HEALTHCARE LEADERSHIP COUNCIL

November 20, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS Innovation Center – New Direction – RFI

Dear Administrator Verma:

Thank you for your leadership of the Centers for Medicare and Medicaid Services (CMS) and your commitment to fostering a quality-driven, value-based, and accessible healthcare system that is sustainable and puts patients first.

The Healthcare Leadership Council (HLC) appreciates the opportunity to share its thoughts with you in response to the CMS request for information (RFI) seeking feedback on a new direction for the Center for Medicare and Medicaid Innovation (CMMI) 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.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable, high-quality care accessible to all Americans. Members of HLC –hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, pharmacies, post-acute care providers, and information technology companies –advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

HLC supports CMMI's mission to test innovative payment and service delivery models to reduce costs and preserve or enhance the quality of care through approaches that provide a platform to test and scale models through a very collaborative and highly transparent process. We view innovation as part of the solution for transforming the healthcare system and believe that CMMI is a key partner for both public and private stakeholders, including providers, payers and manufacturers, for collaboration toward this goal. HLC believes it is essential for the nation to

shift to value-based healthcare models and supports public policy that enables participants to innovate in their quest to provide care of the highest quality and highest value.

We applaud CMS for putting forth this RFI as an opportunity to provide feedback from across stakeholder groups. We have responded to Questions 1, 2, 3, 5, 6 and 7 in the RFI.

Question 1: Do you have comments on the guiding principles or focus areas?

1) Proposed Guiding Principles

The proposed guiding principles should act as critical guideposts for CMMI helping to direct the development of models that adhere to its mission and to ensure that the models are effective tools for testing new ideas for the delivery of a value-driven healthcare system.

As a member of the *Healthcare Leaders for Accountable Innovation in Medicare* (AIM) coalition, HLC believes in dynamic innovation that protects patient access to care and that offers the promise of a Medicare defined by quality, value, and exemplary patient health outcomes. AIM is comprised of organizations from across the healthcare and patient advocacy spectrums, committed to improving CMMI so that it is a more effective incubator for new ideas and an interactive, transparent partner with stakeholder organizations.

As our healthcare system evolves toward value-based care, CMMI has provided and should continue to provide a robust research and development platform to experiment and evaluate new payment and delivery approaches and determine what works and why. Because of the potential impact on patients, healthcare providers, and other health system stakeholders, it is essential that such experimentation comply with the original intent of CMMI and be appropriate in scope and fully transparent. Concerns over both the scale and scope of CMMI's recent demonstrations and its claim of authority to conduct nationwide demonstrations and, in effect, enact permanent policy changes should be addressed. Clearly establishing CMMI's role to verify "proof of concept" and Congress's role to act on that proof would help build the trust and confidence needed to ensure CMMI's success.

In furtherance of these goals, AIM adopted the following set of principles:

- Foster strong scientifically valid testing prior to expansion.
- Respect Congress's role in making health policy changes.
- Consistently provide transparency and meaningful stakeholder engagement.
- Improve sharing of data from CMMI testing.
- Strengthen beneficiary safeguards.
- Collaborate with the private sector.

We believe AIM's principles align with the proposed CMMI guiding principles and have cross-walked the two sets of principles in the following table. We generally support CMMI's proposed guiding principles, taken in their entirety, and have included comments on each of them.

Proposed Guiding Principle	AIM Principles	Comments
Choice and Competition in the Marketplace	• ***Collaborate with the private sector***	We encourage model designs that engage private sector stakeholders, including providers and payors, and other private sector entities, to harness the benefits of competition in the private sector marketplace.
Provider Choice and Incentives	• ***Foster strong scientifically valid testing prior to expansion.*** • ***Consistently provide transparency and meaningful stakeholder engagement.*** • ***Strengthen beneficiary safeguards.***	We support the focus on voluntary models that are designed to minimize administrative burden on healthcare providers. We believe that participants should have the flexibility to determine the tools that will promote innovation, while ensuring regulatory consistency among federal programs. We support creating an environment that facilitates access to data and consistent communication to enable meaningful engagement by beneficiaries and healthcare providers in the development, testing, and expansion of models. Beneficiaries should have access to information that enables informed decision-making, including the decision whether to participate or not participate in a demonstration project.
Patient-Centered Care	• ***Strengthen beneficiary safeguards.***	We believe that safeguards should ensure that beneficiaries are adequately informed and continue to have access to quality care. We support the inclusion of families and caregivers, along with beneficiaries, when determining whether a model is supporting the delivery of patient-centered care.
Benefit Design and Price Transparency	• ***Foster strong scientifically valid testing prior to expansion.*** • ***Consistently provide transparency and meaningful stakeholder engagement.***	We believe that new payment and delivery models should have comprehensive, methodologically sound, transparent evaluation plans that are reviewed on a regular basis to protect beneficiaries and participants

