Trinity Health

November 17, 2017

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Submitted electronically to: CMMI_NewDirection@cms.hhs.gov

Dear Administrator Verma,

Trinity Health appreciates the opportunity to offer recommendations in response to the Centers for Medicare & Medicaid Services: Innovation Center New Direction Request for Information (New Direction RFI), which outlines guiding principles the Agency will use to direct new model design as well as proposed models types for testing. We support the Innovation Center's efforts to test market-based reforms that promote patient-centered care and that empower beneficiaries as consumers, provide transparency and drive quality, reduced costs and improved outcomes.

Trinity Health 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. Trinity Health includes 93 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 2,095 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 131,000 colleagues, including more than 7,500 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 22 Clinically Integrated Networks that are accountable for 1.3 million lives across the country.

As an organization, we are committed to rapid, measurable movement toward value in the delivery of and payment for health care. The Trinity Health Board of Directors have approved our system wide strategy to "Build a People Centered Health System that would be accountable for delivering better health, better care and lower costs for the communities we serve. Our People Centered 2020 Plan includes initiatives to transform the way we deliver care and the ways we are reimbursed. One of our goals is to have 75% of our revenue flowing through alternative payment models by 2020. To that end we currently are accountable for 1.3 million individuals with a total medical spend of $8.3 B across our system. We are currently participating in seven Medicare Shared Savings Program (MSSP) Track 1 ACOs in fourteen markets. Five markets partnering as a Next Generation ACO and five markets are partnering as an MSSP Track 3 ACO. In addition, we have 33 hospitals participating in the Model 2 Bundled Payments for Care Improvement (BPCI) initiative, 11 Skilled Nursing Facilities (SNFs) in Model 3 BPCI, and two hospitals in the Comprehensive Care for Joint Replacement (CJR) program. Our work extends beyond Medicare as illustrated by our participation in 101 non-CMS APM contracts.

Our comments reflect this broad based experience to date and advocate positions that we believe offer CMS the best chance for accomplishing broad delivery-system engagement, investment and ultimately transformation.

We especially look forward to working with the Innovation Center to promote transparent model design across all payers, to support evaluation and measurement of model impacts, and to develop market-based innovations that build on promising practices. Trinity Health urges CMS, through the Innovation Center, to test new – and evolve existing models and programs – that drive value-based care, promote population health and engage beneficiaries. Trinity Health appreciates the opportunity to comment and engage on the future direction of the Innovation Center.

Financially Rewarding and Sustainable Models Are Imperatives

Providers are hungry for programmatic changes that will offer a more promising, predictable and sustainable value opportunity for well-executed programs. Recognizing that delivery transformation represents the best long-term solution to reducing the financial burdens of the Medicare and Medicaid programs, CMS should adopt a long-term strategic approach that entices as many providers as possible to participate and invest. Healthcare providers, hospitals, physicians and others are facing a very challenging environment today with escalating costs, declining or flat reimbursements and heightened demand for services, and an increasingly complex regulatory environment. At the same time, they are delivering highly proficient and complex care to individuals at their most vulnerable time. Transforming care requires a fundamental change to (1) provider approaches to care, (2) the size and character of our work force, (3) capital investments, (4) IT systems and (5) virtually all aspects of our operations. Providers need to make significant investments to support and drive these changes. Those investments compete with other proposals that often have a much more direct impact on clinical operational success. In a world where participation in these models is voluntary, decision makers will weigh the impact and the likely return on investment for these efforts compared to other investments. Most models do not include perspective payments to cover these investments. Thus to ensure that providers make the right investments at a minimum CMS should develop models that present a reasonable expectation for positive returns and return on their investment. Specific issues to address include establishment of benchmarks, avoiding rebasing of targets, higher portions of shared savings to providers.

