



Direct Contracting Model: Global and Professional Options

Request for Applications

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I. Background and Introduction

The Direct Contracting Model creates a new opportunity for the Centers for Medicare & Medicaid Services (CMS) to test an array of financial risk-sharing arrangements, leveraging lessons learned from other Medicare Accountable Care Organization (ACO) initiatives, such as the Medicare Shared Savings Program (Shared Savings Program) and the Next Generation ACO (NGACO) Model, as well as innovative approaches from Medicare Advantage (MA) and private sector risk-sharing arrangements. This model is part of a strategy by the CMS Center for Medicare and Medicaid Innovation (Innovation Center) to use the redesign of primary care as a platform to drive broader health care delivery system reform. Direct Contracting creates a variety of pathways for taking on financial risk supported by enhanced flexibilities. Because the model reduces administrative burden, supports a focus on complex, chronically ill patients, and aims to encourage organizations to participate that have not typically participated in Medicare fee-for-service (FFS), Innovation Center models, or both, we anticipate that this model will appeal to a broad range of physician organizations and other types of health organizations. Direct Contracting provides an opportunity for health care providers that have not previously been eligible for the Shared Savings Program, the NGACO Model, or both due to an insufficient number of aligned Medicare FFS beneficiaries. In addition, Direct Contracting offers a model option for NGACO Model participants to consider after the NGACO Model ends in December 2020.

Under Direct Contracting, CMS will test up to three voluntary risk-sharing options. This Request for Applications (RFA) focuses on two of those options: (1) Professional Option (hereinafter referred to as Professional), a lower-risk option with 50 percent Shared Savings/Shared Losses and a Primary Care Capitation equal to seven percent of the Performance Year Benchmark for enhanced primary care services; and (2) Global Option (hereinafter referred to as Global), a full risk option with 100 percent Shared Savings/Shared Losses and either a Primary Care Capitation or Total Care Capitation. CMS also sought comment on a proposed third option, the Geographic Option, which is a full risk option with 100 percent Shared Savings/Shared Losses that will offer an opportunity to assume total cost of care risk for Medicare Parts A and B services for Medicare FFS beneficiaries in a defined target region. **Please note that this RFA is for Global and Professional only.**

Direct Contracting is intended to test whether these risk-based payment strategies align financial incentives and offer model participants (hereinafter referred to as Direct Contracting Entities (DCEs)) flexibility in engaging health care providers and patients in care delivery that results in preserving or enhancing quality of care and reducing the total cost of care. Following an Implementation Period (IP) in 2020, during which DCEs—including those DCEs that have historically furnished care to relatively few (or even no) Medicare FFS beneficiaries—will engage in beneficiary alignment and other activities, Direct Contracting will have five performance years (PYs) from 2021 through 2025.

II. Statutory Authority

A. General Authority to Test Model

Section 1115A of the Social Security Act (the Act) (added by Section 3021 of the Affordable Care Act) (42 U.S.C. 1315a) establishes the Innovation Center to test innovative payment and service delivery models that have the potential to lower Medicare, Medicaid, and Children's Health Insurance Program (CHIP) spending while maintaining or improving the quality of beneficiaries' care.

B. Financial and Payment Model Authorities

Section 1115A(b)(2) of the Act requires the Secretary to select models to be tested where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The statute also provides a non-exhaustive list of examples of models that the Secretary may select to test, which includes models under which the Innovation Center contracts directly with groups of providers of services and suppliers to promote innovative care delivery models, such as through risk-based comprehensive payment or salary-based payment (see section 1115A (b)(2)(B)(ii) of the Act).

Direct Contracting seeks to improve quality of care and health outcomes for Medicare beneficiaries through alignment of financial incentives to promote effective and appropriate care, emphasis on patient choice, strong monitoring to ensure that beneficiaries maintain access to care, and emphasis on care delivery for the complex, chronically and seriously ill population. Benefit enhancements will be offered to promote greater beneficiary accessibility to innovative, affordable care. The two payment model options available under Direct Contracting are expected to increase beneficiaries' access to innovative, affordable care while maintaining all original Medicare benefits. Direct Contracting also places a greater emphasis on voluntary alignment, empowering beneficiaries to choose the health care providers with whom they want to have a care relationship, enabling stability through stronger patient and provider relationships.

Direct Contracting advances risk-sharing arrangements and builds upon lessons from CMS' ACO portfolio. It addresses stakeholders' concerns that there is no common approach to benchmarking, that the financial methodology in the current CMS risk-based initiatives available through Medicare FFS, such as the Shared Savings Program and NGACO Model, do not borrow sufficiently from private sector approaches, and that they lack access to a true population-based payment structure to drive broad transformation. Further, we are designing financial incentives to attract organizations that manage complex, chronically and seriously ill patients, through refinements in our benchmarking methodology and risk adjustment. Through accountability for the total cost of care and the option for population-based payments, participating providers and suppliers will shift from FFS billing and gain the flexibility to adapt clinical delivery to meet beneficiaries' needs, such as longer visits for high-risk patients or continued care beyond a standard office visit. DCEs may also benefit from risk stratification of patients and tailoring care management strategies to match their patient population.

Building on the lessons learned from and experiences of the previous initiatives, Direct Contracting is expected to reduce administrative burdens and empower primary care providers to spend more time caring for patients while reducing overall health care costs. For many patients, the primary care clinician is the first point of contact with the health care delivery system. Empirical evidence shows that strengthening primary care is associated with high quality of care, better outcomes, and lower costs within and across major population subgroups. Despite this evidence, primary care spending accounts for a small portion of the total cost of care, and is even lower for patients with complex, chronic conditions. CMS' experience with innovative models, programs and demonstrations to date has shown that when incentives for primary care clinicians are aligned to reward the provision of high-value care, the quality and cost effectiveness of patient care improves.

C. Waiver Authority

The authority for Direct Contracting is section 1115A of the Act. Under section 1115A(d)(1) of the Act, the Secretary of Health and Human Services may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and certain provisions of section 1934 of the Act as may be necessary solely for purposes of carrying out section 1115A with respect to testing models described in section 1115A(b). Please refer to the Benefit Enhancements section for a list of programmatic waivers we anticipate offering starting in Performance Year 1 (PY1).

For this model and consistent with the authority under section 1115A(d)(1), the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act. No fraud or abuse waivers are being issued in this document; fraud and abuse waivers, if any, would be set forth in separately issued documentation. Thus, notwithstanding any provision of this RFA, individuals and entities must comply with all applicable laws and regulations, except as explicitly provided in any such separately documented waiver issued pursuant to section 1115A(d)(1) specifically for Direct Contracting. Any such waiver would apply solely to Direct Contracting and could differ in scope or design from waivers granted for other programs or models.

III. Scope and General Approach

The model will be tested over 6 years, with an initial IP, during which DCEs will engage in beneficiary alignment activities (consistent with the model's emphasis on voluntary alignment), care coordination, and care management. The IP will be followed by five performance years (PY1-PY5). For purposes of this RFA, the IP will occur in calendar year 2020, and PY1, PY2, PY3, PY4 and PY5 will occur in calendar years 2021, 2022, 2023, 2024 and 2025 respectively.

The payment options available under Direct Contracting aim to reduce expenditures while preserving or enhancing quality of care for beneficiaries. By aligning financial incentives, providing a prospectively determined and predictable revenue stream for participants, and putting a greater emphasis on beneficiary choice, Professional and Global aim to:

- **Transform risk-sharing arrangements in Medicare FFS** by offering both capitated and partially capitated population-based payments that move away from traditional FFS.
- **Broaden participation in CMS Innovation Center models** by allowing model participation by organizations new to Medicare FFS, such as physician managed organizations currently operating exclusively in the MA program.
- **Empower beneficiaries** to engage in their care delivery through voluntary alignment and potential benefit enhancements.
- **Reduce health care provider burden** to meet health care needs effectively through, for example, a smaller set of core quality measures (than used in the Pioneer ACO model, NGACO, and Shared Savings Program), and waivers to facilitate care delivery.

The payment options available under Direct Contracting are expected to increase beneficiaries' access to innovative, affordable care while maintaining all original Medicare benefits. While a DCE that has selected any one of the payment options available under Direct Contracting may offer benefit enhancements to eligible beneficiaries, these beneficiaries may still choose whether to receive enhanced benefits. Relative

to existing CMS initiatives, Direct Contracting places an emphasis on voluntary alignment; empowering beneficiaries to choose the health care providers with whom they want to have a care relationship. Direct Contracting also aims to improve beneficiaries' experience of care by reducing administrative burdens on practitioners; so that they can focus on what is most important, caring for patients.

CMS is committed to improving care for beneficiaries and thereby reserves the right to modify or terminate Direct Contracting if the model is not achieving its established goals and aims or as may be required under section 1115A.

IV. Application Process

All entities that want to participate in Direct Contracting are required to submit an application.

A. Application

There will be two application submission periods as described below. A Letter of Intent (LOI) is required for an application to be considered valid. The LOI submission period will be reopened for two weeks upon release of the RFA, please continue to check the website for updated timelines. Those who have already submitted an LOI do not need to submit a new one. Applicants that do not submit an LOI will not be considered for participation in Direct Contracting.

Applicants may access the LOI link at: <https://app1.innovation.cms.gov/dc>

CMS will stagger the application periods so it can process applications from DCEs wanting to participate in the IP in 2020 before processing applications for those wanting to start the model in PY1 in 2021 without an IP. The IP will provide an opportunity for DCEs to conduct outreach for voluntary alignment, which may be especially important for organizations new to serving fee-for-service Medicare beneficiaries. The DCE application for organizations interested in the IP will be made available in early December. Please continue to check the website for an updated application timeline. The application period for organizations interested in starting in PY1 will open in Spring 2020. The application questions are provided in Appendix E of this RFA so that all applicants can begin preparing their responses. CMS reserves the right to request interviews, site visits, or additional information related to application responses from applicants in order to assess their applications.

Of important note, and as described in the Legal Entity and State Licensure sections below, applicants to Direct Contracting will not be expected to have formed their legal entity or to have verified the requisite state licensure until after selection. However, these requirements must be satisfied before the organization executes the Direct Contracting Model Participation Agreement with CMS (the "Participation Agreement") for the IP (for applicants submitting the IP application) or PY1 (for applicants submitting the PY1 application). As part of the application submission process and by the applicable deadline, applicants must also submit a list identifying all proposed DC Participant Providers and Preferred Providers. DC Participant Providers and Preferred Providers will all be subject to program integrity screening. Selected applicants also must have a written agreement that meets the criteria set forth in the Participation Agreement with each DC Participant Provider and Preferred Provider on its list prior to signing the Participation Agreement.

DCEs applying for the IP will sign a Participation Agreement for this period and a second Participation Agreement prior to the start of PY1. DCEs applying for PY1, and not the IP, will only sign one participation agreement prior to the start of PY1.

Applicants may access the application portal at: <https://app1.innovation.cms.gov/dcrfa/dcrfaLogin>

To submit an application, applicants must first visit the above URL to create a username and password. Applicants must use the same email address associated with their LOI submission.

Any questions that arise during the application process may be directed to the Direct Contracting Model mailbox: DPC@cms.hhs.gov with the subject “Application Question.”

Additionally, we will provide more detailed information in the coming months on the financial methodology, including risk adjustment and quality performance, prior to the timeframe for review and execution of the Participation Agreements. For example, we anticipate providing more information about the financial methodology and risk adjustment later this fall.

B. Withdrawal of Application

Applicants seeking to withdraw a completed application or to withdraw specific CMS Certification Numbers (CCNs) and/or National Provider Identifiers (NPIs) from a pending application must submit an electronic withdrawal request, prior to signing either the IP or PY1 Participation Agreements, to CMS via email to the Direct Contracting mailbox: DPC@cms.hhs.gov. The request must be submitted as a PDF on the organization’s letterhead and signed by an official authorized to act on behalf of the organization. It should include the applicant organization’s legal name; the organization’s primary point of contact; the full address of the organization; and a description of the reason for the withdrawal. Applicants seeking to withdraw certain CCNs and/or NPIs must specify the CCNs and NPIs the applicant wishes to withdraw. Note that withdrawal of CCNs and/or NPIs from an application will require CMS to reassess the applicant’s eligibility to participate in Direct Contracting, including, for instance, the number of beneficiaries eligible for alignment.

V. Applicant Eligibility and Participation Requirements

The following sections describe the requirements an entity must meet to be eligible to participate in Direct Contracting. Professional and Global aim to attract a range of providers and suppliers operating under a common legal structure, with attention given to advancing primary care as a means to better managing health care overall. We believe this model is well-suited to various types of organizations, including those currently participating in the NGACO Model or the Shared Savings Program that are interested in continuing and deepening their participation in Medicare shared risk arrangements.

In addition to attracting participants from the NGACO Model, one of the goals of Direct Contracting is to add innovative organizations to CMS alternative payment models that have not been eligible for the Shared Savings Program and/or the NGACO Model due to an insufficient number of aligned Medicare FFS beneficiaries or other reasons, including organizations that have similar arrangements with MA organizations. Enhanced opportunities for voluntary alignment, along with an alignment “glide path,” provide opportunities for organizations new to Medicare FFS and/or Innovation Center models to build an aligned Medicare FFS population through means other than claims-based alignment. Similarly, we encourage Medicaid Managed Care Organizations (MCOs) to participate, particularly those with parent organizations that operate fully integrated dual eligible special needs plans (FIDE-SNPs) or Medicare-Medicaid Plans (MMPs). We expect that these organizations will be able to draw upon their expertise managing integrated Medicare and Medicaid services and assuming responsibility for the total cost of care for dually eligible individuals who are enrolled in their MCO and aligned to their affiliated DCE. CMS

will favorably consider such expertise in the application process, whether applying as a Standard, New Entrant, or High Needs Population DCE.¹

A. Eligible Providers and Suppliers

The DCE must be a legal entity that contracts with DC Participant Providers and may contract with Preferred Providers (both are defined in the Glossary at Appendix A). DC Participant Providers may include, but are not limited to:

- Physicians or other practitioners in group practice arrangements
- Networks of individual practices of physicians or other practitioners
- Hospitals employing physicians or other practitioners
- Federally Qualified Health Centers (FQHCs)
- Rural Health Clinics (RHCs)
- Critical Access Hospitals (CAHs)

DCEs may also elect to enter into arrangements with Preferred Providers. While a DCE will not be required to be a Medicare-enrolled provider or supplier in order to participate in Direct Contracting, each DC Participant Provider and Preferred Provider under the DCE must be a Medicare-enrolled provider (as defined at 42 C.F.R. § 400.202) or supplier (as defined at 42 C.F.R. § 400.202) by no later than June 30, 2020, in order to be eligible to participate in the model during PY1.² We have selected this deadline for Medicare enrollment during the IP (2020) because the DCEs that elect to participate in the IP and their DC Participant Providers and Preferred Providers will be engaged in voluntary alignment activities during the IP. These alignment activities will build up the population of beneficiaries that may be aligned to the DCE for PY1, which begins January 1, 2021. Enrollment of DC Participant Providers and Preferred Providers by June 30, 2020 will allow for DCEs to incorporate all of the beneficiaries aligned to these clinicians before the start of PY1. For subsequent years of the model, DCEs will be able to update their list of DC Participant Providers and Preferred Providers annually to add or remove Medicare-enrolled DC Participant Providers or Preferred Providers that satisfy the requirements of the model and are not Prohibited Participants (defined in the Glossary at Appendix A). See Program Overlap at Section V.I below for an explanation of the restrictions on DCEs, DC Participant Providers, and Preferred Providers participating in multiple Medicare initiatives during the IP and subsequent years of the model.

B. Screening

Applications will be screened to determine eligibility for further review. Screening will include the criteria detailed in this RFA for DCEs and applicable law and regulations, including 2 C.F.R Parts 180 and 376. In addition, CMS may deny selection to an otherwise qualified applicant on the basis of information found during a program integrity review of the applicant, its DC Participant Providers, Preferred Providers, or

¹ Alignment of beneficiaries to an MCO participating as a DCE would follow the same rules as described for other DCEs.

² For additional information on Medicare provider and supplier enrollment, see CMS website: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html>.

any other relevant individuals or entities. CMS may also deny individual DC Participant Providers, Preferred Providers, or any other relevant entity participation in Direct Contracting based on the results of a program integrity (PI) review. The PI screening may include, without limitation, the following:

- Confirmation of current Medicare enrollment status and history of adverse enrollment actions;
- Identification of delinquent debt;
- Review of performance in, and compliance with the terms of, other CMS models, demonstration programs, and initiatives;
- Review of compliance with Medicare and Medicaid program requirements;
- Review of billing history and any administrative audits, investigations, or other activities conducted regarding suspicious billing or other potential program fraud and abuse; and
- Review of any civil or criminal actions related to participation in a federal health care program.

Applicants will be required to disclose any investigations of, or sanctions that have been imposed on, the applicant or individuals in leadership positions in the last five years by an accrediting body or state or federal government agency. Individuals in leadership positions include key executives who manage or have oversight responsibility for the organization, its finances, personnel, and quality improvement, including without limitation, a Chief Executive Officer (CEO), Chief Financial Officer (CFO), Chief Operations Officer (COO), Chief Informational Officer (CIO), medical director, compliance officer, or an individual responsible for maintenance and stewardship of clinical data. Applicants will also be required to disclose any outstanding debts owed to Medicare.

C. DCE Organization Types, Legal Entity Status, Governance Structure, and Leadership

DCE Organization Types

A key aspect of Direct Contracting is providing new opportunities for a variety of different organizations to participate in value-based care arrangements in Medicare FFS. In addition to organizations that have traditionally provided services to a Medicare FFS population, Direct Contracting provides new opportunities for organizations without significant experience in FFS to enter into value-based care arrangements.

Under Direct Contracting, there will be three types of DCEs with different characteristics and operational parameters. These three types of DCEs are:

- 1. Standard DCEs** – DCEs comprised of organizations that generally have experience serving Medicare FFS beneficiaries, including dually eligible beneficiaries. These organizations may have previously participated in section 1115A models involving shared savings (e.g., NGACO and Pioneer ACO Model) and/or the Shared Savings Program. Alternatively, new organizations, composed of existing Medicare FFS providers and suppliers, may be created in order to participate as this DCE type. In either case, providers and suppliers participating within these organizations would have substantial experience serving Medicare FFS beneficiaries. Beneficiaries will be aligned to Standard DCEs through voluntary alignment and claims-based alignment.
- 2. New Entrant DCEs** – DCEs comprised of organizations that have not traditionally provided services to a Medicare FFS population and that will primarily rely on voluntary alignment, at least in the first few performance years of the model. Claims-based alignment will also be utilized.
- 3. High Needs Population DCEs** – DCEs that serve Medicare FFS beneficiaries with complex needs,

including dually eligible beneficiaries, who are aligned to the DCE through voluntary alignment or claims-based alignment. These DCEs are expected to use a model of care designed to serve individuals with complex needs, similar to the one employed by the Programs of All-Inclusive Care for the Elderly (PACE), to coordinate care for their aligned beneficiaries.

Given that applicant organizations will be distinct in their composition of providers and suppliers, as well as in their experience in value-based care arrangements in Medicare FFS, CMS has designed these three different DCE types to vary with regard to certain model features, including beneficiary alignment, benchmarking methodology, and alternative payment mechanisms. Design parameters and model requirements will be described separately for each DCE type later in this RFA. A summary table comparing the different elements for each of the three DCE types has been provided in Appendix B.