		from unintended or adverse consequences. We support transparency in decision-making related to model development and implementation that includes impact on price/costs, without disclosing proprietary pricing information.
Transparent Model Design and Evaluation	• ***Improve sharing of data from CMMI testing.*** • ***Respect Congress's role in making health policy changes.*** • ***Collaborate with the private sector****	We encourage CMMI to engage in transparent, comprehensive collaboration with stakeholders throughout the demonstration process. This includes consultation with affected stakeholders as part of the model development process, prior to issuing any new proposed models. We believe data about CMMI demonstration models should be made public on an ongoing basis to facilitate assessments of their impact on care quality and spending. Such data sharing would also inform parallel efforts moving toward value-based healthcare in the private sector. We believe providing for transparency in model design and evaluation allows for appropriate oversight to ensure that models improve quality or reduce cost in a way that does not harm beneficiary access or negatively impact healthcare outcomes. *We applaud the inclusion of a principle that explicitly encourages models that "draw on partnerships and collaboration with public stakeholders," but strongly recommend that language be added to include "private sector stakeholders" to best position the CMMI to "harness ideas from a broad range of organizations and individuals across the country."
Small Scale Testing	• ***Foster strong scientifically valid testing prior to expansion.***	We believe testing smaller scale, yet large enough to be statistically significant, models complies with the original intent of CMMI. However, we recognize that large scale models, such as ACOs and bundled payment initiatives, remain a critical model design for testing model payment and

		delivery alternatives. We find that 3-5 year models can limit the ability for providers to receive benefits from their investments and participation within such a short period of time. We believe providers are best positioned for success when they have the opportunity to participate in the type of model that is most appropriate for their practice, whether ongoing, long-term models or short-term models. Accordingly, we believe a range of types of models – both long-term and short-term, should be widely available and open to participation.

2) Proposed Focus Areas

We believe the eight proposed focus areas are appropriate areas of interest and focus for CMMI and concur with allowing continued testing of models in other areas as well. In addition, to ensure that CMMI is focusing on the most appropriate areas for model testing that is in sync with the ever-evolving healthcare environment, we would recommend a predetermined timeline, such as every three years, for reassessing whether the focus areas remain appropriate and whether additional focal areas should be considered. This assessment should be conducted in a transparent and inclusive manner.

Question 2: What model designs should the Innovation Center consider that are consistent with the guiding principles?

HLC supports CMMI's critical role in facilitating movement away from our fractured, volume-driven healthcare system through the testing of alternative models of care that are value-based and patient-centered and reward improved quality and cost-effective care. We also believe that the proposed guiding principles can help CMMI stay aligned with its mission and be better-positioned for success.

We encourage CMMI to review its current models and consider new model designs with the proposed guiding principles in mind. While not an all-inclusive list, we have included several specific examples of model designs for continued and future consideration that are well-positioned to be consistent with the proposed guiding principles.

1) Population-based Models

Population-based models facilitate coordination and cooperation among healthcare providers to achieve better health outcomes for beneficiaries and reduce overall cost of care. Existing models, such as Accountable Care Organizations (ACOs) and Advanced Alternative Payment models (AAPMs), are important avenues for moving healthcare providers toward value-based healthcare delivery. As part of CMMI's assessment, we recommend a review of existing population-based models for consistency with the guiding principles. In addition, CMMI should consider developing additional population-based models to address current innovation gaps.

Layered Payment Model Demonstration

HLC believes a Layered Payment Model Demonstration is an approach that would fill an innovation gap not addressed by current models. This model is a voluntary demonstration that replaces reimbursement for primary care physicians (PCPs) for their evaluation & management services with a single monthly capitated payment that would be included in total spending for the purposes of comparing an ACO's actual expenditures to its historical Medicare Shared Savings Program (MSSP) benchmark. This limited capitation would allow PCPs to focus their attention away from generating as many services as possible towards better managing a panel of patients through new methods of care. PCP capitation would enable primary care practices to optimize their use of care teams that include physician extenders, such as nurse practitioners and health coaches, to institute electronic visits, and to expand use of patient portals – all of which would facilitate having open access and enhance the patient experience. The care teams would be able to handle much of the routine, less complex care, thereby allowing the PCPs more time for the care of the complex patient within the practice and encouraging them to have more complex patients on their panels.

Combining the shared savings element of the MSSP with a PCP capitation would discourage the PCPs from referring patients unnecessarily to costly specialists. Simultaneously, the rigorous quality measures within the MSSP would ensure that the PCPs focus on appropriate referrals and transitions of care. We believe PCPs would be better able to: 1) care for their patients within the confines of their office, thus utilizing less unnecessary specialist (professional and ancillary) and hospital (emergency department and readmissions) services, and thereby lowering the overall cost of care; and 2) deliver high quality patient care and experience.

If, however, specialty acute care becomes necessary, the underlying payment for such services would fall under bundled payments rather than traditional fee-for-service. By setting unified targets across episodes of acute care, the ACOs can more directly associate savings with the work of specialists and provide more timely compensation for improved care at a lower cost. At the same time, the capitated primary care payments will ensure the continued engagement of the PCP and the overarching ACO incentives will temper the incentive to generate more episodes. All the spending, whether through capitation, bundling, or the remaining fee-for-service would be tallied and reconciled against the ACO's historical benchmark to see if overall spending is lowered. As providers begin to achieve savings through better coordinated and higher quality care, an adjustment would be made to the per-service payment if the changes in practice resulted in a reduced volume of services. This will allow providers to remain financially healthy and ensure that the model continues to provide incentives for even greater improvements in the delivery of care. Understanding that specialty care can be more complex to bundle, we encourage CMMI to consider carefully any bundling of specialty care to ensure that access to care and appropriate reimbursement for complex patients is preserved.

