



May 25, 2018

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

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

Submitted electronically to: [DPC@cms.hhs.gov](mailto:DPC@cms.hhs.gov)

Dear Administrator Verma,

Trinity Health appreciates the opportunity to offer recommendations in response to the Center for Medicare & Medicaid Innovation's (Innovation Center) Request for Information on Direct Provider Contracting Models (DPC RFI), which solicits comments on direct provider contracting between payers and practices to inform the potential testing of an approach in Medicare fee-for-service (FFS), Medicare Advantage (MA), and Medicaid. Trinity Health supports the Innovation Center's efforts to test new – and evolve existing models and programs— that drive value-based care, promote population health, and engage beneficiaries. As an organization, we are committed to rapid, measurable movement toward value in the delivery of— and payment for—health care.

Trinity Health, includes one of the largest medical groups in the country and is 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 131,000 colleagues, including more than 7,800 employed physicians and advanced practice providers, and have more than 15,000 physicians and advanced practice professionals committed to 22 Clinically Integrated Networks (CINs) that are accountable for 1.3 million lives across the country. Trinity Health includes 93 hospitals as well as 121 continuing care locations that include PACE, senior living facilities, and home care and hospice services. We have 35 teaching hospitals with Graduate Medical Education (GME) programs providing training for 2,080 residents and fellows in 184 specialty and subspecialty programs. Our continuing care programs provide nearly 2.5 million visits annually. Committed to those who are poor and underserved, Trinity Health returns almost \$1 billion to our communities annually in the form of charity care and other community benefit 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. Trinity Health is currently participating in 16 markets in Medicare Shared Savings Program (MSSP) ACOs, has five markets partnering as a Next Generation ACO, and several practices in the Comprehensive Primary Care Plus (CPC+) initiative. Our work – and experience in value-based contracting - also extends beyond Medicare as illustrated by our participation in 101 non-CMS APM contracts.

We commend CMS' interest in a model that aims to increase investment in primary care, which has historically been undervalued, and encourage CMS to pursue models that promote flexibility and support providers in delivering high-quality, people-centered care. We evaluated the proposed approach of the DPC model in this RFI, **and it is our recommendation that this model would function best embedded within a total cost of care model – similar to partial or full-risk provider arrangements with Medicare ACO and Medicare Advantage models.**

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**We believe that CMS could achieve many of the goals outlined in the RFI by building on existing payment and delivery reform models that promote care coordination and accountability across the continuum, such as ACOs, and by developing and testing new total cost of care models.**

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. We work each day to create a People-Centered Health System focused on delivering better health, better care, and lower costs in our communities. Trinity Health is committed to working with CMS to promote innovative model designs and testing that support our shared goals and we offer the recommendations below to accompany these objectives.

### **Questions Related to Provider/State Participation**

- 1. How can a DPC model be designed to attract a wide variety of practices, including small, independent practices, and/or physicians? Specifically, is it feasible or desirable for practices to be able to participate independently or, instead, through a convening organization such as an ACO, physician network, or other arrangement?**

#### **Practice Participation**

We believe that for a demonstration to be open to a broad range of organizations and practices, any DPC model will need to include the appropriate financial and infrastructure support practices need—such as upfront payments, HIT, and predictive analytics to identify high-cost patients—to reduce expenditures, while preserving quality of care. Trinity Health is concerned that participation in a DPC model similar to that outlined in the RFI will not be feasible for small practices due to both the administrative burden, complexity and lack of necessary capital to support transformation under such a model (e.g. establishing systems to manage capitated payments for a population of patients). Additionally, primary care has historically been underfunded, so it is imperative that a DPC model does not place providers—especially small practices—at risk for primary care capitation as that could result in unintended consequences such care or cost shifting.

#### **Feasibility for Practices to Participate**

Based on our experience working with small practices, CINs, and ACOs, we believe that larger entities are better positioned to support primary care transformation and are already doing so, including thorough models that include accountability for total costs of care across the continuum. We recommend that any DPC model be contained within a total cost of care model—and recommend CMS explore expanding existing initiatives—as these models support better care coordination across settings and providers, encourage more appropriate use of primary care providers and specialists, support more opportunities for patient engagement, and offer financial and infrastructure support to participating providers. More specifically, CMS could evolve current models to align with some of the goals laid out for a DPC model, including increasing beneficiary engagement in models by including patient attestation as an option for attribution, and facilitating the use of timely, actionable data and feedback to providers (see Question 30 for additional recommendations).

Last, we strongly recommend that in advance of implementation of any new model, CMS provide technical information necessary (e.g. eligible providers and beneficiaries, payment model HIT requirements, etc.) to allow beneficiaries, providers, health systems and other stakeholders) to evaluate the payment impact as well as the feasibility of participation for their practices and systems. We believe this is critical to ensuring robust participation in any model.