Legal Entity

A DCE must be a legal entity identified by a federal taxpayer identification number (TIN) formed under applicable state, federal, or tribal law, and authorized to conduct business in each state in which it operates for purposes of the following:

- Receiving and distributing monies from CMS;
- Repaying monies determined to be owed to CMS;
- Establishing, reporting, and ensuring DC Participant Provider compliance with health care quality criteria, including quality performance standards; and
- Fulfilling other DCE functions identified in the Participation Agreement.

A DCE formed by two or more DC Participant Providers, each of which is identified by a unique TIN, must be a legal entity separate from the legal entity of any of its DC Participant Providers or Preferred Providers. If the DCE is formed by a single DC Participant Provider (such as a group practice), the DCE's legal entity and governing body may be the same as that of the DC Participant Provider.

The DCE must also comply with all applicable laws and regulations, as well as all Direct Contracting participation requirements.

Structure of the Governing Body

DCEs must have an identifiable governing body with sole and exclusive authority to execute the functions and make final decisions on behalf of the DCE. The DCE governing body must be separate and unique to the DCE and must not be the same as the governing body of an entity participating in the DCE (unless the DCE is formed by a single DC Participant Provider, in which case the DCE's governing body may be the same as that of the DC Participant Provider).

Responsibilities of the Governing Body

- The governing body must have responsibility for oversight and strategic direction of the DCE and will be responsible for holding DCE management accountable for the DCE's activities.
- The governing body must have a transparent governing process.

- The DCE governing body's incorporating documents shall require that when acting as a member of the governing body of the DCE, each governing body member shall have a fiduciary duty to the DCE, including the duty of loyalty, and shall act consistent with that fiduciary duty.
- The governing body must receive regular reports from the designated compliance official of the DCE, who is not legal counsel to the DCE, and who must report directly to the governing body.

Composition and Control of the Governing Body

- The DCE governing body must include at least one Medicare beneficiary served by the DCE: (1) who does not have a conflict of interest with the DCE; (2) who has no immediate family member with a conflict of interest with the DCE; (3) who is not a DC Participant Provider or Preferred Provider; and (4) who does not have a direct or indirect financial relationship with the DCE, a DC Participant Provider, or a Preferred Provider, except that such person may be reasonably compensated by the DCE for his or her duties as a member of the governing body of the DCE.
- The DCE governing body must include at least one consumer advocate, who may be the same person as the Medicare beneficiary. The consumer advocate must be a person with training or professional experience in advocating for the rights of consumers and who: (1) does not have a conflict of interest with the DCE; (2) has no immediate family member with a conflict of interest with the DCE; (3) is not a DC Participant Provider or Preferred Provider; and (4) does not have a direct or indirect financial relationship with the DCE, a DC Participant Provider, or a Preferred Provider, except that such person may be reasonably compensated by the DCE for his or her duties as a member of the governing body of the DCE.
- At least 25 percent control of the DCE's governing body shall be held by DC Participant Providers or their designated representatives. The required Medicare beneficiary and consumer advocate representation in the governing body shall not be included in either the numerator or the denominator when calculating the percent control.
- The DCE governing body shall not include a Prohibited Participant (as defined in the Glossary at Appendix A), or an owner, employee or agent of a Prohibited Participant.
- In cases where beneficiary and/or consumer advocate representation on the DCE governing body is prohibited by state law or would be an undue hardship, the DCE shall provide for an alternative mechanism, subject to CMS approval, to ensure that its policies and procedures reflect consumer and patient perspectives.
- The governing body members may serve in similar or complementary roles or positions for a DC Participant Provider or Preferred Provider as the role or position that they serve for the DCE.
- CMS will require common corporate good governance requirements for the DCE governing body in the Participation Agreement. Alternative mechanisms and exceptions to these requirements will be considered, at the discretion of CMS, in instances where compliance with these requirements would create an undue hardship or would conflict with state law and licensure requirements, or where the unique nature of a certain DCE would make the requirement non-applicable.

Conflict of Interest

The DCE governing body must have a conflict of interest policy that applies to members of the governing body. The conflict of interest policy must:

- Require each member of the governing body to disclose relevant financial interests;
- Provide a procedure to determine whether a conflict of interest exists and set forth a process to address any conflicts that arise; and
- Address remedial actions for members of the governing body that fail to comply with the policy.

DCE Leadership and Management

DCEs must have a leadership and management structure that meets the following criteria:

- The DCE's operations must be managed by an executive, officer, manager, general partner, or similar party whose appointment and removal are under the control of the DCE's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve the efficiency of processes and outcomes.
- Clinical management and oversight must be managed by a senior-level medical director who is: (1) a DC Participant Provider; (2) physically present on a regular basis at any clinic, office, or other location participating in the DCE; and (3) a board-certified physician and licensed in a state in which the DCE operates.

D. DC Participant Providers and Preferred Providers

Direct Contracting defines categories of Medicare providers and suppliers based on their respective relationships to the DCE. The two primary categories are DC Participant Providers and Preferred Providers. DC Participant Providers are the core providers and suppliers in Professional and Global. Beneficiaries are aligned to the DCE through the DC Participant Providers and these providers and suppliers are responsible for, among other things, reporting quality through the DCE and committing to beneficiary care improvement. Preferred Providers contribute to DCE goals by extending and facilitating valuable care relationships beyond the DCE. For example, Preferred Providers may participate in benefit enhancements approved and available in PY1 and alternative payment arrangements with the DCE. Beneficiaries will not be aligned to a DCE through the Preferred Providers, and Preferred Providers are not responsible for reporting quality through the DCE. Each provider and supplier that intends to enter into an agreement with the DCE as a DC Participant Provider or Preferred Provider for PY1 must be a Medicare-enrolled provider or supplier by June 30, 2020. Beneficiaries aligned with a DCE may also choose to receive services from Medicare FFS providers and suppliers that are not associated with that DCE.

E. DCE Service Area

A DCE's service area consists of the Core Service Area and the Extended Service Area. The Core Service Area includes the counties in which the DCE's DC Participant Providers have physical office locations. The Extended Service Area includes the counties contiguous to the Core Service Area. Based on the list of the DC Participant Providers submitted by the DCE during the application process, CMS will identify the DCE's service area for purposes of beneficiary alignment. DCEs are permitted to operate in multiple service

areas. For example, a DCE could operate in service areas in the same state or more than one state. The service area is distinct from the DCE's region, which includes all counties where DCE-aligned beneficiaries reside. A DCE's region is used to determine which counties' regional expenditures should be incorporated into the Performance Year Benchmark for a DCE. More details on the benchmark methodology can be found in Section VI.F. For DCEs that meet the definition of rural (see Appendix A for the definition of rural) and High Needs Population DCEs where the clinical model does not necessarily rely on a physical practice location (i.e. through delivery of services in locations other than a provider's office, such as beneficiaries' homes), applicants may propose for CMS' consideration an alternative to the county-by-county physical practice location standard and document their capability to operate in the proposed service area including the provision of face-to-face care and interaction with beneficiaries.

F. State Licensure

In order to participate in Direct Contracting, a DCE must demonstrate compliance with all applicable state licensure requirements regarding risk-bearing entities unless it provides a written attestation to CMS that it is exempt from such state laws. Each state has unique regulatory systems for health care delivery, the practice of medicine, fraud and abuse, and insurance, but CMS understands that states may not have laws that specifically address provider organizations bearing substantial financial risk, distributing savings, or, in the case of certain Capitation Payment Mechanisms, paying claims. Therefore, depending on the particular state laws and the discretion of state authorities, DCEs may be subject to insurer or third-party administrator (TPA) licensure requirements. It is a DCE's responsibility to determine and meet all applicable licensure requirements. Direct Contracting does not alter state law requirements, but CMS intends to engage with relevant state agencies to promote an understanding of Direct Contracting's features and requirements.

G. Outcomes-Based Contracts with Other Purchasers

CMS may require DCEs to report to CMS, in a manner and by a date determined by CMS, information regarding the scope of outcomes-based contracts held by the DCE and/or its DC Participant Providers with non-Medicare Purchasers. For purposes of this model, outcomes-based contracts mean contracts that include financial accountability (e.g., shared savings or financial risk) and evaluate quality performance standards.

H. Use of Certified EHR Technology

DCEs shall ensure that the percentage of DC Participant Providers that are eligible clinicians and that use certified electronic health record technology (CEHRT) to document and communicate clinical care to their patients or other health care providers meets or exceeds the CEHRT use criterion established under 42 C.F.R. 414.1415(a)(1)(i) (<https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf>), currently 75%. For purposes of the previous sentence, the terms "eligible clinician" and "CEHRT" are defined at 42 C.F.R. 415.1305.

DCEs and their DC Participant Providers will also be required to comply with all applicable requirements, if adopted, of the forthcoming final rule on Interoperability and Patient Access for MA Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans (QHPs) in the Federally-facilitated Exchanges and Health Care Providers. (<https://www.federalregister.gov/documents/2019/03/04/2019-02200/medicare-and-medicaid->

[programs-patient-protection-and-affordable-care-act-interopability-and](#)). Any additional Direct Contracting specific interoperability and patient access requirements will be communicated to DCEs before they are required to sign the Participation Agreement.

I. Program Overlap

Internal Model Overlaps

DCEs may not participate in more than one Direct Contracting payment option (Professional or Global) during the model test. Entities participating in one option during the IP cannot switch to another option before signing the PY1 participation agreement or thereafter.

Medicare Shared Savings Program

During the IP, DCEs can participate in both Direct Contracting and the Shared Savings Program. During each performance year from PY1 (CY2021) through PY5 (CY2025), DCEs and their DC Participant Providers may not simultaneously participate in the Shared Savings Program. The determination of whether such an overlap exists during PY1 – PY5 will be made at the TIN level.

Other Medicare Initiatives Involving Shared Savings, Comprehensive Primary Care Plus (CPC+), Primary Care First, and other Innovation Center Models

During the model performance years (PY1 – PY5), DC Participant Providers may not simultaneously participate in Direct Contracting and another model tested or expanded under section 1115A of the Act that involves shared savings, or any other Medicare initiative that involves shared savings unless otherwise instructed by CMS. For example, DC Participant Providers may not participate in the Maryland Total Cost of Care Model (all programs) and the Vermont All-Payer ACO Model. In addition, for the CPC+ and Primary Care First models, overlap is prohibited and determined based on the TIN/NPI combination of their clinicians due to similar payment structures existing in these models despite the fact that they are not shared savings models

DCEs and their DC Participant Providers may participate in other Medicare demonstrations or Innovation Center models that do not involve shared savings, if they meet all applicable eligibility criteria under the applicable demonstration or model. CMS may issue guidance that assists DCEs and their DC Participant Providers in determining how participation in certain demonstrations or models can be combined with participation in Direct Contracting, and whether a beneficiary may be aligned to more than one initiative and in such cases whether there is any reconciliation or adjustment made to account for the potential overlap.

DC Participant Providers

DC Participant Providers will be identified by a combination of their TIN and NPI. However, splitting the TIN will be permitted, which will allow DC Participant Providers with separate NPIs who bill through the same TIN to join separate models. In addition, a DC Participant Provider may participate in another model using another TIN that is not being used for Direct Contracting. DCEs should note that if a DCE includes an NPI on its list of DC Participant Providers who will be billing through a new TIN, the NPI will not be able to contribute claims history to the beneficiary alignment process, unless the NPIs former TIN, known as a “Legacy TIN” is also included on the DCEs Participant list and the legacy TIN is not being used by another CMS model. The Legacy TINs are subject to similar overlap rules as DC Participant Providers. Exceptions

to these statements may be communicated by CMS in future guidance during the model's implementation.

Preferred Providers

The overlap requirements described above generally do not apply to a DCE's Preferred Providers. Specifically, a Preferred Provider may serve in the following roles provided all other applicable requirements are met: (1) Preferred Provider for one or more other DCEs participating in Direct Contracting; (2) DC Participant Provider in another DCE participating in Direct Contracting; (3) ACO participant, ACO provider or supplier and/or ACO professional in an ACO in the Shared Savings Program (note: CMS intends to waive the non-duplication requirements under section 1899(b)(4)(A) of the Act and 42 C.F.R. § 425.114(a) as they apply to Preferred Providers as necessary solely for purposes of testing Direct Contracting); and/or (4) a role similar in function to a DC Participant Provider in another Medicare initiative that involves shared savings.

J. Advanced APM Determination

We anticipate both Global and Professional options under Direct Contracting will meet the criteria for Advanced Alternative Payment Model (APM) determination (42 C.F.R. 414.1410) in PY 2021 and will be subject to annual Advanced APM determinations. Eligible clinicians who are participants in the model and meet the definition of Affiliated Practitioner in 42 C.F.R. 414.1305 under either Global or Professional will be eligible for Qualifying APM Participant (QP) determinations.

K. MIPS APM Scoring

The Global and Professional options of the model are both considered Merit-based Incentive Payment System (MIPS) APMs under the definition at 42 C.F.R. 414.1305. Any MIPS eligible clinicians in these options who do not attain QP status and are participants on a participant list will be scored for purposes of MIPS under the APM scoring standard as codified at 42 C.F.R. 414.1370.

VI. Model Design Elements

Direct Contracting includes a number of key design elements that will test new features in payment and care delivery in Medicare FFS. This section describes beneficiary eligibility, alignment, engagement and marketing requirements, financial risk-sharing arrangements, risk mitigation, Capitation Payment Mechanisms, and an Advanced Payment option. It also includes a detailed discussion of the benchmark methodology, which addresses each of the DCE types individually. In addition, this section describes the benefit enhancements and patient engagement incentives that participating DCEs may choose to implement to support their ability to manage the care of their aligned beneficiaries.

A. Beneficiary Eligibility

In order for a beneficiary to be aligned to a specific DCE, the beneficiary must meet certain eligibility criteria. Once the beneficiary has met the eligibility criteria, they must also meet the DCE alignment criteria, which varies, by DCE type (see below). Beneficiaries will be considered alignment-eligible in a given month across all options for DCE alignment if they meet the following criteria:

- Are enrolled in both Medicare Parts A and B;
- Are not enrolled in an MA plan, Medicare Cost Plan under section 1876, PACE organization, or other

Medicare health plan;

- Have Medicare as the primary payer;
- Are a resident of the United States;
- Reside in a county included in the DCE's service area (defined above); and
- For individuals to be eligible to be aligned to a High Needs Population DCE, they must meet at least one of the following conditions: (1) have conditions that impair their mobility; and/or (2) meet the high needs special conditions for eligibility (described below). Medicare FFS beneficiaries, including dually eligible beneficiaries, meeting at least one of these conditions are eligible for alignment to a High Needs Population DCE.

B. Beneficiary Alignment

Beneficiary alignment is used for two purposes in Direct Contracting. First, CMS prospectively aligns beneficiaries to a DCE for each performance year. DCEs assume accountability for the total cost of care of beneficiaries aligned to their organization for the performance year, according to the risk arrangement selected by their organization (see section VI.D). Second, CMS uses beneficiary alignment to determine an organization's historical baseline expenditure for purposes of calculating the Performance Year Benchmark. DCEs will be required to maintain a minimum number of aligned beneficiaries for each Performance Year; however, lower minimum numbers of aligned beneficiaries are required for New Entrant DCEs and High Needs Population DCEs. This section of the RFA describes the beneficiary alignment options, alignment hierarchies, alignment for beneficiaries with partial-year experience, and lastly, minimum threshold alignment requirements by DCE type.

Beneficiary Alignment Options

For the purpose of assigning accountability for risk-sharing and the total cost of care, beneficiaries may be aligned to a DCE in two ways; however, the beneficiary alignment options available to a DCE will depend upon the DCE type. The two beneficiary alignment options are as follows:

1. Claims-based alignment where beneficiaries are aligned based on the plurality of primary care services received from a DC Participant Provider, as evidenced in claims utilization data; and
2. Voluntary alignment where beneficiaries communicate their desire to be aligned with a DC Participant Provider.

In order to be aligned to a DCE, the beneficiary must also meet the beneficiary eligibility criteria (described above).

Beneficiary alignment options vary by DCE type and also over the course of the Direct Contracting performance period, as outlined in Table 6.1. Further, since beneficiaries may align through more than one option, a hierarchy of alignment precedence will be applied. Standard DCEs, New Entrant DCEs, and High Needs Population DCEs will be able to align beneficiaries through either claims-based alignment or voluntary alignment.

Table 6.1: Beneficiary Alignment Options by DCE Type

DCE Type	Beneficiary Alignment Option: Claims-Based	Beneficiary Alignment Option: Voluntary
Standard DCE	Yes	Yes
New Entrant DCE	Yes	Yes
High Needs Population DCE	Yes	Yes

Beneficiary Alignment Hierarchies

Depending on the DCE type and the alignment options available to it, voluntary alignment will take precedence over claims-based alignment. A key limiting factor will be the beneficiary alignment options available to the DCE type. In instances in which a beneficiary meets the eligibility criteria and can be aligned to more than one DCE (e.g., a beneficiary voluntarily aligns to a DCE, but would be aligned to a different DCE on the basis of claims-based alignment), CMS will apply a set of hierarchical rules to determine the DCE to which the beneficiary will be aligned. First, CMS will align a beneficiary to a DCE on the basis of the beneficiary’s active selection of one of the DCE’s DC Participant Providers as their primary clinician or main source of care through voluntary alignment. Second, CMS will align a beneficiary on the basis of claims-based alignment. This hierarchy is illustrated in the following table.

Table 6.2: Beneficiary Alignment Hierarchy

Alignment Hierarchy	Alignment Type	DCE Model Type
First Priority	Voluntary Alignment	Standard DCEs New Entrant DCEs High Needs Population DCEs
Second Priority	Claims-based alignment	Standard DCEs New Entrant DCEs High Needs Population DCEs

In addition to developing within model alignment hierarchies, CMS also employs a formal (cross-agency) governance structure to execute hierarchical decision-making to prevent the alignment of beneficiaries to multiple models and resolve conflicts when they occur.

Claims-Based Alignment

Claims-based alignment is used in Direct Contracting to align beneficiaries to Standard, New Entrant and High Needs Population DCEs. Claims-based alignment will occur for each performance year prospectively, prior to the start of the performance year, based on historical claims for certain primary care services furnished by the DC Participant Providers, as identified by a TIN and NPI combination. Specifically, CMS will align a beneficiary to a DCE if the beneficiary has historically (i.e., within the two-year alignment “look back” period) received the plurality of their Primary Care Qualified Evaluation and Management (PQEM) services from the DCE’s DC Participant Providers, either from primary care practitioners or select non-primary care specialists. For the list of PQEM services, see Table 6.12. For the list of primary care practitioners and the list of select non-primary care specialists, see Appendix G. If a DCE includes an NPI on its list of DC Participant Providers who will be billing through a new TIN, the NPI will not be able to contribute claims history to the beneficiary alignment process, unless the old TIN for the NPI is also

included on the Participant list. The alignment period is a 2-year period that includes two consecutive 12-month periods, with the second period ending six months prior to the start of the relevant performance year; for example, for PY1 (CY 2021), the 2-year alignment period is July 1, 2018, through June 30, 2020.

Similarly, CMS aligns beneficiaries to a DCE for each base year for the purpose of calculating the baseline expenditure (for the Performance Year Benchmark calculation) on the basis of each beneficiary's receipt of PQEM services from DC Participant Providers during the 2-year alignment period ending six months prior to the start of each of the three base years. Alignment of a beneficiary for a performance year and each base year is determined by comparing:

- a. The weighted allowable charge for all PQEM services that the beneficiary received from DC Participant Providers in the DCE; and
- b. The weighted allowable charge for all PQEM services that the beneficiary received from each physician practice (including institutional practices) whose members are not participating in the DCE.