Multi-payer Cooperation is Essential:
Unfortunately, the private payer sector has not yet fully embraced alternative payment models. As has always been the case, they are waiting to see what Medicare does and ultimately will probably copy the successful models. CMS should build on the experience to date with CPC to build multi-payer models to get the most impact

For instance, **transformation should be cross-payer with Medicare, Medicaid, commercial payers, employers and federal and state agencies, all employing available means to direct payer arrangements toward value.** CMS can most effectively engage providers by offering programs that are attractive, predictable and rewarding from inception. CMS can look for some of the shared savings initially, but should expect the majority of **the impact to be long-term decreases in the Medicare and Medicaid spending trends.**

Transformation will take time: our own experience is consistent with the national ACO experience, it takes several years to put the right operational processes in place to impact the total cost of care. There are few precedents for this approach to transforming an industry, especially one as large as health care. The introduction of APMs and new payment and delivery approaches should be viewed as tests of new models whose impact is uncertain. We should not prejudge the outcomes of a particular approach, and we should provide sufficient time for models to be adequately tested. With the implementation of DRG's it took the industry over 15 years to see the full impact on hospital length of stay. ACOs involve much more complex change affecting many more elements of the delivery system. We need to provide adequate time for a fair test of these models. Given that reality we should also avoid prejudging particular models. Rather we recommend testing a wide variety of models and seeing what work best.

Trinity Health Response to CMMI RFI
November 17, 2017

Evolve Existing Models and Structures to Foster Competition, Improve Quality and Reduce Costs

Through our own work at Trinity Health, and our participation in the private-sector led Health Care Transformation Task Force (HCTTF), we have been learning from existing Innovation Center models, especially the Medicare Shared Savings Program (MSSP), and Next Generation models that take a population-based approach to care delivery and payment and foster movement to total cost of care accountability. We believe that eliminating or significant scaling back these existing models before providers can actualize returns on their investment and make continuous improvements is a lost opportunity. While there is room for new models and innovations—which we offer as well in this response—there is significant opportunity to evolve existing models so that they can more successfully achieve the goals of improving quality, reducing costs and fostering competition in health care markets across the country. As the Innovation Center considers how to modify existing models, we offer a number of suggestions that would build on the investments already made in the market while fostering greater competition for the benefit of the patients we serve.

The Innovation Center should advance APMs that drive accountability for total cost of care, including behavioral health or mental health and substance use services and care. This includes models that incorporate care across the continuum with limited or no carve-outs of populations or services. The Innovation Center should consider models that put the needs of individual patients first and encourage better coordination of payment programs that support comprehensive and coordinated care across providers and settings. **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**. Additionally, we provide the following areas where existing models can be improved based on market-based learnings:

- Changes to MSSP Track 1 Bonus Only. As an organization that has seven ACOs and 22 clinically integrated networks creating value for patients and payers in 24 different communities, we have substantial experience with the changes that occur when providers come together to form an ACO. We know, first-hand, that care model changes to the care delivery system improve coordination across the continuum generating tangible improvements in patient outcomes. We have also experienced how the financial costs and risks associated with the start-up of these models requires an organization to take significant investment risk. Currently the models do not offer the opportunity to share in significant upside potential without taking additional downside financial risk in the model beyond these investments.

  We recommend a new approach which would attract more ACOs to make these significant investments by offering an opportunity of an 80% share in the upside potential with no downside financial risk for up to three years. After a three-year settlement timeframe (reducing random variation), an ACO must be generating savings to stay in the model. In addition to the more enticing financial terms, we 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.

- Prospective Beneficiary Assignment. Expand testing of prospective beneficiary assignment, which increases provider transparency and accountability for patient care and their own performance. Additionally, prospective assignment would increase certainty for the ACO and provide a more narrowly defined, stable, target population and help minimize unexpected changes in its benchmark. These should be an option in each model or track.

- Waivers. Expand eligibility for Medicare waivers in a manner that is not prohibitively burdensome to ACOs that utilize them. Waiving certain 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. In addition, Trinity Health urges CMS to make additional waivers available including those related to site of care, telehealth, hospital discharge planning requirements, homebound requirements for home health, and Medicare primary care co-payments that would enable providers to make optimal treatments options available to beneficiaries.

- Supplemental Benefits. In line with CMS' interest in testing models with a consumer drive focus that may be alternatives to fee-for-service (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. This could also include substituting alternative benefits for specific sub-populations or individuals when in doing so is expected to result in better care or outcomes at a better cost, and is offered as an option to the beneficiary.

- 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 by eliminating requirements amid what "part" of Medicare the benefit sits under.