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- 2. What features should CMS require practices to demonstrate in order for practices to be able to participate in a DPC model (e.g., use of certified EHR technology, certain organizational structure requirements, certain safeguards to ensure beneficiaries receive high quality and necessary care, minimum percent of revenue in similar arrangements, experience with patient enrollment, staffing and staff competencies, level of risk assumption, repayment/reserve requirements)? Should these features or requirements vary for those practices that are already part of similar arrangements with other payers versus those that are new to such arrangements? If so, please provide specific examples of features or requirements CMS should include in a DPC model and, if applicable, for which practice types.**

Trinity Health strongly recommends that any DPC model have sufficient and appropriate incentives to promote high-quality, patient centered, coordinated care. Lack of incentives to improve patient care across the continuum could lead to unintended or negative consequences impacting beneficiary access and care such as stinting on primary care services, the unnecessary shifting of care to higher-cost settings, and lack of coordination across providers. Again, we believe a DPC model could successfully operate within a population-based, total cost of care model such as an ACO or a CIN that can support coordination across settings and providers, help practices implement CEHRT, and assist with performance reporting and feedback.

In addition to accepting financial accountability for the cost and quality of care that primary care practices provide under any DPC model, we believe they should also be required to demonstrate commitment to the five core primary care functions required of practices participating in CPC+.

- 3. What support would physicians and/or practices need from CMS to participate in a DPC model (e.g., technical assistance around health IT implementation, administrative workflow support)? What types of data (e.g., claims data for items and services furnished by non-DPC practice providers and suppliers, financial feedback reports for DPC practices) would physicians and/or practices need and with what frequency, and to support which specific activities? What types of support would practices need to effectively understand and utilize this data? How should CMS consider and/or address the initial upfront investment that physicians and practices bear when joining a new initiative?**

#### Supports for Practices to Participate in DPC Model

As noted earlier, we believe that provider organizations with limited infrastructure or capital are less likely to be able to participate in a DPC model. Specifically, provider organizations and practices would require appropriate payment management system, health IT infrastructure (e.g. CEHRT, predictive analytics to identify high-cost patients, care management tools), and administrative capacity to support a model similar to that proposed in the DPC RFI. In addition, practices will need experience – or be part of larger CINs or ACOs – that have the experience in assuming financial risk for FFS Medicare beneficiaries given the tools needed to manage a population of patients and assume risk for performance on quality and costs.

We also recommend that CMS encourage peer-to-peer sharing of best practices or consider other technical assistance or supports to assist participating practices. For instance, CMS could adopt the approach it has taken with the Medicare ACO initiatives and CPC+ and incorporate a CMS-led learning network to support collaboration across practices.

#### Data Support Needs

To help practices participating in a DPC model better anticipate the cost of caring for their patients, and track spending and quality performance, we believe that CMS would need to provide additional data—this will be especially important for practices that do not have previous experience with

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capitated payments. Specifically, we believe these practices would need historical claims data on enrolled beneficiaries; full claims data (including claims for services provided by non-DPC providers) which is necessary to support delivery of high-quality care and support care delivery that addresses total cost of care; monthly feedback reports on provider performance, including quality data; and monthly financial reports.

Additionally, to ease the burden related to reporting requirements under a new model, CMS should, to the extent possible, align reporting and reconciliation with those of other existing initiatives (e.g. ACOs, bundled payments and CPC+).

**4. Which Medicaid State Plan and other Medicaid authorities do States require to implement DPC arrangements in their Medicaid programs? What supports or technical assistance would States need from CMS to establish DPC arrangements in Medicaid?**

Trinity Health believes that if CMS explores a DPC model, it should consider making it a multi-payer model, including Medicaid. Including Medicaid in a DPC model that offers supplemental payments could incentivize greater provider participation in Medicaid, enhancing access to physicians'—and potentially other—services for Medicaid beneficiaries who are more likely to face barriers to care. However, if CMS explores this option, Trinity Health recommends that CMS consider necessary incentives (e.g. performance-based incentives, or support building the necessary infrastructure or capacity to participate) to encourage provider participation across the continuum (e.g. primary care, specialists, etc.) given existing barriers to participate in Medicaid in certain areas, and the unique challenges facing value-based payment programs in Medicaid.

**5. CMS is also interested in understanding the experience of physicians and practices that are currently entirely dedicated to direct primary care and/or DPC-type arrangements. For purposes of this question, direct primary care arrangements may include those arrangements where physicians or practices contract directly with patients for primary care services, arrangements where practices contract with a payer for a fixed primary care payment, or other arrangements. Please share information about: how your practice defines direct primary care; whether your practice ever participated in Medicare; whether your practice ever participated in any fee-for-service payment arrangements with third-party payers; how you made the transition to solely direct contracting arrangements (if applicable); and key lessons learned in moving away from fee-for-service entirely (if applicable).**

As noted earlier, Trinity Health—and its leadership—has significant experience establishing and supporting physician-led CINs, overseeing physician-run ACOs and participating in previous direct primary care capitation models. Based on our collective experience, we would like to share the following key lessons with CMS.