We believe that current models continue to be built on a foundation of fee-for-service payments with providers seeking to beat their prior performance year over year. At some point, providers will not be able to continue reducing their costs relative to themselves and will need payment models built off the best value in their community. And, as volume declines, providers' per case payments must be adjusted up to a fair rate recognizing that the per case costs increase for those services that remain paid on fee-for-service. We believe this layered payment model approach is an important consideration for future testing.

We also recommend that future models explore the use of regional adjustments, prospective global budgets, and underlying payments based on bundling and partial capitation, provided that there are sufficient incentives to reward improved outcomes, track quality and access to care.

2) Targeted Population-based Models

HLC supports targeted population-based models as important avenues for value-based approaches for specific populations, such as beneficiaries with a chronic illness or multiple chronic conditions. Some current examples are the Medicare Diabetes Prevention Program Model and the Independence at Home Care Coordination Model. We encourage the consideration of models that focus on beneficiaries with complex needs and potentially high costs. In addition, an expansion of the number of options available under Medicare Special Needs Plans (SNPs) to include a Community-Based Institutional Special Needs Plan (CBI-SNPs) would provide a promising option for targeting Medicare beneficiaries who would benefit from long-term services and supports (LTSS).

Medicare Diabetes Prevention Program

The Medicare Diabetes Prevention Program (MDPP) expanded model is a structured behavior change intervention that aims to prevent the onset of type 2 diabetes among Medicare beneficiaries diagnosed with pre-diabetes. The MDPP expanded model was announced in early 2016, when it was determined that the Diabetes Prevention Program model test, tested under the Health Care Innovation Awards, met the statutory criteria for expansion.

Independence at Home Demonstration

Established under the Affordable Care Act, the Independence at Home Demonstration is testing a service delivery and payment incentive model that uses home-based primary care teams designed to improve health outcomes and reduce expenditures for Medicare beneficiaries with multiple chronic conditions. The home-based primary care teams are directed by physicians and nurse practitioners. The Independence at Home Demonstration awards incentive payments to healthcare providers who succeed in reducing Medicare expenditures and meet designated quality measures.

This approach allows health care providers to spend more time with their patients, perform assessments in a patient's home, and assume greater accountability for all aspects of the patient's care. This focus on timely and appropriate care is designed to improve overall quality of care and quality of life for patients served, while lowering health care costs by forestalling the need for care in institutional settings.

Under the Independence at Home Demonstration, selected participants, including primary care practices provide home-based primary care to targeted chronically ill beneficiaries for a five-year period. Participating practices will make in-home visits tailored to an individual patient's needs and preferences and the beneficiary's care experience is tracked through quality measures. Practices that succeed in meeting consistent quality standards, while generating Medicare savings, have an opportunity to share in savings after meeting a minimum savings rate.

Complex-Need and High-Cost Beneficiaries

According to the Congressional Budget Office (CBO), the top 10 percent of the sickest Medicare fee-for-service (FFS) beneficiaries accounted for over 60 percent of total spending. These

beneficiaries are more likely to have multiple chronic conditions, including end-stage renal disease, heart failure, and stroke. They are also more likely to be dual-eligible for Medicare and Medicaid. Their Medicare costs are over six times the average costs of all beneficiaries with a disproportionate amount spent on acute inpatient and skilled nursing facility use; they also have a much higher than average high mortality rate when measured over a three-year period.

Given this dynamic, we think it is important that CMMI makes testing models of care for the sickest and mostly costly FFS beneficiaries a priority as the agency seeks out new ways to innovate in the Medicare program. In particular, we recommend the agency consider testing such models in Medicare Advantage (MA), which has not been afforded as many opportunities as Medicare FFS to test out new models of care and is designed to be a comprehensive, integrated coverage model with extensive care management experience.

Specifically, we recommend CMMI consider a model that draws from legislation introduced in the 114th Congress, (Providing Innovative Care for Complex Cases Demonstration Act (H.R. 3244) and Medicare Program Linking Uncoordinated Services (PLUS) Act (S. 2498)) which would require CMS to establish a pilot program for the highest cost, highest need (top 10%/15%) Medicare FFS beneficiaries. We believe the proposed legislation outlines precisely the sort of innovative program and service delivery model pilot project that CMS should adopt, giving health plans the opportunity to demonstrate that enhanced care, with better outcomes, can be provided at a lower cost.

Community-Based Institutional Special Needs Plan

HLC supports the creation of a CBI-SNP demonstration program to provide home and community-based care to low-income Medicare beneficiaries who are unable to perform two or more activities of daily living. SNPs serve an important role for Medicare beneficiaries who are high-risk because they are dually eligible for Medicare and Medicaid or have severe or disabling chronic conditions. SNPs allow beneficiaries access to care plans and provider networks designed especially for their health conditions. By coordinating care and providing access to supplemental benefits, these plans improve the health of Medicare beneficiaries and reduce costs for taxpayers.

The CBI-SNP program would improve the care of these beneficiaries and eliminate the need for them to spend down their income and assets to qualify for Medicaid. They would instead be provided with home and community-based long-term care services and supports. This would enable beneficiaries to remain at home, where they want to be, and reduce their Medicare and Medicaid costs.

The demonstration would aim to help Medicare beneficiaries remain in the setting of their choice and reduce total costs of both acute and long term care. Specific goals would include:

- Prevent or delay institutionalization for the near-dual population.
- Delay spend-down to Medicaid eligibility.
- Reduce utilization of hospital services.
- Quantify impact of LTSS on state and federal expenditures.

