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Center for Medicare & Medicaid Innovation  
U.S. Centers for Medicare & Medicaid Services  
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Submitted electronically at: [CMMI\\_NewDirection@cms.hhs.gov](mailto:CMMI_NewDirection@cms.hhs.gov)

Dear CMS Innovation Center:

The [Alliance for Nursing Informatics](#) (ANI) advances nursing informatics leadership, practice, education, policy and research through a unified voice of nursing informatics organizations. In collaboration with the American Nurses Association (ANA), ANI has reviewed the Request for Information issued by CMS asking for input on CMS Innovation Center New Directions. ANI and ANA offer our comments as nursing stakeholders to the CMS request for information focused on CMS Innovation Center New Directions.

ANI fully endorses the objective to promote patient-centered care and test market-driven reforms that empower beneficiaries as consumers, provide price transparency, increase choices and competition to drive quality, reduce costs, and improve outcomes. We urge CMS to promote models which fully integrate the registered nurse (RN) and Advanced Practice Registered Nurse (APRN) as care leaders and members of the care team and to empower them to practice at the full scope of their education and training in these care models.

Our specific responses and comments to the questions posed by the CMS Innovation Center are included below.

#### **Comments on the guiding principles or focus areas**

We fully support the Guiding Principles, and recommend the following modifications:

- 1) **Choice and competition in the market** – *Promote competition based on quality, outcomes, and costs.*

We recommend expanding how competition is defined to include care delivery models that promote choice of care setting and type of provider.

Models that are salient to the marketplace in terms of choice and competition while promoting principles of quality, outcomes and cost are both practical for providers and essential for patients.

The focus on value – both to providers and patients – and emphasizing the need for regulatory flexibility for testing models is commendable. In this spirit, we advise the concept of value is clearly defined and a priori identification of measures of value is an expectation for model evaluation.

A critically important variable in measuring and demonstrating value is measuring impacts on health disparities, including unintended consequences. For example, the focus on increased transparency and consumer choice is excellent, but requires oversight to ensure that applications designed to communicate this information and facilitate consumer decision-making are accessible, highly useable, understandable and useful to all consumers. This requires investment in design development as well as testing with consumers to demonstrate the applications usability, usefulness and understandability.

- 2) **Provider Choice and Incentives** – *Focus on voluntary models, with defined and reasonable control groups or comparison populations, to the extent possible, and reduce burdensome requirements and unnecessary regulations to allow physicians and other providers to focus on providing high-quality healthcare to their patients. Give beneficiaries and healthcare providers the tools and information they need to make decisions that work best for them.*

We recommend provider-neutral language to describe collaborative care across healthcare providers that includes Advanced Practice Registered Nurses and other specialty nurses such as, School Nurses and other disciplines (e.g. Pharmacists, Social Workers, and Physical Therapists) that provide care in diverse settings, beyond the physician. In fact, there is ample evidence that demonstrates that APRN-led health care for patients with chronic illness have high quality outcomes including significantly fewer deaths and hospitalization in heart failure patients<sup>1</sup>, improved cost effectiveness in coronary care<sup>2</sup>, and decreased mortality, fewer myocardial infarctions, and improved medication adherence in patients with a range of cardiovascular disease<sup>3</sup> among others.

- 3) **Patient-centered care** – *Empower beneficiaries, their families, and caregivers to take ownership of their health and ensure that they have the flexibility and information to make choices as they seek care across the care continuum.*

We recommend modifying this principle to emphasize empowering beneficiaries, their families and caregivers to take ownership of their health and ensure that they have the flexibility and information to make choices as they seek care across the continuum, including care coordination, care planning, and shared decision-making.

We also suggest that the principle of empowering patient-centered care through ownership of their health includes a statement that the concept of ownership of one's health assumes full access to one's health data.

- 4) **Benefit design and price transparency** – *Use data-driven insights to ensure cost-effective care that also leads to improvements in beneficiary outcomes.*

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<sup>1</sup> Strömberg A, Mårtensson J, Fridlund B, Levin LÅ, Karlsson JE, Dahlström U. Nurse-led heart failure clinics improve survival and self-care behaviour in patients with heart failure: results from a prospective, randomised trial. *European heart journal*. 2003 Jun 1;24(11):1014-23.