- First, it is important to note that managing capitated payments adds administrative complexity and potential burden on providers. This is especially true for small practices that have historically only operated within FFS and would have to manage systems to support FFS billing and capitated payments.
- Second, placing a cap on primary care payments without structuring these payments to encourage accountability for care across the full continuum may result in stinting of primary care services and the shifting of care to other, high-cost settings. Without the appropriate safeguards and incentives, this shifting can drive up overall health care spending. Earlier primary care capitation efforts (such as Primary Care capitation models of the 1980s and 90s) were not successful, partially because the structure of the models did not counteract financial incentives to limit care (stinting) or “cherry-picking” healthier patients or “lemon-dropping” complex patients who are high utilizers.

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- Third, we recommend that any model include patient-experience measures in its quality measure set, as this will help to protect against stinting.
- Fourth, a central component of any value-based payment program is tying performance on quality to payment. We believe this should be central feature of any DPC model to support provision of value-based care and dis-incentivize stinting.
- Finally, it is important that CMS consider that beneficiary choice and alignment with a practice does not guarantee consumer engagement. We recommend that any model include components that ensure providers actively engage with patients.

### **Questions Related to Beneficiary Participation**

- 6. Medicare FFS beneficiaries have freedom of choice of any Medicare provider or supplier, including under all current Innovation Center models. Given this, should there be limits under a DPC model on when a beneficiary can enroll or disenroll with a practice for the purposes of the model (while still retaining freedom of choice of provider or supplier even while enrolled in the DPC practice), or how frequently beneficiaries can change practices for the purposes of adjusting PBPM payments under the DPC model? If the practice is accountable for all or a portion of the total cost of care for a beneficiary, should there be a minimum enrollment period for a beneficiary? Under what circumstances, if any, should a provider or supplier be able to refuse to enroll or choose to disenroll a beneficiary?**

#### **Beneficiary Enrollment and Disenrollment**

Trinity Health is committed to providing people-centered care and encouraging beneficiary engagement in health and health care decision-making. As a result, we believe that beneficiaries should have the choice to enroll in any practice participating in a DPC model; however, we recommend that this option be available once a year—similar to annual enrollment in Medicare Advantage or annual alignment with an ACO under the MSSP or NextGen initiatives. Additionally, we think that any initiative should include a one-year enrollment period, with an appeals process. This will both promote a beneficiary's role in their care decision-making while also allowing practices to appropriately assess and respond to the needs of their patient population.

However, FFS beneficiaries should be able to opt-out of the program and be removed from the practices' attributed population at any time or transfer to another practice if their primary care physician moves practices. Additionally, we strongly recommend that beneficiaries not be reassigned from an ACO to a DPC practice during the year.

Last, we support CMS' goal to structure a DPC model to protect against cherry-picking or lemon-dropping of beneficiaries. As such, practices should not have the ability to choose or influence which beneficiaries enroll or dis-enroll. However, we do recommend that practices be able to prevent annual re-enrollment in cases where the individual receives over 50 percent of their primary care outside of the practice, or in special instances where the practice does not have the appropriate expertise necessary to manage a patient's care.

#### **Encouraging Use of Attributed Practice**

It is also important to note that a DPC model should be structured to incentivize beneficiaries to receive the majority of their care from their designated practice, without limiting freedom to seek necessary care from other providers. While waivers of cost-sharing have been used in other arrangements to incent beneficiaries to receive care from specific providers, the vast majority of Medicare beneficiaries have Medigap coverage and are therefore likely not incentivized by waiving cost-sharing. As a result, we encourage CMS to work with partners to explore more appropriate incentives to encourage beneficiaries to remain within their practice.

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- 7. What support do practices need to conduct outreach to their patients and enroll them under a DPC model? How much time would practices need to “ramp up” and how can CMS best facilitate the process? How should beneficiaries be incentivized to enroll? Is active enrollment sufficient to ensure beneficiary engagement? Should beneficiaries who have chosen to enroll in a practice under a DPC model be required to enter into an agreement with their DPC-participating health care provider, and, if so, would this provide a useful or sufficient mechanism for active beneficiary engagement, or should DPC providers be permitted to use additional beneficiary engagement incentives (e.g., nominal cash incentives, gift cards)? What other tools would be helpful for beneficiaries to become more engaged and active consumers of health care services together with their family members and caregivers (e.g., tools to access to their health information, mechanisms to provide feedback on patient experience)?**

#### Practice “Ramp Up” Support and Timeline

Practice transformation requires time to implement and to start seeing a return on investment in terms of better outcomes and controlled costs. Recognizing that practices need time to implement changes necessary to participate in new value-based care initiatives, Trinity Health recommends that under a DPC model, and any value-based care model, practices have 12 months to develop necessary tools, processes, infrastructure, and an outreach strategy. We also recommend that CMS provide technical support as well as templates for outreach and enrollment materials during any “ramp up” phase to both support practices and ensure outreach materials are consistent and include necessary information about the model.