- Benchmarks. Trinity Health believes it is important for CMMI to recognize that there should be not 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.

    - Historical cost benchmarks - One of the major criticisms of the MSSP program had been its use of a solely historical benchmark and national trend factors. Trinity Health supported the incorporation of regional FFS cost data along with a portion of the ACO's historical costs in reset benchmarks. However, in doing so, CMS reversed previous policy which was to add back shared savings to minimize the impact of the rebase. Now, it does not include savings in the previous agreement period when calculating the rebased benchmark for a new three-year agreement period. The agency argued that transitioning to a benchmark methodology that incorporates regional expenditures would mitigate the impact of no longer accounting for savings in subsequent agreement periods. 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.

    - Market-based benchmarks – 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.

- Simplify Quality Measurement. Trinity Health was delighted to hear about the new "Meaningful Measures" initiative of this Administration. Trinity Health is very pleased with the objectives set forth

for Meaningful Measures, and we look forward to providing input and learning more about where CMS is headed. We believe 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. Quality measures used in existing and new models and programs for payment should be reviewed regularly and be limited such that there are no more than five clinical measures and two patient experience measures and can be aligned across Medicare programs. Topped out measures should be removed. Additionally, patient experience measures should be PROMs, as tested in the Comprehensive Joint Replacement (CJR) initiative. Last, the Innovation Center can also promote reporting approaches that reduce administrative burden (e.g., electronic reporting from certified electronic health records and q-data intermediaries).

- Medicare ACOs and Part D. Trinity Health encourages the Innovation Center to test Medicare ACO models that include Part D drugs and to further management of total cost of care and alignment across benefits and services. This structure would be similar to how Medicare Advantage works. Models that include risk and accountability across all aspects of patient care, including drugs, would allow for greater opportunity and increased transparency (e.g. access to claims data, coordinated care plans, etc.) needed to further improve and coordinate care.

  We strongly believe that reliance on Part D Plans (PDPs) will be an insufficient way for ACOs to integrate Part D spending into their accountability models. The distinction between medical benefits and pharmaceutical benefits is an historical artifact that unfortunately creates misalignment between the goals of PDPs and ACOs. In models like the ACO, encouraging medication adherence becomes an important tool in containing overall health costs, even if it increases drug spending in the short term. Conversely, PDPs are naturally encouraged to reduce short-term drug spending. As a result, to make such a collaboration work successfully, ACOs and PDPs would need to carve out or make special allowances for adherence-dependent therapies.

  Integration of Part D expenditures also illustrates some of the challenges ACOs have with data timeliness. Since medication adherence is such an integral part of population health management, ACOs need to know about non-adherence quickly, far faster than a PDP could reasonably get such data to an ACO. Further, the high barriers for PDPs and ACOs in even identifying beneficiaries limit their ability to collaborate. Last, we recommend that as the Innovation Center considers models that include Part D risk arrangements, they should include testing risk adjustment methodologies that appropriately differentiate between levels of beneficiary severity, as they fundamentally affect the model of care provided to a patient, and overall outcome.

- Limit Overlap of Models. The recent implementation of APMs has resulted in instances of overlap, where multiple providers may be responsible for the same patient under different models. Competing models of accountability, can create inefficiencies and challenges that are ultimately at odds with the end goal of delivering higher quality and more integrated care. Trinity Health strongly urges the Innovation Center to limit overlap of models (e.g. episode-based and population-based payment models) where multiple providers may be responsible for the same patient under different models. **In instances where model overlap continues to exist, the total-cost-of-care model with full accountability for the patient over time should be the recipient of any savings overlap.**

- Encourage Multi-payer Models. Trinity Health strongly recommends that the Innovation Center support design and testing of cross-payer APMs – and Advanced APMs – by working with states to test Medicaid and multi-payer models. In doing so the Innovation Center should consider the unique needs of Medicaid beneficiaries and the capacity for providers serving these populations to assume risk, and set levels at sustainable and appropriate levels. States—in partnership with the federal government—have implemented a range of multi-payer models and the Innovation Center can build on promising approaches or those that have already started to yield positive impact on outcomes and costs. For example, Maryland's all-payer hospital global payment model, which has moved 100

percent of hospital payments into population-based payments, has demonstrated savings to the Medicare program for hospital expenditures ($538 million cumulatively since 2014), and reduced readmissions rates. Ohio has taken a different approach under its State Innovation Model (SIM) and launched episodes of care and a patient-centered medical home model that includes Medicaid, commercial, state employees, and which the state is working to align with Medicare models.