The allowable charges will be weighted one-third for the first year and two-thirds for the second year that beneficiaries are more likely aligned to primary care clinicians they visited more recently. Generally, a beneficiary is aligned to a DCE if its DC Participant Providers furnished the plurality of PQEM services to the beneficiary during the 2-year alignment period. Alignment for a base or performance year uses a two-stage alignment algorithm.

- **Alignment based on primary care services provided by primary care specialists.** If 10% or more of the allowable charges incurred for PQEM services received by a beneficiary during the 2-year alignment period are billed by physicians and practitioners with a primary care specialty, then alignment is based on the allowable charges incurred for PQEM services provided by primary care specialists.
- **Alignment based on primary care services provided by selected non-primary care specialties.** If less than 10% of the allowable charges for PQEM services received by a beneficiary during the 2-year alignment period are billed by primary care specialists, then alignment is based on the allowable charges incurred for PQEM services provided by physicians and practitioners with certain non-primary specialties.

Provider specialty is determined by the specialty code that is assigned to the claim during claims processing, in the case of physician claims, or by the specialty associated with the NPI of the physician or Non-Physician Provider in the Medicare provider enrollment database in the case of certain FQHC, RHC, and Method II CAH claims.

Alignment for Beneficiaries with Partial-year Experience

If a beneficiary does not meet all of the beneficiary eligibility criteria (described above in the beneficiary eligibility section) in a given month of a base year or performance year, the beneficiary will be excluded from expenditure calculations for that month and all subsequent months of the base year or performance year, as applicable. Beneficiaries initially aligned to a DCE, who subsequently lose alignment eligibility (e.g., after a beneficiary enrolls in MA) will contribute partial-year experience for purposes of calculating the Performance Year Benchmark and for purposes of Financial Reconciliation, up to the month prior to

the month in which the beneficiary loses his or her alignment eligibility. For example, a beneficiary who loses Medicare as a primary payer in August of a performance year will contribute a total of seven months of experience to the performance year (January through July).

Voluntary Alignment and Options for Frequency of Prospective Alignment

CMS will align beneficiaries based on voluntary alignment to Standard DCEs, New Entrant DCEs, and High Needs Population DCEs. Beneficiaries will be able to choose to align to a DCE voluntarily by designating a DC Participant Provider affiliated with the DCE as their primary clinician or main source of care through voluntary alignment. Voluntary alignment can be completed by a beneficiary either by selecting a “primary clinician” on MyMedicare.gov or, if the DCE has selected to participate in paper-based voluntary alignment, completing a paper-based form using a template developed by CMS (the “Voluntary Alignment Form”).

Beginning in the IP, DCEs may take steps, within certain parameters, to affirmatively ask beneficiaries to confirm their care relationships with the DCE. Alignment for beneficiaries who select a DC Participant Provider as their primary clinician or main source of care during a year will take effect the subsequent performance year, unless the DCE chooses Prospective Plus Alignment, in which case such alignment may take effect sooner (see the discussion of Prospective Alignment with a Quarterly Update Option below). A beneficiary who completes a Voluntary Alignment Form will have the option to reverse that decision or change the identified care relationship, and beneficiaries may update their selection in MyMedicare.gov at any time. If a beneficiary seeks voluntary alignment through both electronic and paper-based means, the electronic choice will take precedence. For those DCE types for which claims-based alignment applies, a beneficiary’s confirmation of his or her care relationship with a DC Participant Provider through voluntary alignment supersedes claims-based alignment. For example, beneficiaries who designate a DC Participant Provider as their main source of care will generally be aligned to the DCE in which their primary clinician is participating, even if claims-based alignment would not result in alignment. If a DCE joins Direct Contracting after participating in another Medicare shared savings initiative with voluntary alignment during the year prior to the DCE’s first performance year, the DCE may be allowed to retain beneficiaries who voluntarily aligned through the other shared savings initiative when transitioning into Direct Contracting.

DCEs will have two choices for the frequency of prospective alignment of beneficiaries through voluntary alignment. These options were developed in response to the following feedback from organizations that participate in current shared savings initiatives, including the NGACO Model: (1) a prospectively set benchmark is highly important in that it provides a stable goal; and (2) an interest in better engaging beneficiaries through voluntary alignment, including more “real time” alignment for those beneficiaries who choose to voluntarily align. To meet both of these goals, DCEs will have a choice of: (1) Prospective Alignment, or (2) Prospective Plus Alignment. Both of these policies rely on establishing the DCE’s aligned population prospectively; however, for those DCEs that select Prospective Plus Alignment, beneficiaries who voluntarily align to the DCE during the performance year will be added to the DCE’s aligned beneficiary population on a quarterly basis prior to the end of the performance year. Providing DCEs with this choice allows them to make a business decision regarding which goal they value more.

- Prospective Alignment will function similarly to the current prospective alignment methodology used in the NGACO Model. All claims-based alignment and voluntary alignment will be completed prior to

the start of each performance year.

- **Prospective Plus Alignment** will allow DCEs to have beneficiaries who have voluntarily aligned to the DCE added to their aligned beneficiary population on a quarterly basis throughout the performance year. Prospective Plus alignment will be used for two purposes: (1) calculating the benchmark, and (2) determining which beneficiaries are aligned to the DCE for the purpose of making monthly capitated payments and the subsequent payment reconciliation (see section VI.E for details). Prior to the start of each quarter, CMS will compile a list of beneficiaries who have voluntarily aligned through MyMedicare.gov and a list of beneficiaries who have completed a paper-based voluntary alignment form and meet all other beneficiary eligibility criteria. DCEs will be responsible for submitting to CMS updated paper-based voluntary alignment information prior to the start of each quarter in order to allow for timely updates to these CMS lists. Only those beneficiaries who were not already aligned to another DCE or an organization participating in another Medicare shared savings initiative for the performance year will be aligned to the DCE mid-year under Prospective Plus Alignment.

Table 6.3: Voluntary Alignment Dates under Prospective Plus Alignment

Alignment Date	Months DCE Alignment Recognized ¹
January 1	12 months (January through December)
April 1	9 months (April through December)
July 1	6 months (July through December)
October 1	3 months (October through December)

¹Assumes continuous alignment to the DCE through the end of the performance year. Beneficiaries may contribute fewer months due to loss of alignment eligibility or due to mortality.

CMS will incorporate safeguards into the Participation Agreement to ensure that voluntary alignment is used appropriately and that beneficiaries who are voluntarily aligned to a DCE maintain a meaningful primary care relationship with the DCE. For example, DCEs will be able to conduct activities related to voluntary alignment only within the DCE’s service area. As described above, a DCE’s service area will consist of all counties in which DC Participant Providers have physical office locations and the contiguous counties. In addition, DC Participant Providers may not begin conducting activities related to voluntary alignment until the DC Participant Provider is enrolled in Medicare as a provider or supplier.

Minimum Beneficiary Alignment Threshold

In order to participate in Direct Contracting, DCEs will be required to have a minimum number of aligned beneficiaries prior to the start of each performance year. The minimum number of aligned beneficiaries varies by DCE Organization Type, as described in Table 6.4 below. Standard DCEs will be required to have a minimum of 5,000 aligned beneficiaries prior to the start of each Performance Year from PY1 through PY5. New Entrant DCEs will be provided with flexibilities with regard to the minimum aligned beneficiary requirement during the glide path under which the minimum number of aligned beneficiaries will increase incrementally from 1,000 at the start of PY1 to 2,000 and 3,000 prior to the start of PY2 and PY3, respectively before moving to 5,000 prior to the start of PY4 and prior to the start of PY5 (as shown in Table 6.4). High Needs Population DCEs will also have a different minimum number of aligned

beneficiaries, which will increase from at least 250 beneficiaries prior to the start of PY1 to at least 500 prior to the start of PY2, 750 prior to the start of PY3, 1,200 prior to the start of PY4, and 1,400 prior to the start of PY5. Table 6.4 summarizes the minimum beneficiary alignment requirements by DCE type.

Table 6.4: Minimum Number of Aligned Beneficiaries by DCE Organization Type

DCE Organization Type	Minimum Number of Aligned Beneficiaries Required at the Start of Each Performance Year
Standard DCE	Minimum of 5,000 aligned beneficiaries prior to the start of each performance year.
New Entrant DCE	Minimum number of aligned beneficiaries prior to the start of each performance year under the “glide path”: PY1 (2021): 1,000 beneficiaries PY2 (2022): 2,000 beneficiaries PY3 (2023): 3,000 beneficiaries PY4 (2024): 5,000 beneficiaries PY5 (2025): 5,000 beneficiaries
High Needs Population DCE	Minimum number of aligned beneficiaries prior to the start of each performance year under the “glide path”: PY1 (2021): 250 beneficiaries PY2 (2022): 500 beneficiaries PY3 (2023): 750 beneficiaries PY4 (2024): 1,200 beneficiaries PY5 (2025): 1,400 beneficiaries

C. Beneficiary Engagement and Marketing

DCEs will be required to adhere to a number of beneficiary protections, including but not limited to the following:

- The DCE shall require its DC Participant Providers and Preferred Providers to make Medically Necessary Covered Services available to beneficiaries in accordance with applicable laws, regulations and guidance.
- The DCE must permit its aligned beneficiaries to maintain the freedom to choose their providers and suppliers, including the ability to select a primary clinician on MyMedicare.gov, even if the provider or supplier is not a DC Participant Provider or Preferred Provider with an arrangement with the DCE. The DCE is further required to notify its aligned beneficiaries that they have the freedom to select their own primary clinician and to receive services from the providers and suppliers of their choice according to traditional Medicare rules.
- DCEs must inform beneficiaries who have been aligned to the DCE what that means for the beneficiary in terms of the care that they will receive and how to opt-out of CMS sharing certain data about them with the DCE.
- DCEs must communicate the details of their benefit enhancements (where applicable) to all of their aligned beneficiaries, and CMS must approve such written materials prior to use. CMS will consider providing templates that DCEs must use.

CMS reserves the right to review any marketing materials and activities to ensure that the materials comply with the requirements of Direct Contracting, including that they are not inaccurate or misleading, are not discriminatory or used in a manner that is discriminatory, and make clear that alignment to a DCE does not remove or otherwise affect a beneficiary's freedom to choose a provider or supplier. Additional requirements concerning this review process will be provided in the Participation Agreement.

In order to allow for more robust outreach to beneficiaries regarding the DCE, CMS will permit DCEs to proactively communicate with beneficiaries regarding voluntary alignment, provided such communications comply with all applicable laws, regulations, and guidance and with the requirements of the Participation Agreement. For example, DCEs will be able to provide marketing materials and hold outreach events to the extent permitted by law. In addition, CMS may permit DCEs to provide gifts of nominal value to beneficiaries for the purpose of outreach regarding voluntary alignment, as long as the provision of such gifts does not violate applicable federal laws (including the beneficiary inducements prohibition and the anti-kickback statute). However, CMS will restrict DCEs' activities to ensure that DCEs are not misleading beneficiaries to believe that alignment to the DCE removes or otherwise affects their freedom to choose a provider or supplier, or that beneficiaries will receive benefits that are not available under either Medicare FFS or Direct Contracting. DCEs will not be allowed to engage in activities that may be intrusive to beneficiaries or discriminate against beneficiaries (such as based on the anticipated costs of a beneficiary's care).

Patient Engagement Incentives

Except as will be set forth in the Participation Agreement for Direct Contracting, DC Participant Providers, Preferred Providers, and other individuals or entities performing functions and services related to DCE activities are prohibited from providing gifts or other remuneration to beneficiaries to induce them to receive items or services from the DCE, DC Participant Providers, or Preferred Providers, or to induce them to receive or to continue to receive items or services from the DCE, DC Participant Providers, or Preferred Providers.

We believe that patient engagement is an important part of motivating and encouraging more active participation by beneficiaries in their health care. Beneficiary engagement and coordination of care could be enhanced by providing additional incentives to beneficiaries that would potentially motivate and encourage beneficiaries to become actively involved in their care. Subject to compliance with all applicable laws and regulations, DC Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to DCE activities will be permitted to provide in-kind items or services to beneficiaries, if the following conditions are satisfied:

1. There is a reasonable connection between the items or services and the medical care of the beneficiary;
2. The items or services are preventative care items and services or advance a clinical goal for the beneficiary, including adherence to a treatment regime, adherence to a drug regime, adherence to a follow-up care plan, or management of a chronic disease or condition; and
3. The in-kind item or service is not a Medicare-covered item or service for the beneficiary on the date the in-kind item or service is furnished to that beneficiary. For purposes of this exception, an item or service that could be covered pursuant to a benefit enhancement is considered a Medicare-covered

item or service, regardless of whether the DCE selects to participate in such Benefit Enhancement for a given performance year.

For example, under the terms of this model, a DC Participant Provider or Preferred Provider could provide blood pressure monitors to patients with hypertension in order to encourage regular blood pressure monitoring thus educating beneficiaries and engaging them to be more proactive in their disease management.

Additional examples of patient engagement incentives that DCEs could consider offering might include:

- Vouchers for over-the-counter medications recommended by a health care provider.
- Prepaid, non-transferable vouchers that are redeemable for transportation services solely to and from an appointment with a health care provider.
- Items and services to support management of a chronic disease or condition, such as home air-filtering systems or bedroom air-conditioning for asthmatic patients, and home improvements such as railing installation or other home modifications to prevent re-injury.
- Wellness program memberships, seminars, and classes.
- Electronic systems that alert family caregivers when a family member with dementia wanders away from home or gets up from a chair or bed.
- Vouchers for those with chronic diseases to access chronic disease self-management, pain management and falls prevention programs.
- Vouchers for those with malnutrition to access meal programs.
- Phone applications, calendars or other methods for reminding patients to take their medications and promote patient adherence to treatment regimens.
- Vouchers for dental care services, for example, prior to jaw surgery to reduce the risk of infection.

These items and services would be funded by the DCE and therefore, calculation of the DCE's benchmark and performance year expenditures will not account for any of these items or services.

Cost Sharing Support for Part B Services

Subject to compliance with all applicable laws and regulations and CMS approval, a DCE may enter into a cost sharing support arrangement with its DC Participant Providers and Preferred Providers, pursuant to which the DC Participant Providers and Preferred Providers would not collect beneficiary cost sharing amounts (in whole or in part) from categories of aligned beneficiaries and for categories of Part B services (excluding prescription drugs and durable medical equipment) identified by the DCE. DCEs would then make payments to those DC Participant Providers and Preferred Providers to cover some or all of the amount of beneficiary cost sharing not collected. The principal aim of allowing DCEs to offer this cost sharing support is to reduce financial barriers so that certain beneficiaries may obtain needed care and better comply with treatment plans, thereby improving their own health outcomes. In addition, permitting DCEs this flexibility will provide a critical tool to engage aligned beneficiaries, promote the utilization of high-value services, and incentivize aligned beneficiaries to continue receiving their care

from DC Participant Providers and Preferred Providers.

DCEs that select to offer cost sharing support for Part B Services will be required to enter into a cost sharing support arrangement with those DC Participant Providers and Preferred Providers who will participate in this patient engagement incentive. The DCE will also be required to identify the categories (e.g., subset) of beneficiaries, types of Part B services, or both, for which cost sharing support will be provided in an Implementation Plan that it submits to CMS. DCEs will be permitted to specify both primary care and specialty care services for this cost sharing support so that beneficiaries with specialty needs may also be incented to obtain the care they need. To the extent the DCE will not be paying the cost of the cost sharing support entirely, the DCE will also be required to specify in its Implementation Plan how it will determine the relative contributions of the DCE and the DC Participant Providers and Preferred Providers. Cost sharing support payments must come only from the DCE and, if applicable, its DC Participant Providers and Preferred Providers. Participating DCEs will be subject to monitoring and compliance activities in connection with the use of cost sharing support. To minimize possible abuse of this, CMS will incorporate certain beneficiary protections and other safeguards into the Participation Agreement.

Chronic Disease Management Reward Program

Subject to compliance with all applicable laws and regulations and CMS approval, CMS will permit DCEs to provide gift cards to eligible aligned beneficiaries, up to an annual limit of \$75, for the purpose of incentivizing participation in a chronic disease management program. Use of modest beneficiary incentives and rewards – such as gift cards – has been widely adopted by a variety of payers to influence healthy behaviors. DCEs will pay for the gift cards out of their own funds and at their discretion, subject to certain conditions. We believe that allowing DCEs to incentivize beneficiary participation in a chronic disease management program will promote beneficiary self-management, and ultimately improve quality and reduce costs.

DCEs that elect to offer a Chronic Disease Management Reward Program will be required to submit an Implementation Plan detailing how they will structure their program. DCEs will be permitted to offer programs that focus on aligned beneficiaries with a specific disease or chronic condition, as long as the program does not discriminate against any aligned beneficiary who would otherwise qualify for participation. DCEs that elect to offer a Chronic Disease Management Reward Program will be required to maintain records of their reward program, including documentation of the amount and type of each gift card awarded and the basis for beneficiary eligibility. Participating DCEs will be subject to monitoring and compliance activities in connection with their reward program. To minimize possible abuse of this patient engagement incentive, we will incorporate certain beneficiary protections and other safeguards into the Participation Agreement.

D. Financial Methodology: Risk Arrangements, Risk Mitigation, and Financial Reconciliation

The financial methodology for Direct Contracting includes the Performance Year Benchmark, risk-sharing arrangements, risk mitigation strategies, Capitation Payment Mechanisms, Advanced Payment, and Financial Reconciliation. The Performance Year Benchmark represents the average Medicare beneficiary total cost of care for aligned beneficiaries and refers to the target expenditure amount that will be compared to Medicare expenditures for items and services furnished to aligned beneficiaries (Direct Contracting beneficiaries) during a performance year. This comparison will be used to calculate Shared

Savings and Shared Losses. The Performance Year Benchmark will be addressed in a later section (see section VI.F) and will be discussed relative to each DCE type because there are variations in the way the Performance Year Benchmark will be calculated across the different DCE types. First, however, this section of the RFA will address the risk-sharing arrangements, risk mitigation strategies, and Financial Reconciliation, which will generally be applicable to all of the DCE types.

The risk-sharing arrangements are a key driver in determining the percent of savings/losses (either 50% or 100%) that DCEs are eligible to receive as Shared Savings or may be required to repay as Shared Losses. The risk mitigation mechanisms include risk corridors and stop-loss arrangements. During Financial Reconciliation, Medicare expenditures for Part A and Part B items and services furnished to aligned beneficiaries during the performance year (inclusive of capitated payments and Advanced Payments paid by CMS to the DCE as well as FFS claims paid by CMS directly to the Medicare providers and suppliers) will be reconciled against the Performance Year Benchmark after the performance year has ended. Additionally, an optional Provisional Financial Reconciliation will be offered to provide a timelier distribution of provisional Shared Savings/repayment of provisional Shared Losses.

Table 6.5: Risk Arrangements, Risk Mitigation, and Financial Reconciliation by Professional and Global

	Policy	Professional	Global
1	Risk Arrangement	50% of savings/losses.	100% of savings/losses.
2	Risk Corridors	Apply at the aggregate savings/losses level. Risk corridors for Professional have lower cutoffs than Global’s risk corridors with DCEs being responsible for a lower proportion of savings or losses in every corridor.	Apply at the aggregate savings/losses level. Risk corridors for Global have higher cutoffs than Professional’s risk corridors with DCEs being responsible for a higher proportion of savings or losses in every corridor.
3	Stop-Loss Arrangement	Addresses random, high cost expenditures.	Addresses random, high cost expenditures.
4	Provisional Financial Reconciliation (Optional)	Provides timely distribution of provisional Shared Savings/repayment of provisional Shared Losses following the end of the performance year (January 31 st target).	Provides timely distribution of provisional Shared Savings/repayment of provisional Shared Losses following the end of the performance year (January 31 st target).
5	Final Financial Reconciliation	Conducted approximately six months after the performance year ends.	Conducted approximately six months after the performance year ends.

