Trinity Health

May 30, 2019

Adam Boehler
Deputy Administrator
Director of the Center for Medicare & Medicaid Innovation
Centers for Medicare & Medicaid Services
US Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Information; Direct Contracting—Geographic Population-Based Payment Model Option. Submitted electronically to DPC@cms.hhs.gov

Dear Mr. Boehler,

Trinity Health appreciates the opportunity to comment on the Direct Contracting Geographic Population-Based Payment model. We commend CMS' interest in models that aim to increase investment in primary care, which has historically been undervalued, and encourage CMS to continue to pursue models that promote flexibility and support providers in delivering high-quality, people-centered care. Trinity Health shares CMS' commitment to transforming the health care delivery system through person-centered and market-driven approaches that empower beneficiaries as consumers, increase choices and competition to drive quality, reduce costs, and improve outcomes.

Trinity Health is deeply committed to value-based care. We are one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 22 states. We employ approximately 133,000 colleagues, including more than 7,800 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 18 Clinically Integrated Networks (CINs) that are accountable for approximately 1.5 million lives across the country through alternative payment models (APMs) across all populations and product lines: Medicaid, Commercial, Medicare Advantage and Medicare ACOs. Trinity Health participates in the Next Generation ACO, Medicare Shared Savings Program (MSSP) Tracks 1, 1+ and 3, the Comprehensive Primary Care Plus (CPC+) program, and the Bundle Payment for Care Improvement Advanced program. We are building a People-Centered Health System to put the people we serve at the center of every behavior, action and decision. This brings to life our commitment to be a compassionate, transforming and healing presence in our communities. Trinity Health includes 94 hospitals as well as 109 continuing care locations that include PACE, senior living facilities, and home care and hospice services. Our continuing care programs provide nearly 2.5 million visits annually. Committed to those who are poor and underserved, Trinity Health returns $1.1 billion to our communities annually in the form of charity care and

other community benefit programs. We have 35 teaching hospitals with graduate medical education (GME) programs providing training for more than 2,000 residents and fellows in 184 specialty and subspecialty programs.

Our comments and recommendations are informed by the significant experience our system—and its leadership—has in establishing and supporting physician-led CINs, overseeing physician-run ACOs and participating in previous direct primary care capitation models.

As a Next Generation ACO with 80,000 attributed beneficiaries and having generated tens of millions of dollars of savings with year over year improvements in quality, we have demonstrated that physician-led clinical integrated networks with a commitment to vulnerable populations can be successful in managing risk and accountability for cost, quality and patient experience. The evaluation of the first performance year of Next Generation ACO model overall resulted in an estimated $63 million in net savings while maintaining quality for patients. As you implement the Direct Contracting models, we urge CMS to continue to offer a full-risk model similar to the Next Generation ACO in the Pathways to Success program.

The Next Generation ACO program is a success, largely due to prospective benchmarking, 100 percent risk/reward opportunity, and flexible payment models which are not currently available in Pathways to Success. Making the model design more broadly available aligns with the agency's goals of allowing providers who are ready to move to higher levels of financial and clinical accountability. Creating a permanent Next Generation ACO program, while building on its success by further defining Direct Contracting options, will create opportunities for a broad range of providers to enter higher level risk arrangements.

Trinity Health shares your commitment to creating a healthcare system that delivers high quality, coordinated care to all patients. We believe that models that have been tested and proven to reduce cost and improve quality should be given an expanded role in traditional Medicare, which will help facilitate the transition of more providers to an accountable care environment. Further, parity should be provided across advanced APMs, Medicare Advantage, and the Direct Contracting model.

As we look to lessons learned over the history of the movement toward value-based care, we caution that the managed care approach created administrative complexity and generated profits for health plans that added costs without delivering additional value. To avoid re-creating this scenario and potentially increasing costs to the trust fund, these newly offered CMMI models should require DCEs to implement APMs with downstream provider-participants, and meet the quality and performance requirements for participants to achieve QP status by participating in an Advanced APM. This requirement would insure against recreating a downstream fee for service model, and would instead support the goal of creating accountability for the triple aim to the participant level, with at least 75% of all care being provided under a value-based arrangement.