Last, states may need longer timeframes to design and gain participation in multi-payer models, for which future SIM or similar efforts should account. In addition, the Federal government could advance APM development and participation through the Federal Employee Health Benefit Program (FEHBP). FEHBP could require that participating payers offer APM arrangements for providers in their networks, and require all parties to demonstrate progress and performance on quality, outcomes, patient experience, and cost trend over time.

- Incorporate Social Determinants of Health into Models. Trinity Health is committed to advancing the health of individuals and populations. We strong 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. For example, Michigan is using Community Health Innovation Regions (CHIRs) to conduct community health needs assessments to identify local and regional social determinants of health that will inform action plans to address key population health priority areas and connect providers with community partners. Idaho, as part of its SIM, developed a Community Health Worker training program to capitalize on community-based workers and resources better aimed at addressing population health needs.

- Improve Information Sharing and Transparency. CMS should supply sufficient technical information when proposing new payment models to allow stakeholders to realistically evaluate payment impact. Models such as BPCI and CJR incorporate benchmarking and reconciliation processes that are both complicated and complex. Process step descriptions that are not accompanied by examples using real data do not allow model participants to accurately forecast the economic consequences of such models to their institutions, clinicians and patients. Such opacity discourages potential participants in voluntary payment models and imposes unfair expectations upon participants in mandatory models. Payment model methodologies (including all components of those methodologies) should be transparent to all health care providers, payers, purchasers, and patients involved in an episodic or population-based payment model.

Expanded Opportunities for Participation in Advanced APMs

- Adjusting the Definition of "More than Nominal" Risk. In order to expand participation in Advanced APMs, we recommend that CMS evolve the definition of nominal risk to include the investment risk assumed by all ACOs including Track 1. Currently, financial risk is defined as monetary loss that is tied to performance under the model as opposed to costs related to financial investments made by APMs. Trinity Health strongly disagrees with this perspective and believes that this definition does not take into account the significant investment that is required to redesign care delivery to improve beneficiary health. These investments include the following:
  - Care managers and patient educators, who provide non-billable services to beneficiaries.
  - Engaging billing providers in redesigning care delivery, and training staff to change their approach to patient care.
  - Developing and implementing technology to identify and engage patients on a proactive basis.

- Utilizing new population health management tools as well as advanced analytics and reporting.
- Coordinating patient care between visits.
- Upgrading appointment systems to ensure easy and timely access for high-risk patients.
- Expanding access to clinicians after hours to meet patients' urgent needs.

For example, the multi-year investment to start up and run an ACO can be in excess of $3-5 million over a 3-year period with no guarantee of achieving savings, even if an ACO reduces Medicare spending. ACOs incur ongoing costs for care management, consultation between different physicians, and other services that are not covered by Medicare FFS payments, and will not usually generate a return within the investment year. Beyond the initial investment costs and ongoing operating costs, providers also forego their own FFS billings when they successfully reduce hospital admissions, readmissions and other billable events.

To expand participation in Advanced APMs, CMMI could evaluate ways to redefine nominal risk in a way that considers the investments made as a critical component or risk, and thus allow MSSP Track 1 ACOs to qualify as an Advanced APM.

- Or - Providing Transition Period for Track 1 ACOs to Count as Advanced APMs. Until the time that CMS adjusts the definition of nominal risk to include Track 1 ACOs, we strongly encourage a transition period within which MIPS APMs qualify as Advanced APMs. Historically CMS has used transition periods to provide a pathway for stakeholders to implement new policy. A transition period would expand Advanced APM participation and further the broad public policy goal of advancing transformation of the delivery and payment system.

  An example of the recommendation of a transition period would allow MSSP Track 1 ACOs to meet the Advanced APM definition for three years, with the expectation that such ACOs transition to a two-sided risk model by the end of that three-year period or the end of the existing ACO contract term. By providing a more flexible approach, it would establish the expectation that MSSP Track 1 ACOs would move forward into two-sided risk, while also recognizing and rewarding the transformation that is already taking place in that initial period of investment.