A demonstration explicitly designed to test the impact of LTSS on utilization of expensive acute care and nursing home services, the rate of spend down to Medicaid eligibility, and health-

related quality of life would fill an important gap in our current understanding of the value of LTSS. The demonstration would also contribute to the evidence base on how to most effectively target what specific services to provide individuals. The results of the demonstration would therefore also be very useful to state Medicaid programs, which provide LTSS through Home and Community Based Services (HCBS) waiver programs, and do so in the absence of clear guidelines about what services to provide and to whom. Medicaid Home and Community-Based Services Waivers allows states to target LTSS to Medicaid beneficiaries who are at risk of long-term nursing home placement, without making these services available to all other community dwelling Medicaid beneficiaries in the community.

HLC is encouraged by Congressional consideration of the Community-Based Independence for Seniors Act to establish a CBI-SNP demonstration.

3) Multi-payer (Public and Private) Models

For CMMI to have an optimal impact on improving healthcare quality and cost-efficiency, it must work collaboratively with the private sector. We encourage CMMI to prioritize partnerships involving providers, payers, and other private sector entities throughout the healthcare continuum.

Community Health Workers

HLC believes the integration of Community Health Workers (CHW) into care teams and comprehensive care models is a promising strategy for encouraging better value-based care that has been increasingly embedded within healthcare delivery systems, both private and public. Community Health Workers are lay members of communities who may share ethnicity, language, socioeconomic status, and life experiences with the community members served. Services often focus on social determinants of health with CHWs acting as a critical link to health and social services, that may include access to preventive care, teaching chronic disease management, encouraging healthier lifestyle choices, and increasing adherence to treatment regimens.

According to the Bureau of Labor and Statistics, there were 99,400 CHWs in the United States in 2012 with the number expected to increase by 21% by 2022. The effectiveness of CHWs in the United States have been considered somewhat dependent on the type of beneficiaries being served.[1] In particular, CHWs have been most effective when targeted to low-income, minority, or other underserved populations.

CHWs are currently incorporated in to several models being tested within CMMI, including a number of State Innovation Models strategies and in many demonstration projects funded through CMMI's Health Care Innovation Awards.

Given the changing demands of our country's evolving healthcare system, as well as our growing and aging population, HLC believes that CHWs can play an increasingly important role as a link between healthcare providers and communities in the US health care workforce. We also believe that more is needed to test their effectiveness. HLC encourages the continued incorporation of CHWs into existing and future care coordination models.

[1] John Snyder, Office of the Assistant Secretary for Planning and Evaluation, Community Health Workers: Roles and Opportunities in Health Care Delivery System Reform, January 2016. https://aspe.hhs.gov/system/files/pdf/168956/CHWPolicy.pdf at page 7.

4) Concurrent models

HLC recommends the alignment of interests across payment models and across payors, both public and private, for concurrent models. Given CMMI's efforts to promote patient-centered care and test market driven reforms, there is an increasing likelihood that the expansion of multiple payment and healthcare delivery models will lead to increased interactions among models. This interaction presents operational challenges, such as the proper attribution of cost savings, and has the potential to increase administrative burdens on healthcare providers. We recommend that CMMI review incentives within the structure of an individual model for potential interactions with other models within the larger healthcare system.

Question 3: Do you have suggestions on the structure, approach, and design of potential models? Please identify potential challenges or risks associated with any of these suggested models?

1) Feedback on Proposed Potential Models

<u>Expanded Opportunities for Participation in AAPMs</u>

HLC supports the expansion of opportunities for participation in AAPMs as an important step forward in the movement toward value-based healthcare delivery.

Providing for MA plans, commercial health plans, Medicaid managed care organizations (MCOs), and other appropriate entities to be eligible for Other Payer Advanced APMs is a viable option for expanding participation in AAPMs. We believe that making the Other Payer Advanced APM category as broad and as flexible as possible will help move the entire health system toward care focused on value and optimal patient outcomes.

In furtherance of this expansion, HLC encourages CMS to be transparent, flexible, and consistent regarding the criteria for APM "eligibility" for advanced model consideration. We note that the mandated 25% Medicare volume is making eligibility difficult for many providers. It is equally important for CMS to consider the sensitivity of patient and proprietary contractual information to ensure that transparency efforts are also protective of disclosure. Similarly, the Other Payer certification process and timelines will need to reflect the realities of the market, and would be best supported by a flexible, rolling AAPM certification process.

CMS should also focus on the alignment of measurement across all programs to ensure current incentives (such as MA benchmark calculations) facilitate the transition to Other Payer Advanced APM arrangements. CMS should recognize that MA plans forming Other Payer Advanced APM arrangements will need to adjust their bids to account for increased risk and the requirements of other value-based initiatives; and the benchmarks must be adjusted accordingly.

One approach to facilitating a strategy for Other Payer Advanced APMs would be use of through 1115A waiver authority. Treating providers who contract with private sector alternative payment arrangements and who meet requirements regarding electronic health record (EHR) usage, quality, and financial risk, as participating AAPMs would allow for consistent application of APM requirements across the Medicare program while reducing provider burden. A voluntary demonstration project designed to test risk contracts between health plans and other stakeholders for inclusion as Other Payer Advanced APMs would allow both CMS and the private sector time to perfect the rules for MA and other programs to become a qualifying MACRA AAPM.

A CMMI demonstration could also allow for experimentation in harmonizing performance measures across programs.