In addition to our responses below, Trinity Health supports the comments on the geographic model submitted by the Health Care Transformation Task Force and the Next Gen ACO Coalition.

Questions Related to General Model Design

1. How might DCEs in the Geographic PBP model option address beneficiary needs related to social determinants of health (such as food, housing, and transportation)?

Trinity Health is committed to advancing the health of individuals and populations. We strongly believe that new payment and delivery models—as well as existing ones—should support addressing the social determinants of health, which research has shown to be related to health outcomes, while also reducing costs. As CMMI seeks to bring local and state market innovations forward for testing, this is an area where CMS can continue to work with state, regional and local stakeholders to find ways to integrate social services into care management programs—and to foster payment models—including adjustment to payment based upon sociodemographic factors; factors that support holistic care of patients.

CMMI has the opportunity to test whether screening for key determinants or influencers of health will have an impact on the Triple Aim. Nationwide, there is significant ongoing work on addressing social determinants to reduce healthcare costs and improve outcomes. We recommend CMS engage with groups who are doing this work on a national level, such as through the Gravity Project. CMS could participate in the broader conversation and play a significant role as a convener. In addition, it would be helpful if CMS shared what has been successfully implemented in other models—for example, what has been learned from the Accountable Health Communities Model and the duals demonstrations.

Services to address social determinants of health are not allowable under the traditional Medicare benefit and as such, are not incorporated in the historic benchmark. Absent adjusting the benchmark for these services, DCEs should not have accountability to provide services to address social determinants of health. CMS could incorporate measures into the payment structure that would encourage DCEs to partner with social services, public health, agencies, and other providers of services to address social determinants—this would allow DCEs to test a consistent screening tool to identify beneficiaries in need of services.

Based on data collection, CMS could then identify key supplemental benefits that may be included—and accounted for in the budget--to inform future model years or bids.

Selection of Target Regions

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

There is no clarity on how Geographic DCEs will overlap/integrate with existing Medicare alternative payment models (APMs) in selected target regions. Given the investment of existing advanced APMs, CMS should finalize selection criteria for DCEs in regions where there has been less uptake of advanced APMs to avoid model overlap.

If selected regions do include existing advanced APM participants, we suggest CMS address overlaps in a way that recognizes early adoption, investment, and commitment of these participants—which have made significant investments in long-term success that are only just starting to bear fruit. As CMS evaluates potential participants in this model, preference should

be given to organizations with an established record of accomplishment in performance-based risk and their existing model participation should be supported.

We recommend excluding from the Geographic model beneficiaries who are already aligned with existing APMs and maintain attribution to these models with prospective alignment policies to lessen the impact on model evaluation and provide predictability aligned with supporting continued investment.

Questions Related to DCE Eligibility

1. What other selection criteria and core competencies should CMS consider requiring applicants to address? Please describe the benefits of including such additional selection criteria.

We recommend entities participating in the Geographic Direct Contracting model should be required to 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. In addition, Next Generation ACOs must have an identifiable governing body for which 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 mode—and these ACOs have to demonstrate compliance with applicable state licensure requirements governing risk-bearing entities. At least 75% control of the ACO's governing body must be held by Next Generation participants or their designated representatives, and we recommend the same requirement for DCEs.

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

2. Should we consider allowing States to participate as a Geographic PBP DCE or in partnership with a Geographic PBP DCE?

Allowing states to participate as a DCE would improve care coordination for beneficiaries across the continuum of care—some of whom currently receive services and care management across different programs. In addition, including Medicaid may incentivize greater provider participation in the program, enhancing access to physicians'—and potentially other—services for Medicaid beneficiaries who are more likely to face barriers to care. However, we recommend CMS discuss with states specific barriers to risk bearing arrangements and unique challenges facing value-based payment programs in Medicaid to inform development of the Geographic DCE model.