<sup>2</sup> Raftery JP, Yao GL, Murchie P, Campbell NC, Ritchie LD. Cost effectiveness of nurse led secondary prevention clinics for coronary heart disease in primary care: follow up of a randomised controlled trial. *Bmj*. 2005 Mar 24;330(7493):707.

<sup>3</sup> Al-Mallah MH, Farah I, Al-Madani W, Bdeir B, Al Habib S, Bigelow ML, Murad MH, Ferwana M. The impact of nurse-led clinics on the mortality and morbidity of patients with cardiovascular diseases: a systematic review and meta-analysis. *Journal of Cardiovascular Nursing*. 2016 Jan 1;31(1):89-95.

We recommend that quality of life and wellbeing be included in beneficiary outcomes.

- 5) **Transparent model design and evaluation** – *Draw on partnerships and collaborations with public stakeholders and harness ideas from a broad range of organizations and individuals across the country.*

We recommend including a broad range of organizations, communities and individuals.

- 6) **Small Scale Testing** – *Test smaller scale models that may be scaled if they meet the requirements for expansion under 1115 A(c) of the Affordable Care Act (the Act).*

We recommend funding to test and spread smaller scale models and encourage CMS and CMMI to continue to advance initiatives at all levels.

**What model designs should the Innovation Center consider that are consistent with the guiding principles?**

We support the Innovation Center’s interest in testing models in the eight focus areas: (1) Increased participation in Advanced Alternative Payment Models (APMs); (2) Consumer-Directed Care & Market-Based Innovation Models; (3) Physician Specialty Models; (4) Prescription Drug Models; (5) Medicare Advantage (MA) Innovation Models; (6) State-Based and Local Innovation, including Medicaid-focused Models; (7) Mental and Behavioral Health Models; and (8) Program Integrity.

The eight focus areas are well scoped; however, we note the need to include patient centered and nurse-driven innovation care delivery models. We suggest inclusion of models that support home-based care, particularly for elderly individuals choosing to age in place, school-based care and APRN-led primary care and chronic disease management clinics.

We call attention for CMS and CMMI, to **The Raise the Voice: Edge Runner Initiative** at the American Academy of Nurses, <http://www.aannet.org/initiatives/edge-runners>, highlighting several such models.

Coalescing on common appreciation that health care in America today is inaccessible to many, expensive for most and fragmented for all, these nurse-driven innovation models offer alternatives. Examples include: care coordination models such as the 11th Street Family Health Services, based on trans-disciplinary care teams and community partnerships; the Aging in Place model which applies registered nurse care coordination and health promotion to support high quality services in the home; and telehealth initiatives, such as the Complex Care Center model which links providers through evidence-based and innovative solutions. Each of the Edge Runner programs have demonstrated an improvement in patient outcomes and progress toward fundamental transformation in enabling our healthcare system to deliver the best possible care at an acceptable cost – moving American health care away from its current hospital-based, acuity-oriented, physician-dependent paradigm toward a patient-centered, convenient, helpful and affordable system.

**Do you have suggestions on the structure, approach, and design of potential models? Please also identify potential challenges or risks associated with any of these suggested models.**

We appreciate the inclusion of care coordination for physician specialty models and recommend that care coordination be framed to address needs across the continuum of care and across communities and emphasized as a core guiding principle of these models. The focus on program integrity is of high value as a cross-cutting initiative and we recommend the inclusion of social determinants of health as context for care and outcomes.

We also recommend a tighter coupling between care delivery model innovation and advanced payment model innovation. Pilot programs should focus on engaging consumers in shared-decision making and

evidence-based<sup>4</sup> as well as innovative approaches for activating patients to be more effective managers of their health and healthcare. In fact, research supports that higher patient activation levels are associated with healthy behaviors and lower cost.<sup>5</sup> Both engagement and activation are key area for nursing impact and expertise<sup>6</sup>, however, we believe additional education that focuses on patient engagement and activation is needed to improve this skill across all clinician types.

