

Health Care Innovation Awards Round Two

U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services (CMS)
Center for Medicare & Medicaid Innovation (CMMI)

Cooperative Agreement

Initial Announcement

Funding Opportunity Number: CMS-1C1-14-001 **Competition ID:** CMS-1C1-14-001-017996

CFDA: 93.610

Applicable Dates:

Letter of Intent to Apply Due: June 28, 2013, by 3:00 p.m. EDT

Electronic Cooperative Agreement Application Due Date: August 15, 2013 by 3:00 p.m. EDT

Anticipated Awardee Announcements: Phase 1 – January 15, 2014; Phase 2 – January 31, 2014

Anticipated Notice of Cooperative Agreement Award: Phase 1 and Phase 2 – February 28, 2014

Anticipated Cooperative Agreement Period of Performance: April 1, 2014 to March 31, 2017

OVERVIEW INFORMATION

Agency Name: Department of Health and Human Services

Centers for Medicare & Medicaid Services

Center for Medicare & Medicaid Innovation

Funding Opportunity Title: Health Care Innovation Awards Round Two

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I. FUNDING OPPORTUNITY DESCRIPTION

1. Purpose

This is the second round of an initiative that will fund applicants who propose new payment and service delivery models that will provide better health, better health care, and lower costs through improved quality for Medicare, Medicaid, and Children's Health Insurance Program (CHIP) enrollees. Applicants will propose new service delivery models along with the design of corresponding new payment models. If their applications are funded, awardees will be required to implement the service delivery models at the start of the three-year cooperative agreement period and submit a fully developed new Medicare, Medicaid, or CHIP payment model by the end of the cooperative agreement period. The Centers for Medicare & Medicaid Services (CMS), at its discretion and consistent with the requirements of Section 1115A of the Social Security Act, may further develop one or more of these payment and service delivery models and open them to participation through a subsequent solicitation. Successful applicants will demonstrate that they can implement a model that improves quality of care and reduces cost within the first six months of the award and delivers net savings to CMS within three years.

2. Authority

Section 1115A of the Social Security Act (the Act) (added by Section 3021 of the Affordable Care Act) authorizes the Center for Medicare and Medicaid Innovation (Innovation Center) to test innovative health care payment and service delivery models that have the potential to lower Medicare, Medicaid, and CHIP spending while maintaining or improving the quality of beneficiaries' care. Under the statute, models must address defined populations for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Innovation Center will use its authority to test alternative models for payment and service delivery.

3. Background

To date, the Innovation Center has supported this care transformation effort through an array of initiatives that are listed on the Innovation Center's web site. The initiatives cover a broad range of payment and service delivery models, including accountable care organizations; bundled payment; primary care transformation; initiatives focused on the Medicare, Medicaid, and CHIP enrollee populations; initiatives to accelerate the development and testing of new payment and service delivery models; and initiatives to speed the adoption of best practices.

Together, these models provide a broad array of opportunities for providers to engage with CMS to transform care systems. We know, however, that these initiatives do not address every opportunity and need for improved care. We also know that innovators in both rural and urban communities have developed other payment and service delivery models that could address some of these needs. The Innovation Center is interested in being an effective partner to such innovators and strengthening the current portfolio of models available for testing.

To that end, we launched the first round of Health Care Innovation Awards. It was designed to support innovative organizations, providers, and communities in developing new care models to improve outcomes and efficiency for CMS beneficiaries. These initiatives may have the potential

to be expanded to broader populations across the country. Emphasis was placed on models that could transform the workforce, launch quickly, reduce costs, improve quality, and improve health.

The first round of Innovation Awards supports 107 models. Awards range from approximately \$1 million to \$26.5 million for a three-year period. Applications were submitted by providers, payers, local governments, public-private partnerships, and multi-payer collaborations. They include models that enhance primary care, coordinate care across multiple settings, deploy new types of health care workers, help patients and providers make better decisions, and test new service delivery technologies. In this first round, less than 5% percent of applications were funded. Given the interest and desire to continue learning from the nation's innovators, we are launching the second round of Health Care Innovation Awards.

4. Initiative Requirements

The second round of Health Care Innovation Awards will fund applicants who propose new payment and service delivery models that have the greatest likelihood of driving health care system transformation and delivering better outcomes for Medicare, Medicaid, and CHIP beneficiaries in four Innovation Categories. "Service delivery model" refers to the manner in which providers organize and deliver care to patients. "Payment model" refers to the manner in which Medicare, Medicaid, or CHIP pay providers in order to incentivize them to provide efficient, high quality care.

In Round Two, CMS plans to award up to \$900 million. However, CMS reserves the right to award less than this amount if the agency does not receive an adequate number of proposed innovations that meet the selection criteria. This round of Health Care Innovation Awards differs from the first round of awards in several respects.

The first round was a broad solicitation in which CMS welcomed a wide variety of types of proposals. In this round, CMS is specifically seeking new payment and service delivery models in four broad Innovation Categories, as described below. These categories were identified as gaps in the current Innovation Center portfolio and as areas that could result in potentially usable models for changes in Medicare, Medicaid, and CHIP payment methods. This round of Innovation Awards encourages a strong focus on Medicaid and CHIP populations. In addition, models that primarily focus on acute hospital inpatient care are excluded from this round and will not be reviewed. (Hospitals are eligible to apply for awards if they propose a model within one of the four Innovation Categories described below.)

- Models that are designed to rapidly reduce Medicare, Medicaid, and/or CHIP costs in outpatient and/or post-acute settings. Priority areas are diagnostic services, outpatient radiology, high-cost physician-administered drugs, home based services, therapeutic services, and post-acute services. While preference will be given to submissions within these priority areas, CMS will consider submissions in other outpatient and/or post-acute areas within this Category.
- Models that improve care for populations with specialized needs. Priority areas are high-cost pediatric populations, children in foster care, children at high risk for dental disease, adolescents in crisis, persons with Alzheimer's disease, persons living with HIV/AIDS (in particular, efforts to link and retain patients in care and improve medication

- adherence that lead to viral suppression), persons requiring long-term support and services, and persons with serious behavioral health needs. While preference will be given to submissions within these areas, CMS will consider submissions that improve care for other populations with specialized needs.
- Models that test approaches for specific types of providers to transform their financial and clinical models. Priority areas are models designed for physician specialties and subspecialties (for example, oncology and cardiology), and for pediatric providers who provide services to children with complex medical issues (including but not limited to care for children with multiple medical conditions, behavioral health issues, congenital disease, chronic respiratory disease, and complex social issues); and that include, as appropriate, shared decision-making mechanisms to engage beneficiaries and their families and/or caregivers in treatment choices. While preference will be given to submissions within these areas, CMS will consider submissions in other areas within this Category and from other specific types of non-physician providers.
- Models that improve the health of populations defined geographically (health of a community), clinically (health of those with specific diseases), or by socioeconomic class - through activities focused on engaging beneficiaries, prevention (for example, a diabetes prevention program or a hypertension prevention program), wellness, and comprehensive care that extend beyond the clinical service delivery setting. These models may include community based organizations or coalitions and may leverage community health improvement efforts. These models must have a direct link to improving the quality and reducing the costs of care for Medicare, Medicaid, and/or CHIP beneficiaries. Priority areas are: models that lead to better prevention and control of cardiovascular disease, hypertension, diabetes, chronic obstructive pulmonary disease, asthma, and HIV/AIDS; models that promote behaviors that reduce risk for chronic disease, including increased physical activity and improved nutrition; models that promote medication adherence and self-management skills; models that prevent falls among older adults; and broader models that link clinical care with community-based interventions. While preference will be given to submissions within these areas, CMS will consider submissions in other areas within this Category.

In this round – in contrast to the first round – CMS specifically seeks new payment models to support the service delivery models funded by this initiative.

All applicants must submit, as part of their application, the *design* of a payment model that is consistent with the new service delivery model funded by this second round of Health Care Innovation Awards. The payment model design must include Medicare, Medicaid, and/or CHIP, though it should ideally include other payers as well. This payment model design should include a description of how funds would flow under the model, a description of the specific provider or beneficiary incentives the payment model would create, a description of risk parameters, a description of how the payment model would deliver a positive return on investment for CMS, and a description of how the parameters of the payment model would progress over time.

Applicants have the option to submit, as part of their application, a *detailed and fully developed* payment model as well as a list of payers interested in testing the new payment and service delivery model.

If they have not already done so as part of the application, awardees must deliver, during or by the conclusion of the cooperative agreement period, a detailed and fully developed version of the payment model required above, as well as a list of payers interested in testing the payment and service delivery model.

CMS encourages applications from organizations that were not awarded previous Health Care Innovation Awards. While previous awardees may apply under this funding opportunity announcement, organizations that received funding from CMS under Round One of the Health Care Innovation Awards may not receive additional funding to support models funded under Round One. CMS encourages organizations serving rural or underserved areas to apply.

4(a) Initiative Requirements - Model

Proposals should demonstrate how payment and service delivery models being tested relate to benefit designs and/or new payment approaches that CMS can consider for broader application. Proposals should explain how the model being tested would result in improved patient care and ensure protection of beneficiary access to care. In HCIA Round Two, applicants must submit the design of a payment model as part of their application, and may optionally choose to submit a fully developed payment model as part of this application. If they have not already done so as part of the application, awardees must deliver, during or by the conclusion of the cooperative agreement period, a detailed and fully developed version of the payment model required above, as well as a list of payers interested in testing the payment and service delivery model. The payment model should be designed to provide a sustainable source of funding for the delivery model after the cooperative agreement period has ended. CMS also invites applicants to propose tests of scalability for models known to improve quality and reduce costs, that is, models to spread proven interventions to different or broader Medicare, Medicaid, and/or CHIP populations. Payment models that propose new alternative approaches rather than simply expanding or supplementing fee-for-service payments will be preferred. CMS will not fund proposals that duplicate models that CMS or other HHS entities are currently testing in other initiatives.