HLC and CMS share a goal of moving clinicians to advanced alternative payment models. We believe these changes would remove current barriers to participation in AAPMs while helping to accelerate the transition to value-based healthcare delivery across a broader marketplace.

Consumer-Directed Care & Market-Based Innovation Models

HLC agrees that beneficiaries should be empowered consumers when it comes to their healthcare. We believe that consumer-directed care and market-based innovation models are important avenues for maximizing beneficiary engagement in the healthcare system's transformation from volume-based to value-based.

We view MA as a demonstrable approach that both supports consumer choice and promotes market competition. MA enables beneficiaries to gravitate toward health plans that provide them with high-quality healthcare at the most affordable costs and we encourage the promotion of MA as an important and valued option for Medicare beneficiaries.

Beneficiary choice is a key component of consumer-directed approaches, such as MA. For these models to work effectively, beneficiaries need access to data and, ideally, decision support tools to evaluate their coverage options and select the plan that best meets their needs.

Access to data, or information, is at the core of any consumer-directed model and that data should be accessible, understandable, and meaningful. The models should facilitate and encourage price and quality transparency – including the compilation, analysis and release of cost data and quality metrics. However, we caution that the information is not provided in a format that is overwhelming, like an "information dump," and should be easy for beneficiaries to understand. We also believe parameters should be in place to protect proprietary information.

To best operationalize a consumer-focused, market-driven model, we recommend starting with the beneficiaries themselves. As the ultimate consumers of healthcare, beneficiaries are the most effective source of insight into how they want to be engaged and how best to provide them the information they need to make informed decisions on their healthcare relative to cost, quality, and access to care.

Physician Specialty Models

HLC supports physician specialty models as a viable option for encouraging specialists to participate in alternative payment models that improve quality and lower costs. We appreciate efforts to engage specialists and the potential benefits for beneficiaries who have complex or chronic medical conditions, including multiple chronic conditions.

While we support physician specialty models, we have concerns with the suggested model that CMS put forth in the RFI as a potential option for cancer care. Specifically, CMS included consideration of a potential model that could test full prepayment for Medicare and Medicaid beneficiaries, possibly incorporating elements from the existing Oncology Care Model (OCM).

First, we believe it is premature to incorporate elements of the existing OCM model because it is still in the early stage of testing; we do not support the incorporation of elements of existing pilots and demonstrations until they have been fully tested and evaluated. Second, we have several specific concerns about the OCM model, including its focus on cost cutting, its insufficient patient protections to ensure access to appropriate and innovative therapies, and the lack of robust quality and outcomes measures that capture patient reported outcomes in the model. And, finally, we have great concerns about a prepayment (e.g., capitation) model in oncology for Medicare and Medicaid beneficiaries, particularly when it is not clear what protections CMS would be able to put in place to protect patient access to care if full-risk is shifted to providers.

As CMMI considers physician specialty models in general, we caution that while the value of coordinated care for beneficiaries with multiple chronic conditions should hopefully result in better health outcomes, there may not always be decreased costs, due to the unpredictability of managing chronic disease. Additionally, we encourage CMMI to consider physician specialty models in which the specialist takes on the role of primary care provider, which is common with specialists who provide longitudinal care, such as nephrology, cardiology and pulmonology.

Physician-Focused Payment Model Technical Advisory Committee (PTAC)

As a facilitator for consideration of physician-focused models, the Physician-Focused Payment Model Technical Advisory Committee (PTAC) is a useful venue for working with such proposals. However, PTAC's processes would benefit from streamlining and shorter timeframes for review. PTAC also would benefit from deeper technical support to enable more timely decisions regarding physician-focused models.

Prescription Drug Models

HLC supports prescription drug models that seek better value and health outcomes for beneficiaries and would encourage the testing of novel arrangements for plans, pharmaceutical manufacturers, and stakeholders across the supply chain. However, we note that current Medicaid "best price" policy has severely restricted innovative arrangements with pharmaceutical manufacturers who are concerned that engaging in risk-based contracts would run the risk of best-price calculations triggering a $0 price for their products in Medicaid. To address this, HLC recommends the use of waivers regarding the calculation of a drug's best price to remove this disincentive and encourage creative innovation in these models. We also urge CMS to issue safe harbors, exceptions, or guidance that effectively extend federal Anti-Kickback statute waivers for prescription drug models that involve the integration of care, items, services, and payment across stakeholders that meet established value-based healthcare criteria and that are designed to improve patient outcomes and reduce the overall cost of providing care.

Medicare Advantage Innovation Models

HLC supports more models in the MA market and encourages CMS to demonstrate the regulatory flexibility required for testing such models.

In the RFI, CMS noted that the current MA-Value-Based Insurance Design (VBID) model could be modified to provide more flexibility to MA plans and potentially test the model in additional states. We support the voluntary expansion of the existing VBID model to other states and for other diseases with significant health implications for the Medicare population, such as

osteoporosis. In support of this effort, we recommend reductions in marketing restrictions to permit at least some pre-enrollment marketing of plan designs and cost sharing adjustment of designs. We would also like to request a clarification on the cost neutrality requirement. Currently, demonstrations must show cost savings or cost neutrality for the plan at year 5 of implementation. We seek clarification if "savings" refers to the plan only, or if it includes other savings such as societal savings or savings to the beneficiary. We also suggest an extension beyond the 5-year time frame for an alternative time frame of 7, 8, or 10 years.