#### Beneficiary Outreach

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, Trinity health recommends that as part of outreach under a DPC model, 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,
- any incentives the beneficiary could receive,
- their rights with respect to accessing care from other providers and dis-enrolling from the model,
- incentives for their provider to deliver high-quality care, and
- the potential for overall savings to the health system.

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.

#### Beneficiary Engagement and Incentives

Trinity Health also supports the use of tools and approaches that both encourage and make it easier for beneficiaries to engage in their health care. As part of a DPC model, we recommend that CMS consider tools that can help beneficiaries and their family members or caregivers easily access and understand their health information. Beneficiaries should also be able to share personal health data with third-party sources in a timely manner—and at no cost. Trinity Health would welcome being a resource to CMS in sharing lessons learned on effective beneficiary and caregiver engagement tools and approaches.

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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.

- 8. The Medicare program, specifically Medicare Part B, has certain beneficiary cost-sharing requirements, including Part B premiums, a Part B deductible, and 20 percent coinsurance for most Part B services once the deductible is met. CMS understands that existing DPC arrangements outside the Medicare FFS program may include parameters such as no coinsurance or deductible for getting services from the DPC-participating practice or a fixed fee paid to the practice for primary care services. Given the existing structure of Medicare FFS, are these types of incentives necessary to test a DPC initiative? If so, how would they interact with Medicare supplemental (Medigap) or other supplemental coverage? Are there any other payment considerations or arrangements CMS should take into account?**

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 DPC and preferred network. Given these challenges, we encourage CMS work with partners to explore appropriate incentives to encourage beneficiaries to remain within their practice.

#### **Questions Related to Payment**

- 9. To ensure a consistent and predictable cash flow mechanism to practices, CMS is considering paying a PBPM payment to practices participating in a potential DPC model test. Which currently covered Medicare services, supplies, tests or procedures should be included in the monthly PBPM payment? (CMS would appreciate specific Current Procedural Terminology (CPT®1 )/Healthcare Common Procedure Coding System (HCPCS) codes as examples, as well as ICD-10-CM diagnosis codes and/or ICD-10-PCS procedure codes, if applicable.) Should items and services furnished by providers and suppliers other than the DPC-participating practice be included? Should monthly payments to DPC-participating practices be risk adjusted and/or geographically adjusted, and, if so, how? What adjustments, such as risk adjustment approaches for patient characteristics, should be considered for calculating the PBPM payment?**

#### **PBPM Payment Structure**

As mentioned earlier, Trinity Health is concerned that any model that does not include accountability for total costs of care will create unintended consequences by redirecting care outside of the practices. We believe that a DPC model operating within a population-based, total cost of care model such as an ACO or a CIN –that includes DPC and non-DPC services— could best support care coordination across settings and providers, accountability for the cost of care, and appropriate use of care as well as support other needs such as helping practices implement CEHRT and assist with performance reporting and feedback. Within this construct, Trinity Health believes that a PBPM payment that appropriately values the full range primary care services (including non-face-to-face care) could provide an upfront, predictable payment level that allows for investments in infrastructure and care management required to succeed in such a model.

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### Risk Adjustment

Trinity Health supports the use of a prospective, risk adjusted payment model. To begin, we recommend that CMS should use the same approach to risk adjusting for ACOs and Medicare Advantage programs. However, we believe that CMS must evolve current risk adjustment models so they adjust for functional status, disease severity, and social risk factors. Launching a DPC-model could be an opportunity for CMS to test a more comprehensive risk adjustment methodology that takes into account the range of factors that affect an individual's health and their outcomes.

We believe when using measures to reward or penalize a provider, the context within which providers are working, and the patients whom they are serving, must be considered. Risk adjustment allows for fair cross-provider comparisons and does not penalize one provider over another or convey one provider is lower quality simply due to their willingness to treat any patient, or vulnerable populations more broadly, despite an increased risk in poor outcomes due to endogenous factors that are captured in proxy measures such as socio-demographic variables. For example, we recommend CMS to look at the [National Quality Forum's Report on Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors](#) as a resource to help expend their efforts in this area.