CMS also recognizes that new types of data analytics and other technological approaches may be important to achieving optimal efficiency and improved outcomes in health care delivery. Models that use data analytics to improve care could include but are not limited to: models that test the implementation of analytical tools to coordinate and improve care; models that improve transparency; and models that use health information exchanges, telemedicine and remote monitoring, clinical registry systems, medication reconciliation systems, and decision support and shared decision-making systems. Award dollars may be used to implement specific technology, software, applications, or other analytical tools, but only if they are being implemented and tested in the context of a health care service delivery model that has a clear pathway to a payment model.

CMS recognizes that in order for providers to have meaningful incentives to change their service delivery models they must engage multiple payers. Therefore, applications must include a feasible approach for securing participation of multiple payers for their proposed models. This could include demonstrable commitments from current payer partners, current contracts, letters of support or commitment from private insurers, state¹ governments, or local governments.

¹ By "state," we refer to the definition provided under 45 CFR 74.2 as "any of the several States of the U.S., the

Preference will be given to applications that include participation by non-CMS payers at the outset of the model's implementation.

4(b) <u>Initiative Requirements – Key Attributes</u>

4(b)(1) Speed to Implementation: Proposed models should be capable of rapid implementation. Awardees will be expected to complete the infrastructure and capacity-related activities within six months of the award, and start improving care as rapidly as possible. Preference will be given to models that implement their care improvement activities faster than six months.

4(b)(2) Payment Model: As noted above, applicants are expected to submit the design of a payment model with their initial application. They should define a clear pathway to ongoing sustainability through the creation of a fully developed Medicare, Medicaid, and/or CHIP payment model. This fully developed payment model may be submitted at the option of applicants as part of the application, and if not so submitted, must be submitted by awardees either during or by the end of the three-year cooperative agreement. This payment model should result in savings for Medicare, Medicaid, and/or CHIP. Funding is intended to support the implementation of a service delivery model, and potentially an initial period of implementation of the payment model. While CMS encourages awardees to implement new payment models within the award period, CMS is not obligated to implement payment policy changes during or after the award period. Each proposal should include a description of how it will reduce programmatic costs for CMS and improve outcomes – as well as the resulting business model.

Examples of such payment models could include, but are not limited to:

- New Medicare, Medicaid, and/or CHIP payment models supporting innovative care service delivery models with commitment from other payers;
- Models that share savings (and risk) with providers;
- Tiered value-based payment schedules that pay more for services with a strong evidence base for their effectiveness and less for services that are not as effective as alternatives;
- Hybrid models that blend unit-based and per-case payment; and
- Other innovative forms of payment for specific types of services designed to reduce barriers to use of the most appropriate forms of care and to reward efficient providers of high-quality, evidence-based services.

4(b)(3) Certified Financial Plan: To facilitate the review process and increase the probability that awards yield savings, each applicant must submit a Financial Plan estimating the proposal's return on investment for Medicare, Medicaid, and/or CHIP. For applicants requesting less than \$10 million in funding, the Financial Plan must be reviewed and certified by the chief financial officer of the applicant organization. (The chief financial officer cannot be the executive director.) These applicants are encouraged but not required to submit an external actuarial review of their Financial Plan.

District of Columbia, the Commonwealth of Puerto Rico, (or) any territory or possession of the U.S." By "territory or possession," we mean Guam, the U.S. Virgin Islands, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Applicants requesting \$10 million or more in funding are required to obtain and submit an external actuarial certification of their Financial Plan with their application. A qualified actuary who is a member of the American Academy of Actuaries must complete the external certification. CMS will make available to applicants a template for this purpose on or about June 14, 2013 on the Innovation Center website at http://innovation.cms.gov. In addition, the chief financial officer of the applicant must review and certify the Financial Plan.

CMS may conduct an actuarial review of any application, regardless of funding amount. The CMS Office of the Actuary will assist the GMO in review of the reasonableness of the estimated cost to the government, and will review the potential for federal savings. This review will be one of the criteria for the CMS Approving Official to consider during the application review process. The strength of the external actuarial certification, as well as the review of the CMS Actuary, will be part of the CMS Approving Official's consideration in final selection of awardees.

4(c) <u>Initiative Requirements – Evaluation and Monitoring</u>

CMS will evaluate the funded proposals in accordance with the requirements set forth in Section 1115A of the Social Security Act (added by Section 3021 of the Affordable Care Act).² Each awardee must clearly include quantifiable means for regularly monitoring the impact of its proposed model on the three key outcomes of improved care, improved health outcomes, and reduced costs. Each awardee will be responsible for monitoring and reporting to CMS on the progress and impact of its model. In addition to this self-monitoring, CMS contractors will conduct an independent evaluation.

4(c)(1) Impact on improved care and health quality outcomes: Each applicant will propose quality indicators with a continuous improvement method of measurement to be used to evaluate the impact of the proposed model on better care and better health.

Improved care and health quality outcomes metrics should address the following domains (if relevant):

- Patient satisfaction and/or patient experience
- Adhering to evidence-based practices and reducing inappropriate utilization
- Clinical quality
- Patient access
- Patient outcomes

Metrics will be jointly developed by awardees and CMS, and will be based on a standard measure set developed by CMS as well as input from awardees.

Measures should be collected and analyzed on an on-going basis, and enabled where possible by health IT such as certified electronic health records, registries, data analytics, and other electronic reporting mechanisms. CMS will make more information on standard measures available at http://innovation.cms.gov.

² See pp. 306-313 in the full text of the Affordable Care Act and Reconciliation Act at http://housedocs.house.gov/energycommerce/ppacacon.pdf.

4(c)(2) Impact on Lower Costs: Each model is expected to generate savings for the total cost of care for Medicare, Medicaid, and/or CHIP beneficiaries. CMS will require applicants to complete budget form SF 424A and a Financial Plan demonstrating their ability to achieve savings over the three-year term of the award as well as on a projected annualized basis after the term of the award is finished. Financial Plans must be signed by the chief financial officer of the applicant organization. SF 424A and the Financial Plan template (to be provided on or about June 14, 2013 on the Innovation Center website at http://innovation.cms.gov.) will be utilized so that each initiative applicant can demonstrate its anticipated use of funds and explain how its interventions will reduce overall cost of care for the beneficiaries its model serves. Applicants are required to provide detailed back-up financial models explaining the logic driving their forecast cost of care savings. CMS will provide further guidance as part of the Financial Plan template.

Successful applicants will demonstrate the ability to achieve satisfactory improvement in cost of care, while ensuring protection of care quality and access for beneficiaries, along the following dimensions:

- Net savings to Medicare, Medicaid, and/or CHIP over the duration of each award to CMS: and
- Medical cost trend reduction that results from building a sustainable new payment model that continues after the cooperative agreement period is complete.

4(c)(3) Operational Performance: Awardees will be measured and monitored on their ability to execute their proposed operational work plan. The Operational Plan is described below in "Section Six: Supplementary Materials." Key components of this monitoring will include, but are not limited to:

- Meeting proposed milestones and deliverables;
- Producing timely and accurate reports with clear progress on quality and cost performance as described above; and
- Building and/or enhancing required infrastructure.

Award recipients will be required to report their actual performance on cost and quality outcomes and operational performance, and CMS will regularly monitor the results. Awardees will be required to provide, or cooperate in providing, as applicable, the necessary data elements to CMS.

In addition to this self-monitoring and self-evaluation, CMS will also collect from awardees a standard minimum set of performance indicators through CMS monitoring and evaluation contractors. CMS will contract with independent entities to assist in monitoring the models and to conduct an independent evaluation. More details are provided in Section VI.4(a) of this funding opportunity announcement.

4(d) Initiative Requirements – Learning and Diffusion

Awardees will be required to participate in CMS-sponsored learning sessions about how care delivery organizations can achieve performance improvements quickly and effectively. Awardees

will also be required to participate in opportunities to share their experiences with one another and with participants in other Innovation Center initiatives, both through in-person and online activities.

To best support the broad range of anticipated innovators for this initiative, CMS will create learning networks based on the Innovation Categories above or other similar factors. The goal of these learning networks is to allow awardees to learn best practices from their peers and to further develop their models throughout the duration of this initiative. The Innovation Center will use various approaches to group learning and exchange, helping awardees to effectively share their experiences, track their progress, and rapidly adopt new ways of achieving improvement in payment and service delivery models. CMS will require awardees to actively participate in and shape these shared learning network activities.

4(e) <u>Initiative Requirements – Restrictions on Awards</u>

The funds shall be used to implement models that support system transformation toward higher quality care at lower costs, and to plan and develop complementary payment models. CMS will not fund models that focus primarily on acute hospital inpatient care. Award dollars may be used for specific components, devices, equipment, software, analytical tools, or personnel provided that they are integrated into the service delivery and payment model. Award dollars cannot be used to make permanent improvements to property not owned by the federal government; minor alterations and renovations are permissible under certain circumstances that will be described in the Financial Plan template (to be provided on or about June 14, 2013 on the Innovation Center website at http://innovation.cms.gov.). CMS will not fund proposals that duplicate models that CMS is currently testing in other initiatives (see Section I.4) or other proposals being investigated elsewhere in HHS. CMS will not fund the provision of services to non-CMS beneficiaries. Finally, CMS will not fund applicants that cannot monitor, self-evaluate, and report on the progress and impact of their model in a timely manner.

4(f) <u>Initiative Requirements – Alignment of Proposed Models</u>

The Innovation Center anticipates that a large number and a wide variety of proposed models will be submitted. All Innovation Center initiatives require evaluation and close operational initiative monitoring and reporting. In order to facilitate learning that will ultimately inform CMS policy making, the Innovation Center may work with awardees to identify opportunities to modify and adjust models and their metrics.

5. Technical Assistance

Prior to the application deadline, CMS will host a series of Open Door Forums or webinars to provide details about this initiative and to answer any questions from potential applicants. Information about the forums will be posted on the Innovation Center website at http://innovation.cms.gov.

CMS recognizes that some awardees may be interested in receiving Medicare, Medicaid, and/or CHIP data to inform and measure their models. CMS is open to discussing data needs with awardees and may provide data, when appropriate. However, timely access to Medicaid data is dependent on state data capabilities. Existing laws, rules, and CMS policies for accessing data apply.