HLC appreciates that CMS has included MA as a focal area for innovation for CMMI. In support of this focus, we call for risk arrangements in MA to be afforded the same credit under the Medicare Access and CHIP Reauthorization Act (MACRA) as risk arrangements in traditional Medicare FFS. A physician should have equal incentives to take risk in traditional Medicare FFS as in a contract with a MA plan. Leveling the playing field across Medicare will result in better care for patients and more equitable opportunities for physicians.

Today, MA makes up a third of the enrollment in Medicare. In some counties, MA makes up nearly half of all Medicare enrollees.

Studies[2] have shown that alternative payment models in MA deliver care that is of higher quality and lower cost than care delivered in fee-for-service. In fact, a recent publication in the American Journal of Managed Care demonstrated that patients in capitated MA had a six percent higher survival rate, and were 11 percent less likely to visit the Emergency Room and 12 percent less likely to have an inpatient admission.

To echo our comments related to the expansion of opportunities for participation in AAPMs, since current policy does not allow for MA arrangements to count as AAPMs and MA risk does not count toward the AAPM risk threshold, we propose the creation of a voluntary MA APM, or, alternatively, modifications to the current threshold requirements. These are critical steps should CMMI wish to focus on innovative models in MA.

In addition, given the maturity in the MA space for exploring and implementing alternative value-based arrangements, we suggest that CMMI consider assuming the primary role of overseer, rather than administrator, of these arrangements for MA Innovation models. In this role, CMMI would run data on performance, but would not be responsible for contract administration.

<u>State-Based and Local Innovation, including Medicaid focused models</u>

HLC supports the development of state-based and local innovation models that include Medicaid-focused models. Focusing on opportunities at the state and local level is firmly in line with CMMI's mission to take locally-driven approaches –from doctors and other healthcare partners providing care to patients every day – and give them a platform to scale through a very collaborative and highly transparent process.

[2] "Value-Based Contracting Innovated Medicare Advantage Healthcare Delivery and Improved Survival" by AK Mandal, et al. American Journal of Managed Care Vol 23, No 2. http://www.ajmc.com/journals/issue/2017/2017-vol23-n2/value-based-contracting-innovated-medicare-advantage-healthcare-delivery-and-improved-survival.

As noted earlier in our response to Question #2, CHWs are already incorporated into several models being tested within CMMI, including a number of State Innovation Models strategies and in many demonstration projects funded through the Center's Health Care Innovation Awards. Given this, we would encourage CMMI to continue to look at opportunities to incorporate CHWs into future, state-based and local models.

Mental and Behavioral Health Models

HLC appreciates the proposed focus on mental and behavioral health models, particularly given the public health emergency our nation is facing with opioid addiction. Healthcare providers have played and will continue to play critical roles in combatting opioid abuse.

Efforts to combat this crisis require collaboration at the local, regional, and state levels, and the engagement of diverse sectors within communities such as public health, government regulators, law enforcement, and social services, in addition to health care. We have two recommendations for consideration related to mental and behavioral health models and their potential role in addressing the opioid crisis.

First, given the importance of focusing on the issue at the community level, HLC believes this is a viable opportunity for Community Health Workers (CHW) to act as a critical link to health and social services and work with beneficiaries who may be at risk for opioid addiction as well as with beneficiaries who are facing opioid addiction. This would be a particularly helpful approach for the increasing number of aging Americans facing opioid addiction. A report from 2016 found that one out of every three enrollees in Medicare's prescription drug benefit program received an opioid prescription.[3]

And, second, HLC recommends that in order to best position these models for success, efforts should be made to align provisions in the "Confidentiality of Alcohol and Drug Abuse Patient Records" under 42 CFR Part 2 regulations with the privacy provisions under the Health Insurance Portability and Accountability Act (HIPAA). Currently, 42 CFR Part 2 regulations do not allow substance and alcohol use information to flow with medical information under HIPAA. As such, these provisions are currently not compatible with the way healthcare is delivered and can act as barriers to appropriate care in efforts to help patients with opioid addiction.

Providers and organizations need access to a patient's entire medical record, including addiction records, in order to provide safe, effective, high-quality treatment, and care coordination. In other words, healthcare providers need to be able to treat the "whole person" based on data that presents a complete healthcare picture. Regulations on substance abuse records extend far beyond the requirement in HIPAA, and compliance with two separate sets of confidentiality regulations has proven unnecessary and impedes coordinated care.

We believe the requirements for sharing patients' substance use records should be aligned with the strong confidentiality requirements in the HIPAA regulation that allow the use and disclosure of patient information for treatment, payment, and healthcare operations. We believe the 42 CFR Part 2 regulations duplicate the already strong privacy protections for health information under HIPAA and act as unnecessary barriers to ensuring appropriate care.

2) Incorporating Socioeconomic Status Adjustments

[3] HHS, OIG Data Brief-02-17-00250. https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf.

To better incentivize alternative payment arrangements in areas of high need, HLC recommends that CMS quality measurement should better incorporate socioeconomic status adjustments. It is critical that all efforts to move to outcome-based payment properly account for both complexities of patients as well as the socioeconomic challenges that providers face in caring for patients.

3) Incorporating Telehealth Across Proposed Potential Models

Telehealth has the potential to enhance the impact of value-driven, patient-centered, quality-focused initiatives while improving the access to and convenience of healthcare delivery. It is an effective tool to strengthen the cost-efficiency of healthcare.