There is an opportunity for CMMI to advance the Administration's position on opioids by developing and implementing models that focus on alternatives to pain management strategies, decreasing opioid use, and prescribing practices – including APRN prescription authority. These initiatives should be data driven and include metrics to facilitate evaluation of outcomes. Telehealth services for mental health and substance use disorders could be leveraged as a strategy to address the comprehensive approach required to address this national crisis. Demonstration waivers focused on opioid use, such as those approved by the Administration for the New Jersey and Utah Medicaid programs,<sup>7</sup> offer a promising start and could be built upon and brought to scale to combat opioid use disorder nationwide in line with the President's declaration of a nationwide public health emergency regarding the opioid crisis.

**What options might exist beyond FFS and MA for paying for care delivery that incorporate price sensitivity and a consumer driven or directed focus and might be tested as a model and alternative to FFS and MA?**

We recommend developing volunteer pilot incentive programs that share rewards with consumers and eligible providers (including APRNs) who mutually review cost and quality transparency information to support consumer directed decision making about affordability, choice of provider, care setting, care coordination support and frequency of visits. These pilots would aim to shift the balance of care delivery to include virtual and remote care settings, and support consumers and their authorized caregivers to understand the full scope of practice of APRNs and other eligible providers, while tracking affordability and savings over an episode of care. This supports our overall emphasis on moving American health care away from its current hospital-based, acuity-oriented, physician-dependent paradigm toward a patient-centered, convenient, helpful and affordable system.

**How can CMS further engage beneficiaries in development of these models and/or participate in new models?**

Greater understanding of the investment required in adopting community participation methodology to allow consumers to participate in model evaluation is needed. CMS should apply the National Quality Forum (NQF) framework on telehealth measurement to these models, given its inclusiveness of access to care and multiple stakeholders.

**Are there payment waivers that CMS should consider as necessary to help healthcare providers innovate care delivery as part of a model test?**

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<sup>4</sup> Shively MJ, Gardetto NJ, Kodiath MF, Kelly A, Smith TL, Stepnowsky C, Maynard C, Larson CB. Effect of patient activation on self-management in patients with heart failure. *Journal of Cardiovascular Nursing*. 2013 Jan 1;28(1):20-34.

<sup>5</sup> Greene J, Hibbard JH, Sacks R, Overton V, Parrotta CD. When patient activation levels change, health outcomes and costs change, too. *Health Affairs*. 2015 Mar 1;34(3):431-7.

<sup>6</sup> Pelletier LR, Stichler JF. Action brief: patient engagement and activation: a health reform imperative and improvement opportunity for nursing. *Nursing Outlook*. 2013 Jan 1;61(1):51-4.

<sup>7</sup> Centers for Medicare & Medicaid Services. *CMS announces new Medicaid policy to combat the opioid crisis by increasing access to treatment options*. November 1, 2017. Web: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-11-01.html>

We are aware that CMMI is currently developing and implementing several innovative payment models in the following areas: Accountable Care; Episode-Based Payment Initiatives; Primary Care Transformation; Medicaid and CHIP Initiatives; Medicare and Medicaid Dual-Eligible Enrollee Initiatives; and Initiatives to Accelerate the Development and Testing of New Payment and Service Delivery Models.<sup>8</sup> We believe that RNs and APRNs have a crucial role to play in the development and implementation of these types of care delivery models under state payment waivers. We support payment waivers under this umbrella which also ensure access to quality and comprehensive healthcare services for beneficiaries, particularly those in vulnerable populations across the care continuum. We believe that this is a golden opportunity to provide incentives for APRNs under these models, particularly in payment waivers dealing with the Medicaid and CHIP populations and Medicare-Medicaid dual eligible populations.