II. AWARD INFORMATION

1. Total Funding

The Innovation Center expects to spend up to \$1 billion on this initiative, and is making up to \$900 million in funding available through this Funding Opportunity Announcement (FOA) to support a diverse portfolio of new and innovative payment and service delivery models that will reduce the cost of health care and improve its quality in Medicare, Medicaid, and/or CHIP. Cooperative agreements will be awarded with consideration to the criteria listed below in Section V(2). Awardees might not receive the award amount requested and may be asked to adjust the service delivery model, payment model, work plan, budget, or other application deliverable.

2. Award Amount

The Innovation Center expects to make awards to cover a three-year performance period, depending on the scope and nature of the individual proposals received. CMS reserves the right to allocate the total funding amount between Innovation Categories based on the need to achieve a portfolio of projects that best meets the objectives of this FOA and the quality of applications received within each Category.

3. Anticipated Award Date

CMS expects to announce the first phase of awardees of cooperative agreements on or about January 15, 2014, and the second phase of awardees of cooperative agreements on or about January 31, 2014.

4. Period of Performance

The anticipated period of performance for the 3-year model period is April 1, 2014 to March 31, 2017. The budget period is 12 months.

CMS is under no obligation to make additional awards under this initiative.

5. Number of Awards

CMS intends to fund the best qualified applications within the scope of available funds. CMS estimates that there will be approximately 100 awards, with a range of approximately \$1 million to \$30 million per award, however CMS is not obligated to fund a minimum number of applicants, or to distribute a minimum amount of funds available for the second round of Health Care Innovation Awards.

6. Other Important Award Elements

Awards will be made through Cooperative Agreements. CMS will continually evaluate each awardee's performance and ability to show demonstrated progress toward initiative goals. Pending CMS approval of the awardee's completed operational plan, funding is restricted to program planning activities only.

7. Termination of Award

Continued funding is dependent on satisfactory performance compared with operational performance measures and a decision that continued funding is in the best interest of the federal government. CMS also may terminate or modify an agreement based upon CMS review of the awardee's progress, including a review of whether or how well quality and savings targets are met. Proposals will be funded subject to meeting terms and conditions specified in the Cooperative Agreement, and awards may be terminated if these terms and conditions are not met. See also section 1115A(b)(3)(B) of the Social Security Act.

8. Anticipated Substantial Involvement by Awarding Office

CMS anticipates substantial involvement in the Health Care Innovation Award Round Two cooperative agreements. CMS will provide guidance to applicants through webinars, trainings, and other web-based materials. CMS will also monitor, measure, and evaluate awardees on:

- Impact on quality of care and health status;
- Impact on costs; and
- Operational performance, including:
 - Meeting proposed milestones;
 - Producing timely and accurate reports with clear progress on quality and cost performance; and
 - O Building and/or enhancing required infrastructure.

While awardees are expected to cooperate with and facilitate the role of the awarding office and work of the evaluation contractor, it is not necessary to budget for these activities beyond allowance for staff time for interactions and data reporting. For example, the awardee is not expected to provide working space for federal participants.

Applications should propose plans and budgets without any assumption of operational programmatic support from the awarding office. For example, the awarding office will not make facilities or other resources available beyond the cooperative agreement award amount. Proposals that would require such additional support will be considered non-responsive and will be eliminated from consideration. Proposals that require data from CMS should explicitly specify this need. CMS is under no obligation to provide requested data.

III. ELIGIBILITY INFORMATION

1. Eligible Applicants

The intent of this initiative is to engage with a wide variety of innovators. Interested parties of all types that meet the eligibility requirements specified in this section and have developed innovations that will drive significant improvement in population health, quality of care, and total cost of care and who can create a clear pathway to an alternate payment model based on their innovation are welcome to apply. Examples of the types of organizations expected to apply are: provider groups, health systems, payers and other private sector organizations, faith-based organizations, state and/or local governments, academic institutions, research organizations, public-private partnerships, and for-profit organizations. In addition, certain organizations may apply as conveners that assemble and coordinate the efforts of a group of participants. Unsuccessful applicants from prior CMS funding competitions are eligible to apply. Technology developers, including software designers and others creating solutions for health care providers, are welcome to apply. However, any such technology model needs to reflect the actual use, not the development, of a product in a broader service delivery or payment model. Applicants that develop open source technology or software that are placed in the public domain will be given preference.

Additional technical requirements for eligibility are listed below. Please allow sufficient time to obtain or complete each of the required items as certain items may take some time to obtain. Applicants that are unable to obtain a required item by the application deadline will not be eligible for an extension, except as described below.

1(a) Eligible Applicants – Legal Status

To be eligible, a non-governmental organization must be recognized as a single legal entity by the state where it is incorporated, and must have a unique Tax Identification Number (TIN) designated to receive payment. The organization must have a governing body capable of entering into a cooperative agreement with CMS on behalf of its members.

1(b) Eligible Applicants – Eligibility Threshold Criteria

1(b)(1) Application deadline: Applications not submitted by 3:00 pm Eastern Daylight Time on August 15, 2013 through <u>www.grants.gov</u> will not be reviewed.

I(b)(2) Application requirements: Applications will be considered for funding only if the application meets the requirements as outlined in Section III, Eligibility Information, and Section IV, Application and Submission Information.

1(b)(3) Page limit: Applications must not be more than 50 pages in length which includes the Cover Letter and Project Narrative (uploaded together in Grants.gov on Project Narrative Attachment Form"), and Budget Narrative (uploaded in Grants.gov on "Budget Narrative Attachment Form"). Supplementary Materials are limited to 50 pages in length, and include the Financial Plan, Operational Plan, and Executive Overview, and for applicants requesting \$10

million or more, the Actuarial Certification. Supplementary materials are uploaded in Grants.gov on 'Other Attachments Form.' CMS will provide templates and instructions for these forms on or about June 14, 2013 on the Innovation Center website at http://innovation.cms.gov. These templates will be based upon standard software packages (Excel, Word, and/or PDF), as determined by CMS. These templates must be uploaded in Grants.gov in the native format provided by the Innovation Center. Applicants may also include profiles of participating organizations, relevant letters of commitment to participate in the initiative, and other supporting materials with the Supplementary materials. Standard forms are not included in these page limits. For more information, see Section IV.2.A, Content and Form of Application Submission.

1(c) Eligible Applicants – Review Criteria

Applicants are strongly encouraged to use the review criteria information provided in Section V, Application Review Information, to help ensure that the proposed model adequately addresses all the criteria that will be used in evaluating the models.

2. System for Award Management (SAM) Requirement

System for Award Management (SAM) Requirement: All applicants must provide their DUNS and EIN/TIN numbers in order to be able to register in the System for Award Management (SAM)* https://www.sam.gov/portal/public/SAM/. Registering an account with SAM is a separate process from submitting an application. Applicants are encouraged to register early. Registration should be completed in sufficient time to ensure that it does not impair your ability to meet required submission deadlines.

*Applicants were previously required to register with the Central Contracting Registration (CCR) database. However, SAM has integrated the CCR and 7 other federal procurement systems into a new, streamlined system. If an applicant has an active record in CCR, there will be an active record in SAM. Nothing more is needed unless a change in the business circumstances requires updates to the Entity record(s) in order for the applicant to be paid, receive an award, or to renew the Entity prior to expiration. Please consult the SAM website listed above for additional information.

Applicants must successfully register with SAM prior to submitting an application or registering in the Federal Funding Accountability and Transparency Act Subaward Reporting System (FSRS) as a prime awardee user. See Section IV, Application and Submission Information, for more guidance on SAM registration. Prime recipients must maintain a current registration with the SAM database, and may make subawards only to entities that have DUNS numbers.

Organizations must report executive compensation as part of the registration profile at https://www.sam.gov/portal/public/SAM/ by the end of the month following the month in which this award is made, and annually thereafter (based on the reporting requirements of the Federal Funding Accountability and Transparency Act (FFATA) of 2006 (Pub. L. 109-282), as amended by section 6202 of Public Law 110-252 and implemented by 2 CFR Part 170). See Section VI, Award Administration Information, for more information on FFATA.

3. Cost Sharing or Matching

Cost sharing and matching are not required.

4. Foreign and International Organizations

Foreign and international organizations are ineligible to apply.

5. Faith-Based Organizations

Faith-based organizations are eligible to apply.

IV. APPLICATION AND SUBMISSION INFORMATION

1. Application Package

1(a) Application Package – Letter of Intent to Apply

Applicants must submit non-binding Letters of Intent to Apply. Letters of Intent to Apply provide information that helps CMS in determining expertise and personnel necessary to review applications and issue awards. Letters of Intent to Apply must be received by 3:00 pm Eastern Daylight Time on June 28, 2013. Failure to submit a Letter of Intent to Apply will disqualify the application from that organization from being reviewed. The information specified for the Letter of Intent to Apply must be provided through an online form. Additional information and detailed instructions for submitting Letters of Intent to Apply will be posted on the Innovation Center website at http://innovation.cms.gov.

1(b) Application Package – Application Materials

This Funding Opportunity Announcement serves as the application package for this cooperative agreement and contains instructions to enable a potential applicant to apply.

Application materials will be available for download at http://www.grants.gov. Please note that HHS requires applications for all announcements to be submitted electronically through http://www.grants.gov. For assistance with grants.gov, contact support@grants.gov or call 1-800-518-4726. The Funding Opportunity Announcement can also be viewed on the Innovation Center website at http://innovation.cms.gov.