- 10. How could CMS structure the PBPM payment such that practices of varying sizes would be able to participate? What, if any, financial safeguards or protections should be offered to practices in cases where DPC-enrolled beneficiaries use a greater than anticipated intensity or volume of services either furnished by the practice itself or furnished by other health care providers?**

Trinity Health supports beneficiary choice and access, but believes a DPC model should incorporate safeguards for practices in circumstances in which beneficiaries use greater than anticipated volume of services from providers outside of the practice. To this end, we recommend that practices be able to prevent annual re-enrollment in cases where the individual receives over 50 percent of their primary care outside of the practice.

Further, in situations in which a beneficiary uses a higher intensity of services from a practice than anticipated, risk adjustment is necessary to ensure financial safeguards are in place to protect the practice. Additionally, it is important to note this will be more feasible for larger practices and those operating within an ACO.

- 11. Should practices be at risk financially (“upside and downside risk”) for all or a portion of the total cost of care for Medicare beneficiaries enrolled in their practice, including for services beyond those covered under the monthly PBPM payment? If so, what services should be included and how should the level of risk be determined? What are the potential mechanisms for and amount of savings in total cost of care that practices anticipate in a DPC model? In addition, should a DPC model offer graduated levels of risk for smaller or newer practices?**

### Financial Risk

Trinity Health recommends that a DPC model should operate within a population-based, total cost of care model such as an ACO or a CIN—that includes DPC and non-DPC services. Based on our experience, population-based models best support care coordination across settings and providers, accountability for the cost of care, and appropriate use of care. This may also allow practices to assume risk in the context of a larger organization that includes specialists and the full care continuum to comprehensively manage a patient's needs across settings and episodes of care.

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#### Level of Risk

Trinity Health recommends that the level of risk included in this model should, at a minimum, align with the nominal risk threshold for Advanced APM models established under the Quality Payment Program. This is similar to the approach CMS has taken with the CPC+ and MSSP Tracks 2, 3 and NextGen ACO models. We believe that recognition as an Advanced Alternative Payment Model could help to encourage participation in a DPC model.

#### **12. What additional payment structures could be used that would benefit both physicians and beneficiaries?**

We recommend CMS also explore models that encourage practices to partner with community-based organizations, local agencies and social service, which would support addressing the social-determinants of health.

Additionally, CMS should prioritize multi-payer models that include Medicaid and commercial payers to drive greater alignment across populations and reduce administrative burden on providers.

#### Questions Related to General Model Design

#### **13. As part of the Agency's guiding principles in considering new models, CMS is committed to reducing burdensome requirements. However, there are certain aspects of any model for which CMS may need practice and/or beneficiary data, including for purposes of calculating coinsurance/deductible amounts, obtaining encounter data and other information for risk adjustment, assessing quality performance, monitoring practices for compliance and program integrity, and conducting an independent evaluation. How can CMS best gather this necessary data while limiting burden to model participants? Are there specific data collection mechanisms, or existing tools that could be leveraged that would make this less burdensome to physicians, practices, and beneficiaries? How can CMS foster alignment between requirements for a DPC model and commercial payer arrangements to reduce burden for practices?**

#### Reporting Requirements and Data Collection

Trinity Health supports CMS' goal of minimizing administrative burden, but questions whether burden related to reporting requirements can be decreased under a DPC model. Our previous experience with capitated payments in primary care has shown that practices' burden increases as they have to adjust to manage two systems—one for Medicare FFS and one for a capitated payment.

However, Trinity Health proposes that there are a number of ways CMS could collect necessary data from practices without placing additional, or minimizing, administrative burden on practices, including allowing health plans to share encounter and claims data for provider organizations with which they have an existing Medicare Advantage contract with CMS.

#### Alignment of Quality Measures

Trinity Health believes that greater alignment of quality measures across programs will reduce the administrative burden for all providers and produce more actionable and relevant data for Medicare. A key element of harmonization is to ensure that data collection is standardized so that it can be leveraged across program. To this end, we recommend that CMS explore alignment of quality measures and performance-related reporting with those in existing Medicare Advantage contracts or ACO models. Additionally, we recommend that CMS limit the number of quality measures used in new models and initiatives to a manageable set (e.g., 5-7 measures) that emphasize patient-reported and patient-generated data.

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**14. Should quality performance of DPC-participating practices be determined and benchmarked in a different way under a potential DPC model than it has been in ACO initiatives, the CPC+ Model, or other current CMS initiatives? How should performance on quality be factored into payment and/or determinations of performance-based incentives for total cost of care? What specific quality measures should be used or included?**

A central component of any value-based payment program is tying performance on quality to payment. We believe this should be a central feature of any DPC model to support provision of value-based care and dis-incentivize stinting.