Risk Arrangement

Direct Contracting will offer two risk arrangements, which determine the portion of the savings or losses in relation to the Performance Year Benchmark that will accrue to the DCE as Shared Savings or Shared

Losses. The applicable risk arrangement will depend on whether the DCE is participating in the Professional or the Global option:

- **Professional:** offers a partial risk arrangement of 50% of savings/losses, with risk corridors and optional stop-loss protection risk mitigation strategies.
- **Global:** offers a full risk arrangement of 100% of savings/losses, with broader risk corridors and optional stop-loss protection risk mitigation strategies.

No Minimum Saving Rate (MSR) or Minimum Loss Rate (MLR) will apply to aggregate savings/losses for either Global or Professional. As such, DCEs will retain “first dollar” savings or be responsible for “first dollar” losses.

Risk Corridors

The aggregate amount of savings or losses that DCEs in Global or Professional will be eligible to receive as Shared Savings or be required to repay as Shared Losses will be constrained by a series of risk corridors. DCEs will receive a portion of Shared Savings, or be liable for a portion of Shared Losses, above each risk band, with the portion of gross savings/losses decreasing with each risk band. To illustrate using Professional as an example, for all savings or losses up to, and including, 5% of the Performance Year Benchmark (Risk Band 1), the DCE is responsible for 50% of savings or losses and CMS is responsible for the remaining 50%. DCEs will be responsible for a progressively smaller portion of additional savings or losses as their savings or losses reach Risk Bands 2, 3, and 4. Should a DCE’s savings or losses be above 5% of the Performance Year Benchmark but below 10% (Risk Band 2), the DCE will be responsible for 35% of savings or losses that fall between 5% and 10% of the Performance Year Benchmark (in addition to the 50% of savings or losses in Risk Band 1). Meanwhile CMS would be responsible for 65% of savings or losses in Risk Band 2. Should a DCE’s savings or losses be above 10% of the Performance Year Benchmark but below 15% (Risk Band 3), the DCE will be responsible for 15% of savings or losses that fall between 10% and 15% of the Performance Year Benchmark (in addition to the 50% of savings or losses in Risk Band 1 and 35% of savings or losses in Risk Band 2). Meanwhile CMS would be responsible for 85% of savings or losses in Risk Band 3. Finally, for the portion of DCE savings or losses that exceed 15% of the Performance Year Benchmark (Risk Band 4), the DCE will be responsible for 5% of savings or losses, and CMS will be responsible for 95%. Risk Corridors for Global operate in an analogous manner, but with different cutoff points for each Risk Band. Global DCEs also will be responsible for a higher portion of savings or losses in each Risk Band compared to DCEs in Professional.

The series of Shared Savings/Shared Losses caps are outlined below for the Professional (Table 6.6) and Global (Table 6.7) options:

Table 6.6: Series of Shared Savings/Shared Losses Caps under Professional

Gross Savings/Losses as a percent (%) of the Final PY Benchmark	DCE Shared Savings/ Shared Losses cap	CMS Shared Savings/ Shared Losses cap
Risk Band 1: Gross Savings/Losses Less than 5%	50% of savings/losses	50% of savings/losses
Risk Band 2: Gross Savings/Losses Between 5% and 10%	35% of savings/losses	65% of savings/losses

Gross Savings/Losses as a percent (%) of the Final PY Benchmark	DCE Shared Savings/ Shared Losses cap	CMS Shared Savings/ Shared Losses cap
Risk Band 3: Gross Savings/Losses Between 10% and 15%	15% of savings/losses	85% of savings/losses
Risk Band 4: Gross Savings/Losses Greater than 15%	5% of savings/losses	95% of savings/losses

Table 6.7: Series of Shared Savings/Shared Losses Caps under Global

Gross savings/losses as a percent (%) of the Final PY Benchmark	DCE Shared Savings/ Shared Losses cap	CMS Shared Savings/ Shared Losses cap
Risk Band 1: Gross Savings/Losses Less than 25%	100% of savings/losses	0% of savings/losses
Risk Band 2: Gross Savings/Losses Between 25% and 35%	50% of savings/losses	50% of savings/losses
Risk Band 3: Gross Savings/Losses Between 35% and 50%	25% of savings/losses	75% of savings/losses
Risk Band 4: Gross Savings/Losses Greater than 50%	10% of savings/losses	90% of savings/losses

Stop-Loss

The purpose of the stop-loss arrangement is to reduce the financial uncertainty associated with infrequent, but high-cost, expenditures for aligned beneficiaries. Stop-loss protects DCEs from financial liability for individual beneficiary expenditures that are above the stop-loss “attachment points” (i.e., dollar thresholds at which stop-loss protection begins). The stop-loss arrangement will be an optional feature of both Global and Professional, and must be selected by the DCEs prior to the start of the Performance Year. DCEs may choose to change their stop-loss preference prior to the start of each Performance Year.

CMS will develop the stop-loss attachment points prospectively, prior to the start of each Performance Year, based on expenditure data derived from a national reference population of Medicare FFS beneficiaries and adjusted to reflect regional differences in Medicare payment rates for each DCE, using the same DCE-specific Geographic Adjustment Factors (GAFs) that will be used in calculating the Performance Year Benchmarks. Applying DCE-specific GAFs to the attachment points will better reflect the differences in spending that result from regional differences in Medicare FFS payments.

Under the stop-loss arrangement, if selected, DCEs will retain liability for a portion of expenditures above each attachment point. Requiring organizations to retain a percentage of liability for the beneficiary expenditures above the attachment point provides a direct economic incentive for the organization to continue to manage costs even after a beneficiary’s annual expenditures exceed the attachment point. This approach builds on the voluntary stop-loss methodology currently utilized in the NGACO Model, which introduced the use of multiple attachment points with decreasing levels of liability for spending

above each attachment point.

DCEs that elect the stop loss arrangement are effectively charged for this protection. CMS will apply a per-beneficiary per-month stop loss “charge” to the DCE’s Performance Year Benchmark. This charge will be based upon the percent of expenditures above each of the DCE’s attachment points in the baseline period. Additional information on the calculation of the stop-loss methodology will be provided in subsequent benchmarking methodology papers.

Optional Provisional Financial Reconciliation and Final Financial Reconciliation

Financial Reconciliation is the process by which CMS determines Shared Savings or Shared Losses by comparing actual Medicare expenditures (inclusive of capitated payments Total Care Capitation or Primary Care Capitation) and Advanced Payments paid by CMS to the DCE as well as FFS claims paid by CMS directly to the Medicare providers and suppliers) for Medicare Part A and Part B items and services furnished to Direct Contracting beneficiaries against the Performance Year Benchmark. Final Financial Reconciliation will be conducted after the Performance Year has ended and sufficient time has passed to allow for claims processing. Final Financial Reconciliation will be conducted for all DCEs; however, DCEs will also have the option to select Provisional Financial Reconciliation, which will be conducted shortly after the end of the Performance Year. This Provisional Financial Reconciliation will allow for more timely distributions of provisional shared savings or repayment of provisional shared losses, but it will not account for full claims processing run out due to the immediacy of this reconciliation shortly after the close of the Performance Year.

The Final Financial Reconciliation process will be conducted on/or about July 31st of the calendar year following the close of the Performance Year. This reconciliation will include claims run out through the end of Q1 of the calendar year following the Performance Year for expenditures incurred in the Performance Year. Final Financial Reconciliation will be based on risk adjusting the Performance Year Benchmark using the final risk scores for the Performance Year and then comparing the Performance Year Benchmark against Performance Year expenditures for aligned beneficiaries to determine Shared Savings or Shared Losses. For more details on the calculation of a Performance Year Benchmark, refer to the financial methodology for the applicable DCE type in the following sections.

Prior to the start of each Performance Year, CMS will provide DCEs participating in either Global or Professional with the option of the Provisional Financial Reconciliation, including the disbursement of provisional Shared Savings or the requirement to repay provisional Shared Losses, which will occur shortly following the end of the Performance Year, with a target date of January 31st of the calendar year following the Performance Year. The purpose of the Provisional Financial Reconciliation is to provide DCEs with a timelier disbursement of provisional Shared Savings and to require DCEs to more promptly repay provisional Shared Losses to CMS. This Provisional Financial Reconciliation will include DCE expenditures for the first six months of the Performance Year (through June 30) with six months of claims run-out. The parameters of the Provisional Financial Reconciliation are described below.

All DCEs, including those that opt for the Provisional Financial Reconciliation, will also be subject to the Final Financial Reconciliation. Final Financial Reconciliation will occur on or about July 31st of the calendar year following the performance year for both DCEs that opt into Provisional Financial Reconciliation and those that elect not to do Provisional Financial Reconciliation.

6.8: Provisional Financial Reconciliation and Final Financial Reconciliation

	Provisional Financial Reconciliation	Final Financial Reconciliation
Target Date for Reconciliation	January 31 st of calendar year following the Performance Year	July 31 st of calendar year following the Performance Year
Claims Included in Reconciliation	Performance year expenditures incurred through June 30 th	Performance year expenditures incurred through December 31 st
Claims Run-out	Through December 31 st of the Performance Year	Through March 31 st of the calendar year following Performance Year
Risk Scores	Initial risk scores	Final risk scores

For purposes of calculating Shared Savings or Shared Losses as part of the Provisional Financial Reconciliation, CMS may make adjustments to the DCE's performance year expenditures included in the Provisional Financial Reconciliation to account for anticipated differences between the DCE's expenditures included in the Provisional Financial Reconciliation and those that will be included in the Final Financial Reconciliation, including the use of an Incurred But Not Reported (IBNR) estimate of Performance Year expenditures, and a seasonal adjustment to account for anticipated seasonal fluctuations in expenditures throughout the Performance Year. These expenditures are then compared to a *Provisional* Performance Year Benchmark; provisional insofar as several elements of the Performance Year Benchmark are not finalized until well after the end of the Performance Year. For example, the DCE's quality performance and final risk scores are components of the benchmark, which will not be available when CMS performs Provisional Financial Reconciliation. Consequently, CMS may use a default quality score (e.g., the average quality score from a prior year) to account for quality performance in the calculation of the Provisional Performance Year Benchmark for purposes of the Provisional Financial Reconciliation. Furthermore, the Provisional Financial Reconciliation will need to be performed using either initial or mid-year risk scores. Final risk scores and the DCE's actual quality performance will be incorporated into the Performance Year Benchmark for the Final Financial Reconciliation.

CMS will apply a de minimis threshold for the payment of provisional Shared Savings or recoupment of provisional Shared Losses resulting from the Provisional Financial Reconciliation to avoid the distribution of Shared Savings or repayment of Shared Losses on amounts that may be the product of projection error, and are thus more likely to need to be repaid to or recouped from the DCE as part of the Final Financial Reconciliation.

The DCE must have the ability to repay all Shared Losses and Other Monies Owed for which it may be liable under this model and shall secure a financial guarantee for each Performance Year. If CMS does not receive payment for Shared Losses and Other Monies Owed by the date the payment is due, CMS shall pursue payment under the financial guarantee and may withhold payments otherwise owed to the DCE under this model or any other CMS program or initiative.

E. Financial Methodology: Direct Contracting Payment Mechanisms

In Direct Contracting, Medicare Parts A and B expenditures for aligned beneficiaries will be compared to the DCE's benchmark (the Performance Year Benchmark), a target Per Beneficiary Per Month (PBPM) dollar amount representing the total cost of Medicare Parts A and B services provided to the DCE's aligned beneficiaries, to determine the DCE's savings or losses. In addition, CMS is introducing a series of Direct Contracting Payment Mechanisms including, capitation and Advanced Payment, that will allow for prospectively determined and more predictable revenue streams paid on a monthly basis to DCEs. DCEs

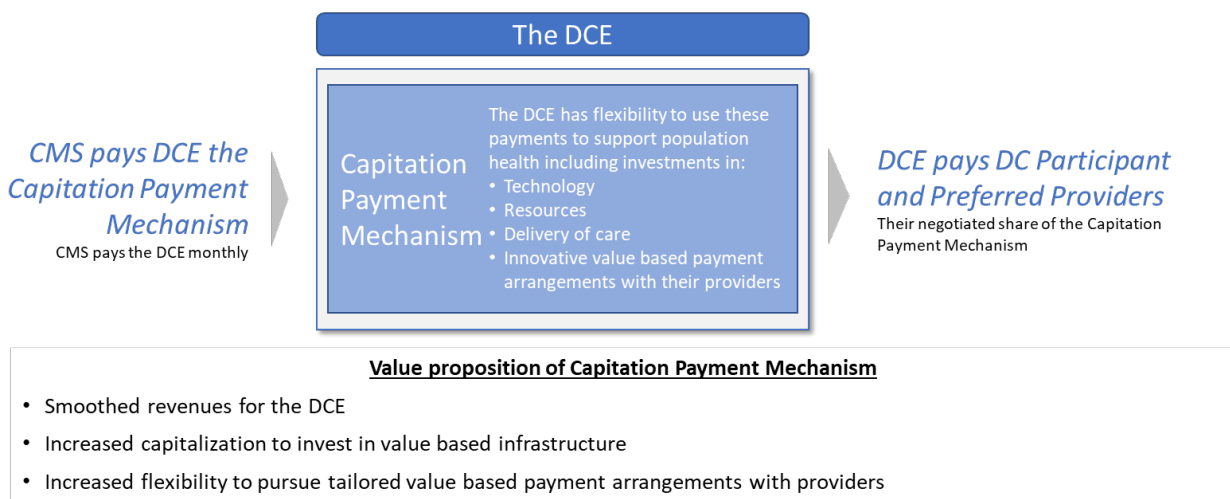
are required to select a Capitation Payment Mechanism and may also select the Advanced Payment option.

The Capitation Payment Mechanisms offered in Direct Contracting will test advances in the NGACO Model’s test of the All-Inclusive Population Based Payment (AIPBP) policy. AIPBP tests a “capitation-like” payment approach, in which CMS prospectively pays ACOs that select to participate in AIPBP an estimation of total spending based on historical utilization, while claims payments for participating providers and suppliers are reduced by 100%. Under AIPBP, the amount paid to the ACO is ultimately reconciled against the reductions actually made to claims payments to AIPBP-participating providers and suppliers. While AIPBP enhances the ability of organizations to contract with providers and suppliers in innovative payment arrangements, AIPBP remains directly linked to Medicare FFS payment and utilization.

The new Capitation Payment Mechanisms may be used by the DCE to support population health, for example, by allowing the DCE to enter into value-based payment arrangements with downstream providers or to invest in health care management tools, such as health care technologies. By giving DCEs a monthly cash flow through the Capitation Payment Mechanism, DCEs will have greater leverage to enter into downstream payment arrangements that can incent providers to work together and coordinate care for a defined set of aligned beneficiaries, with the potential to generate better outcomes and lower costs.

The amount of the capitated payment made by CMS to the DCE will partially depend on the Capitation Payment Mechanism selected by the DCE. CMS anticipates that the Capitation Payment Mechanisms in Direct Contracting will support a range of DCE activities including not only delivery of care, but also infrastructure to support the provision of primary care and care coordination services to aligned beneficiaries, including investments in resources, technology, and processes. All expenses incurred for Parts A and B items and services furnished to aligned beneficiaries, including the monthly cash flow received by the DCE through its selected Capitation Payment Mechanism, will be compared against the DCE’s Performance Year Benchmark to determine savings and losses.

Figure 6.1: Capitation Payment Mechanism



All DCEs must select a Capitation Payment Mechanism. The two Capitation Payment Mechanisms available to DCEs are:

1. **Total Care Capitation:** A PBPM capitated payment for all services provided by all DCE Participant Providers and those Preferred Providers who have opted into the capitated arrangement to aligned beneficiaries. This Total Care Capitation payment amount will reflect the estimated total cost of care for the DCE’s aligned population (i.e. the risk adjusted, trended, and regionally blended benchmark). This Capitation Payment Mechanism is only offered as a choice to DCEs participating in Global.
2. **Primary Care Capitation:** A PBPM capitated payment for primary care services provided by all DCE Participant Providers and those Preferred Providers who have opted into the capitated arrangement to aligned beneficiaries. This Primary Care Capitation payment amount will be equal to seven percent of the estimated total cost of care for the DCE’s aligned population (i.e. the risk adjusted, trended, and regionally blended benchmark). This Capitation Payment Mechanism is required for all DCEs participating in Professional. DCEs participating in Global may choose between Primary Care Capitation or Total Care Capitation as described in more detail below.

The Capitation Payment Mechanisms that are available in each payment option are highlighted in Table 6.9 below.

Table 6.9: Capitation Payment Mechanisms by Global and Professional

Option	Professional	Global
Total Care Capitation	No – not available.	Optional – must select one of the two Capitation Payment Mechanisms.
Primary Care Capitation	Yes –only available Capitation Payment Mechanism for Professional.	Optional – must select one of the two Capitation Payment Mechanisms.

Under the model, the DC Participant Providers will continue to submit claims to CMS for services provided to aligned beneficiaries. The CMS FFS claims processing system will then reduce claims payment amounts to \$0 for a select set of services furnished to these aligned beneficiaries by DC Participant Providers. The set of services furnished by DC Participant Providers and then zeroed out under the applicable Capitation Payment Mechanism, will be determined by the DCE’s selection of either the Total Care Capitation or Primary Care Capitation.

Preferred Providers will have the option, but not the obligation, to participate in whatever Capitation Payment Mechanism their DCE has selected. As noted, this is intended to allow DCEs and their Preferred Providers to enter into their own downstream value-based payment arrangements. This is operationalized by allowing Preferred Providers who opt into the Capitation Payment Mechanism to agree to have their FFS claims paid by CMS reduced. Specifically, Preferred Providers can negotiate with their DCE to agree to a reduction in the amount of FFS claims payment that they receive from CMS between 1% and 100% for services furnished to beneficiaries aligned to the DCE. CMS will continue to pay Preferred Providers their remaining FFS claim amounts. The DCE would pay the Preferred Provider in accordance with what has been agreed to between the DCE and Preferred Provider, whether on a value-based payment basis (e.g., bundle or sub-capitation) or on a FFS basis. If a Preferred Provider agrees to reduce the amount of FFS claims payment they receive from CMS by 100%, the Preferred Provider would receive 100% of their payments from the DCE. If any Preferred Providers elect to either not participate in the capitated arrangement or to participate but reduce their FFS claims by less than 100%, CMS will withhold a portion

of the monthly capitated payment paid to the DCE to account for the remaining expected claims expenditures. These efforts are intended to avoid the need for significant year-end recoupments from DCEs. CMS will determine the withhold for each DCE prior to the start of the Performance Year, based upon historical utilization of aligned beneficiaries.

For DCEs that select the Primary Care Capitation, an additional flexibility is Advanced Payment. The purpose of this additional flexibility is to support DCEs operating under the Primary Care Capitation in collaborating with DC Participant Providers and Preferred Providers to improve value-based arrangements associated with non-primary care services by providing an opportunity for DC Participant Providers and Preferred Providers to reduce FFS claims paid by CMS for non-primary care services and instead receive a different form of payment. In turn, the DCE will receive an Advanced Payment from CMS reflecting the value of the reduced FFS claims. This additional flexibility is unnecessary in the context of the Total Care Capitation where flexibility in payments for non-primary care services furnished by DC Participant Providers and Preferred Providers is already addressed. The key distinction between the approaches is that under Advanced Payment and Prospective Claims Reduction, the Advanced Payments are reconciled against the underlying utilization of services furnished by DC Participant Providers and by Preferred Providers that have agreed to a claims reduction. This means for example that if utilization associated with a Preferred Provider that agrees to a claims reduction is lower than expected the DCE would need to return to CMS at reconciliation the difference between the now lower value of the claims payment and the Advanced Payment, which before reconciliation will exceed the dollar value of claims. The Advanced Payment flexibility thus serves as a cash flow mechanism – it does not on its own reward or penalize DCEs for increased or reduced FFS claims expenditures. By contrast, where a Preferred Provider is participating in a DCE’s capitation option and agrees to say a 50% reduction on FFS claims paid by CMS, the estimated value of the claims reduction serves to reduce the capitation withhold amount and by implication increases the capitation payment to the DCE by the same amount.