- Thresholds for Qualifying as an Advanced APM. We encourage the Innovation Center to test models that use broader and more flexible thresholds for nominal risk across Advanced APMs and Other-Payer Advanced Payment Models (including Medicare Advantage (MA), PACE, Medicare-Medicaid Plans (MMPs) and Medicaid). Trinity Health believes that the amount of risk an entity bears must take into account the significant investment of capital and other resources necessary to redesign care delivery to improve beneficiary health (e.g. care management infrastructure, patient education, staff training, development of patient management and engagement tools, etc.) and we recommend these factors be considered when designing models.

  Further, Trinity Health encourages the Innovation Center to examine how existing risk arrangements in MA, PACE, and MMPs meet Advanced APM criteria and explore testing these models in advance of Other-Payer Advanced APMs starting in 2019. We believe this is important for promoting cross-payer alignment and reducing administrative burden for providers across payers and programs. We also encourage the Innovation Center to explore approaches through which providers or entities participating in existing commercial ACO or bundled payment could qualify for Advanced APM status.

- Eligibility of PACE as Advanced APM. Trinity Health PACE operates 13 programs in nine states across five CMS regions, including Regions 1, 2, 3, 4 and 5. These Trinity Health PACE programs serve approximately 3,800 participants nationwide. Based on its extensive PACE model experience, Trinity Health urges CMMI to use its demonstration and waiver authorities to recognize the PACE model as currently configured as an Advanced APM and to allow PACE contract clinicians to apply their PACE patient care towards reaching Qualifying Participant status.

The PACE model satisfies most of the Advanced APM requirements. Waivers of the remaining requirements seem readily justifiable since the PACE model meets or exceeds standards for communicating clinical care and for continuous quality assessment and monitoring, and the PACE organization bears full, capitated, financial responsibility for each beneficiary's costs of care. Recognizing the PACE model as an Advanced APM would incentivize PACE participation by more clinicians, who thereby would gain increased probability of reaching QP status, while facilitating the sustainability and expansion of a sophisticated, totally integrated, alternative payment model that is already active and been proven successful. **We strongly encourage CMS and CMMI to issue the waivers necessary to recognize the PACE model as an Advanced APM as soon as operationally feasible.**

Consumer-Directed Care and Market-Based Innovations

Trinity Health urges the Innovation Center to continue to advance sustainable, continuous, total cost of care models including ACOs. Trinity Health offers the following recommendations to CMS to support greater market-based innovations, to foster consumer-directed care, and to reduce regulatory burdens on participating providers.

- Full Risk ACO with CMS as TPA. Trinity Health has demonstrated successfully that ACOs are a viable alternative to FFS and MA. 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 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. Trinity Health has demonstrated successfully that ACOs are a viable alternative to FFS and MA. 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, with CMS remaining as enrollment organization. CMS should look for ways to use ACOs as options for bringing a lower cost approach as compared to MA.

- Innovating and Expanding Use of the PACE model for Medicare-only Beneficiaries
  The majority (or, 90%) of participants in traditional PACE are dual eligible beneficiaries, given that (1) Nineteen states have not elected PACE as a Medicaid state option (preventing Medicare-only beneficiaries from accessing PACE services), and, (2) PACE requirements related to Medicare-only beneficiaries' Part D premiums and premiums for non-Medicare covered services in PACE prevent Medicare beneficiaries from enrolling in PACE in large numbers. A PACE pilot directed at Medicare-only beneficiaries would promote consumer choice and enhance Medicare beneficiaries' access to PACE. We recommend CMMI proceed with a pilot including the following three components:
  1. Allow for two-way program agreements in states that have not elected PACE as an option: A two-way agreement between a PACE organization and CMS would provide Medicare-only beneficiaries access to PACE in the 19 states which have not elected PACE as a state option.
  2. Allow PACE organizations to develop Part D coverage options for Medicare-only individuals.
  3. Allow PACE organizations greater flexibility to set premiums for non-Medicare services for Medicare-only participants.