HLC believes telemedicine should be a critical facet of any strategy to increase access to care. Telehealth removes barriers to care by enabling more beneficiaries to receive healthcare within their own homes rather than in a healthcare facility — improving patient experiences while reducing costs and freeing up capacity in health facilities for more acute cases. Telehealth also allows for more flexibility in providing telehealth services to individuals in both urban and rural areas.

As CMMI considers new payment and delivery models, HLC recommends the incorporation of telehealth in model designs. Opportunities for telehealth adoption already exist in several alternative payment models, including NextGeneration ACO initiatives, MA Value-Based Insurance Design (VBID) Model, State Medicaid alternative payment models, and existing Commercial ACOs.

We believe incorporating telehealth into the new model designs is consistent with the guiding principle of patient-centered care that is both sensitive and responsive to a beneficiary's interest in determining how their healthcare services are delivered.

Question 5: How can CMS further engage beneficiaries in development of these models and/or participate in new models?

HLC believes that beneficiary engagement is an essential consideration in the development and implementation of new models and should be embedded in all aspects of model design, including measurement, transparency efforts, benefit design, and payment. We believe that increased beneficiary engagement at multiple levels will promote a more active interest and involvement by beneficiaries in their health, with the potential for an increased focus on prevention and self-management, and, ultimately, produce better health outcomes.

We believe a key driver to beneficiary engagement is the availability of data that is accessible, understandable, and meaningful.

Beneficiaries should have access to information about payment and delivery models that include specifics about model design and implementation. Beneficiaries should also be fully informed about their ability to choose to participate or to not participate in a particular model.

Beneficiaries should also have easy and secure access to their own health data in an electronic health format and should be able to direct that data to desired locations. They should also be fully informed on how their information is adequately protected, shared, and used.

Data should also be easy-to-understand and meaningful to beneficiaries. For example, while most programs link quality to payment and publicly report quality information, this data is often not in a format that is readily accessible to beneficiaries and does not translate in a meaningful way. The type of information provided and how that information is delivered should be clear and easily translatable for beneficiaries.

In addition to incorporating beneficiary engagement in model design, we also recommend using tools for engagement that are likely to be familiar and easy to use by beneficiaries, such as through brief online surveys, in order to encourage feedback on model design and on impact to beneficiary care prior to and during implementation. We believe this approach would be helpful for assessing levels of beneficiary engagement, potentially identify areas for improvement, and would support uptake and continued participation in new models.

Question 6: Are there payment waivers that CMS should consider as necessary to help healthcare provider innovate care delivery as part of a model test?

1) Physician Self-Referral (Stark) Law, Anti-Kickback Statute, and Civil Monetary Penalty Statute

HLC believes that a comprehensive modernization of physician self-referral and anti-kickback laws is needed to support healthcare providers seeking to successfully implement innovate care delivery models.

When the Anti-Kickback Statute (1972) and the Physician Self-Referral (Stark) Law (1988) were enacted, the healthcare system provided little or no incentive to providers to coordinate healthcare delivery. Reimbursement models based on the number of services provided rewarded volume, rather than rewarding health promotion and maintenance. As a result, policymakers sought to restrict financial arrangements that could lead to overutilization, influence provider decision-making, and compromise patient care. Other laws also came into play with additional restrictions on healthcare provider and payor arrangements, such as the Civil Monetary Penalties (CMP) Law related to both beneficiary inducement (i.e., providing anything of value to a patient in order to encourage the patient to utilize a particular provider) and gainsharing (i.e., sharing savings among providers based on limited or reduced medically necessary services).

As reimbursement models have evolved to become more patient-centered, the Anti-Kickback Statute, the Stark Law, the CMP Law, and their implementing regulations, have become barriers to value-oriented care models that improve health outcomes and reduce costs. While these laws have been minimally modified (e.g., CMMI waivers for particular demonstration projects) in an attempt to keep pace with these changes, these modifications are piecemeal and do not apply to all value-based care models that require appropriate coordination among stakeholders.[4]

To more appropriately support a healthcare system transforming from volume to value-based through creative service delivery and payment arrangements, HLC calls for the development and adoption of a modernized legal framework that facilitates broader collaboration among stakeholders that include payers, providers, and manufacturers, to accelerate ongoing improvements in care quality and patient safety while driving down costs.

[4] See HLC's February 2017 paper, "Health System Transformation: Revisiting the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law to Foster Integrated Care Delivery and Payment Models"; https://www.hlc.org/app/uploads/2017/02/HLC_StarkAntiKickback-White-Paper.pdf.

2) Telehealth Use and Reimbursement Restrictions

HLC recommends an examination of restrictive reimbursement and regulatory requirements that can act as barriers for healthcare providers seeking to improve patient care through the use of telehealth. We believe telehealth has the potential to enhance the impact of value-driven service delivery and payment models while improving beneficiary access to healthcare.

Under current policy, CMS approves new telehealth services on a case-by-case basis, with the result that Medicare pays for only a small percentage of services when they are delivered via telehealth. HLC recommends that CMS lift current restrictions on telemedicine, including patient location restrictions, communication technology restrictions, and coverage restrictions (known as 1834m restrictions). CMS should also eliminate originating site restrictions for telehealth to allow MA plans more flexibility in providing basic telehealth services to individuals in both urban and rural areas and allow for increased innovation in MA delivery systems. Currently, MA plans must use their rebate dollars to pay for these services as a supplemental benefit for their members.