These approaches are described further below.

Total Care Capitation

Total Care Capitation is offered in Global and encompasses all Medicare Part A and Part B services furnished to aligned beneficiaries. The Total Care Capitation payment will encompass services provided by DC Participant Providers, and services provided by Preferred Providers that have agreed to a claims reduction. Under Total Care Capitation, DC Participant Providers will be required to agree to prospective 100% claims reductions and Preferred Providers, who have agreed to participate, will be subject to Prospective Claims Reductions (as shown in the Table 6.10 below). Preferred Providers are not required to elect 100% claims reduction if they opt into the Total Care Capitation. Instead Preferred Providers have more flexibility, and may choose a lower claims reduction amount.

Table 6.10. Total Care Capitation

Type	Requirements	Claims Reduction
DC Participant Providers	Capitation required	100%
Preferred Providers	Optional flexible capitation with prospective claims reduction	1-100%

The monthly Total Care Capitation amount will equal one-twelfth of the Performance Year Benchmark, adjusted for the Total Care Capitation Withhold (described below). However, payments made by CMS for

services furnished to aligned beneficiaries by providers and suppliers not participating in the Total Care Capitation arrangement will be debited against the DCE’s Total Care Capitation amount. As it is expected that a portion of the total cost of care for aligned beneficiaries will be for services provided by providers and suppliers not participating in the Total Care Capitation arrangement, CMS will “withhold” a portion of the monthly Total Care Capitation amount to offset the expected payments that will be made by CMS to these providers and suppliers. This withhold will be referred to as the “Total Care Capitation Withhold.” This withhold is intended to avoid the need for significant year end recoupments from DCEs to account for the claims payments that have been made by CMS to providers and suppliers not participating in the Total Care Capitation arrangement. CMS will determine the Total Care Capitation Withhold for each DCE, prior to the start of the performance year, based on aligned DC beneficiaries’ historical utilization of services furnished by DC Participant Providers, Preferred Providers that have agreed to participate in Total Care Capitation with an optional claims reduction, and all other providers and suppliers. Following the conclusion of the performance year, CMS will reconcile the Total Care Capitation Withhold against actual expenditures incurred by aligned beneficiaries for services provided by providers and suppliers not covered by the capitation arrangement.

For example, if the Total Cost of Care Performance Year Benchmark (which has been risk adjusted) for a DCE is \$1,000 PBPM and the Total Care Capitation Withhold is 40% (\$400 PBPM), the monthly capitated payment made to the DCE would be \$600 PBPM. If, through reconciliation, actual CMS payments to providers and suppliers not participating in Total Care Capitation accounted for \$350 PBPM, CMS would distribute the remaining \$50 PBPM that was “withheld” to the DCE (\$400 PBPM - \$350 PBPM). Alternatively, if actual CMS payments to providers and suppliers not participating in the Total Care Capitation accounted for \$450 PBPM, the DCE would owe CMS \$50 PBPM, which represents payments that were made to non-participating providers and suppliers beyond the amount withheld by CMS under the Total Care Capitation Withhold.

A further example of the Total Care Capitation reconciliation for a DCE with a risk adjusted Total Cost of Care Performance Year Benchmark of \$1100 PBPM is provided in Tables 6.11-A through D below.

Table 6.11-A: Simplified Example of the Total Care Capitation Withhold Reconciliation

Calculations	Total Cost of Care Performance Year Benchmark	Total Care Capitation	Total Care Capitation Withhold (Payments to Providers and Suppliers Not Participating in Capitation)	Total
Total Cost of Care Performance Year Benchmark (PBPM)	\$1,100.00			

Table 6.11-B: Prior to the Start of the Performance Year: Calculation of the Total Care Capitation Withhold

Calculations	Total Cost of Care Performance Year Benchmark	Total Care Capitation	Total Care Capitation Withhold (Payments to Providers and Suppliers Not Participating in Capitation)	Total
Projection (historical experience)		70.5%	29.5%	100%

Calculations	Total Cost of Care Performance Year Benchmark	Total Care Capitation	Total Care Capitation Withhold (Payments to Providers and Suppliers Not Participating in Capitation)	Total
Total Care Capitation Payment Amount and Total Care Capitation Withhold Calculation		\$775.50 (PBPM Total Care Capitation payment amount)	\$324.50 (PBPM Representing <u>Projected</u> Payments made by CMS for services furnished by Non-Participating Providers and Suppliers)	\$1,100.00

Table 6.11-C: After Performance Year: Calculation of Actual Claims Paid by CMS Outside of Total Care Capitation

Calculations	Total Cost of Care Performance Year Benchmark	Total Care Capitation	Total Care Capitation Withhold (Payments to Providers and Suppliers Not Participating in Capitation)	Total
Actual Paid Amount By CMS		\$775.50 (PBPM Total Care Capitation payment amount)	\$299.50 (PBPM <u>Actual</u> Claims payments made by CMS to Non-Participating Providers and Suppliers)	\$1,075.00

Table 6.11-D: Reconciliation: Reconciling the Actual Payments to Non-Participating Providers and Suppliers Against the Total Care Capitation Withhold

Calculations	Total Cost of Care Performance Year Benchmark	Total Care Capitation	Total Care Capitation Withhold (Payments to Providers and Suppliers Not Participating in Capitation)	Total
Payment to DCE (Reconciling Total Care Capitation Withhold Against Actual Claims Paid to Non-Participating Providers)		\$324.50 Withhold - \$299.50 Actual Claims Outside Total Care Capitation = \$25.00 PBPM Owed to DCE		\$25.00
Total Reimbursement PMPM (Total Care Capitation + Claims to Non-				\$1,100.00

Calculations	Total Cost of Care Performance Year Benchmark	Total Care Capitation	Total Care Capitation Withhold (Payments to Providers and Suppliers Not Participating in Capitation)	Total
Participating Providers				

Primary Care Capitation

The Primary Care Capitation Payment Mechanism is available to DCEs participating in both Global and Professional. This Capitation Payment Mechanism will provide participating DCEs a monthly payment that is intended to cover the Primary Care Based Services furnished to aligned beneficiaries by DC Participant Providers and those Preferred Providers who have agreed to a claims reduction along with an additional amount for enhanced primary care services, which can include infrastructure, technology, tools, and resources to support increased access to primary care, provision of care, and care coordination. CMS is proposing to define Primary Care Based Services as claims for Evaluation and Management (E/M) office visits for both new and established patients using the current procedural terminology (CPT)³ and Healthcare Common Procedure Coding System (HCPCS) codes described in Table 6.12 below. This method of defining primary care-based services, however, for the purpose of primary care capitation may be subject to additional revision. Primary Care Capitation will encourage greater flexibility in payment and innovative primary care service delivery as a means of improving the quality and cost effectiveness of care overall.

Table 6.12: Primary Care Based Services Proposed to be Included Under the Primary Care Capitation

Description	CPT ¹ /HCPCS Codes
Office or other outpatient visit for new patient	99201–99205
Office or other outpatient visit for established patient	99211–99215
Prolonged care for outpatient visit	99354–99355
Transitional Care Management Services	99495-99496
Home Care E/M	99324-99328, 99334-99337, 99339-99345, 99347-99350
Advance Care Planning	99497-99498
Welcome to Medicare and Annual Wellness Visits	G0402, G0438, G0439
Chronic Care Management Services	99490
Virtual Check-Ins	G20212

¹CPT codes, descriptions and other data only are copyright 2018 American Medical Association. All Rights Reserved. Applicable FARS/HHSAR apply. CPT is a registered trademark of the American Medical Association.

The Primary Care Capitation payment will equal seven percent of the DCE’s monthly Performance Year

³ CPT codes, descriptions and other data only are copyright 2018 American Medical Association. All Rights Reserved. Applicable FARS/HHSAR apply. CPT is a registered trademark of the American Medical Association.

Benchmark. Under Primary Care Capitation, CMS pays the DCE the capitated payment for primary care services and then the DCE is responsible for entering into payment arrangements with its DC Participant Providers and, if applicable, Preferred Providers, who furnish primary care services to aligned beneficiaries. DC Participant Providers in DCEs that elect Primary Care Capitation will be subject to a 100% claims reduction for Primary Care Based Services (as defined in Table 6.12 above). DC Participant Providers will continue to submit claims for all services furnished to aligned beneficiaries, including Primary Care Based Services. CMS will reduce claims payment amounts to \$0 when Primary Care Based Services are furnished to aligned beneficiaries. DC Participant Providers will continue to be fully reimbursed under FFS for their non-primary care claims.

Preferred Providers may also choose to participate in the Primary Care Capitation. Preferred Providers who participate in the Primary Care Capitation will have additional flexibility regarding the amount by which their Primary Care FFS claims will be reduced. Preferred Providers can negotiate with the DCE regarding the amount of the claims reduction, and agree to have their claims payments for primary care services reduced by between 1% and 100%. CMS would pay Preferred Providers their remaining FFS claim amounts for primary care services and fully reimburse them under FFS for their non-primary care claims.

Table 6.13. Primary Care Capitation

Type	Requirements	Claims Reduction
DC Participant Providers	Full capitation for Primary Care Based Services required.	100%
DC Preferred Providers	Claims reduction optional for Primary Care Based Services. Preferred Providers also have additional flexibility regarding the capitation amount and associated claims reduction.	1-100%

The Primary Care Capitation payment amount includes an initial estimated base payment to cover Primary Care Based Services and an upfront additional payment for providing enhanced primary care services that will be recouped by CMS at the close of the performance year. CMS will calculate the estimated base primary care capitation amount using claims data submitted for primary care-based services provided to aligned beneficiaries by DC Participant Providers and participating Preferred Providers during the baseline period (services billed with the CPT codes identified in Table 6.12 used to identify Primary Care Based Services). The enhanced capitation amount is the difference between the estimated base primary care capitation amount and the Primary Care Capitation payment amount (i.e., seven percent of the Total Cost of Care Performance Year Benchmark). As the seven percent Primary Care Capitation payment is anticipated to be greater than the expenditures for the primary care-based services specified using primary care CPT codes (per Table 6.12 above), CMS will recoup the entirety of the enhanced capitation amount, i.e. the difference between the base primary care capitation amount and the Primary Care Capitation payment amount at the Final Financial Reconciliation. This will occur prior to the application of the risk-sharing arrangement in the context of Professional and by including as part of the Total Cost of Care in Global.

For example, for a DCE selecting Primary Care Capitation where three percent of the DCE’s historical claims expenditures are determined to be expenditures for primary care-based services, CMS will recoup the full enhanced primary care capitation amount of four percent as part of the Final Financial Reconciliation. This four percent is the difference between the seven percent Primary Care Capitation

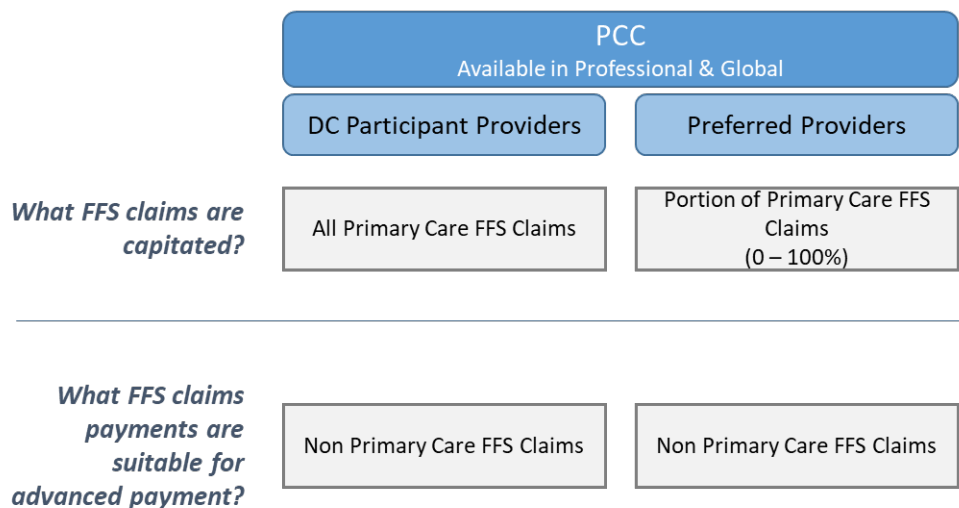
payment the DCE received from CMS and the DCE’s estimated base primary care capitation amount of three percent. In practice, this means that when conducting the Final Financial Reconciliation following each performance year, CMS will first recoup the full enhanced capitation amount separately from applying the risk arrangement (e.g., 50% for DCEs in Professional) to determine Shared Savings/Shared Losses. The estimated base primary care capitation amount for Primary Care Based Services (three percent) will also be included as a performance year expenditure in the calculation of Shared Savings/Shared Losses for the performance year.

The enhanced capitation amount CMS recoups at Final Financial Reconciliation will not be impacted by the amount of the actual primary care claims submitted by DC Participants and participating Preferred Providers. Using the example illustrated above, if a DCE with three percent primary care-based services (based on its historical claim expenditures) experiences actual primary care expenditures above three percent, CMS would still recoup four percent for enhanced capitation at Final Financial Reconciliation. Likewise, if the DCE experienced actual primary care claims below three percent, CMS would still recoup four percent for enhanced capitation at Final Financial Reconciliation.

Optional Advanced Payment with Prospective Claims Reduction for DCEs Electing Primary Care Capitation

DCEs that elect Primary Care Capitation will have additional flexibility to contract with DC Participant Providers and Preferred Providers under a claims reduction mechanism, which builds upon the Alternative Payment Mechanism in the NGACO Model referred to as “Population Based Payments.” The Advanced Payment will only apply to any non-primary care FFS claims payment that CMS continues to make to DC Participant Providers and Preferred Providers in the DCE (where primary care claims are defined by the CPT/HCPCS Codes described in Table 6.12).

Figure 6.2: DCE Capitation under the Primary Care Capitation Payment Mechanism, Advanced Payments to Preferred Providers and Proportion of FFS Claims Covered



Under the Advanced Payment mechanism, DCEs can enter into arrangements for non-primary care services whereby CMS would reduce the remaining non-primary care claims payment amount for participating DC Participant Providers and Preferred Providers, between 1% and 100% of the value of the

FFS claims payment amount, as agreed to by the DCE and the DC Participant Providers and Preferred Providers. In exchange, CMS would make a monthly Advanced Payment to the DCE equivalent to the estimated value of the FFS claims reductions for non-primary care services furnished to aligned beneficiaries by DC Participant Providers and Preferred Providers who have agreed to participate in Advanced Payment and Prospective Claims Reduction. The amount of the Advanced Payment is estimated by CMS based on historical utilization for aligned beneficiaries and the amount of the claims reduction negotiated by the DCE and the participating DC Participant Providers and Preferred Providers. These Advanced Payments will be reconciled against actual FFS claims at Final Financial Reconciliation. The Advanced Payment will be paid by CMS to the DCE which is then responsible for paying the participating DC Participant Providers and Preferred Providers based on what was negotiated between the DCE and the participating providers (subject to applicable laws).

CMS reserves the right to adjust the amount of the monthly Advanced Payments in subsequent months of the Performance Year if it is determined that the Advanced Payment amount has been under- or over-estimated, in excess of \$25,000 or more per month at the DCE level. This adjustment will help to protect CMS from making under- or overpayments, potentially resulting in cash flow issues for the DCE or necessitating significant payment recoupments in the Final Financial Reconciliation.

F. Financial Methodology: Beneficiary Alignment and the Performance Year Benchmark for Each of the Three DCE Types

In this section, we describe the unique beneficiary alignment requirements and the specific financial benchmarking methodology for each of the three DCE types. In general, the benchmarking methodology for Standard DCEs will serve as the framework for the benchmarking methodology for the other two DCE types, so we will describe this methodology first and refer back to it. A detailed financial methodology paper will be made available to potential participants prior to the deadline for signing the Participation Agreement. This financial methodology paper will address a variety of issues, including providing additional details regarding the benchmarking methodology (see Table 6.14 below), Capitation Payment Mechanisms, and the methodology for calculating Shared Savings/Shared Losses. A more detailed summary table comparing the different design elements of the three DCE types has been provided in Appendix B.

Table 6.14. Alignment and Financial Benchmarking Methodology for Each of the Three DCE Types

	Standard	New Entrant	High Needs Population
Description	DCEs with substantial historical experience serving Medicare FFS beneficiaries	DCEs with limited historical experience delivering care to Medicare FFS beneficiaries. Beneficiaries aligned via claims in any baseline year must not exceed 3,000 ²	DCEs that focus on beneficiaries with complex, high needs including dually eligible individuals
Alignment Options	1. Voluntary ¹ 2. Claims-based	1. Voluntary 2. Claims-based	1. Voluntary 2. Claims-based

	Standard	New Entrant	High Needs Population
			<i>Under both options, aligned beneficiaries must meet high needs criteria</i>
Performance Year Benchmark Overview: Voluntarily aligned beneficiaries¹	<p>For the first three years of beneficiary alignment to the DCE:</p> <ul style="list-style-type: none"> - Regional expenditures (Adj MA Rate Book) - Aligned beneficiary historical expenditures not incorporated <p>For all subsequent years of alignment to the DCE:</p> <ul style="list-style-type: none"> - Blends regional expenditures with aligned beneficiary recent historical expenditures 	<p>For the first three years of beneficiary alignment to the DCE:</p> <ul style="list-style-type: none"> - Regional expenditures (Adj MA Rate Book) - Aligned beneficiary historical expenditures not incorporated <p>For all subsequent years of alignment to the DCE:</p> <ul style="list-style-type: none"> - Blends regional expenditures with aligned beneficiary recent historical expenditures 	<p>For the first three years of beneficiary alignment to the DCE:</p> <ul style="list-style-type: none"> - Regional expenditures (Adj MA Rate Book) - Aligned beneficiary historical expenditures not incorporated <p>For all subsequent years of alignment to the DCE:</p> <ul style="list-style-type: none"> - Blends regional expenditures with aligned beneficiary recent historical expenditures
Performance Year Benchmark Overview: Claims-based aligned beneficiaries	Blends regional expenditures (Adjusted MA Rate Book) with aligned beneficiary historical expenditures (CY 2017-19)	<p>For the first three years of beneficiary alignment to the DCE:</p> <ul style="list-style-type: none"> - Regional expenditures (Adjusted MA Rate Book) - Aligned beneficiary historical expenditures not incorporated <p>For all subsequent years of alignment to the DCE:</p> <ul style="list-style-type: none"> - Blends regional expenditures with aligned beneficiary recent historical expenditures 	<p>For the first three years of beneficiary alignment to the DCE:</p> <ul style="list-style-type: none"> - Regional expenditures (Adjusted MA Rate Book) - Aligned beneficiary historical expenditures not incorporated <p>For all subsequent years of alignment to the DCE:</p> <ul style="list-style-type: none"> - Blends regional expenditures with aligned beneficiary recent historical expenditures

1. Beneficiaries who could be aligned via both voluntary and claims-based alignment, will be treated as having claims-based alignment for benchmarking purposes.
2. If the 3,000 threshold is exceeded, DCEs will have the opportunity to participate as a Standard DCE, provided the model requirements are met. Additionally, of the 5,000 aligned beneficiaries a New Entrant DCE is required to have by PY4, 3,000 or more must have been aligned via claims to show progress in establishing patient provider relationships.