Questions Related to Beneficiary Alignment

1. What should CMS consider in thinking though beneficiary alignment in target regions with multiple DCEs?

CMS currently plans to select target regions with at least two DCEs to encourage competition and is considering randomly aligning beneficiaries in the target region to one of the DCEs or allowing beneficiaries to voluntarily align themselves to a specific DCE. We caution having more than one DCE in a region may cause confusion for beneficiaries. Regardless of the number of DCEs in a target region, CMS should ensure beneficiaries are provided with clear and accurate information outlining the Geographic model and what rights beneficiaries have. CMS should clearly specify which educational functions will be the responsibility of the DCEs and which functions CMS will perform. We urge CMS to engage beneficiaries and consumer advocates directly in designing and implementing the model.

In addition, for reasons outlined earlier in our letter, CMS should carefully consider and outline how the Geographic model would interact with existing alternative payment models in a target region.

2. Are there transparency/notification requirements, in addition to or in lieu of the requirements described above, that CMS should consider to protect beneficiary freedom of choice of any Medicare provider or supplier for beneficiaries aligned to a DCE participating in the Geographic PBP model option?

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. Where there is overlap, members should remain in their existing ACO unless they actively select out to join the DCE. CMS should test educational documents and other materials with focus groups to ensure they are achieving the desired result—we recommend building off of experiences and lessons learned from the process implemented through existing alternative payment models.

We also recommend that these materials include evidence supporting CMS' views of the benefits of the model to the beneficiary. This recommendation is based on our experience that the materials sent to beneficiaries participating in Medicare ACOs were not effective at communicating information about the model of care or potential benefits to enrollees. We also strongly recommend that CMS work to train Medicare call-center staff who may speak to FFS beneficiaries about enrollment in any models tested by CMS or the Innovation Center.

3. How might DCEs inform beneficiaries of the payment model option and engage them in their care? What barriers would DCEs face in engaging with beneficiaries in their target region?

It is essential for beneficiaries in new models to understand their participation and the potential impact of the model on their care. To this end, we recommend that as part of outreach under the Direct Contracting models, beneficiaries have access to materials and information on:

- what the model is,
- how the model impacts payment and the care the beneficiary receives,

- what alignment to a practice means and the length of the enrollment period,
- how a beneficiary can maintain alignment to their existing providers/ACO where they have been receiving care,
- any incentives the beneficiary could receive
- incentives for their provider to deliver high-quality care, and
- the potential for overall savings to the health system.

Lessons learned from existing programs should inform the types of communications that are most effective. We encourage CMS 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. The agency should consider whether additional waiver flexibility is needed to assess the best program options for beneficiaries and have conversations 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 monitoring methods can CMS employ to ensure beneficiary access to care is not compromised and that beneficiaries are receiving the appropriate level of care? What data or methods would be needed to support these efforts?

CMS should prioritize outcomes-focused and patient satisfaction measures to evaluate access, quality and outcomes in the Geographic model and closely review any patient complaints. In addition, we recommend CMS align measure across existing models and encourage alignment with commercial payers by adopting high-value performance metrics from MA contracts.

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

CMS should streamline waiver flexibility across APMs, including the Geographic model, and recommend providers who are in down-side risk arrangements have the ability to use all waiver flexibility afforded by Medicare, regardless of the level of risk assumed. These flexibilities (including the telehealth and SNF Three Day waiver) are essential to successfully reducing the costs, improving care access, and increasing quality.

In addition, CMS should clarify what waivers will be available to health care providers in the target region and those providers that contract directly with a DCE.

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 provides during an 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 ability to limit this to beneficiaries who do not have Medigap coverage.

- AWVs - 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 current waiver to allow for chair car or supported transportation as alternative to ambulance.
- Home Health Aide -- as a stand-alone service outside of a certified episode, especially for beneficiaries with dementia.
- Paramedic/EMT visit – future compatible with ET3, allowing the ACO to send a paramedic to the home (could be an expansion of home visit waiver to include EMTs/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/PartD.
- 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.

3. Providing incentives to beneficiaries to positively influence their behavior and healthcare decision-making could implicate the fraud and abuse laws and potentially raise quality of care, program cost, or competition concerns, particularly if the incentives would cause beneficiaries to be aligned to one DCE over another entity participating in DC or another CMS initiative. What safeguards should CMS put in place to ensure that any beneficiary incentives provided do not negatively impact quality of care, program costs, or competition?