1(c) <u>Application Package – Information for Submission of Applications via http://www.grants.govand/or as otherwise specified</u>

Please observe the following guidelines in your use of http://www.grants.gov:

- You can access the electronic application for this proposal at http://www.grants.gov. You must search the downloadable application page by the CFDA number shown on the cover page of this announcement.
- At the http://www.grants.gov website, you will find information about submitting an application electronically through the site, including the hours of operation. HHS

- strongly recommends that you do not wait until the application due date to begin the application process through http://www.grants.gov.
- As noted above, all applicants must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number. The DUNS number is a nine-digit identification number that uniquely identifies business entities. To obtain a DUNS number, access the following website: www.dunandbradstreet.com, or call 1-866-705-5711. This number should be entered in the block with the applicant's name and address on the cover page of the application (Item 8c on the Form SF 424, Application for Federal Assistance). The name and address in the application should be exactly as given for the DUNS number. Applicant should obtain this DUNS number immediately to ensure all registration steps are completed in time.
- The Authorized Organizational Representative (AOR) who will officially submit an application on behalf of the organization must register with Grants.gov for a username and password. The AOR must complete a profile with Grants.gov using its organization's DUNS Number to obtain a username and password. http://grants.gov/applicants/get_registered.jsp
 AORs must wait one business day after registration in SAM before entering their profiles
 - AORs must wait one business day after registration in SAM before entering their profiles in Grants.gov. Applicants are strongly advised to begin this process immediately to ensure this step is completed in time to apply before application deadlines.
 - When an AOR registers with Grants.gov to submit applications on behalf of an organization, that organization's E-Biz point-of-contact will receive an email notification. The email address provided in the profile will be the email used to send the notification from Grants.gov to the E-Biz POC with the AOR copied on the correspondence.
 - The E-Biz POC must then login to Grants.gov (using the organization's DUNS number for the username and the special password called "M-PIN") and approve the AOR, thereby providing permission to submit applications.
 - The AOR and the DUNS number must match. If you organization has more than one DUNS number, be sure you have the correct AOR for your application.
- Any files uploaded or attached to the Grants.gov application must be PDF file format and must contain a valid file format extension in the filename, unless otherwise specified in this FOA. Please note that the templates to be provided by the Innovation Center must be uploaded in the native format provided by the **Innovation Center.** Even though Grants.gov allows applicants to attach any file format as part of their application, CMS restricts this practice and only accepts PDF file format, unless otherwise specified in this FOA. Any file submitted as part of the Grants.gov application that is not in a PDF file format or in another format otherwise specified in this FOA, or contains password protection, will not be accepted for processing and will be excluded from the application during the review process. In addition, the use of compressed file formats such as ZIP, RAR or Adobe Portfolio will not be accepted. The application must be submitted in a file format that can easily be copied and read by reviewers. It is recommended that scanned copies not be submitted through Grants.gov unless the applicant confirms the clarity of the documents. Pages cannot be reduced resulting in multiple pages on a single sheet to avoid exceeding the page limitation. All documents that do not conform to the above will be excluded from the application during the review process.

- Applicants are now limited to using the following UTF-8 characters in all attachment file names: A-Z, a-z, 0-9, underscore (_), hyphen (-), space, period.
 If applicants use any other characters when naming their attachment files their applications will be rejected.
- Prior to application submission, Microsoft Vista and Office 2007 users should review the Grants.gov compatibility information and submission instructions provided at http://www.grants.gov/. Click on "Vista and Microsoft Office 2007 Compatibility Information"
- You must submit all standard documents electronically in PDF format and/or other electronic or web-based format(s) specified by CMS, including all information included on the SF 424 and all necessary assurances and certifications, and all other attachments.
- After you electronically submit your application, you will receive an automatic email notification from Grants.gov that contains a Grants.gov tracking number. Please be aware that this notice does not guarantee that the application will be accepted by **Grants.gov. It is only an acknowledgement of receipt.** All applications that are successfully submitted must be validated by Grants.gov before they will be accepted. Please note applicants may incur a time delay before they receive acknowledgement that the application has been validated and accepted by the Grants.gov system. In some cases, the validation process could take up to 48 hours. If for some reason your application is not accepted, then you will receive a subsequent notice from Grants.gov citing that the application submission has been rejected. Applicants should not wait until the application deadline (date and time) to apply because notification by Grants.gov that the application fails validation and is rejected may not be received until close to or after the application deadline, eliminating the opportunity to correct errors and resubmit the application. Applications that fail validation and are rejected by Grants.gov after the deadline will not be accepted and/or granted a waiver. For this reason CMS recommends submission of applications prior to the due date and time.
- The most common reasons why an application fails the validation process and is rejected by Grants.gov are:
 - o SAM registration cannot be located and validated
 - SAM registration has expired
 - The AOR is not authorized by the E-Biz POC to submit an application on behalf of the organization
 - o File attachments do not comply with the Grants.gov file attachment requirements
- HHS retrieves applications from Grants.gov only after Grants.gov validates and accepts the applications. Applications that fail validation and are rejected by Grants.gov are not retrieved by HHS, and HHS will not have access to rejected applications.
- After HHS retrieves your application from Grants.gov, you will receive an email notification from Grants.gov stating that the agency has received your application and once receipt is processed, you will receive another email notification from Grants.gov citing the Agency Tracking Number that has been assigned to your application. It is important for the applicant to keep these notifications and know the Grants.gov Tracking Number and Agency Tracking Number associated with their application submission.
- Each year organizations and entities registered to apply for federal grants and cooperative agreements through Grants.gov will need to renew their registration with the System for Award Management (SAM). You can register with the SAM online at;

- https://www.sam.gov/portal/public/SAM. Failure to renew SAM registration prior to application submission will prevent an applicant from successfully applying.
- All applications must be submitted electronically by 3:00 p.m. Eastern Daylight Time on August 15, 2013.
- All applications will receive an automatic time stamp upon submission and applicants will receive an automatic e-mail reply acknowledging the application's receipt.
- To be considered timely, applications must be sent on or before the published deadline date and time. However, a general extension of a published application deadline that affects all applicants or only those applicants in a defined geographical area may be authorized by Grants.gov under circumstances that affect the public at large, such as natural disasters (e.g., floods or hurricanes) or disruptions of electronic (e.g., application receipt services) or other services, such as a prolonged blackout.
- Applications cannot be accepted through any email address. Applications can only be accepted through http://www.grants.gov. Applications cannot be received via paper mail, courier, or delivery service, unless a waiver is granted per the instructions below.
- The applicant must seek a waiver **at least** ten days prior to the application deadline if the applicant wishes to submit a paper application. Applicants that receive a waiver to submit paper application documents must follow the rules and timelines that are noted below.
- In order to be considered for a waiver application, an applicant **must** adhere to the timelines for SAM and Grants.gov registration, as well as request timely assistance with technical problems.

Please be aware of the following:

- If you experience technical challenges while submitting your application electronically, please contact Grants.gov Support directly at: www.grants.gov/customersupport or (800) 518-4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on federal holidays).
- Upon contacting Grants.gov, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- If it is determined that a waiver is needed from the requirement to submit your proposal electronically, you must submit a request in writing (emails are acceptable) to OAGMGrantsBaltimore@cms.hhs.gov (please put 'HCIA Round Two Waiver Request' in the subject line) with a clear justification for the need to deviate from the standard electronic submission process.
- If the waiver is approved, the Division of Grants Management will provide instructions as to submission of the application.

Grants.gov complies with Section 508 of the Rehabilitation Act of 1973. If an individual uses assistive technology and is unable to access any material on the site including forms contained with an application package, they can email the Grants.gov contact center at support@grants.gov or call 1-800-518-4726.

2. Content and Form of Application Submission

2(a) Content and Form of Application Submission – Form of Application Submission

Each application must include all contents described below, in the order indicated, and in conformance with the following specifications:

- Use 8.5" x 11" letter-size pages (one side only) with 1" margins (top, bottom, and sides).
- Other page sizes will not be accepted. This is particularly important because it is often not possible to reproduce copies in a size other than 8.5" x 11".
- All pages of the Project Narrative must be paginated in a single sequence.
- Font size must be no smaller than 12-point with an average character density no greater than 14 characters per inch.
- The narrative portions of the application must be DOUBLE-SPACED.
- The Project Abstract is restricted to a one-page summary which should be single-spaced.

Applications must not be more than 50 pages in length which include the Cover Letter and Project Narrative (uploaded in Grants.gov on 'Project Narrative Attachment Form') and Budget Narrative (uploaded in Grants.gov on 'Budget Narrative Attachment Form'. Supplementary Materials are limited to 50 pages in length, and include the required Financial Plan, Actuarial Review (for applicants requesting \$10 million or more), Operational Plan, and Executive Overview (CMS will provide detailed guidance on all needed templates on or about June 14, 2013 on the Innovation Center website at http://innovation.cms.gov.) Also included in the Supplementary Materials are documentation related to financial projections, profiles of participating organizations, relevant letters of endorsement, etc. The total size of all uploaded files may not exceed a total file size of 13 MB. Standard forms are NOT included in the page limits and in the file-size limits. Please review these technical criteria carefully and allow sufficient time to comply. Applications that fail to meet the criteria described here will be rejected. CMS will not allow resubmissions after the deadline from applicants that fail to meet these criteria. For awarded applicants, CMS may require additional submissions related to an awardee's Operational Plan. Pending CMS approval of the awardee's completed Operational Plan, funding is restricted to model planning activities only.

2(b) <u>Content and Form of Application Submission – Overview of Cooperative Agreement Application Structure and Content</u>

2(b)(1) Standard Forms: The following standard forms must be completed with an original signature and enclosed as part of the proposal:

- SF 424: Official Application for Federal Assistance (see note below)
- SF 424A: Budget Information Non-Construction
- SF 424B: Assurances-Non-Construction Programs
- SF LLL: Disclosure of Lobbying Activities
- Project/Performance Site Location(s) form
- Project Abstract Summary

In addition to the Standard Forms, the following are required and are uploaded in Grants.gov on "Other Attachments Form":

• Letters of support and participation from major stakeholders

- Financial Plan*
- Operational Plan*
- Executive Overview (as described in Section Six on Supplementary Materials)*
- Actuarial Review (if applicable required for applicants requesting \$10 million or more)*

*CMS will provide templates and detailed instructions for these submissions on or about June 14, 2013 on the Innovation Center website at http://innovation.cms.gov.