Standard DCE

It is anticipated that Direct Contracting will attract organizations that have previously participated in section 1115A shared savings models (e.g., Next Generation ACO Model and Pioneer ACO Model) and/or the Shared Savings Program. In addition, CMS anticipates that new organizations, composed of existing

Medicare FFS providers and suppliers, may be created in order to participate in Direct Contracting. In either case, providers and suppliers participating within these organizations—referred to as Standard DCEs—would have substantial experience serving Medicare FFS beneficiaries. Organizations interested in serving as Standard DCEs must indicate their preferred DCE type in their response to this RFA. Summary alignment and benchmarking information for Standard DCEs is provided in Table 6.15 below and then described in more detail in the remainder of this section.

Table 6.15. Alignment and Financial Benchmarking Methodology for Standard DCEs

	Prospective Benchmarking Methodology for Voluntary alignment	Prospective Benchmarking Methodology for Claims-based alignment
Historical Baseline	<ul style="list-style-type: none"> Regional expenditures, measured via Adjusted MA Rate Book, for first three years of beneficiary alignment Incorporates aligned beneficiary recent historical expenditures for PY4 and PY5 	<ul style="list-style-type: none"> Aligned beneficiary historical expenditures (2017, 2018, and 2019)
Regional Expenditure	<ul style="list-style-type: none"> Adjusted MA Rate Book 	<ul style="list-style-type: none"> Adjusted MA Rate Book
Risk Adjustment	Yes	Yes
Discount (Global only) and Quality Withhold	Yes	Yes

Alignment Requirements

Alignment options available to Standard DCEs are premised on the notion that certain types of organizations that would be interested in the Direct Contracting Model will have DC Participant Providers that will have had past experience providing services to Medicare FFS beneficiaries. Standard DCEs have two beneficiary alignment options available to them, which are claims-based alignment and voluntary alignment. For Standard DCEs, voluntary alignment will take precedence over claims-based alignment. Standard DCEs will be required to have a minimum of 5,000 aligned beneficiaries prior the start of each Performance Year.

Benchmarking Methodology for Beneficiaries with Claims-Based Alignment

Under both Global and Professional, CMS will use a prospective benchmarking methodology to determine the Performance Year Benchmark for Standard DCEs. A per-beneficiary per-month (PBPM) benchmark will be developed for both the Aged & Disabled (A&D) and End Stage Renal Disease (ESRD) beneficiary categories, identified based on the reason for entitlement to Medicare. Development of the Performance Year Benchmark will include five steps (described in more detail below): (1) calculation of the historical baseline expenditures, (2) trending the historical baseline expenditures forward, (3) blending the historical baseline expenditures with regional expenditures using an Adjusted MA Rate Book, (4) risk adjustment, and (5) applying necessary adjustments for quality performance and the discount (Global

only). The Performance Year Benchmark is used to calculate Shared Savings or Shared Losses for the Performance Year. The Performance Year Benchmark is also used to derive the monthly capitated payments paid to DCEs during the Performance Year under both the Total Care Capitation and the Primary Care Capitation Payment Mechanisms. For purposes of calculating monthly capitated payments during the Performance Year, CMS will estimate certain inputs of the Performance Year Benchmark that are not finalized until after the end of the performance year (such as the quality adjustment). These estimates will be finalized and incorporated into the Performance Year Benchmark during the Final Financial Reconciliation process.

Historical Baseline Expenditures

CMS will determine the historical baseline expenditures for beneficiaries who are aligned to the Standard DCE through claims-based alignment, using the Parts A and B expenditures for those beneficiaries during a baseline period. (The benchmark calculation methodology for beneficiaries aligned to a Standard DCE on the basis of voluntary alignment, which is a different variant of this methodology, is described in more detail later in this section). For the duration of the Direct Contracting performance period, the baseline period will be a fixed period of the following three base years: 2017, 2018, & 2019. This period represents the most recent full calendar years for which full expenditure experience and claims run-out will be complete prior to the start of PY1 (2021). These base years will be weighted to give additional weight to the more recent base years, recognizing that the population of base year aligned beneficiaries for more recent base years is likely more comparable to the population of aligned beneficiaries for the relevant performance year.

Table 6.16. Historical Base Year Weighting for the Baseline Period (CY 2017, CY 2018 and CY 2019)

CY 2017	CY 2018	CY 2019
Base Year 1 (BY1)	Base Year 2 (BY2)	Base Year 3 (BY3)
10% weight	30% weight	60% weight

The *baseline period* will be static across all of the performance years of the model. However, the *historical baseline expenditures* will be updated each year, as CMS will use a DCE’s most recent list of DC Participant Providers (Participant List) to identify the beneficiaries that would have been aligned to the DCE for each of the base years and their associated expenditures. For example, the historical baseline expenditures that will be used for purposes of calculating the PY1 Performance Year Benchmark will be determined based on the DCE’s Participant List for PY1. For PY2, the same baseline period will be used, but the historical baseline expenditures will be determined based on the DCE’s Participant List for PY2.

Prospective Trend and Regional Geographic Adjustment Factor

Building on the experience of the NGACO Model and consistent with the goal of further aligning with MA payment methodologies, CMS will utilize a prospective trend that will be based on the projected US Per Capita Cost (USPCC) growth trend, developed annually by the CMS Office of the Actuary (OACT) and announced in the annual Announcement of Calendar Year (CY) Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies released the first Monday in April of the prior calendar year. The USPCC annual growth trend will be applied to the DCE’s historical baseline expenditures. CMS will apply the Aged & Disabled and Dialysis-only ESRD (“ESRD”) USPCC growth trends to the historical baseline expenditures for the Aged & Disabled and ESRD populations of aligned beneficiaries, respectively.

Under limited circumstances, additional adjustments to the baseline expenditures may be made. For

example, an adjustment based on a comparison of the projected USPPC to the experience and trend for specific populations, may be made to take into account differences in the expenditure trend for the FFS population as a whole, and for the subset of FFS beneficiaries that are alignment eligible under Direct Contracting. As an additional example, CMS may use an adjusted projected trend figure in response to unforeseeable events that have a substantial impact on Medicare FFS expenditures (such as hurricanes or other natural disasters). Adjustments to the trend adjustments would be intended to prevent DCEs from being unfairly penalized or rewarded for major payment changes beyond their control.

Furthermore, the trended historical baseline expenditures will be adjusted to reflect the anticipated impact of changes in the regional Geographic Adjustment Factors (GAFs) applied to payment amounts under the Medicare FFS payment systems. This GAF adjustment is intended to prevent the benchmark from being unfairly understated (or overstated) because of differences in the local geographic price adjustments that Medicare uses to calculate provider and supplier payments between the baseline period and the performance year. This process accounts for variations in the cost-of-doing-business adjustments that Medicare applies under most of its FFS fee schedules (e.g., the Medicare area wage index, and the geographic practice cost index), which are typically updated annually.

Regional Expenditures – Adjusted Medicare Advantage (MA) Rate Book

CMS will incorporate regional expenditures into the DCEs' historical baseline expenditures, in order to further align Medicare FFS and MA payment policies, as well as to move toward a more predictable calculation of benchmarks in risk-based Medicare FFS models. CMS will use the most recently available MA Rate Book data to derive the DCE's regional expenditures. The MA Rate Book establishes county-level rates for MA Plans for Aged and Disabled beneficiaries and state-level rates for ESRD beneficiaries. For purposes of Direct Contracting, CMS will make adjustments to the MA Rate Book as discussed in more detail below to make it appropriate for use in the model, establishing an *Adjusted MA Rate Book* which will be made available to DCEs in advance of each performance year. CMS will blend the regional expenditures with the DCE's historical baseline expenditures, which have been trended forward to the performance year in determining the Performance Year Benchmark. The composition of the Performance Year Benchmark will be a weighted average of the historical baseline expenditures and regional expenditures, with the percentage of the benchmark contributed by the regional expenditures increasing each Performance Year.

To develop the Adjusted MA Rate Book, CMS will make adjustments to the MA Rate Book figures to ensure that the rates used for this model serve as an accurate representation of regional costs for purposes of benchmarking. First, CMS will remove the impact of certain adjustments that are incorporated into the MA Rate Book for purposes of MA plan payment, but that are not relevant to Direct Contracting, such as the Quality Bonus Payment (QBP) percentage based on star ratings. Second, CMS will make adjustments to account for differences in expenditure types that are included for purposes of the MA Rate Book, but are not relevant for purposes of Direct Contracting, for example, the FFS quartile assignment rules may not apply. Third, CMS will make adjustments to account for differences between the subset of FFS beneficiaries eligible to be aligned to DCEs and Medicare FFS beneficiaries generally. For example, DCE aligned beneficiaries must be enrolled in both Medicare Parts A and B (see the beneficiary eligibility section for other differences between the DCE aligned population and the general FFS population).

To account for where the aligned beneficiaries live for the calculation of a DCE's regional expenditures, CMS will calculate a weighted average of the county rates (or state level rates for ESRD beneficiaries) from

the Adjusted MA Rate Book that correspond to where the aligned beneficiaries live. CMS will make use of the most recently available Adjusted MA Rate Book data to derive these rates.

Regional expenditures will then be combined with the DCE’s trended, historical baseline expenditures through blending to calculate a weighted payment rate. The proportion of regional expenditures that will be blended with the historical baseline expenditures will increase incrementally over the course of the Direct Contracting Performance Period, beginning with regional expenditures comprising 35% of the benchmark in PY1 and increasing to 50% of the benchmark by PY5. This transition toward an increasing percentage of regional expenditures comprising the benchmark is highlighted in Table 6.17 below.

Table 6.17: Composition of the Performance Year Benchmark

PY1 (2021)	PY2 (2022)	PY3 (2023)	PY4 (2024)	PY5 (2025)
65% Historical Baseline Expenditures	65% Historical Baseline Expenditures	60% Historical Baseline Expenditures	55% Historical Baseline Expenditures	50% Historical Baseline Expenditures
35% Regional Expenditures	35% Regional Expenditures	40% Regional Expenditures	45% Regional Expenditures	50% Regional Expenditures

For purposes of incorporating regional expenditures into a DCE’s benchmark, the DCE’s region will include all counties in which one or more beneficiaries aligned to the DCE in the baseline period reside. Note that the “region” for purposes of the financial benchmarking methodology is defined at the county-level and calculated for each DCE, and that this “region” is separate and distinct from the DCE’s “service area” which is used for purposes of beneficiary alignment.

CMS will establish limits on the maximum upward and downward adjustment that can result from incorporating regional expenditures into the benchmark. Specifically, CMS will limit the overall upward adjustment from incorporating the regional expenditures to a flat dollar amount equal to five percent of the FFS USPCC for the performance year. We will limit the overall downward adjustment from incorporating the regional expenditures to a flat dollar amount equal to two percent of the FFS USPCC for the performance year. For example, in a hypothetical performance year in which the FFS USPCC (Aged & Disabled) estimate is \$1,000.00 PBPM, the maximum upward adjustment to the historical benchmark (Aged & Disabled) would be \$50.00 PBPM and the maximum downward adjustment to the historical benchmark (Aged & Disabled) would be \$20.00 PBPM.

While CMS will not distinguish between “efficient organizations” (i.e., lower cost than region) and “inefficient organizations” (i.e., higher cost than region) for purposes of determining the percentage of regional expenditures that comprise the benchmark, we believe that the limit on the maximum upward adjustment resulting from incorporating regional expenditures allows for a meaningful reward for DCEs that are efficient relative to their region, while mitigating potential windfall savings for those DCEs with significantly lower costs than their region. Imposing a more modest limit on the negative regional adjustment continues to drive higher-cost DCEs towards efficiency compared with their region, while maintaining an attainable objective that does not discourage participation in the model by those organizations whose aligned beneficiaries have historically incurred above average costs for their region.

Risk Adjustment

CMS will use risk adjustment to account for the underlying health status of the population of beneficiaries aligned to a DCE. CMS will apply a modified risk adjustment methodology to achieve two primary goals:

1. Mitigate the influence of coding intensity on risk adjustment.
2. Improve the accuracy of risk adjustment for organizations specializing in serving complex, high-risk patients.

Additional information regarding this modified risk adjustment methodology will be provided in subsequent financial methodology papers. CMS anticipates publishing a risk adjustment methodology technical methods paper in late 2019. This technical paper will address various aspects of the risk adjustment methodology for Global and Professional under Direct Contracting.

Discount and Quality Incentives

CMS will apply a series of adjustments to the trended, regionally blended, risk adjusted benchmark at this stage in the calculation of the Performance Year Benchmark. These adjustments will serve to incentivize quality performance, reward higher performing DCEs, and help to generate savings under the model.

Discount Applied to the Performance Year Benchmark (Global Only)

CMS will apply a discount to the trended, regionally blended, risk adjusted benchmark for DCEs participating in Global. As DCEs in Global will retain 100% of savings relative to the Final Performance Year Benchmark achieved during the performance year, this discount to the benchmark will provide the primary mechanism for CMS to obtain savings from DCEs participating in this option. This discount will be set at two percent of the benchmark for PY1 and PY2. For each subsequent performance year, the discount to the benchmark will increase by one percentage point, thereby requiring continuous improvement from participants in Global. For Professional DCEs, the Performance Year Benchmark does not include this discount.

Quality Incentive

In both Global and Professional, a portion of the Performance Year Benchmark will be held “at risk,” dependent on the DCE’s performance on a pre-determined set of quality measures (see Appendix C for the proposed set of measures) and continuous improvement/sustained exceptional performance (CI/SEP). Specifically, this quality incentive will be structured as a quality “withhold,” set at five percent of the value of the trended, regionally blended, risk adjusted benchmark, and will be recalculated for each performance year. The DCE would then have the opportunity to “earn back” some or all of the quality withhold, depending on the DCE’s performance on the quality measure set and continuous improvement/sustained exceptional performance (CI/SEP). CMS anticipates using pay-for-reporting for the quality measure set that will be used to determine the DCEs quality performance for PY1.

To encourage DCEs to deliver high quality, high value care, payment for improvement on quality will also be tied to demonstrable continuous improvement in reducing unnecessary or avoidable health care service utilization in PY2-5. Specifically, half of the quality withhold will be tied to a set of “continuous improvement/sustained exceptional performance” (CI/SEP) criteria. CMS recognizes that DCEs achieving high performance rates may have less room to show improvement. Accordingly, when establishing these

continuous improvement targets, CMS will establish targets that still incentivize higher performing DCEs to continue to improve.

The amount of the quality withhold that a DCE earns back will be calculated as a function of the DCE's quality score for each performance year multiplied by 5% if the DCE meets the continuous improvement/sustained exceptional performance (CI/SEP) or by 2.5% if the DCE does not meet the continuous improvement/sustained exceptional performance (CI/SEP) (e.g., a DCE with a 95% quality score that meets the CI/SEP will receive a quality incentive of 4.75% [= 95% * 5%] whereas a DCE that does not meet the CI/SEP would receive half the incentive for that same quality score). A DCE that achieves a full (100%) quality score and also meets the CI/SEP will earn back the full amount of the quality withhold for the performance year.

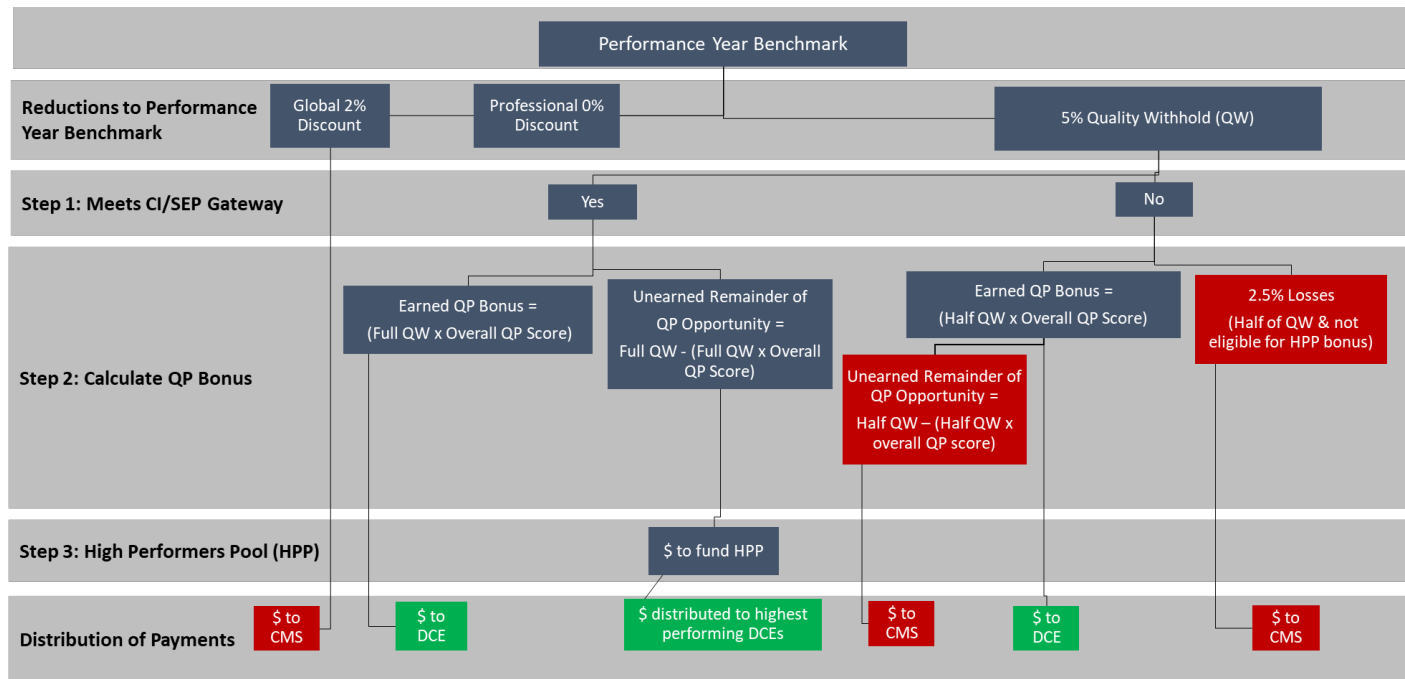
High Performers Pool (HPP)

Professional and Global will also test the use of an HPP to further incentivize high performance and continuous improvement on the quality measure set provided in Appendix C. DCEs in Global and Professional will qualify for a bonus from the HPP if they meet the CI/SEP and also demonstrate a high level of performance or meet improvement criteria on a pre-determined subset of the quality measures from the quality measure set. The HPP will be "funded" from quality withholds not earned back by the DCEs who met the CI/SEP. For example, a DCE that earns back 4.75% of its 5% quality withhold contributes the remaining 0.25% of its Total Cost of Care Performance Year Benchmark (that is, the remainder of its quality withhold) to the HPP. The funds in the HPP will be distributed to the highest performing DCEs through an HPP Bonus based on quality performance or improvement. The criteria for assessing quality performance or improvement may be based on an individual DCE's performance on the specified measures in the current performance year compared to the prior performance year, or may be based on performance against the quality measure benchmark, or a combination of both. Because the first performance year is pay for reporting, there will be no HPP in the first performance year. The criteria for the HPP will be shared prior to the first performance year and the detailed HPP methodology will be provided at the beginning of the second performance year. Although DCEs will receive 100% quality credit in the first performance year, quality performance on each measure will be assessed and will serve as the baseline for the DCEs' ongoing quality improvement activities in future performance years.