  Expanding Medicare beneficiaries' access to PACE in states that have not elected PACE as a Medicaid option would require all three components of the pilot. For PACE organizations in states that already have PACE, only components 2 and 3 are needed to enhance Medicare beneficiaries' access to PACE.

- Normalize the Use of Hierarchical Condition Category (HCC) Coding Across ACOs & MA. While Trinity Health acknowledges that HCC coding is flawed, it is important to have consistency across programs. It is important that CMS take steps to normalize HCC coding across MA and ACOs.

- Incentivizing Use of High-Value Providers While Maintaining Beneficiary Choice. Meaningfully engaging beneficiaries as partners in care and delivering patient-centered care that meets the needs of patients and families is the best way to encourage beneficiaries to consistently seek care from providers in APMs. To this end, Trinity Health strongly encourages that CMS develop policies that would lower the out-of-pocket-cost burden and encourage beneficiaries to seek care from APM-aligned providers. The would be similar to what is allowed in the MA Value-Based Insurance Design (VBID) Model under "Reduced Cost-Sharing for High-Value Providers."

  Because the majority of beneficiaries have Medigap coverage that blunts the effects of changes in cost-sharing policies, Trinity Health encourages CMS to allow ACOs to offer "wrap around" Medigap products with pricing and cost-sharing to encourage beneficiaries to use APM providers without requirements for network adequacy and geographic boundaries of service areas.

- Price & Quality Transparency. Trinity Health supports transparency and believes that CMS should work to help consumers understand price and quality information. More and more stakeholders are providing cost and quality information to consumers to enable informed care decision making. Gross level charges, however, are not useful to patients in that it does not consider contractual allowances, plan coinsurance structures, charity care policies, mission driven expenses such as teaching programs, etc. Moreover, it is difficult to identify the actual costs associated with care because the components such as staffing, overhead, and materials costs are accounted for inconsistently across the health care system. CMS should consider ways to progress in being able to better identify costs, which would assist in estimating expected payment by the uninsured, under-insured and those patients with health savings accounts.

Physician Specialty Models

Consistent with our earlier recommendations—while the Innovation Center should test physician specialty models—there should be an emphasis on total cost of care models that limit carve-outs of populations or conditions. In addition, it is especially important to limit overlap across models,especially ACO and total cost of care models and episodic, specialty-focused models. Patient needs should be at the center of all models; and models should, therefore, be designed to coordinate care across the continuum.

Advanced Bundled Payment for Care Improvement Initiative (BPCI)
Trinity Heath recommends that the Innovation Center implement an Advanced BPCI model. We believe that clinical episode-based models can promote high-quality, high-value care for Medicare beneficiaries, and that models should allow entities to assume flexible levels of risk that enable them to also meet Advanced APMs criteria.

While Trinity Health urges CMS to utilize various models of care ACOs and different models for bundling to transform as much of the delivery system as possible to APMs. Trinity Health Senior Communities has been a successful participant in the CMS Bundled Payment Care Model 3 program for the past two plus years. **Our post-acute bundles have generated significant savings for Medicare and the program is anticipated to sunset next fall in 2018. Bundled programs in the post-acute setting should be a critical part of a new bundled options that proposed by CMMI.** Trinity Health also believes that CMS should re-consider opportunities where it makes sense to pilot mandatory bundling programs.

- Limit Overlap of Models. The recent implementation of APMs has resulted in instances of overlap, where multiple providers may be responsible for the same patient under different models. Competing

models of accountability, can create inefficiencies and challenges that are ultimately at odds with the end goal of delivering higher quality and more integrated care. Trinity Health strongly urges the Innovation Center to limit overlap of models (e.g. episode-based and population-based payment models) where multiple providers may be responsible for the same patient under different models. **In instances where model overlap continues to exist, the total-cost-of-care model with full accountability for the patient over time should be the recipient of any savings overlap.**

- Rebasing. Similar to our position on benchmarking with the ACO models, Trinity Health urges CMMI to consider a rebasing approach that accounts for all of the shared savings in reset episode prices. 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.