These templates must be uploaded in native formats provided by the Innovation Center.

Note: On SF 424 "Application for Federal Assistance":

- On Item 11 "Descriptive Title of Applicant's Project", state the specific cooperative agreement opportunity for which you are applying: the Health Care Innovation Awards Round Two.
- For Item 15 please provide a succinct descriptive title of the applicant's project. Please do not add attachments in Item 15.
- Check "No" to item 16b, as Review by State Executive Order 12372 does not apply to these cooperative agreements.

2(b)(2) Cover Letter (to be enclosed with the project narrative): A letter is required from the applicant's Authorized Organizational Representative, indicating the title of the proposal, the principal contact person, the amount of funding requested, and the name of the organization that will administer the cooperative agreement. The letter must be uploaded with the application and will be included under the 50-page limit for standard application materials. If it is sent separately through postal mail, it will <u>not</u> be included with the application and the application will be ineligible. Please address the letter to:

Mary Greene
Grants Management Officer
Office of Acquisition and Grants Management
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Mail Stop B3-30-03
7500 Security Blvd, Baltimore, MD 21218

2(b)(3) Project Abstract: The one-page abstract (single-spaced) must identify the specific Innovation Category and priority being addressed. The abstract also serves as a succinct description of the proposal and should include the goals of the proposal; the total budget; the number of included beneficiaries, providers, and payer participants; the projected total cost of care savings; and a description of how the funds will be used. The abstract is often distributed to provide information to the public and Congress, so please write the abstract so that it is clear, accurate, concise, and without reference to other parts of the application. Personal identifying information should be excluded from the abstract.

2(b)(4) Project Narrative: The application must address how the applicant will implement the cooperative agreement model, and meet the objectives of the HCIA Round Two initiative. The

required sections of the application are listed below. Also provided is a brief description of the type of information that is required to be addressed within each specific section. The application must be organized by these headings, noted as the operations element sections, outlined below.

SECTION ONE: DESIGN

- 1.1 Model Goals and Targeting: The application must identify up front the Innovation Category and specific priority the payment and delivery model addresses. The application must list, describe, and justify the selected proposal goals. It must also define the following elements: the targeted populations (which must include, but need not be limited to, Medicare, Medicaid, and/or CHIP beneficiaries), the number of beneficiaries served, the number of participating providers, the services to be delivered, the proposed partners, and the geographic area of the proposed model. A detailed discussion should be included that explains the rationale for why these elements are important in the context of explaining the overall expected impact of the model and potential suitability for expansion to other settings, areas, and/or populations. It should also include an explanation of why this model is a strategic match for the applicant's overall mission.
- 1.2 Comprehensive Description of the Model and Supporting Evidence Base: The application must describe the design of the proposed model including the Innovation Category and priority area addressed. The description provided must describe the type, duration, and scope of the services to be provided in the service delivery model. The description must describe the theory of action for the model and demonstrate specifically and concretely how the model will actually reduce costs and improve quality outcomes. It should also address how the proposed model is evidence-based. It should also explain how the model will affect the targeted population and demonstrate whether and how the proposed model will impact the priority populations and care improvement areas outlined, address health disparities, reduce the effect of multiple comorbidities, and/or modify risk factors. The applicant should also identify the primary challenges to successful implementation of the model and explain how these anticipated risks will be mitigated. The applicant must describe a payment model that would, if implemented by CMS, support the applicant's service delivery model absent additional federal spending after the end of the cooperative agreement period.
- 1.3 Participant Recruitment and Enrollment: The application must include a description of the recruitment strategies that will be employed, including strategies for identifying and targeting prospective beneficiaries. This must include a plan for identifying and managing the applicable population. There should be a discussion of ongoing strategies that promote continuous coverage and retention so that results of the model are not confounded due to beneficiaries cycling through the model during the operational period.
- **1.4** Education and Outreach: The application must describe the plan for conducting the required outreach and education campaign to ensure potential beneficiaries and providers would be aware of the model if selected.

- **1.5 Community Integration:** The application must identify and describe the applicant's method for involving external stakeholders in the initial implementation of the model and its method for continuing to have them meaningfully involved throughout the model. The application must also describe how the proposed model will be integrated into the broader health care community during the cooperative agreement period and in the future.
- **1.6 Targeting Medicaid and CHIP Populations:** The application must identify whether the proposed model includes a specific focus on a population of Medicaid or CHIP beneficiaries, either exclusively or in addition to other populations not served by these programs.
- **1.7** *Multipayer Engagement*: The application must describe the extent to which non-CMS payers are involved with the model within the period of performance

SECTION TWO: ORGANIZATIONAL CAPACITY

Organization and Administration: The application must describe the guiding principles of the organization and its past experience and track record of performance. It must also demonstrate an understanding of the needs of the community or population that the applicant seeks to target. The application must include a description of the governance, organizational, and structural functions that will be in place to implement, monitor, and operate the model. The tasks to be conducted by each administrative component must also be described. The applicant must demonstrate the financial strength and stability needed to operate the model after the completion of the three-year cooperative agreement period. If the applicant has not delivered in the application a detailed and fully developed payment model, the applicant must demonstrate the ability to do so during or by the end of the cooperative agreement period.

SECTION THREE: RETURN ON INVESTMENT

Each proposed model must provide a detailed explanation of how it expects to meaningfully reduce medical cost trend for the identified population and reduce net programmatic expenditure for CMS. Applicants should show credible, favorable performance along the following dimensions:

- a high percentage reduction in per beneficiary per year total cost of care expenditures for the population the model serves,
- strong return on investment to CMS over the three-year period as shown by the data in the template for the Financial Plan, and
- meaningful annualized model run-rate savings.

The return on investment analysis includes three parts outlined below:

3.1 Financial Plan: The Financial Plan is supplemental to Form SF 424A, and included in the Supplementary Materials. Applicants must submit a Financial Plan and supplemental narrative and schedules explaining how they plan to reduce medical cost

for their identified population. The Financial Plan must include an annual summary of the costs of the model in relation to the expected savings under the model. Data from Form SF 424A and Financial Plan must match. The Financial Plan must be signed by the chief financial officer of the applicant organization. The chief financial officer cannot be the same person as the Executive Director or Project Director.

Applicants must provide a Financial Plan narrative and supplementary schedules explaining the rationale behind all assumptions used to develop the Financial Plan. Some examples of supplementary schedules with accompanying narratives include:

- A narrative and supplementary schedules explaining the specific mechanisms by which the model will produce a <u>net reduction</u> in the total cost of care (e.g., how cost increases in one category of spend will drive cost reductions elsewhere);
- An account of personnel costs, including detailed salary and fringe benefit costs, as well as identification of the costs associated with the training aspects of the innovation;
- A schedule describing proposed population and patient characteristics that explain projections of total cost of care (e.g., demographics, risk factors, health disparities, etc.); and
- A schedule connecting the funding request to detailed expenditures to proposed impact.

CMS will provide further materials, including a template for the Financial Plan, on or about June 14, 2013 on the Innovation Center website at http://innovation.cms.gov. The estimates provided in the Financial Plan narrative must match those provided in the Financial Plan template. In addition, the Financial Plan narrative must provide either a source or a rationale for the estimates in the Financial Plan template. CMS will also host a series of webinars to assist initiative applicants with their Financial Plan. More information including dates and times will be posted at a later date at www.innovation.cms.gov.

- 3.2 Model Sustainability Plan: The Model Sustainability Plan must include a clear description of the expected positive impact on the delivery system. This section must describe a payment model that would, if implemented by CMS, support the applicant's service delivery model absent additional federal spending after the end of the cooperative agreement period. This design should include, at a minimum, a description of:
 - Payment details: How funds would flow under the payment model;
 - <u>Payment principles:</u> What specific provider or beneficiary incentives the payment model would create;
 - <u>Description of risk parameters</u>: How the payment model adjusts, shifts, insures, and/or limits risk;
 - Return on investment: How the payment model will deliver a positive return on investment for CMS, and how it will result in net programmatic savings for Medicare, Medicaid, and/or CHIP;

- <u>Application:</u> Description of services or providers to which the payment model would be applied;
- <u>Scaling:</u> How the payment model can be made available to other providers and potentially serve as a basis for a subsequent solicitation by CMS; and
- <u>Progression</u>: How parameters of the payment model will progress over time.
- 3.3 Actuarial Review: Applicants requesting \$10 million or more in funding are required to obtain and submit an external actuarial certification with their application. A qualified actuary who is a member of the American Academy of Actuaries must complete the certification. CMS will provide further materials, including a template for the Actuarial Review, on or about June 14, 2013 on the Innovation Center website at http://innovation.cms.gov. Applicants requesting less than \$10 million are encouraged but not required to submit an external actuarial review. CMS reserves the right to conduct an actuarial review of any application (regardless of funding amount) and such a review will be included as one of the criteria for the CMS Approving Official to consider during the application review process.

SECTION FOUR: MONITORING, REPORTING, AND EVALUATION

4.1 Reporting and Evaluation: The application must include a description of the applicant's plan for collecting and producing the data and analysis of the model that will be provided to CMS and its evaluation and monitoring contractors. CMS believes that awardees that actively self-monitor will have the greatest opportunities for improvement in quality and reductions in overall healthcare costs. The application must include detailed information on the self-monitoring plan. Careful monitoring and reporting of the effect of the model on the quality of care received as well as health care outcomes and costs are expected. Awardees also will be required to monitor patient satisfaction with their care experience by using validated tools that measure the patient experience of care. Monitoring reports must be provided to CMS quarterly and they must include information on the use of cooperative agreement funding and an assessment of model implementation, lessons learned, patient experience, quality improvements, clinical outcomes, and estimates of cost savings. Note that awardees will also be required to cooperate fully with the monitoring and evaluation contractors in reporting data that they require for the model evaluations.

CMS plans to conduct rigorous evaluation of each of these models through a separate evaluation contract. This work will entail establishing treatment and control or comparison groups and measuring the model effects on costs and outcomes. Applicants will be expected to facilitate evaluation contractor work in these areas by providing all necessary information and access required for the evaluation. Awardees may be required to report information in standard format and measure and report outcomes in a standardized way, if requested by the evaluation contractor.