In order to account for potential variation in the size of organizations that may qualify to receive an HPP Bonus, the funds from the HPP will be distributed to DCEs proportionally, based on each qualifying DCE's overall number of beneficiary alignment-months in the performance year relative to the overall number of beneficiary alignment-months for other DCEs that qualify for this bonus. The highest performing DCEs may earn a net surplus as a result of their quality performance bonus and HPP Bonus.

If a DCE meets the CI/SEP criteria but fails to recoup 100% of the quality withhold as a result of their quality performance, the amount that the DCE fails to recoup will go into the HPP pool, for eligible high performing DCEs to earn. However, if the DCE fails to meet the CI/SEP, it would lose 50% of the quality withhold amount and these dollars would be retained by CMS and not added to the HPP pool. In such an instance, any additional amount of the quality withholds not "earned back" would also be retained by CMS, rather than distributed through the HPP. The quality strategy is designed to provide achievable performance criteria that incentivize practice transformations necessary to reduce utilization and improve quality of care.

Figure 6.3 Overview of Discount, Quality Performance, and Quality Bonus



CI/SEP = Continuous Improvement/Sustained Exceptional Performance
HPP = High Performers Pool
QP = Quality Performance
QW = Quality Withhold

Table 6.18: Application of Discount and Quality Withhold to the Performance Year Benchmark

	Global	Professional
PY1 (CY 2021)	<p>Benchmark is adjusted as follows: 2% discount applied to the benchmark; 5% of discounted benchmark subject to quality withhold, which may be earned back based on quality performance score (pay-for-reporting measures only).</p> <p>All DCEs will meet the continuous improvement/sustained exceptional performance (CI/SEP) and receive 100% quality score if they completely and accurately report on the quality measures.</p> <p>Because PY1 is pay for reporting and all DCEs who successfully report will earn a quality performance score of 100%, there will be no HPP Bonus.</p>	<p>Benchmark is adjusted as follows: 5% of benchmark subject to quality withhold, which may be earned back based on performance (pay-for-reporting measures only).</p> <p>All DCEs will meet the continuous improvement/sustained exceptional performance (CI/SEP) and receive 100% quality score if they completely and accurately report on the quality measures.</p> <p>Because PY1 is pay for reporting and all DCEs who successfully report will earn a quality performance score of 100%, there will be no HPP Bonus.</p>
PY2 (CY 2022)	<p>Benchmark is adjusted as follows: 2% discount applied to the benchmark;</p>	<p>Benchmark is adjusted as follows: 5% of benchmark subject to quality withhold, which may be earned back</p>

	Global	Professional
	5% of discounted benchmark subject to quality withhold, which may be earned back based on meeting the continuous improvement/sustained exceptional performance (CI/SEP) and quality performance score. If DCE meets CI/SEP criteria, eligible for consideration for HPP Bonus.	based on meeting the continuous improvement/sustained exceptional performance (CI/SEP) and quality performance score. If DCE meets CI/SEP criteria, eligible for consideration for HPP Bonus.
PY3 (CY 2023)	Benchmark is adjusted as follows: 3% discount applied to the benchmark; 5% of discounted benchmark subject to quality withhold, which may be earned back based on meeting the continuous improvement/sustained exceptional performance (CI/SEP) and quality performance score. If DCE meets CI/SEP criteria, eligible for consideration for HPP Bonus.	Benchmark is adjusted as follows: 5% of benchmark subject to quality withhold, which may be earned back based on meeting the continuous improvement/sustained exceptional performance (CI/SEP) and quality performance score. If DCE meets CI/SEP criteria, eligible for consideration for HPP Bonus.
PY4 (CY 2024)	Benchmark is adjusted as follows: 4% discount applied to the benchmark; 5% of discounted benchmark subject to quality withhold, which may be earned back based on meeting the continuous improvement/sustained exceptional performance (CI/SEP) and quality performance score. If DCE meets CI/SEP criteria, eligible for consideration for HPP Bonus.	Benchmark is adjusted as follows: 5% of benchmark subject to quality withhold, which may be earned back based on meeting the continuous improvement/sustained exceptional performance (CI/SEP) and quality performance score. If DCE meets CI/SEP criteria, eligible for consideration for HPP Bonus.
PY5 (CY 2025)	Benchmark is adjusted as follows: 5% discount applied to the benchmark; 5% of discounted benchmark subject to quality withhold, which may be earned back based on meeting the continuous improvement/sustained exceptional performance (CI/SEP) and quality performance score. If DCE meets CI/SEP criteria, eligible for consideration for HPP Bonus.	Benchmark is adjusted as follows: 5% of benchmark subject to quality withhold, which may be earned back based on meeting the continuous improvement/sustained exceptional performance (CI/SEP) and quality performance score. If DCE meets CI/SEP criteria, eligible for consideration for HPP Bonus.

Benchmarking Methodology for Beneficiaries Aligned Solely through Voluntary Alignment

Direct Contracting places a high emphasis on voluntary alignment, providing additional opportunities for active beneficiary choice and new tools for DCEs to engage and communicate with beneficiaries. Though also initially offered in the Shared Savings Program and the NGACO Model, voluntary alignment plays a modest role in beneficiary alignment to ACOs in those initiatives, with the vast majority of beneficiaries aligned to an ACO through claims-based alignment. With an increased emphasis on voluntary alignment

in Direct Contracting, the characteristics of beneficiaries aligned to a DCE in the performance year may differ from those aligned in the baseline period, creating a potential for asymmetry that may under-predict or over-predict expenditures for voluntarily aligned beneficiaries. As a result, CMS will test a new prospective benchmarking methodology to calculate a Performance Year Benchmark for beneficiaries that are aligned to a DCE solely through voluntary alignment. This new approach will further provide CMS with the ability to incorporate aligned beneficiary expenditure experience into the Performance Year Benchmark over time, as voluntarily aligned beneficiaries begin to accumulate claims history under Direct Contracting (see methodology below).

In addition to the goals outlined above, this approach will seek to meet the following objectives:

- Test a benchmarking approach that departs from an organization’s historical expenditures, towards a payment mechanism that uses fully regional rates.
- Provide an incentive for efficient organizations to compete for and engage with beneficiaries in managing their care.
- Provide the basis for the financial methodology for New Entrant DCEs, described in section VI.F.2, as these organizations will not have sufficient FFS experience to establish a historical baseline for the initial performance years of the model.

This alternative benchmarking methodology will apply only for those beneficiaries who are aligned to the DCE solely through voluntary alignment and who meet certain alignment criteria. This will include a determination from CMS that the beneficiary is *newly aligned* to the DCE. Specifically, CMS will confirm that the beneficiary has not previously been aligned to the DCE through claims-based alignment. CMS will also establish claims-based exclusion criteria, which will identify low utilization by voluntarily aligned beneficiaries of services furnished by DC Participant Providers, to ensure that DCEs establish and maintain a meaningful primary care relationship with each beneficiary who voluntarily aligns to the DCE over the DC Model’s performance period (PY1 – PY5).

This alternative benchmarking methodology will apply for the first three performance years of the model for individual beneficiaries are newly aligned to a DCE solely on the basis of voluntary alignment (plus any additional months of alignment if the beneficiary was aligned mid-performance year through Prospective Plus Alignment). Following this three-year period, if the beneficiary maintains alignment to the DCE, the benchmark will be derived from recent beneficiary historical expenditures and regional expenditures (as described below). Under this approach, the benchmarking methodology that will apply for PY4 and onwards will incorporate the beneficiary’s recent historical experience, following their alignment to the DCE.

Incorporating the Experience of Voluntarily Aligned Beneficiaries into the Historical Baseline

CMS will incorporate the experience of voluntarily aligned beneficiaries into the historical baseline used to develop the Performance Year Benchmark after PY 3. Prior to PY4, only the regional rates will be used to establish the historical baseline for these beneficiaries. As described in the above sections, regional expenditures will be determined through the use of an Adjusted MA Rate Book. CMS will use the beneficiary’s county of residence during the performance year for purposes of identifying the applicable regional expenditures. We will distinguish between Aged & Disabled beneficiaries and ESRD beneficiaries in determining the applicable regional expenditures and calculating the benchmark expenditures for

voluntarily aligned beneficiaries.

For PY4 and PY5, the same benchmarking methodology as applies for the claims-based aligned beneficiaries will be followed, with one exception. Whereas for claims-based alignment, the baseline period is a fixed three-year window (CY2017–CY2019), the methodology for these voluntarily aligned beneficiaries will use expenditures for more recent calendar years to calculate the historical experience.

Incorporating the historical experience of these beneficiaries will allow CMS to capture any differences in the characteristics (e.g., overall health status, expenditures) of beneficiaries that voluntarily align versus those that are aligned through the claims-based algorithm in the baseline period over the course of the model. In addition, using more recent calendar years for beneficiaries that were originally aligned to the DCE solely through voluntary alignment allows CMS to draw on historical experience from a period in which the DCE was engaged in the care of the beneficiary.

Risk Adjustment

CMS will apply risk adjustment to the blended regional expenditures/recent historical expenditures. A risk score will be calculated for each beneficiary who is voluntarily aligned to the DCE for a specific performance year (PY1-PY5). Additional information regarding the risk adjustment methodology is forthcoming and will be provided in subsequent financial methodology papers.

Discount, Quality Incentive, and HPP

To establish the Performance Year Benchmark, as described above, CMS will apply a discount (Global only) and quality withhold. DCEs may be eligible to receive a bonus from the HPP based on their quality performance. For these newly voluntarily aligned beneficiaries, CMS will apply the same methodological approach as claims-based aligned beneficiaries for applying the discount and quality withhold for purposes of developing the Performance Year Benchmark. Similarly, the same approach will be used to determine what portion of the quality withhold the DCE will earn back and whether it is eligible to receive a bonus from the HPP.

New Entrant DCE

An objective of Direct Contracting is to incent organizations that have not traditionally provided services to a Medicare FFS population to join a risk-based total cost of care model for the Medicare FFS population. The opportunity for organizations to participate in Direct Contracting as New Entrant DCEs is designed to advance this objective. Beneficiary alignment to a New Entrant DCE will be driven primarily by voluntary alignment and consequently, payments will be heavily based on regional expenditures and an adjusted MA Rate Book.

Table 6.19. Alignment and Financial Benchmarking Methodology for the New Entrant DCEs

	Prospective Benchmarking Methodology for Voluntary alignment	Prospective Benchmarking Methodology for Claims-based alignment
Historical Baseline	<ul style="list-style-type: none"> Regional expenditures, measured via Adjusted MA Rate Book, for first three years of beneficiary alignment 	<ul style="list-style-type: none"> Regional expenditures, measured via Adjusted MA Rate Book, for first three years of beneficiary alignment

	<ul style="list-style-type: none"> Incorporates aligned beneficiary recent historical expenditures for PY4 and PY5 	<ul style="list-style-type: none"> Incorporates aligned beneficiary recent historical expenditures for PY4 and PY5
Regional Expenditure	<ul style="list-style-type: none"> Adjusted MA Rate Book 	<ul style="list-style-type: none"> Adjusted MA Rate Book
Risk Adjustment	Yes	Yes
Discount (Global only) and Quality Withhold	Yes	Yes

Organizations that intend to participate in Direct Contracting as a New Entrant DCE must specify this selection as part of their application.

CMS will use a set of criteria to determine the applicant’s eligibility to participate as a New Entrant DCE, which will include the following:

- A New Entrant DCE’s proposed DC Participant Providers and Preferred Providers must be Medicare-enrolled by June 30, 2020, in order to participate in the model during PY1 (CY2021). DCEs will be required to attest that their DC Participant Providers and Preferred Providers will be Medicare-enrolled by the June 30, 2020 deadline.
- New Entrant DCEs must identify any “legacy” TIN under which a DC Participant Provider billed prior to affiliating with the DCE, commonly referred to as a “legacy TIN” under existing CMS guidance for the NGACO model. CMS will use this legacy TIN information to align beneficiaries to the DCE based on claims where such alignment does not interfere with the operation of other initiatives such as the Shared Savings Program. This approach is intended to help ensure that DCEs treated as new entrants should not more properly be treated as Standard DCEs based on the number of beneficiaries that can be aligned to a DCE based on claims.
- Not more than 50% of the DC Participant Providers in a New Entrant DCE may have prior experience in the Shared Savings Program, the Next Generation ACO Model, the Comprehensive ESRD Care Model, or the Pioneer ACO Model. Organizations found ineligible to participate as New Entrant DCEs on the basis of this criterion will have the opportunity to participate as a Standard DCE, provided all other model requirements are met.
- New Entrant DCEs may not have more than 3,000 beneficiaries that are “alignable” through claims-based alignment in any of the base years (CY2017, CY2018, and CY2019), as this suggests that the organization has significant experience serving Medicare FFS beneficiaries. For purposes of this criterion, CMS will assess the volume of services historically provided by the applicant’s proposed DC Participant Providers to Medicare FFS beneficiaries to determine the population of beneficiaries who would have been aligned to the applicant in each of the three base years on the basis of claims. Organizations found ineligible to participate as New Entrant DCEs on the basis of this criterion will have the opportunity to participate as a Standard DCE, provided all other model requirements are met.
- New Entrant DCEs must have the capability to assume risk for the total cost of care of an aligned Medicare FFS beneficiary population. For purposes of this assessment, CMS may solicit information

from the DCE on prior experience with risk-based or capitated arrangements, including but not limited to MA plans, PACE programs, and private health plans.

Alignment Requirements

In an effort to encourage organizations new to Medicare FFS to participate in Direct Contracting, CMS will provide an alignment “glide path” to allow these New Entrant DCEs an adequate time to grow their population of aligned beneficiaries. Voluntary alignment and claims-based alignment will serve as the sources of beneficiary alignment for these DCEs.

Organizations that fail to meet the applicable requirement regarding the minimum number of aligned beneficiaries prior to the start of each performance year will not be permitted to continue to participate in Direct Contracting. New Entrant DCEs may participate in Direct Contracting during the IP and engage in activities related to voluntary alignment to meet the minimum of 1,000 aligned beneficiaries prior to the start of PY1 (2021). New Entrant DCEs will be required to increase the minimum number of aligned beneficiaries to 2,000, 3,000 and 5,000 for PY2, PY3 and PY4 respectively. They will further be required to maintain a minimum of 5,000 aligned beneficiaries for PY5 as described in Table 6.20 below. Further, by PY4 and also for PY5 the New Entrant DCE must have more than 3,000 beneficiaries aligned using claims-based alignment. If this is not the case, the DCE will not be permitted to continue participating in the model.

Table 6.20: Minimum Number of Aligned Beneficiaries for New Entrant DCEs

Performance year	Minimum number of aligned beneficiaries at the start of the PY
PY1 (CY 2021)	1,000
PY2 (CY 2022)	2,000
PY3 (CY 2023)	3,000
PY4 (CY 2024)	5,000 (more than 3,000 aligned using claims-based alignment)
PY5 (CY 2025)	5,000 (more than 3,000 aligned using claims-based alignment)

Benchmarking Methodology

Baseline Expenditures

As New Entrant DCEs will not have substantial Medicare FFS experience prior to starting participation in Direct Contracting, the Performance Year Benchmark for these organizations will not reflect the historical spending experience of their aligned beneficiaries for the first three Performance Years. In the initial three performance years, CMS will use regional expenditures as the basis for determining the Performance Year Benchmark for all beneficiaries that are aligned to a New Entrant DCE regardless of how long the beneficiary has been aligned to the DCE or whether the beneficiary is aligned to the DCE on the basis of claims or voluntary alignment. As described in the above sections, regional expenditures will be determined through the use of an Adjusted MA Rate Book. CMS will use the beneficiary’s county of residence during the performance year for purposes of identifying the applicable regional expenditures. We will distinguish between Aged & Disabled beneficiaries and ESRD beneficiaries in calculating the regional expenditures for aligned beneficiaries.

Incorporating recent Claims Expenditure Experience into the Performance Year Benchmark Beginning in Performance Year 4 (2024)

After three Performance Years in the model, CMS will begin to incorporate aligned beneficiary experience from the recent years to develop a historical baseline for New Entrant DCEs. Specifically, CMS will develop a historical benchmark that incorporates the experience of beneficiaries aligned to the DCE in prior Performance Years. Beginning in Performance Year 4, CMS will establish a historical baseline period which uses expenditure data for CY 2021 (the calendar year encompassing PY1) and CY 2022 (the calendar year encompassing PY2). These base years will be weighted at one-third for CY 2021 and two-thirds for CY 2022. In Performance Year 5, the baseline period will encompass CY 2021, CY 2022, & CY 2023, which will be weighted at 10%, 30%, and 60%, respectively. In establishing the historical spending during this baseline period, CMS will incorporate beneficiaries who were aligned to the DCE on the basis of claims in the baseline period, as well as beneficiaries who voluntarily aligned to the DCE during those base years by designating a DC Participant Provider as their primary clinician. In the event that a credible benchmark cannot be generated using expenditures for those beneficiaries, CMS may consider also incorporating the historical experience of those beneficiaries voluntarily aligned to the DCE in the intermediate calendar year (CY 2023 in PY4 & CY 2024 in PY5) and the Performance Year into the baseline experience. Further information on the historical baseline period for New Entrant DCEs will be forthcoming in the Participation Agreement.

Using expenditure data from prior Performance Years allows CMS to establish a historical baseline for an organization that otherwise does not have substantial Medicare FFS experience. In addition, incorporating the historical experience of aligned beneficiaries will allow CMS to better reflect any differences in the characteristics (e.g., overall health status, expenditures) and total expenditures for beneficiaries that are aligned to the DCE, rather than using the regional average.

Risk Adjustment

CMS will risk adjust the regional expenditures and recent historical expenditures (incorporated in PY4 and PY5) to establish the Performance Year Benchmark for these aligned beneficiaries. Additional information regarding the risk adjustment methodology is forthcoming and will be provided in subsequent financial methodology papers.

Discount, Quality Incentive, and HPP

To establish the Performance Year Benchmark, as described above, CMS will apply a discount (Global only) and quality withhold. DCEs may earn back some or all of the quality withhold and may be eligible to receive a bonus from the HPP based on their quality performance.

High Needs Population DCE

An important goal of Direct Contracting is to enable organizations that focus on high needs populations to participate in Direct Contracting in order to test models of care tailored to these populations and to do so while allowing these beneficiaries to remain in Medicare FFS, if that is their preference. This goal extends to Medicare FFS beneficiaries, including high needs dually eligible beneficiaries. To support this goal, Direct Contracting will allow organizations focused on complex, high needs dually eligible beneficiaries and Medicare FFS beneficiaries at risk of becoming dually eligible--referred to as High Needs Population DCEs—to participate in Direct Contracting in order to test whether provider-led entities can replicate the successful clinical approaches of the PACE and similar models of care for a broader Medicare

FFS population. These approaches generally aim to enable individuals to continue living in non-institutional, community settings as long as medically and socially feasible and rely on interdisciplinary teams that typically (1) emphasize preventative care, meet regularly to update the care plan in response to changes in beneficiaries' functional and health status and provide regular clinical monitoring (which helps to reduce hospitalization due to ambulatory sensitive conditions); and (2) manage beneficiaries' care across all settings, which helps to facilitate smooth transitions between settings and reduce re-hospitalizations.

High Needs Population DCEs may serve individuals dually eligible for Medicare and Medicaid and/or Medicare FFS beneficiaries at risk of becoming dually eligible (based on the factors below), with:

- Conditions that impair their mobility (see Appendix F for an illustrative ICD-10 code list, which will be finalized for inclusion in Direct Contracting Participation Agreement); **AND/OR**
- Complex, high needs who have:
 - a. Significant chronic or other serious illness (defined as having a risk score of 3.0 or greater using the CMS Hierarchical Condition Category (CMS-HCC) methodology); **OR**
 - b. A CMS-HCC risk score greater than 2.0 and less than 3.0 **AND** two or more unplanned hospital admissions in the previous 12 months; **OR**
 - c. Signs of frailty, as evidenced by a claim submitted by a provider or supplier specifically for a hospital bed or transfer equipment for use in the home.