Prescription Drug Models

The Innovation Center has already shown a willingness to bring greater value to drug pricing. Trinity Health believes rising drug costs are a significant issue for beneficiaries, payers and providers. We encourage the Innovation Center to work with all stakeholders, including beneficiaries, payers, providers, pharmacy benefit managers (PBMs) and drug manufacturers in testing changes to drug pricing models; and in designing value-based payment arrangements that are transparent and tied to outcomes to ensure that there is increased access to affordable drugs and improvements in quality. We urge CMS to work with all those affected by prescription drug pricing to design models to ensure they are improving quality, outcomes, and reducing total cost of care.

Medicare Advantage (MA) Innovation Models

Medicare Advantage Special Needs Plans (SNPs). Trinity Health recommends that the Innovation Center test changes to the SNP program that allow providers to more easily compete for covered lives in SNPs, either through direct provider contracting with CMS, provider-based SNPs, or other means. Testing such a model could also provide an alternative to MA and FFS models. To be considered for contracting with CMS, these providers must develop a required skill set (e.g., paying claims, compliance expertise, etc.), meet the ACO financial reserve requirement, and establish a qualifying network of providers with which a health plan must contract. Or, the Innovation Center could also evaluate the opportunity for the SNP to use CMS as the claim payer, enrollment and stop-loss organization, similar to a TPA.

Trinity Health believes that allowing providers to participate as SNPs would enable even more CMS dollars to be used for care of members or be reinvested into the community. Potential benefits of a provider-sponsored SNP model include:

- Provider-sponsored SNPs can offer unique opportunities that improve beneficiary outcomes.
- Providers can better build upon the existing trusted provider/patient relationship.
- Integrated Care Teams can define protocols and care patterns with knowledge stemming from trusted relationships and hands on experience.
- Providers can leverage their proximity to data to more effectively provide immediate adjustments to care.

State-Based and Local Innovation, including Medicaid-focused Models

Trinity Health believes that states make great incubators for health care innovation and transformation both within the Medicaid program and through cross-payer models. Trinity Health supports the design and testing of multi-payer, state-led APM—including Advanced APMs—which leverage the unique position states are in to serve as incubators for new care and payment delivery models. Today, states are employing a range of innovations—through their Medicaid programs and cross payer efforts such as state

innovation models—and their buy-in and support is critical to the stability and sustainability of reform efforts.

Across the Trinity Health footprint, we care for more than five million individuals covered by Medicaid, including more than one million who have gained coverage as a result of Medicaid expansion. We celebrate the health improvements achieved from individuals having coverage and see the economic benefits in our communities. We believe there is significant opportunity for innovation within the Medicaid program and have embraced expansion and payment and delivery reform initiatives in many of our states.

Medicaid Innovation. Trinity Health believes that Medicaid innovation should put patients at the center of innovative approaches that drive value without creating obstacles to care. We believe that innovation within the Medicaid program creates the opportunity for states to implement public policies that support patient-centered care, better health, better care and lower costs to ensure affordable, high-quality, people-centered care for all. To support this view, we have developed a Medicaid Innovation Resource Center, which includes public policy tools and resources that aim to increase transparency and help stakeholders assess the impact of emerging policy trends and innovations on states, beneficiaries and care.

As part of this work, we have developed the following safeguards and principles around how best to innovate while ensuring sustainability within this important safety-net program; and encourage the Innovation Center to consider the following in developing Medicaid-focused models:

- Innovation should ensure comprehensive and affordable coverage and care that engages Medicaid beneficiaries in their health care decision-making and ensures access to benefits that improve their health.
- Reforms should build on sustainable and shared Federal and State funding that ensures Medicaid is sustainable for years to come. We believe that this requires adequate federal funding for all enrollees, including expansion populations, especially in times of economic distress or unforeseen public health crisis.
- States must be encouraged to use their Medicaid programs to provide value-based care—including through Medicaid managed care partners—to drive accountability through participation in APMs for health outcomes and reduced costs, which is necessary to improve health on a national scale.