Quality Measures

Trinity Health believes that the Innovation Center can play an important role in testing the use of measures that are well-defined, evidence-based and designed to fill gaps in measurement without adding undue burden on providers. Further with relation to inclusion and further development of quality measures, we recommend and support:

- Regular review of measures used in existing and new models and programs for payment and removal of topped out measures.
- Collection of data to enable further development of patient-reported outcomes measures (PROMs) and functional status measures into a demonstration's quality measure set.
- Engagement of patients in development of provider performance measures that are relevant to them and can be applied across all payers.
- Support for instruments that measure both disease-specific and quality of life outcomes.

**15. What other DPC models should CMS consider? Are there other direct contracting arrangements in the commercial sector and/or with Medicare Advantage plans that CMS should consider testing in FFS Medicare and/or Medicaid? Are there particular considerations for Medicaid, or for dually eligible beneficiaries, that CMS should factor in to designing incentives for beneficiaries and health care providers, eligibility requirements, and/or payment structure? Are there ways in which CMS could restructure and/or modify any current initiatives to meet the objectives of a DPC model?**

We believe that for models to be more attractive to small or independent practices, CMS needs to ensure participation is financially viable and not administratively burdensome. Based on our experience, there should be an emphasis on total cost of care models that limit carve-outs of populations or conditions and recommend that the Innovation Center test –or build on existing—APMs that drive accountability for total cost of care, including behavioral health or mental health and substance use services and care. Building on—and fostering greater sustainability of— models that are comprehensive and have demonstrated triple aim success while reducing fragmentation is critical. In particular, continuing and evolving the Next Generation ACO model based on feedback from participating providers could powerfully advance common goals.

Medicaid Models

We also recommend that CMS consider permitting select ACOs with demonstrated expertise in assuming risk to become financially accountable for a regional population of Medicaid, Medicare and dual eligible beneficiaries. This model would test improvements in patient health status and savings generated through combining numerous Medicare and Medicaid programs into a single, seamless program with a single regulatory standard and funding stream. Beneficiaries—who today could receive services and care management across different programs—would now have a single accountable care team responsible for coordinating all of their health care services based on clinical and social needs. The accountable care team, situated within a single integrated delivery system, would collaborate closely with both payers and providers to generate a unified care plan, reflecting all health care needs and relevant social supports. In addition, CMS could partner with ACOs to

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refine existing models in order to allow qualified ACOs to voluntarily assume full financial risk for dual eligibles' Medicaid benefit. CMS should use its authority to support these refinements as appropriate, including but not limited to 1115 waivers or state plan amendments, to incorporate Medicaid financing within ACO models.

### **Questions Related to Program Integrity and Beneficiary Protections**

- 16. CMS wants to ensure that beneficiaries receive necessary care of high quality in a DPC model and that stinting on needed care does not occur. What safeguards can be put in place to help ensure this? What monitoring methods can CMS employ to determine if beneficiaries are receiving the care that they need at the right time? What data or methods would be needed to support these efforts?**

#### Total Cost of Care Model

As previously stated, Trinity Health is concerned that any model that does not include accountability for total costs of care will create misaligned incentives and unintended consequences by redirecting care outside of the practices. This could result in unnecessary or inappropriate care for beneficiaries and increased costs to the Medicare program. This is especially an issue for small practices, that will be incentivized to unduly influence beneficiaries related to enrollment (cherry picking and lemon dropping) or shift care to inappropriate, often higher-cost settings in order to see savings under the capitated payment. As a result, Trinity Health recommends that a DPC model should operate within a population-based, total cost of care model such as an ACO or a CIN which as a result of their construct have safeguards that support care coordination across settings and providers, accountability for the cost of care, and appropriate use of care.

#### Quality Measures

As discussed above, use of appropriate quality measures is necessary to ensure delivery of high-quality care and protect against stinting or inappropriate care. We strongly recommend that CMS include out-comes based measures, including patient-reported outcomes, as well as disease-specific measure sets.

- 17. What safeguards can CMS use to ensure that beneficiaries are not unduly influenced to enroll with a particular DPC practice?**

It is essential that beneficiaries in new models are not unduly influenced to enroll—or not enroll—with a particular practice and that they understand their participation and the potential impact of the model on the care. As stated above, Trinity Health recommends that as part of outreach under a DPC model, 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,
- any incentives the beneficiary could receive,
- their rights with respect to accessing care from other providers and dis-enrolling from the model,
- incentives for their provider to deliver high-quality care, and
- the potential for overall savings to the health system.

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 MSSP ACOs were not effective at communicating information about the model of care or potential benefits to enrollees. We also strongly recommend that CMS

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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.