We would also like to reiterate the role that APRNs can and should play in APMs. While nurse practitioners, certified registered nurse anesthetists, and clinical nurse specialists were included in the description of APMs under MACRA, there is no requirement that APMs include APRNs in their networks as independent providers eligible for direct billing and participating in potential incentives. Further, opportunities for an enrolled APRN Medicare Part B provider to meaningfully join an APM may be severely limited based on both rural location and on the lack of welcoming behavior with respect to APM networks. We believe that APRNs have an important and positive role to play in the implementation of APMs and we urge CMS to implement policies and payment waivers which not only support the inclusion of APRNs under the definition of physician-focused payments models (PFPMs) but also expand their ability to practice to the full scope of their education and training.<sup>9</sup> This role includes engaging patients and their families and caregivers – through innovative technologies such as telehealth – in order to ensure that this care is both consumer driven and consumer focused. As CMMI itself notes on its own website,<sup>10</sup> “The Innovation Center is working in consultation with clinicians to increase the number and variety of models available to ensure that a wide range of clinicians, including those in small practices and rural areas, have the option to participate.” We urge CMMI to ensure that this is actually the case.

When considering overarching guiding principles for innovative models, we encourage CMS to look to the recent NQF report, *Creating a Framework to Support Measure Development for Telehealth*.<sup>11</sup> The NQF report identifies that although the use of telehealth continues to expand, there are considerable differences in its comprehensive use due to constraints in reimbursement. The NQF Report points out that there is more flexibility in the Medicaid program versus the Medicare program in regards to reimbursement.<sup>12</sup> We encourage CMS to consider evaluating the need for equivalent reimbursement to incentivize the implementation of technology to support innovative telehealth models in both the Medicare and Medicaid programs and for those individuals who are dually eligible for both programs.

We also urge CMS to consider the NQF report and the identified “domains and subdomains of the telehealth measurement framework”<sup>13</sup> when considering strategies for CMS to further engage

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<sup>8</sup> Centers for Medicare & Medicaid Services. *Innovation Models*. Web: <https://innovation.cms.gov/initiatives/index.html#views=models>

<sup>9</sup> American Nurses Association. *Comment Letter from ANA to CMS on the Merit-Based Incentive Payment System and Alternative Payment Model Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models*. June 27, 2016. Web: <http://nursingworld.org/MIPS-APM-ANACCommentLetter-062716>

<sup>10</sup> Centers for Medicare & Medicaid Services. *Innovation Models*.

<sup>11</sup> National Quality Forum. *Creating a Framework to Support Measure Development for Telehealth*. August 2017. Web:

[http://www.qualityforum.org/Publications/2017/08/Creating\\_a\\_Framework\\_to\\_Support\\_Measure\\_Development\\_for\\_Telehealth.aspx](http://www.qualityforum.org/Publications/2017/08/Creating_a_Framework_to_Support_Measure_Development_for_Telehealth.aspx)

<sup>12</sup> Ibid. Pg. 4.

<sup>13</sup> Ibid. Pg. 7.

beneficiaries in the development of these models. Specifically, the third domain which “focuses on the experience of telehealth, which represents the usability and effect of telehealth on patients, care team members, and the community at large, and whether the use of telehealth resulted in a level of care that individuals and providers expected. The Committee divided this domain into three separate subdomains: patient, family, and/or caregiver experience; care team member experience; and community experience”.<sup>14</sup>

**Are there any other comments or suggestions related to the future direction of the Innovation Center?**

There is a need for nurse driven innovation models and we strongly reiterate the need to use provider-neutral language to communicate that models should include advanced practice nurses, supporting practicing to the full extent of their professional licensure and education.

ANI, in collaboration with ANA, commends CMS’ careful consideration the future of the Innovation Center and appreciates the opportunity to contribute to the conversation on this important topic for improved science and innovation that fosters an affordable, accessible healthcare system that puts patients first.

Sincerely,



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The [Alliance for Nursing Informatics](#) (ANI), cosponsored by AMIA & HIMSS, advances nursing informatics leadership, practice, education, policy and research through a unified voice of nursing informatics organizations. We transform health and healthcare through nursing informatics and innovation. ANI is a collaboration of organizations that represents more than 5,000 nurse informaticists and brings together 25 distinct nursing informatics groups globally. ANI crosses academia, practice, industry, and nursing specialty boundaries and works in collaboration with the more than 3 million nurses in practice today.

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<sup>14</sup> Ibid. Pg. 9.