3) Medicaid Best Price Policy

An additional regulatory challenge that impacts the movement toward value-based care across healthcare payors is the Medicaid "best price" policy. Specifically, the policy requires that pharmaceutical manufacturers participating in the Medicaid program provide rebates based on that best price. "Best price" regulations make it nearly impossible for pharmaceutical manufacturers to engage in risk-based contracts without running the risk of best-price calculations triggering a $0 price for their products in Medicaid. We understand that CMMI does not have the authority to waive Medicaid best price law, but we emphasize that this policy severely limits how pharmaceutical manufacturers, a key stakeholder and potential contributor in the move toward value-based care, can engage and collaborate with payer and provider customers. HLC believes that policy changes regarding the calculation of a drug's best price, as well as federal price reporting requirements generally, could remove this disincentive.

Question 7: Are there any other comments or suggestions related to the future direction of the Innovation Center?

Innovation and the Role of Data: Access, Analytics, Harmonization, Infrastructure, and Interoperability

HLC recognizes the increasing importance of the efficient and timely transfer of patient information throughout the healthcare system, enabling care to be delivered to the patient more quickly and guided by meaningful data. We believe in a future in which health organizations work not as "silos" of information, but as an interoperating health system using shared data to accelerate progress in medicines, technologies, and healthcare delivery.

HLC believes that data analytics are critical to the successful development and implementation of value-based payments and alternative payment models. Successful quality improvement by healthcare providers requires effective use of clinical, pricing, and other data. Access to data can empower risk modeling, and help providers identify patients who may benefit from targeted interventions, engage in effective patient engagement initiatives, design and evaluate quality improvement initiatives, identify and close clinical care gaps and cost control costs.

However, the current regulatory framework for data sharing, the nation's underdeveloped information technology architecture, and the barriers to electronic health record interoperability frustrate providers' ability to access and harness data. Data sharing is governed by a series of crisscrossing state and federal regulations that are often inconsistent with one another and incompatible with a digital health world. The same data sharing effort might be permitted by some federal laws and prohibited by others, undermining the conduct of important research and public health efforts. The lack of harmonization often results in an incomplete picture of a beneficiary, such as with dual-eligible patients who participate in both state and federal programs.

Moreover, the Medicare program expects providers to take on increasing accountability for beneficiaries, but the data provided to support these efforts are neither timely nor complete. For example, CMS currently does not provide claims data containing substance use diagnoses (whether it is the primary purpose of a visit or just listed as a comorbidity) to any providers in alternative payment models. Protecting the confidentiality of sensitive health information is laudable, but disparate treatment for alcohol and substance disorder information compared with other types of health information (for example, mental health), frustrates comprehensive data sharing and the development of a complete patient-centered care approach to care and the ability of healthcare providers to engage in managing their entire population's health.

In addition, missing and lagged data prevent providers from developing a truly patient-centered approach to managing the entire population's care. Electronic health record interoperability is the cornerstone for state of the art medical care, enhancing patient satisfaction and enabling data sharing in the event of national security events. Despite recognition of the importance of interoperability, it has been widely documented that that our electronic health systems remain fractured and siloed, and that more work is also needed to create adequate exchange of health information.

While CMS has made great strides in promoting access to government data, continued investments in its infrastructure and statutory permissions are needed.

Healthcare providers currently have limited access across federal programs. Streamlined access to this information would assist healthcare providers with effectively managing care transitions between state and federal health programs. The web of different state and federal laws should be harmonized to increase clarity and reduce burden on providers. Moreover, the conflicting federal laws should also be harmonized and updated to reflect the digital age. Interoperable electronic health record (EHR) systems are needed to ensure patient information can be seamlessly shared across providers to improve care outcomes and efficiency.

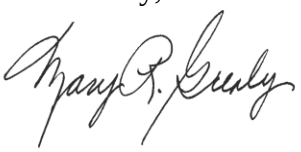
HLC CEOs, who are leaders in every healthcare field, have agreed upon the need for an interoperable health IT infrastructure that takes shape in a way that is both beneficial to consumers and workable for industry. We encourage CMS to consider our recommendations below as it works to toward the healthcare system of tomorrow using the healthcare data of today.

- We believe that policymakers should **encourage exchange of material and meaningful health data** through the use of technologies and applications that enable bidirectional and real-time exchange of health data currently residing in electronic health record (EHR) systems (e.g., open and secure API technology).

- Policymakers should also use appropriate authority to **certify only those EHR technology products that do not block or otherwise inhibit health information exchange**. The HHS Office of the National Coordinator should decertify "Meaningful Use" products that intentionally block the sharing of information, or that create structural, technical, or financial impediments or disincentives to the sharing of information.
- The federal government, in collaboration with the private sector, should **build on current and emerging best practices in patient identification and matching** to identify solutions to ensure the accuracy of every patient's identity, and the availability and accessibility of their information, absent lengthy and costly efforts, wherever and whenever care is needed.
- Any interoperability **requirements or incentives should be "technology neutral" and focused on outcomes**—active interoperation between and among systems—rather than on adoption or use of specified technologies. It is critical that future policies do not stifle potential innovations in health system connectivity

Thank you for this opportunity to provide feedback on the future direction of CMMI. HLC looks forward to continuing to work with you. Should you have any questions, please do not hesitate to contact Tina Olson Grande at (202) 449-3433 or tgrande@hlc.org.

Sincerely,



Mary R. Grealy
President