- 18. CMS wants to ensure that all beneficiaries have an equal opportunity to enroll with a practice participating in a DPC model. How can CMS ensure that a DPC-participating practice does not engage in activities that would attract primarily healthy beneficiaries (“cherry picking”) or discourage enrollment by beneficiaries that have complex medical needs or would otherwise be considered high risk (“lemon dropping”)? What additional beneficiary protections may be needed under a DPC model?**

Protecting Beneficiary Choice

As previously stated, Trinity Health supports beneficiary choice and access as well as CMS’ goal to structure a DPC model to protect against cherry-picking or lemon-dropping of beneficiaries. Practices should not have the ability to choose or influence which beneficiaries enroll or dis-enroll and we strongly recommend that CMS establish strict standards with regard to marketing and engagement (e.g. prohibited practices from targeted marketing to existing patients based on health status) as well as disincentives for practices to engage in these behaviors.

Additionally, we believe that CMS’ stated concerns with cherry picking and lemon dropping can better be addressed through total cost of care models, like ACOs, that allow providers to better respond to the acuity of patients by supporting coordination across the care continuum. These models also include quality measures and risk adjustment to incent high-quality care. To this end, we recommend that CMS consider further strengthen these models (e.g. continue to refine risk adjustment, align quality measures, and strengthen performance incentives) to attract greater provider participation.

Review Claims History to Prevent Discrimination To prevent discrimination based on health status, CMS could review the recent claims history of beneficiaries who enroll in a DPC program. If it appears that a practice may be discriminating based on health status, CMS should reserve the right to review further claims/encounter data from the practice’s Medicare Advantage and FFS beneficiaries to ensure that the organization is not cherry-picking the healthiest beneficiaries to enroll in the DPC model.

- 19. Giving valuable incentives to beneficiaries to influence their enrollment with a particular DPC practice would raise quality of care, program cost, and competition concerns. Providers and suppliers may try to offset the cost of the incentives by providing medically unnecessary services or by substituting cheaper or lower quality services. Also, the ability to use incentives may favor larger health care providers with greater financial resources, putting smaller or rural providers at a competitive disadvantage. What safeguards should CMS put in place to ensure that any beneficiary incentives provided in a DPC model would not negatively impact quality of care, program costs, and competition?**
- 20. How can CMS protect beneficiaries from potential risks, such as identity theft, that could arise in association with a potential DPC model?**

Questions Related to Existing ACO Initiatives

- 21. For stakeholders that have experience working with CMS as a participant in one of our ACO initiatives, how can we strengthen such initiatives to potentially attract more physician practices and/or enable a greater proportion of practices to accept two-sided financial risk? What additional waivers would be necessary (e.g., to facilitate more coordinated care in the right setting for a given patient or as a means of providing regulatory relief necessary for**

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**purposes of testing the model)? Are there refinements and/or additional provisions that CMS should consider adding to existing initiatives to address some of the goals of DPC, as described above?**

#### Strengthening Current Initiatives

As noted above, Trinity Health is currently participating in Medicare ACOs in 16 markets, with five markets partnering as a Next Generation ACO. Primary care is foundational to the success of ACOs and we believe strongly that creating a mutually exclusive DPC model could detract from CMS' ACO initiatives' successes and undermine the investment in current models at a critical inflection point for these programs.

Building on—and fostering greater sustainability of— models that are comprehensive and have demonstrated triple aim success while reducing fragmentation is critical. Trinity Health offers the following recommendations to CMS to foster beneficiary engagement, reduce burdens on participating providers, and support greater market-based innovations by strengthening and evolving these existing programs.

- Direct Provider Contracting with CINs. DPC principles could be applied to ACOs and CINs. For instance, CMS could contract directly with CINs, which have experienced developing the necessary services and capacity to support delivery of high-quality, efficient primary care services, and ultimately help control total cost of care. Additionally, CINs are well positioned to scale. Such an approach could be the next iteration of ACOs, building upon the Next Generation ACO model.
- Changes to MSSP Track 1 Bonus Only. Based on our experience, we believe that current ACO models do not offer the opportunity to share in significant upside potential without taking additional downside financial risk in the model beyond these investments. To attract more ACOs to make these significant investments, we recommend offering 80% share in the upside potential with no downside financial risk for up to three years, after which an ACO must generate savings to stay in the model. We also recommend that all of the features associated with the downside risk models such as robust waivers and prospective beneficiary alignment should be available to drive savings farther and faster.
- Full Risk ACO with CMS as TPA. We recommend that CMS consider allowing any ACO that is willing and able to assume full risk across Parts A, B and D to do so, and to market the ACO product directly to consumers. We believe this would allow providers willing to assume full risk to do so, with CMS remaining as the claim payer, enrollment and stop-loss organization, similar to a third party administrator (TPA). This model provides a lower-cost option to Medicare beneficiaries while generating savings for Medicare, promoting market competition and consumer-directed care.
- Full Risk ACO with capitation. We recommend that CMS consider allowing any ACO that is willing and able to become fully capitated across Parts A, B and D to do so, and to market the ACO product directly to consumers. We believe this would allow providers willing to assume full risk, to remain as the enrollment organization.

