overall wellness and physical health status of people with serious mental illness (SMI), including individuals with co-occurring substance use disorders (SUDs), by making available an array of coordinated primary care (PC) services available to patients. ACOs are well positioned to take on this role of more integrated, better coordinated care for this population and could build on this grant program's success by being provided with upfront funding to employ these strategies within the ACO model. Additionally, CMS should provide ACOs with support to allow more work in this area by providing ACOs full access to substance use claims data. A recent Surgeon General [report](#) found that effective integration of prevention, treatment, and recovery services across health care systems is key to addressing substance misuse and

represents the most promising way to improve access to and quality of treatment.² The report notes that the traditional separation of substance use disorder treatment and mental health services from mainstream health care has created obstacles to successful care coordination. By providing ACOs with all claims data, including that of substance use disorder treatment claims, ACOs can better support integrating the patient's mental health and physical health treatment including screening, assessments, interventions, use of medications, and care coordination between general health systems and specialty substance use disorder treatment services. As our country continues to grapple with an unprecedented opioid epidemic, NAACOS believes ACOs could have a meaningful impact on the treatment of both those struggling with opioid addiction as well as providing better treatment for patients battling mental illness.

Finally, NAACOS also recommends CMS provide increased access to and payment for telehealth services to facilitate behavioral health care in ACOs. Telehealth and remote monitoring enable clinicians to reach and monitor patients outside of institutional settings; engage beneficiaries; expand access to care; improve population health management; and increase care coordination, all of which are key to successfully transforming care and improving quality while reducing costs. There is significant evidence that telehealth usage can replace more expensive care and prevent costly medical interventions in the long-run. The Agency for Healthcare Quality and Research (AHRQ), Government Accountability Office (GAO), and the Veterans Health Administration (VHA) have issued reports, and there are many peer-reviewed studies showing telehealth's efficacy. Because reimbursement is only available in Medicare for certain services if a beneficiary receives care at an "originating site" located in a rural Health Professional Shortage Area (HPSA) or a county outside an MSA), the vast majority of providers in Medicare fee-for-service (FFS) do not utilize telehealth.

NAACOS believes the most impactful telehealth expansion CMS can make within the agency's authority in the Medicare FFS program is a waiver of 1834(m) restrictions for ACOs participating in MSSP. A waiver of section 1834(m) is supported by authority in section 1899(b)(2)(G) of the [Social Security] Act. This waiver is appropriate for several reasons. First, telehealth tools align with the quality metrics for ACOs. From patient and caregiver engagement to preventive health and readmission avoidance, telehealth facilitates improvement. Telehealth enables communication between patient and providers outside of the walls of the office, thereby increasing meaningful communication and contributing to the ability of providers to follow up with patients. For example, all of the following Consumer Assessment of Healthcare Providers and Systems Survey (CAHPS) measures can be achieved through telehealth: timely care, appointments and information; access to specialists; health promotion and education; shared decision making; health and functional status assessments; stewardship of patient resources. Telehealth can provide more timely diagnoses and enhance in-person services by supporting patients between visits. Telehealth is also a tool for expanding access to primary care, which is the dominant use of telehealth in the commercial and veterans market today. The HHS Office of Inspector General (OIG) released a report in 2017 evaluating the first three years of the ACO program. They found that ACOs were able to reduce Medicare costs by \$3.4 billion with a net savings to the Medicare program of \$1.1 billion (accounting for incentive payments). Of the 428 ACOs analyzed, 36 ACOs accounted for half the savings, or \$1.7 billion. The OIG dubbed these ACOs "high performing" and analyzed how they approached care. They found that "high performing" ACOs provided the highest number of primary care visits compared to other ACOs in the program. Expanding access to telehealth services could allow ACOs to provide these critical visits, even in areas where there are access issues for patients.

² "Facing Addiction in America, The Surgeon General's Report on Alcohol, Drugs, and Health." Substance Abuse and Mental Health Services Administration (US); Office of the Surgeon General (US). Washington (DC): [US Department of Health and Human Services](https://www.hhs.gov/ashhsa/sa/201611); 2016 Nov.