In general, we support policies that lower the out-of-pocket cost burden for beneficiaries, but these supports should reflect the amount and level of acuity of care. For example, waiving cost-sharing for items/services that treat a chronic condition or prevent the progression of a chronic disease, which more directly addresses the needs of those with chronic illness by correlating with each patient's out- of-pocket burden. However, there are challenges to engaging beneficiaries with lower co-pays as the vast majority of Medicare beneficiaries have supplemental Medigap coverage which covers Part B coinsurance and deductible requirements, making it a less effective benefit or mechanism for beneficiaries to enroll and receive care from a preferred provider. Given these challenges, we recommend CMS work with partners to explore appropriate incentives to encourage beneficiaries to remain within their practice, such as allowing DCEs to offer a point of service wrap-around Medigap plan.

We also caution against the use of cash or other incentives that could result in beneficiaries being unduly influenced to join a particular practice – or that could create an unlevel playing field between practices with varying levels of resources. Incentive programs must be closely

monitored to ensure they do not negatively impact quality of care, program costs, or competition. CMS should also review incentive programs to ensure that they are not being used to unfairly tip the balance in favor of one model over another—the agency should require parity across models that take 75-100% downside risk.

Questions Related to Payment

1. Feedback regarding adjustments CMS should consider in calculating the benchmark for the performance year, such as the use of the U.S. Per Capita Cost national trend, other trend factors or specific geographic adjustments.

We recommend using this opportunity to move to a national benchmark over a five-year period to eliminate unjustified disparities in utilization and unit cost. This benchmark would be adjusted for true wage index differences but would not "bake in" current overutilization patterns—which should be a key goal of any new CMMI model. We note that in this model, CMMI would need to balance enrollment across historically high cost and low cost areas when accepting applications to avoid increasing costs. Similarly, as you continue to move away from historic cost-based models and rebasing across models, this model too should move away from historic costs and the inherent problems of rebasing.

MS should consider the additional administrative actions that will be optional or required under the Geographic model—such as processing claims—to ensure DCEs are appropriately reimbursed for these activities. In addition, if CMS desires DCEs to *provide* services that address social determinants of health, rates should be adjusted to incorporate these activities.

2. Feedback on the range of discounts we might expect applicants to propose and why (e.g., by analogy or reference to other experiences). How might we think about requiring applicants to structure these proposed discounts over the life of the model?

A starting place for discounts in the Geographic DC model could resemble the discount in the Next Generation ACO model. DCEs could offer a reduced discount for providing services not currently included in the baseline costs such as waivered services outlined above that require and investment of or direct payment for additional services.

3. We are interested in feedback on the payment methods available to DCEs in the Geographic PBP model option. In particular, we would like feedback on the "notional" account policy, described above, under which DCEs could select to have CMS continue to make FFS claims payments to all healthcare providers in the region. These FFS claims payments would be reconciled against the DCE's benchmark as part of final settlement.

CMS staff have stated that Direct Contracting Entities assuming full capitation in the Global PBP Model would be required to process fee-for-service claims for participating providers. We strongly recommend claims processing remain voluntary.

Claims processing has been a voluntary option in the Next Gen program, and few ACOs elect to partake or express a 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.

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

Further, we support quarterly settlements where either party could request payment over a nominal amount.

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

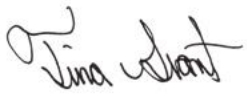
Given the number of Part D plans and PBMs, we recommend Geographic DCE participants have the flexibility to determine whether they want to include Part D drug costs in their benchmark and do not recommend making it a requirement. In addition, CMS should allow for a shared-risk (between the DCE and Medicare) option for providers who wish to implement a Part D plan through the model.

CONCLUSION

We thank CMS for the opportunity to comment on this RFI. The above comments and recommendations reflect our strong interest in testing new models and evolving existing models that drive value-based care, promote population health, and engage beneficiaries. We look forward to our continued partnership with the CMS Innovation Center.

If you have questions on our comments, please feel free to contact me at granttw@trinity-health.org or 734-343-1375.

Sincerely,



Tina Weatherwax Grant, JD
Vice President, Public Policy and Advocacy