SECTION FIVE: FUNDING AND SUSTAINABILITY

5.1 Budget Form SF 424A and Budget Narrative

Form SF 424A

All applicants must submit an SF 424A. Instructions for completing the SF 424A can be found on Grants.gov. For this cooperative agreement the application must include budgets for each year of the 3-year model period. All budget periods are one year.

In Section B – Budget Categories, please use column (1) for the first budget year; column (2) for the second budget year; and column (3) for the third budget year. Column (5) should be used for the total for all three budget years.

Budget Narrative

In addition, applicants must supplement Budget Form SF 424A with a Budget Narrative. The Budget Narrative must include a <u>yearly</u> breakdown of costs for the 3-year model period. Specifically, the Budget Narrative must provide a detailed cost breakdown for each line item outlined in the SF424A by year including a breakdown of costs for each activity/cost within the line item. The proportion of cooperative agreement funding designated for each activity should be clearly outlined and justify the organization's readiness to receive funding through 2017, including complete explanations and justifications for the proposed cooperative agreement activities. The budget must separate out funding that is administered directly by the awardee from any funding that will be subcontracted.

The application must include detailed descriptions and breakdowns of expenses in the following cost categories:

- Personnel**
- Fringe benefits
- Contractual costs, including subcontracts
- Equipment
- Supplies
- Travel
- Indirect costs, in compliance with appropriate OMB Circulars and subject to Section IV(5)(a), below. If requesting indirect costs in the budget, a copy of the Federally negotiated indirect cost rate is required. Indirect costs will be capped at 20% or the applicant's Federally negotiated indirect cost rate or the applicant's provisional rate, whichever of these is lowest. Applicants may elect to waive their Federally negotiated indirect cost rate.
- Other costs, including those not otherwise associated with training and education

** NOTE: Consistent with section 203 of the Consolidated Appropriations Act, 2012 (P.L. 112-74) none of the funds appropriated in this law shall be used to pay the salary of

an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II (\$179,700).

The Budget Narrative should outline the strategies and activities of the model, and provide detailed cost breakdowns for any subcontracts that will be implemented to achieve anticipated outcomes.

The Budget Narrative should also clearly distinguish the funding source of any given activity/cost, as either federal or non-federal. Applicants should pinpoint those costs funded through in-kind contributions. Applicants must include detailed salary and fringe benefit costs for staff dedicated to the model through an in-kind contribution, to include yearly salary costs and the percentage of time dedicated to the model (for any given year).

Applicants must include with the Budget Narrative an organizational chart for the entity that is responsible for the management of the cooperative agreement. In addition, Applicants must provide a Narrative Staffing Plan to include:

- The number and titles of staff that will be dedicated to the cooperative agreement.
- Percentage of time each individual/position is dedicated to the cooperative agreement.
- Brief description of roles/responsibilities of each position.
- How the proposed key staff members have relevant skills and leadership ability to successfully carry out the model.
- Any positions providing in-kind support to the cooperative agreement.
- Percentage of time each position will provide to the cooperative agreement.
- A résumé for the proposed Project Director.

SECTION SIX: SUPPLEMENTARY MATERIALS

6.1 Operational Plan: Applicants must submit a detailed Operational Plan that describes the activities and budgets for each year of the model, a detailed timeline for implementation with major milestones, and a plan for model monitoring and evaluation. The Operational Plan must show how the applicant plans to ramp up to operational start and improve care within six months of receiving funding. The plan should also include roles and responsibilities of key partners and payer participants and major milestones and dates for successfully executing the Operational Plan. The applicant must provide an organizational chart that demonstrates the entity that is responsible for the management of this cooperative agreement as well as the relationship between that entity and all other organizations that will provide services and work with the beneficiaries under the model. In addition, the application should show that the applicant has the resources and track record needed to operate the model and report on the progress it is making during the operation. Applicants also should include a list of key personnel; for each person on this list, applicants should describe their relevant background, their roles, and overall responsibility.

CMS will provide further materials, including detailed instructions and an Operational Plan template, on or about June 14, 2013 on the Innovation Center website at http://innovation.cms.gov.

6.2 Executive Overview: Applicants must submit an Executive Overview. CMS will provide further materials, including detailed instructions and an Executive Overview template, on or about June 14, 2013 on the Innovation Center website at http://innovation.cms.gov.

3. Submission Dates and Times

3(a) Submission Dates and Times – Letter of Intent to Apply

Applicants must submit a non-binding Letter of Intent to Apply. Letters of Intent to Apply provide information that helps CMS in determining expertise and personnel necessary to appropriately review applications and issue awards. Letters of Intent to Apply are due by 3:00 pm Eastern Daylight Time on June 28, 2013. Failure to submit a Letter of Intent to Apply will disqualify the application from that organization from being reviewed.

The information specified for the Letter of Intent to Apply must be submitted through an online form. CMS will post additional information and detailed instructions for submitting a Letter of Intent to Apply, including require fields and information, on the Innovation Center website at http://innovation.cms.gov.

3(b) Submission Dates and Times – Cooperative Agreement Applications

All applications are due by August 15, 2013. Applications must be submitted through http://www.grants.gov by 3:00 p.m. Eastern Daylight Time on Wednesday, August 15, 2013 or they will not be eligible for review.

4. Intergovernmental Review

Applications for these cooperative agreements are not subject to review by states under Executive Order 12372, "Intergovernmental Review of Federal Programs" (45 CFR 100). Please check box "C" on item 19 of the SF 424 (Application for Federal Assistance) as Review by State Executive Order 12372, does not apply to these cooperative agreements.

5. Funding Restrictions

5(a) Funding Restrictions – Indirect Costs

<u>Indirect costs will be capped at 20% or the applicant's Federally negotiated indirect cost</u> <u>rate or the applicant's provisional rate, whichever of these is lowest.</u> Applicants may elect to waive their Federally negotiated indirect cost rate. If requesting indirect costs, a Federally negotiated Indirect Cost Rate Agreement will be required.

5(b) <u>Funding Restrictions – Direct Services</u>

Cooperative Agreement funds may not be used to provide individuals with services that are already funded through Medicare, Medicaid and/or CHIP. In compliance with the OMB Circulars, which define allowed cost, funding from the Innovation Center may not supplant funding for services that are currently authorized through the Medicaid State Plan. This also applies to funding provided through waivers or other grants, including federal grants. Travel or participation in conferences may require CMS approval.

5(c) Funding Restrictions – Reimbursement of Pre-Award Costs

No cooperative agreement funds awarded under this solicitation may be used to reimburse preaward costs.

5(d) Funding Restrictions – Prohibited Uses of Cooperative Agreement Funds

No cooperative agreement funds awarded under this solicitation may be used:

- To match any other federal funds;
- To provide services, equipment, or supports that are the legal responsibility of another
 party under federal or state law (e.g., vocational rehabilitation or education services) or
 under any civil rights laws. Such legal responsibilities include, but are not limited to,
 modifications of a workplace or other reasonable accommodations that are a specific
 obligation of the employer or other party;
- To provide services to non-CMS beneficiaries;
- To supplant existing federal, state, local, or private funding of infrastructure or services, such as staff salaries, etc.;
- To be used by local entities to satisfy state matching requirements;
- To pay for the use of specific components, devices, equipment, or personnel that are not integrated into the entire service delivery and payment model proposal; or
- To engage in lobbying activities of any kind (including, but not limited to, the costs for lobbying activities to influence the introduction, enactment, or modification of legislation by the U.S. Congress or a state legislature).

V. APPLICATION REVIEW INFORMATION

In order to receive an award under this funding opportunity announcement, applicants must submit a Letter of Intent and an application, each in the required format, no later than the applicable deadline.

Applications that focus primarily on acute hospital inpatient care will not be reviewed. Applications that do not propose service delivery models in one of the Innovation Categories specified in this FOA will not be reviewed.

If an applicant does not submit all of the required documents and does not address each of the topics described below, the application will not be reviewed and will consequently be ineligible for an award.

As indicated in Section IV, Application and Submission Information, all applicants must submit the following:

- Standard Forms
- Letters of support and participation from major stakeholders
- Cover Letter
- Project Abstract
- Project Narrative
- Budget and Budget Narrative
- Supplementary Materials (including the Financial Plan, the Operational Plan, the Actuarial Review for applicants requesting \$10 million or more, and the Executive Overview)

As noted above, templates will be provided for the Financial Plan, the Operational Plan, the Actuarial Review, and the Executive Overview on or about June 14, 2013 on the Innovation Center website at http://innovation.cms.gov.

1. Criteria

This section fully describes the evaluation criteria for this cooperative agreement model. In preparing applications, applicants are strongly encouraged to review the programmatic requirements detailed in Section I, Funding Opportunity Description. The application must be organized as detailed in Section IV, Application and Submission, of this solicitation.

Applications will be scored with a total of 100 points available. The following criteria will be used to evaluate applications received in response to this solicitation.

Design of Proposed Model (25 points)

The proposed model is well-designed to meet the goals of the model, including meeting the goals of improved outcomes for targeted populations. The design is based on relevant evidence and has a high likelihood of success, and the funding level requested is commensurate with the level of evidence. The model is operationally feasible. The model design is innovative in concept and operational design and not duplicative to existing CMS models or demonstrations, or to other HHS activities. The proposal indicates which Innovation Category the model falls within, as well as which priority areas, if any, are addressed.

The proposal indicates the overall expected magnitude and breadth of impact of the model on improving outcomes and reducing costs for the population it targets. The goals set for improvement are aggressive but credible given the description of the model. Proposals should demonstrate how the model will enable more effective and efficient system-wide functioning to deliver better outcomes and reduced costs.