Physician Specialty Models

As detailed in our comments above, the agency's current approach to handling the intersection of bundled payments, which often focus on a specific procedure or condition, and population health-focused models, which focus on the patient and population served as a whole, has created inequities within APMs. NAACOS supports any efforts to further engage specialists in value-based care efforts, however CMS must also continue to encourage and emphasize the population-health care models that are accountable for a patient's total cost of care rather than focusing on a patient's condition or procedure. To further encourage collaboration among specialists within the ACO model, NAACOS believes CMS could provide opportunities for "shadow bundles" to take place within the ACO model. Using this approach an ACO structures its own internal bundle for the providers, typically specialists, that are part of their ACO. This increases involvement of the specialists while measuring them on quality and cost in a way that is meaningful for them and directly related to the services and care they provide.

A growing number of ACOs are using this approach as a way to engage specialists and to measure and control cost and quality of care within their ACO. Providing more flexibility in this area for ACOs would allow more innovation and address issues of increased volume, which is a concern related to isolated bundled payment programs that are not also connected to programs responsible for the whole patient population and total cost of care. There are a number of approaches that would complement the ACO's work, such as gain share arrangements for specialists which incent the adoption of a particular evidence based treatment protocol. For example, a retina specialist could have a gain share arrangement within the ACO for adhering to evidence based protocols for patients with macular edema or for cardiology specialists focusing on the successful adoption of protocols such as medication management for patients with angina. There are a number of clinical areas that would lend themselves to shadow bundles within the Medicare ACO including chronic obstructive pulmonary disease, joint replacements and other cardiac episodes to name a few. To employ this strategy, CMS must provide more data, including historical data, to ACOs to allow for accurate and risk adjusted target prices to be developed.

NAACOS believes shadow bundles implemented within the ACO model would allow ACOs to engage specialists and more effectively incentivize and involve specialists in value-based payment efforts. Doing so will allow for specialists to perform against a standardized target price regardless of whether the patient is an ACO patient or a patient in a formal CMS bundled payment program such as Bundled Payments for Care Improvement (BPCI) or Comprehensive Care for Joint Replacement (CJR). Further, this will incentivize changes in health care delivery such as creating and implementing standardized discharge protocols while also being connected and responsible for total cost of care through the ACO.

Medicare Advantage Innovation Models

Many Medicare ACOs also participate in accountable care contracts with other payers. To reinforce an ACO's overall commitment to population health, it is important to participate in multiple payment arrangements that similarly reward providers for high quality care while holding them accountable for overall cost and utilization. Many ACOs already have accountable care contracts with MA plans and that trend is growing as ACOs aim to expand their number of contracts across payers. Given the growth in MA accountable care contracts and the high proportion of MA beneficiaries in certain markets, it is important for the Innovation Center to meaningfully support and reward ACO participation in MA accountable care contracts. As explained in the RFI, CMS seeks comments on what options might exist beyond FFS and MA for paying for care delivery that incorporates consumer choice and could be tested as alternatives to FFS and MA. The ACO model does just that, which is why we urge the Innovation Center to leverage the model by using ACOs to experiment with the new initiatives outlined in previous sections of this letter.

In a recent [letter](#) to CMS, we urged the agency to modify regulations to give credit under MACRA for participation in MA Advanced Alternative Payment Models (APMs). This would allow MA contracts meeting CMS requirements for quality, risk and use of certified electronic health record technology to be counted in calculations to qualify ACOs for 5 percent Advanced APM bonuses. In the final 2018 QPP rule, CMS explains its plans to support exploring ways to enable eligible clinicians' participation in MA APM arrangements to be counted in the Qualifying APM Participant (QP) determinations under the Medicare Option. We urge the Innovation Center to use its waiver and demonstration authority to do so. Providing credit for MA APM participation would properly recognize participation in alternative payment arrangements with MA, which would be especially important for providers who would not receive credit for such participation under the regular APM incentive rules. We urge CMS to pursue such a demonstration beginning in 2018 and to include ACOs in this demonstration. This would not only incentive provider participation in MA APMs but would reinforce the role of Medicare APMs, including ACOs, by rewarding broad adoption of APMs across payers.

Prescription Drug Models

As part of the Innovation Center's interest in testing new models for prescription drug payment, in both Medicare Part B and Part D, we recommend the agency consider the role ACOs play in providing a holistic approach to total cost of care. While ACOs are accountable for Part B drug costs, there has been interest in exploring whether an ACO model could also incorporate Part D drug costs. This is something that MedPAC has considered but not yet provided recommendations for, in part due to the challenges of figuring out how to introduce Part D costs into an ACO model and the complex methodological considerations involved.