#### Refinements and Additions to Existing Models

In addition to proposing advanced versions of existing ACO initiatives, based on our experience and based on market-based learnings, we have also identified the following opportunities for refinement and improvement of existing models that would also advance CMS' goals outlined in the current RFI.

- Prospective Beneficiary Assignment. Expand testing of prospective beneficiary assignment in each model or track, which increases provider transparency and accountability for patient care and performance. Prospective assignment would also increase certainty for the ACO and provide a more narrowly defined, stable, target population and help minimize unexpected changes in its benchmark.
- Waivers. Expand eligibility for Medicare waivers in a manner that is not prohibitively burdensome to ACOs that utilize them – and streamline the waiver process. Waiving certain

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payment regulations is essential so that these models can effectively coordinate care and ensure that it is provided in the right place at the right time. This includes SNF 3-day waivers and waivers to rules limiting post-acute care payment.

- Fraud and Abuse Waivers. We also recommend that CMS and the Office of the Inspector General prioritize development of unified guidance related to the program's fraud and abuse waivers and develop a more expedited approach for providers to get input on what qualifies under waivers.
- Supplemental Benefits. In line with CMS' interest in testing models with a consumer drive focus that may be alternatives to FFS and MA, we recommend giving ACOs and total cost of care models the explicit ability to provide supplemental services, including social services, transportation for specific clinical purposes or a remote patient monitoring system. This approach would be similar what is allowed in MA Value-Based Insurance Design (VBID) Model under "Coverage of Additional Supplemental Benefits". Experience demonstrates that these care management initiatives have the potential to achieve meaningful improvements in quality and reductions in cost.
- Site of Care Restrictions. The Innovation Center should also consider waiving site of care and/or Medicare Parts A, B and D restrictions to support increased access to high-value care for consumers, such as through "hospital at home" programs. These waivers provide ACOs and total cost of care models with valuable tools to foster greater accountability for increasing quality and reducing unnecessary costs across the full continuum.
- Benchmarks. Trinity Health believes it is important for CMMI to recognize that there should not be a one-size-fits-all solution to setting benchmarks. There should be different benchmarking approaches to appeal to providers that have (1) those that don't have prior experience in risk-based models and are higher-cost providers and (2) those that already participated in CMMI models or MSSP and have done work to reduce costs and improve quality.
  - We urge CMMI to consider a benchmarking approach that not only accounts for the shared savings in reset benchmarks, but to account for all savings – not just the ACO's portion – and add that amount to reset benchmarks. We believe that CMMI will be best served by creating a benchmark that presents real opportunity for savings, thereby encouraging providers to aggressively invest and manage quality and cost.
  - Additionally, Trinity Health recommends that new and existing models test changes to benchmarks that move away from a simple historical amount toward a more fully regional baseline that is reflective of the actual market in which a provider operates. CMS should also test market-based benchmarks that include a national factor/portion in the blend which will result in redistribution of dollars for high-cost markets to lower-cost markets.
- Incorporate Social Determinants of Health into Models. 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 the Innovation Center 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. Specifically, the Innovation Center should consider scaling community health worker programs as well as enhanced care management programs that target high need, high cost patients.

**22. Different types of ACOs (e.g., hospital-led versus physician-led) may face different challenges and have shown different levels of success in ACO initiatives to date. Would a DPC model help address certain physician practice-specific needs or would physician practices prefer refinements to existing ACO initiatives to better accommodate physician-led ACOs?**

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As described above, Trinity Health recommends that CMS make adjustments to existing ACO initiatives to better support physician-led ACOs and identify opportunities to incorporate the components of direct provider contracting into two-sided risk ACOs. Primary care is foundational for success in ACOs and we believe strongly that creating a mutually exclusive direct provider contracting model could detract from CMS' ACO initiatives' successes and discount the investment in current model at a critical inflection point. To this end, we urge CMS to consider ways to build on—and foster greater sustainability of— models that are comprehensive and have demonstrated triple aim success while reducing fragmentation is critical.

**CONCLUSION**

We thank CMS for the opportunity to comment on this RFI and intend for our comments and recommendations to reflect our strong interest in testing new— and evolve existing models and programs— that drive value-based care, promote population health, and engage beneficiaries. As an organization, we are committed to rapid, measurable movement toward value in the delivery of—and payment for—health care. We look forward to working with you advance our shared goals and to partnering with the Innovation Center. If you have any questions or need further information, please feel free to contact me at [wellstk@trinity-health.org](mailto:wellstk@trinity-health.org) or 734-343-0824.

Sincerely,



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