The proposed model can be replicated and can be productively adopted in other organizations nationwide. The proposed model effectively targets the intended population including health

disparities and underserved populations as applicable. The proposal includes plans to effectively integrate the model with relevant community providers of health care and related services, and to coordinate effectively with other relevant groups. The proposal also describes the extent to which health IT and health information exchange is used to support care coordination across all treating providers in the community and specific quality improvement goals. The proposal includes the design of a payment model that is based on a sound business case for CMS. The proposed payment model is operationally feasible for CMS and has a high probability of leading to a viable new, fully developed payment model for CMS – with ready applicability to Medicare, Medicaid, and/or CHIP – by the end of the cooperative agreement period or earlier. Preference will be given to applicants that describe payment models that can be implemented earlier. Applications must include a feasible approach for securing participation of multiple payers for their proposed payment model. Preference will be given to models that include a specific focus on a population of Medicaid or CHIP beneficiaries, either exclusively or in addition to other populations not served by these programs.

Organizational Capacity and Management Plan (25 points)

The organization has relevant experience in successfully operating previous innovative and relevant models. The proposed Operational Plan is specific and shows a realistic probability of successful implementation. Plans to partner with health care providers and other implementing organizations shows a likelihood of being successful, and the model partners identified by the applicant have the administrative ability to carry out their part of the model. The applicant must show evidence that it could implement the model and deploy it as rapidly as possible within six months. Preference will be given to applicants who can demonstrate their ability to begin care improvement activities earlier than six months. The applicant also demonstrates the organizational capacity to test innovative payment and service delivery models.

The Operational Plan is well-described and shows evidence of effectively supporting the model. The applicant organization has the needed facilities and infrastructure to carry out the model.

The applicant organization shows plans for model accountability, including plans to report on model operations, cooperate with the government monitoring plans, and provide information needed to evaluate the model results.

The staff proposed to lead the model has the skills and experience needed to assure smooth and effective implementation.

Return on Investment (20 points)

The proposal identifies and develops a model that has strong probability of delivering net programmatic savings to CMS in a short period of time and/or would, if successful, provide a sound basis for payment and/or program changes with wide applicability for which the investment in model development would be much more than offset over time by Medicare, Medicaid, and/or CHIP savings if adopted on a national or state basis. Each proposed model should provide a detailed explanation of how it expects to meaningfully reduce medical cost trend for the identified population. Applicants should show credible, favorable performance along the following dimensions:

- a high percentage reduction in per beneficiary per year total cost of care expenditures for the population the model serves,
- strong return on investment for CMS over the three-year period as shown by the data in the template for the Financial Plan, and
- a projected medical cost trend reduction that is meaningfully lower.

Applicants should propose an efficient model that minimizes the total cost of implementation in order to deliver net programmatic savings to CMS. Applicants may elect to waive their Federally negotiated indirect cost rate in order to reduce the total cost of implementation. The applicant describes a payment model that will provide a sustainable source of funding for the service delivery model after the cooperative agreement period – and this payment model is likely to produce a positive return on investment for CMS.

Budget, Budget Narrative, and Model Sustainability (20 points)

The proposed Budget, Budget Narrative, Financial Plan, and Model Sustainability Plan are carefully developed, with plans for efficient use of funds. Overhead and administrative costs are reasonable and will be considered in the evaluation of the proposal. The preponderance of funding is expected to be used for start-up costs for service delivery models and ongoing services. They should be focused on health services operations, not administration. It is desirable, but not required, for the proposal to include cost sharing from the sponsoring organization or other partners to demonstrate financial support from other entities or otherwise leverage financial resources.

The Budget and Financial Plan have a thoughtful, data-driven evidence-base that informs their projections. The awardee must describe a track record or a path to establishing the required process and infrastructure to achieve projections (e.g., having patient recruitment processes in place, an identified new workforce, necessary infrastructure to implement models). The model has a likelihood of being cost-effective, saving money for the Medicare, Medicaid, and/or CHIP programs as well as for the health care system at large. Every proposal must include the design of a Medicare, Medicaid, or CHIP payment model that will become the ultimate path to sustainability. The payment model must result in net programmatic savings for Medicare, Medicaid, and/or CHIP. Preference will be given to applicants who can demonstrate potential for financial sustainability sooner than three years by creating a payment model that could be used during the term of the cooperative agreement, if adopted by CMS, and in a broad solicitation of other providers.

Monitoring and Reporting (10 points)

The applicant includes a well-designed and credible plan to provide regular reporting of performance and quantitative data for monitoring the progress of the model including information on staffing and staff development, quality of services delivered, numbers of people included in the model, frequency and nature of contacts with both beneficiaries and participating providers, and other process and quality data that give a full picture of the progress of the applicant in carrying out the model proposed. The applicant clearly includes a quantifiable means for monitoring the progress of its model and evaluating the impact of the model on the improving outcomes and reducing costs. The applicant includes a clear plan for obtaining all data necessary for CMS to conduct its evaluation of the proposed model, including state data if needed.

2. Review and Selection Process

Prior to submission of the application to the review panel, a preliminary eligibility screen will be conducted by CMS staff or CMS contractors to ensure that the technical requirements of the application are met. For example, applications that go over the required page count or do not use the required font and spacing requirements will not move on to a review panel.

A team consisting of HHS staff from outside CMMI and other outside experts will review all eligible applications. The review process will include the following:

- Applications will be screened again to determine eligibility for further review using criteria detailed in this solicitation and in applicable law, including 2 CFR Parts 180 and 376. In addition, CMS may deny funding to an otherwise qualified applicant on the basis of information found during a program integrity review regarding the applicant, its affiliates, or any other relevant individuals or entities. Applicants must disclose any adverse action including, but not limited to, sanctions, investigations, probations, or corrective action plans that have been imposed on it, or to which it has otherwise been subject, in the last three years. Applicants must submit this information on the Executive Overview template, which will be provided by CMS on or about June 14, 2013 on the Innovation Center website at http://innovation.cms.gov. Applications received late or that fail to meet the eligibility requirements as detailed in the solicitation or do not include the required forms will not be reviewed.
- The review panel will assess each application to determine the merits of the proposal and
 the extent to which the proposed model furthers the purposes of Health Care Innovation
 Awards Round Two. Reviewers will award points in each area to determine scores.
 CMS reserves the right to request that applicants revise or otherwise modify their
 proposals and budget based on the recommendations of the panel.
- Concurrently, the CMS Office of the Actuary will assist the GMO in review of the
 reasonableness of the estimated cost to the government, and will review the potential for
 federal savings. This review will be one of the criteria for the CMS Approving Official to
 consider during the application review process. The CMS Approving Official may utilize
 information provided by the CMS Actuary's assessment of applicants' potential for savings
 in determining award recipients.
- The results of the objective review of the applications by qualified experts will be used to advise the CMS Approving Official. Final award decisions will be made by the CMS Approving Official. In making these decisions, the CMS Approving Official will take into consideration:
 - o recommendations of the review panel;
 - o the geographic diversity of awardees;
 - o the range of service delivery and payment models proposed and fit with the current CMS portfolio;
 - whether the portfolio of awards adequately covers each or any of the priority areas and CMS program populations identified in this document, and is not duplicative to other CMS or HHS activities:

- o reviews for programmatic and cooperative agreement management compliance;
- o the reasonableness of the estimated cost to the government and anticipated results (including potential savings);
- o the inclusion of Medicaid and CHIP populations in the service model design;
- o results of any actuarial reviews, including but not limited to those performed by the CMS actuary or CMS actuarial contractors;
- the ability of the model to generate net financial savings for Medicare, Medicaid, and/or CHIP; the magnitude of the expected savings; the ROI of the proposal; and the anticipated improved quality outcomes;
- o the extent of participation by multiple payers during the performance period;
- whether the proposal promotes interoperability and exchange of secure, privacyprotected health information across disparate organizations, providers, and stakeholders, in alignment with Meaningful Use requirements;
- o whether an applicant develops open source technology or software that is placed in the public domain;
- o the potential for implementation of the proposed payment model, the speed with which the payment model could be introduced and result in a solicitation of other participants, and the likelihood of success of sustainability;
- the degree to which the proposed payment model would be operationally feasible for CMS and likely to deliver the expected results over time, should it be pursued by CMS; and
- o the likelihood that the proposed model will result in the benefits expected.

Interviews may be conducted with applicants prior to selection in order to clarify Application and Submission Information as needed. CMS reserves the right to request that applicants revise or otherwise modify their proposals and budget based on the recommendations of the panel and the review of the CMS Approving Official.

Successful applicants will receive one cooperative agreement award issued under this announcement.

Unsuccessful applicants may request reviewer's comments; however, appeals of CMS' decisions are not permitted.

CMS intends to fund models in communities with a wide variety of geographic and socioeconomic characteristics, including underserved urban and rural areas.

CMS reserves the right to approve or deny any or all proposals for funding. Note that section 1115A of the Social Security Act states that there is no administrative or judicial review under sections 1869 or 1878 of the Act for the selection of organizations, sites, or participants to test models under section 1115A of the Act.

3. Anticipated Announcement and Award Dates

Opportunity Announcement: May 15, 2013

Anticipated Awardee Announcements: Phase 1 – January 15, 2014; Phase 2 – January 31, 2014

VI. AWARD ADMINISTRATION INFORMATION

1. Award Notices

The Authorized Official of successful applicants will receive an electronic Notice of Award (NoA) signed and dated by the CMS Grants Management Officer that will set forth the amount of the award and other pertinent information. The award will also include standard Terms and Conditions, and may also include additional specific cooperative agreement terms and conditions. Potential applicants should be aware that special requirements could apply to cooperative agreement awards based on the particular circumstances of the effort to be supported and/or deficiencies identified in the application by the review panel.

The NoA is the legal document issued to notify the awardee that an award has been made and that funds may be requested from the HHS payment system. Any communication between CMS and awardees prior to issuance of the NoA is not an authorization to begin performance of a model.

Unsuccessful applicants will be notified by letter, sent through the U.S. Postal Service to the applicant organization as listed on its SF 424, within 30 days of announcement of Notices of Award.