As a first step of considering potential integration of Part D costs into an ACO model, we recommend the Innovation Center conduct a market analysis. This would focus on arrangements currently available with Part D plans, such as gainsharing arrangements with providers, and arrangements with commercial payers, some of which include provider accountability and risk for prescription drug costs for patients. Following that, we recommend the Innovation Center create a *voluntary* demonstration for ACOs interested in assuming a level of accountability for Part D costs and an increased opportunity for shared savings. Given the operational and programmatic complexities of such an initiative, we recommend the Innovation Center begin with a small demonstration that would allow flexible policy approaches and an ability to improve and refine the program as it develops. It would be essential that such a demonstration provide ACOs with robust data related to Part D. However, given the concerns about an inability for ACOs to control drug costs in our existing healthcare system, we reiterate the need for any such program to be strictly voluntary for ACOs. Given ACOs' focus on population health and effective management of a patient's care across the healthcare continuum, including medication management and adherence, ACOs are uniquely positioned to effectively manage medications. With the right incentives and program structure, a demonstration incorporating ACOs and Part D could provide significant benefits to patients and to the Medicare Trust Fund.

Program Integrity

For several years, health care industry stakeholders and policy makers have discussed the extent to which the federal physician self-referral law (or "Stark Law") prevents or inhibits integrated care models critical to an efficient, effective and successful transition to value-based reimbursement. There is a consensus that the Stark Law inhibits a wide range of integrated care initiatives. To their credit, through the establishment of multiple fraud and abuse waiver programs, CMS and HHS OIG have attempted to address at least some of the industry's concerns. While these waivers have been helpful, they are too limited. For example, in order for an ACO to effectively promote accountability for the quality, cost, and overall care for both Medicare and other patient populations, the ACO and its participants must (1) enter into arrangements with outside parties and (2) address more than just Medicare FFS patients.

With respect to the first issue, although the preamble to the waivers suggests that third-party arrangements are permissible, the waiver language itself is ambiguous, providing that MSSP waivers protect arrangements “of an ACO, one or more of its ACO participants or its ACO providers/suppliers, or a combination thereof.” 80 Fed. Reg. 66726, 66735-36 (preamble) and 66743 (participation waiver) (Oct. 29, 2015). Regarding the second issue, while the existing fraud and abuse waivers may protect shared savings arrangements with providers as they relate to the specific federal program at issue (e.g., the MSSP), it is less clear that they protect such arrangements as they relate to other patient categories (e.g., commercially insured patients). As a result, there is significant uncertainty concerning whether or the extent to which an incentive program offered to a physician with respect to his or her assigned MSSP patients may, without creating potential Stark Law issues, also be offered to the same physician for his non-MSSP patients. This uncertainty inhibits the implementation of efficient, broad-based, clinically-supported incentive programs that might otherwise serve to promote accountability for the quality, cost, and overall care for both Medicare and other patient populations. We urge CMS and HHS to provide increased Stark Law protection for ACOs, especially as it pertains to addressing the uncertainty about acceptable arrangements with parties outside of the ACO and for patients beyond traditional Medicare.

Closing Remarks

In closing, we support the Innovation Center’s guiding principles and look forward to working with staff to develop and deploy innovative strategies within the ACO model that could further improve quality and efficiency of healthcare provided to millions of Medicare beneficiaries. With the onset of a number of new payment models being advanced by stakeholders in response to MACRA as well as this request for information, NAACOS believes the issues highlighted in this letter must be resolved immediately. Without action by the agency, we risk losing valuable momentum gained by ACOs and others focusing on population health and total cost of care. It is critical that CMS protect the goals of population health focused delivery models. These models, such as the ACO model, are just now gaining momentum and an evidence base to learn from. It is critical that we allow these models to realize their full potential. NAACOS supports the exploration of new payment models and initiatives to leverage existing payment models through the Innovation Center, which will ultimately benefit all who are working to reform health care delivery and payment models to better support patients and to contain costs while providing exceptional care. However new payment reform efforts must work in tandem with existing models to prevent impediments to the progress organizations such as ACOs have worked so hard to accomplish to date.

Sincerely,



Clif Gaus, Sc.D.
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