Multi-Payer, State-Based Models. In addition to Medicaid innovation, states are ripe for testing multi-payer innovations. First, we strongly encourage the Innovation Center to continue to build on existing cross-payer models, including SIM grants given their progress in driving state-led health care transformation and innovation. With facilities in nine SIM Testing states and five SIM Design states, Trinity Health has been a leader on SIM public policy development, influencing the pace and process by which our states reach the goal of achieving value-based, APMs for 80 percent of their population. Through work partnering with state leaders and other stakeholders to shape and evaluate state's SIM reform efforts and other cross-payer initiatives, we have identified essential components of successful multi-payer reforms, which include:

- Multi-stakeholder engagement (e.g. beneficiaries, providers, plans, state leaders, etc.).
- Multi-payer engagement (e.g. Medicare, Medicaid, commercial, state employee health programs, and FEHBP).
- Robust Health Information Technology (HIT) infrastructure.
- Population health efforts, including behavioral health integration efforts.
- Cross-payer quality metric development (e.g. use of the core quality measure collaborative measure sets or state-developed cross-payer measure sets).
- Tracking and transparency in progress and evaluation.
- High-value, high-performing networks.
- Alignment across state and federal efforts.

Open Up Existing ACO models to Dual-eligible Populations. Permit 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 refine existing models in order to allow qualified ACOs to voluntarily assume 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.

Expansion of Effective Models Across States. States are designing and testing a range of innovative models, and we believe that it is important to promote expansion of those models that have proven to be effective. To this end, we encourage CMS to pursue a streamlined process—through waivers, or other methods—that promote the adoption of successful models across states lines. The Innovation Center could also support the accelerated replication of successful state models and sharing of evidence, data and best practices. This could be achieved through the development of a learning collaborative that includes both providers and state leaders

Mental and Behavioral Health Models

Opioid-related deaths have reached an all-time high across the nation resulting in nearly 100 Americans dying daily from an opioid overdose, according to the Centers for Disease Control and Prevention (CDC). Altering the course of opioid addiction must include the following imperatives that encompass prevention, intervention, treatment and recovery:

- Building awareness, education and engagement across all stakeholders including patients, providers, pharmacists, families and communities. Broad community education is critical.
- Ensuring resources and coordinated, comprehensive solutions across local, state and federal levels of government.
- Supporting a whole-person approach to meet the full range of an individual's physical, behavioral and social support needs in an integrated fashion and recognizing that each of these dimensions impacts a patient's experience of pain as well as his/her health and wellness.
- Enhancing prevention through communication, transparency and accountability among all stakeholders.
- Breaking down barriers to effective treatment and recovery including reducing stigma and ensuring appropriate insurance coverage.

CMMI should develop integrated models of care with incentives that address the items above. While traditional barriers to integration, such as workforce shortages and a lack of payer alignment, must be addressed to transform care for the people and communities Trinity Health serves, recent policy changes—including expanded coverage for behavioral health services and the movement to APMs—have created new opportunities to integrate care and services across the continuum. Trinity Health is committed to a person-centered health system that incorporates mental health and substance use into total cost of care models.

Trinity Health encourages CMS to work with SAMHSA to amend federal privacy rules to fully align requirements for sharing a patient's substance use records with the requirements in the Health Insurance Portability and Accountability Act (HIPAA) to ensure integrated care across providers and settings.

Program Integrity

Trinity Health believes that the complexity and redundancy of the existing regulatory process has become overly intrusive and is distorting the practice of medicine. We believe the old framework of overregulation can be modified and instead regulation can rely on transparency, database monitoring, and selective focus where abuse has been detected.

Medicare has excellent mechanisms in place to hold providers accountable for the outcomes of care via value-based payment programs as well as transparency initiatives such as Hospital Compare and the star ratings system. We believe the greatest opportunity for change is for CMS to use these value-based and transparency mechanisms to drive provider innovation and consistency around the processes of care that can deliver the best outcomes. The Innovation Center should focus on outcomes-based mechanisms that identify a small number of high-level key metrics that are meaningful to patients and that reflect successful performance against the desired outcomes of better care, smarter spending and healthier people. Coupling measurement that is based on outcomes with transparency tools allows the marketplace to drive providers to develop and continuously improve upon the most effective care processes.

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 public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all. We look forward to working with you to advance these goals and to partner on the Innovation Center's new direction. If you have any questions or need further information, please feel free to contact me at wellstk@trinity-health.org or 734-343-0824.

Sincerely,

Tonya K. Wells
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Trinity Health