2. Administrative and National Policy Requirements

The following standard requirements apply to applications and awards under this FOA:

- Specific administrative requirements, as outlined in 2 CFR Part 225 and 45 CFR Parts 74 and 92, apply to cooperative agreement awarded under this FOA.
- All awardees must comply with all applicable federal statutes relating to nondiscrimination including, but not limited to:
 - o Title VI of the Civil Rights Act of 1964,
 - o Section 504 of the Rehabilitation Act of 1973,
 - O The Age Discrimination Act of 1975,
 - O Hill-Burton Community Service nondiscrimination provisions, and
 - O Title II Subtitle A of the Americans with Disabilities Act of 1990.
- The SF-424 form is a requirement of the Office of Management and Budget.
- All equipment, staff, other budgeted resources, and expenses must be used exclusively
 for the model identified in the awardee's original cooperative agreement application or
 agreed upon subsequently with HHS, and may not be used for any prohibited uses.

• The applicant organization should retain documents in support of this application for potential examination under the Freedom of Information Act.

3. Terms and Conditions

Cooperative agreements issued under this FOA are subject to the *Health and Human Services Grants Policy Statement (HHS GPS)* at http://www.hhs.gov/grantsnet/adminis/gpd/. Standard Terms and Special Terms and Program Specific Terms and Conditions will accompany the Notice of Award. Potential awardees should be aware that special requirements could apply to awards based on the particular circumstances of the effort to be supported and/or deficiencies identified in the application by the HHS review panel. The General Terms and Conditions that are outlined in Section II of the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary (as specified in the Notice of Award).

Under section 1115A(d)(1) of the Social Security Act, the Secretary of Health and Human Services may waive such requirements of Titles XI, XVIII, and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) of Title XIX as may be necessary solely for purposes of carrying out section 1115A with respect to testing models described in section 1115A(b). Consistent with this standard, the Secretary is authorized to issue waivers of certain provisions in sections 1128A, 1128B, and 1877 of the Social Security Act with respect to participation in the second round of Health Care Innovation Awards. No waivers are issued in this document; waivers, if any, would be set forth in a separately issued Notice of Waiver. Thus, notwithstanding any other provision of this Funding Opportunity Announcement, Awardees and Subawardees must comply with all applicable laws and regulations, except as explicitly provided in any such separately issued Notice of Waiver issued pursuant to section 1115A(d)(1) specifically for the Health Care Innovation Awards Round Two. Any such waiver would apply solely to the Health Care Innovation Awards Round Two, and may differ in scope or design from waivers granted for other programs or models.

4. Reporting (Frequency and Means of Submission) and Oversight

4(a) Reporting, Monitoring, and Evaluation

4(a)(1) Reporting: Awardees must agree to cooperate with any federal evaluation of the model and provide required quarterly, semi-annual (every six months), annual and final (at the end of the cooperative agreement period) reports in a form prescribed by CMS. Reports will be submitted electronically. These reports will outline how cooperative agreement funds were used, describe model progress, and describe any barriers and measurable outcomes. CMS will provide the format for model reporting and technical assistance necessary to complete required report forms. Awardees must also agree to respond to requests that are necessary for the evaluation of the national efforts and provide data on key elements of their own cooperative agreement activities.

4(a)(2) Initiative Monitoring: CMS will award a third party entity to assist CMS in monitoring the models. CMS plans to collect data elements to be part of monitoring for all of the different models, and these monitoring and surveillance elements will feed into the evaluation. All awardees will be required to cooperate in providing the necessary data elements to CMS or a CMS contractor. The contractor will assist CMS in developing a quality monitoring and review model to

ensure model requirements are met; tracking performance across awardees and providing for early detection of quality problems; developing a system to collect, store, and analyze data to assess quality of care, costs, and utilization; and assisting with awardee implementation, including coordination between awardees and CMS and its other contractors.

Data for monitoring will include process, safety, and performance measures. It will include, but will not be limited to, data on the background characteristics of the target population and target area, data characterizing the activities of the model, and a battery of follow-up data describing relevant characteristics of the target population or target area and metrics at selected intervals after commencement of the model. This will include detailed information on model participant (i.e., beneficiaries participating in the model) characteristics and outcomes reported in a standard format. Data for monitoring will be collected from awardees and/or CMS claims data sources. The monitoring aspect of this initiative will balance the examination of the extent to which awardees demonstrate fidelity to their proposed models of care and the potential need to make mid-course corrections that improve the models of care based on feedback from the monitoring and evaluation findings. Moreover, the evaluation will assess whether there are unintended consequences as a result of the model.

4(a)(3) Evaluation: For purposes of continuous model improvement, and reporting of progress, accomplishments and difficulties encountered, each awardee must conduct its own continuous monitoring and evaluation of its model on the impact on cost and quality outcomes. In addition, CMS will contract with a third party entity to conduct an independent evaluation of the models. All awardees will be required to cooperate with the independent evaluator to track and provide required performance data as needed for the evaluation. The evaluation will assess the impact and/or potential impact of the models on quality outcomes and the cost of care. Where appropriate and feasible, this will include assessments of patient experience of care, health services utilization, health outcomes, Medicare, Medicaid, and/or CHIP expenditures, provider costs, quality, and access to care.

The independent evaluation will include multi-pronged data collection efforts, including qualitative and quantitative approaches. Primary data collection will be needed to acquire qualitative information from providers to understand their perceptions, including satisfaction with the model, barriers to implementation, and enablers to care improvement. Primary data collection will also include patient and provider surveys to understand perceptions of self-reported health (patient), perceptions of care (patient and provider), and perceptions of the model (patient and provider). The evaluators will also utilize existing CMS data resources such as claims and performance monitoring data. Evaluation questions include but are not limited to:

- Do the models of care being tested under the Health Care Innovation Awards Round Two provide better quality of care and/or better patient experiences of care for high risk target populations? If so, how much improvement was seen and which participant characteristics were associated with greater benefit?
- Do the various models reduce expenditures in absolute terms? Do they slow the growth in expenditures? Do the models reduce or eliminate variations in utilization and/or expenditures that are not attributable to differences in health status?
- Do the various models provide better care coordination? If so, how and for which beneficiaries?

- Do they reduce disparities in care? If so, how have they accomplished these changes? Are the models well received by the practitioners and providers implementing them?
- What factors are associated with the pattern of results (above)? Specifically, are they related to:
 - o Characteristics of the models?
 - Characteristics of the Health Care Innovation Award Round Two awardees' approaches to their chosen model? (e.g., types and nature of participating providers, utilization of non-traditional types of providers who can interact with patients in their respective communities, specific care coordination interventions used, specific payment or incentives, etc.)
 - Characteristics of the Health Care Innovation Award Round Two awardees' specific features and ability to carry out their proposed model?
 - Characteristics of the Health Care Innovation Award Round Two awardees' market or patient populations?
 - o Programmatic changes undertaken in response to CMS-sponsored learning and diffusion activities and/or rapid-cycle evaluation results?

Depending on the mix of awarded models, the evaluation will examine the proposed models independently, but will group similar models and analyze the groups accordingly. Ultimately, the evaluation results from all of the models will be reconciled in order to identify and characterize the most effective models to inform future policy making around improving beneficiary care, improving beneficiary health, and reducing costs.

The evaluator, with assistance of the awardees, will be expected to identify control/comparison groups who did not participate in one of the interventions to examine the effect of the interventions on outcomes of interest. Difference-in-difference models and segmented linear regression models with concurrent controls will be employed to examine the effects of each intervention group compared to controls. Sensitivity analyses combining similar models will also be conducted to examine broad model effects. Sensitivity analyses examining specific geographic regions will be conducted to attempt to disentangle intervention effects in sites where multiple interventions are implemented.

The evaluation will be sensitive to the continual need for rapid-cycle and close-to-real-time production of findings that can be used by awardees and policy makers to make decisions about programmatic changes throughout the life of the model. The evaluation will gather quantitative and qualitative data and use claims data to both assess real time performance and feed that information back to awardees for ongoing improvement. Qualitative approaches such as interviews, site visits, and focus groups are envisioned in order to compare the planned and actual performance of each awardee's model. Multiple cycles of interviews may be necessary due to the changing nature of the models used by the awardees in response to rapid-cycle feedback.

4(b) Federal Financial Report

Awardees are required to submit the FFR SF425 on a semi-annual basis. More details will be outlined in the Notice of Award.

4(c) <u>Transparency Act Reporting Requirements</u>

New awards issued under this funding opportunity announcement are subject to the reporting requirements of the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109–282), as amended by section 6202 of Public Law 110–252 and implemented by 2 CFR Part 170. Grant and cooperative agreement recipients must report information for each first-tier sub-award of \$25,000 or more in federal funds and executive total compensation for the recipient's and sub-recipient's five most highly compensated executives as outlined in Appendix A to 2 CFR Part 170 (available online at www.fsrs.gov). Competing Continuation awardees may be subject to this requirement and will be so notified in the Notice of Award.

4(d) Audit Requirements

Awardees must comply with the audit requirements of Office of Management and Budget (OMB) Circular A-133. Information on the scope, frequency, and other aspects of the audits can be found on the Internet at www.whitehouse.gov/omb/circulars.

4(e) Payment Management Requirements

Awardees must submit a quarterly electronic SF 425 via the Payment Management System. The report identifies cash expenditures against the authorized funds for the cooperative agreement. Failure to submit the report may result in the inability to access funds. The SF 425 Certification page should be faxed to the PMS contact at the fax number listed on the SF 425, or it may be submitted to:

Division of Payment Management HHS/ASAM/PSC/FMS/DPM PO Box 6021 Rockville, MD 20852 Telephone: (877) 614-5533

VII. AGENCY CONTACTS

1. Programmatic Contact Information

All programmatic questions about the Health Care Innovation Awards Round Two must be directed to the initiative email address: InnovationAwards@cms.hhs.gov. Responses to Frequently Asked Questions will be posted on http://innovation.cms.gov.

2. Administrative Questions

Administrative questions about the Health Care Innovation Awards Round Two may be directed to the following email: OAGMGrantsBaltimore@cms.hhs.gov. In the subject line please put: HCIA Round Two question