Organizations can care for specific sub-populations so long as each beneficiary within a sub-population still meets the eligibility criteria provided above. Organizations caring for one or more specific sub-populations must also clearly specify the clinical criteria used to define these populations. This may include patients with one particular disease, disease at a particular stage, or a combination of diseases. These clinical criteria must be reported as diagnoses in claims data, so that the aligned population can be identified.

Organizations interested in serving as High Needs Population DCEs must indicate their preferred DCE type in their responses to this RFA. CMS will select organizations to participate as High Needs Population DCEs that have experience serving high cost, high acuity individuals and where applicable in providing a range of Medicaid-covered services and demonstrate an ability to coordinate services across Medicare and Medicaid for dually eligible beneficiaries, and prevent unnecessary utilization of higher cost institutional care in Medicare and Medicaid. They must also demonstrate capabilities in coordination of services that emphasize person-centered care, such as an interdisciplinary care team that includes primary care, behavioral health, and Long-Term Services and Supports (LTSS) providers and that manages care across a range of settings. On an optional basis, at states' discretion, we will work with such applicants and state Medicaid agencies to explore potential Medicaid contracting strategies – and as applicable, necessary authorities -- that could replicate and/or support High Needs Population DCE payment approaches in the Medicaid program. The goal would be to maximize provider accountability and flexibility to provide the full range of services necessary to promote community integration for dually eligible individuals. We believe that multiple existing Medicaid authorities could support the delivery and financing of Medicaid services furnished by DC Participant Providers and Preferred Providers to dually eligible individuals, but this will depend on how each state administers its Medicaid program.

In general, the Standard DCE parameters will apply to High Needs Population DCEs. In addition, a High Needs Population DCE can participate in Direct Contracting under either Professional or Global.

Table 6.21. Alignment and Financial Benchmarking Methodology for High Needs Population DCEs

	Prospective Benchmarking Methodology for Voluntary alignment	Prospective Benchmarking Methodology for Claims-based alignment
Historical Baseline	<ul style="list-style-type: none"> Regional expenditures, measured via Adjusted MA Rate Book, for first three years of beneficiary alignment Incorporates aligned beneficiary recent historical expenditures for PY4 and PY5 	<ul style="list-style-type: none"> Regional expenditures, measured via Adjusted MA Rate Book, for first three years of beneficiary alignment Incorporates aligned beneficiary recent historical expenditures for PY4 and PY5
Regional Expenditure	<ul style="list-style-type: none"> Adjusted MA Rate Book 	<ul style="list-style-type: none"> Adjusted MA Rate Book
Risk Adjustment	Yes	Yes
Discount (Global option only) and Quality Withhold	Yes	Yes

Alignment Requirements

CMS will align individuals to a High Needs Population DCE if they meet the above high needs criteria prior to initial alignment and are otherwise eligible for voluntary or claims-based alignment to a DCE. Additionally, unlike PACE, the population being served by this High Needs Population DCE will not be limited to individuals who are 55 years of age or older.

DCEs focused on serving complex, high-risk dually eligible individuals may be unable to achieve the required minimum of 5,000 aligned Medicare FFS beneficiaries applicable to Standard DCEs, because high needs individuals do not exist in most health care markets in sufficient concentration to meet this threshold. Rather than excluding such organizations from participation in Direct Contracting, CMS will establish an alignment “glide path” for High Needs Population DCEs. Specifically, CMS will align Medicare FFS beneficiaries to these High Needs Population DCEs based on voluntary and claims-based alignment. These High Needs Population DCEs will be required to meet an increasing minimum number of aligned beneficiaries, with a minimum of at least 250 beneficiaries prior to the start of PY1 to at least 500 prior to the start of PY2, 750 prior to the start of PY3, 1,200 prior to the start of PY4, and 1,400 prior to the start of PY5.

Note that High Needs Population DCEs will not be eligible to align beneficiaries through a “legacy TIN” which will ensure that larger organizations could not simply create multiple High Needs Population DCEs by sub-dividing an existing larger organization.

Benchmarking Methodology

Baseline Expenditures

For the initial performance years, due to the low volume of aligned beneficiaries that we generally expect for High Needs Population DCEs, it will not be possible to construct a credible benchmark on the basis of

the historical expenditures of aligned beneficiaries. In the initial three performance years, CMS will use regional expenditures as the basis for determining the Performance Year Benchmark for all beneficiaries that are aligned to a High Needs DCE regardless of how long the beneficiary has been aligned to the DCE or whether the beneficiary is aligned to the DCE on the basis of claims or voluntary alignment. As described in the above sections, regional expenditures will be determined through the use of an adjusted MA Rate Book. CMS will use the beneficiary's county of residence during the performance year for purposes of identifying the applicable regional expenditures. We will distinguish between Aged & Disabled beneficiaries and ESRD beneficiaries in calculating the regional expenditures for aligned beneficiaries.

Incorporating Recent Claims Expenditure Experience into the Performance Year Benchmark Beginning in Performance Year 4 (2024)

After three Performance Years in the model, CMS will begin to incorporate aligned beneficiary experience from the recent years to develop a historical baseline for High Needs DCEs. Specifically, CMS will develop a historical benchmark that incorporates the experience of beneficiaries aligned to the DCE in prior Performance Years. Beginning in Performance Year 4, CMS will establish a historical baseline period which uses expenditure data for CY 2021 (the calendar year encompassing PY1) and CY 2022 (the calendar year encompassing PY2). These base years will be weighted at one-third for CY 2021 and two-thirds for CY 2022. In Performance Year 5, the baseline period will encompass CY 2021, CY 2022, & CY 2023, which will be weighted at 10%, 30%, and 60%, respectively. In establishing the historical spending during this baseline period, CMS will incorporate beneficiaries who were aligned to the DCE on the basis of claims in the baseline period, as well as beneficiaries who voluntarily aligned to the DCE during those base years by designating a DC Participant Provider as their primary clinician. In the event that a credible benchmark cannot be generated using expenditures for those beneficiaries, CMS may consider also incorporating the historical experience of those beneficiaries voluntarily aligned to the DCE in the intermediate calendar year (CY 2023 in PY4 & CY 2024 in PY5) and the Performance Year into the baseline experience. Further information on the historical baseline period for High Needs DCEs will be forthcoming in the Participation Agreement.

Incorporating the historical experience of aligned beneficiaries will allow CMS to better reflect any differences in the characteristics (e.g., overall health status, expenditures) and total expenditures for beneficiaries that are aligned to the DCE, rather than using the regional average.

Risk Adjustment

In the process of calculating the Performance Year Benchmark, CMS will apply risk adjustment for beneficiaries aligned to the High Needs Population DCE during the Performance Year. Additional information regarding the risk adjustment methodology is forthcoming and will be provided in subsequent financial methodology papers.

Discount, Quality Incentive, and HPP

To establish the Performance Year Benchmark, as described above, CMS will apply a discount (Global only) and quality withhold. DCEs may earn back some or all of the quality withhold and may be eligible to receive a bonus from the HPP based on their quality performance.

G. Medicare Part D

CMS is interested in exploring ways in which DCEs can support beneficiaries in their management of and adherence to prescription drugs. Part D prescription drug spending is not included in Direct Contracting

benchmarks. Beginning in PY1, DCEs are only accountable for total Parts A and B expenditures for aligned beneficiaries. CMS will continue to look at options for Part D integration for future performance years of Direct Contracting.

H. Benefit Enhancements

In order to emphasize high-value services and support the ability of DCEs to manage the care of beneficiaries, CMS has designed policies using the authority under Section 1115A of the Social Security Act (Section 3021 of the Affordable Care Act) to conditionally waive certain Medicare payment requirements as part of testing Direct Contracting. A DCE may choose not to implement all or any of these benefit enhancements. Applicants will be asked to provide information regarding their proposed implementation of these benefit enhancements, but acceptance into Direct Contracting is not contingent upon a DCE agreeing to implement any particular benefit enhancement.

The table below includes BEs that we anticipate will be available for PY1. We are considering additional BEs for future years, but they will not be available for PY1.

Table 6.22: Benefit Enhancements

Benefit Enhancements Anticipated for PY1	Proposed Benefit Enhancements for PY1	Potential Future Benefit Enhancements and Patient Engagement Incentives Under Consideration by CMS
<ul style="list-style-type: none"> • SNF 3-Day Rule Waiver • Asynchronous Telehealth • Post-Discharge Home Visits • Care Management Home Visits 	<ul style="list-style-type: none"> • Home Health Services Certified by Nurse Practitioners • Homebound Requirement Waiver for Home Health • Concurrent Care for Beneficiaries that Elect the Medicare Hospice Benefit 	<ul style="list-style-type: none"> • Tiered Cost Sharing Reduction • Alternative Sites of Care • Cost-sharing Support for SNF Services • Long-Term Care Hospital 25-day average Length of Stay requirement and Other Site of Care Restrictions

Following acceptance into Direct Contracting, each DCE will be required to provide additional information to CMS, to enable the DCE’s use of the optional benefit enhancements that it has elected to implement. The DCE will be required to submit an implementation plan for each optional benefit enhancement it wishes to offer. This implementation plan will be required to include, for example: (1) descriptions of the DCE’s planned strategic use of the benefit enhancement; (2) self-monitoring plans reflecting meaningful safeguards to prevent unintended consequences; and (3) documented authorization by the governing body to participate in the benefit enhancement.

As part of Direct Contracting monitoring and oversight strategy, CMS will incorporate a variety of program integrity safeguards (described in Section VIII) to ensure that these benefit enhancements do not result in program or patient abuse.

Benefit Enhancements Anticipated for PY1

The following are benefit enhancements that are anticipated for PY1. In pursuit of policy goals based upon accountable care and driving beneficiary value, CMS may continue to explore the operational feasibility

and potential effectiveness of additional benefit enhancements and patient engagement incentives in future performance years, including tiered cost sharing reductions; alternative sites of care; cost sharing support for SNF services; and reducing the long-term care hospital 25-day average length of stay requirement. Although we are continuing to explore these additional policies, we may ultimately determine that some or all of those potential future benefit enhancements and patient engagement incentives are not feasible under Direct Contracting.

3-Day Skilled Nursing Facility Rule Waiver

CMS will make available to qualified DCEs a conditional waiver of the three-day inpatient stay requirement prior to admission to a skilled nursing facility (SNF) or an acute-care hospital or CAH with swing-bed approval (swing-bed hospital) for SNF services. This benefit enhancement will allow eligible DC beneficiaries to receive Medicare-covered SNF services from qualified SNFs or swing-bed hospitals that are DC Participant Providers or Preferred Providers either directly or with an inpatient stay of fewer than three days.

A Direct Contracting beneficiary will be eligible to receive covered SNF services under the terms of this benefit enhancement if (1) the beneficiary does not reside in a SNF or long-term care setting at the time of the admission to the SNF or swing-bed hospital; and (2) the beneficiary meets all other CMS criteria for coverage of SNF services, including that the beneficiary must:

- Be medically stable;
- Have confirmed diagnoses (e.g., does not have conditions that require further testing for proper diagnosis);
- Not require inpatient hospital evaluation or treatment; and
- Have an identified skilled nursing or rehabilitation need that cannot be provided on an outpatient basis or through home health services.

DCEs will identify the SNFs and swing-bed hospitals with which they will partner in this benefit enhancement. Partner SNFs and swing-bed hospitals may be either DC Participant Providers or Preferred Providers. Through the application and implementation plan, DCEs may be asked to describe how the identified DC Participant Providers and Preferred Providers have the appropriate staff capacity and necessary infrastructure to carry out proposed coordination activities. In addition to the information the DCE includes in its implementation plan, a SNF must have an overall rating of three or more stars under the CMS 5-Star Quality Rating System in at least seven of the previous twelve months, as reported on the Nursing Home Compare website. This star standard is subject to change in response to changes in the scoring methodology.

Asynchronous Telehealth

CMS will make available to qualified DCEs a conditional waiver of the interactive telecommunications system requirement under section 1834(m)(1) of the Act and 42 C.F.R. § 410.78(b) with respect to otherwise covered dermatology and ophthalmology services furnished using asynchronous store and forward technologies. Asynchronous telehealth includes the transmission of recorded health history (for example, retinal scanning and digital images) through a secure electronic communications system to a practitioner, usually a specialist, who uses the information to evaluate the case or render a service outside

of a real-time interaction. Asynchronous telecommunication systems in single media format do not include telephone calls, images transmitted via facsimile machines, and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patients' condition and adequate for rendering or confirming a diagnosis or treatment plan.

Payment will be permitted for dermatology and ophthalmology services furnished to eligible beneficiaries using asynchronous telehealth in single or multimedia formats that is used as a substitute for an interactive telecommunications system. Distant site practitioners will bill for these services using Innovation Center specific asynchronous telehealth codes (G9868 – G9870). The distant site practitioner must be a DC Participant Provider or Preferred Provider who has elected to participate in this benefit enhancement.

Post-Discharge Home Visits

CMS will make available to qualified DCEs a conditional waiver of the requirement for direct supervision to allow payment for certain home visits furnished to eligible, non-homebound beneficiaries by auxiliary personnel (as defined in 42 C.F.R. § 410.26(a)(1)) under general supervision, rather than direct supervision, incident to the professional services of physicians or other practitioners that are DC Participant Providers or Preferred Providers.

Payment will be made for these home visits only when they are furnished following the beneficiary's discharge from an acute inpatient hospital, inpatient psychiatric facility, inpatient rehabilitation facility, long-term care hospital, or skilled nursing facility. Further, the beneficiary must not qualify for Medicare coverage of home health services (or qualifies for Medicare coverage of home health services on the sole basis of living in a medically underserved area).

Specifically, under this benefit enhancement, a beneficiary is eligible to receive up to nine post-discharge home visits within 90 days following discharge. The nine home visit services do not accumulate across multiple discharges; if the beneficiary is readmitted within 90 days of the initial discharge and before receiving nine home visits, the beneficiary may receive only nine home visits in connection with the subsequent discharge.

Care Management Home Visits

CMS will make available to qualified DCEs a conditional waiver of the requirement for direct supervision to allow for payment for certain home visits that are furnished to eligible beneficiaries proactively and in advance of potential hospitalization. The items and services provided as part of these home visits are those that would be covered under Medicare Part B as "incident to" the services of a physician or other practitioner, and would be furnished by auxiliary personnel (as defined in 42 C.F.R. § 410.26(a) (1)) under general supervision, rather than direct supervision. These care management home visits are intended to supplement, rather than substitute for, visits to a primary care practitioner in a traditional routine outpatient health care setting. As such, these home visits are not intended to be performed on an ongoing basis, nor to serve as a substitute for the Medicare home health benefit or as the primary mechanism to meet beneficiaries' care needs.

An eligible beneficiary is permitted to receive up to twelve care management home visits within a calendar year. Further, DC Participant Providers and Preferred Providers who have elected to use this benefit enhancement will be able to receive payment for services furnished to eligible beneficiaries under the

following circumstances:

- The beneficiary is determined to be at risk of hospitalization;
- The beneficiary does not qualify for Medicare coverage of home health services (unless the sole basis for qualification is living in a medically underserved area);
- The beneficiary is not currently utilizing the Post-Discharge Home Visits Benefit Enhancement or the proposed home health for non-homebound beneficiaries benefit enhancement; and
- The services are furnished in the beneficiary's home by auxiliary personnel under the general supervision of a DC Participant Provider or Preferred Provider who is a physician or other practitioner after a DC Participant Provider or Preferred Provider has initiated a care management plan that includes such services.

Home Health Services Certified by Nurse Practitioners

This proposed benefit enhancement, which is currently under consideration by CMS, would allow nurse practitioners that are DC Participant Providers or Preferred Providers to order home health services. Currently, to receive Medicare reimbursement for home health services, a physician must first certify that a beneficiary is eligible to receive home health services under Section 1814(a)(2)(C) of the Act and 42 C.F.R. § 424.22(a)(1). As a result, a beneficiary who lacks access to a primary care physician and is instead under the care of a nurse practitioner must often first be admitted to a facility and placed under the care of a facility-based physician before home health services can be ordered. This requirement limits the ability of nurse practitioners, who can order the services associated with home health but not certify them, to effectively coordinate and manage beneficiary care.

Under this waiver, a DCE would allow nurse practitioners to certify that aligned beneficiaries are eligible to receive the home health benefit in accordance with Section 1814(a)(2)(C) of the Act and 42 C.F.R. § 424.22(a)(1). Medicare would continue to pay for these home health services as this waiver would only broaden the category of practitioners who can certify that home health care services are required for a Medicare beneficiary. Lastly, this benefit enhancement would only be available in those states that allow nurse practitioners to order home health care for beneficiaries within their scope of practice.

Home Health Homebound Requirement

Currently, to receive Medicare reimbursement for home health care services, a Medicare beneficiary must be homebound as defined in Sections 1814(a)(2) and 1835(a)(2) of the Act because (1) the beneficiary must either (a) need the assistance of a supportive device, special transportation, or another person to leave their residence or (b) have a condition that makes leaving his or her home medically contraindicated; and (2) there must be a normal inability to leave the home and leaving home must require a considerable and taxing effort. This policy often prevents a beneficiary who might be able to achieve greater health outcomes through home health care services from receiving these services because they do not meet the statutory definition of homebound.

Under the proposed Home Health Homebound Requirement Benefit Enhancement, CMS would waive the requirement under Sections 1814(a)(2) and 1835(a)(2) of the Act, and 42 C.F.R. § 409.42(a) that a beneficiary must be confined to the home to receive Medicare reimbursement for qualified home health

services for eligible beneficiaries. Specifically, to qualify for home health services under this waiver, beneficiaries must (1) otherwise qualify for home health services under 42 C.F.R. § 409.42 except that the beneficiary is not required to be confined to the home; and (2) have a combination of clinical risks, which will be determined by CMS at a later date. DCEs would identify home health providers that are DC Participant Providers or Preferred Providers that would provide these services to eligible beneficiaries. All other requirements regarding Medicare coverage and payment for home health services would continue to apply. Lastly, a beneficiary would not be eligible to receive covered home health services under this benefit enhancement if they are receiving services under the post-discharge visits or care management home visits benefit enhancements.

Concurrent Care for Beneficiaries that Elect the Medicare Hospice Benefit

The proposed benefit enhancement currently under consideration by CMS would be limited to DCEs participating in Global and would eliminate the requirement that beneficiaries who elect the Medicare Hospice Benefit give up their right to receive curative care (sometimes referred to as “conventional care”) as a condition of electing the hospice benefit. Currently, under Section 1812(d)(2)(A) of the Act and its implementing regulations, *“if an individual makes such an election for a period with respect to a particular hospice program, the individual shall be deemed to have waived all rights to [Medicare] payment made under this title with respect to— (i) hospice care provided by another hospice program(ii) services furnished during this period that are determined to be (I) related to the treatment of the individual’s condition with respect to which a diagnosis of terminal illness has been made or (II) equivalent to (or duplicative of) hospice care.”* CMS intends to allow DCEs to provide care to beneficiaries that have waived their rights to Medicare payment of services related to the treatment of their terminal condition as a result of electing hospice care. All expenditures incurred by Medicare on behalf of such beneficiaries, whether for hospice or non-hospice services, would be included as part of total cost of care of the DCE for the relevant performance year.

Similar to the approach used for the 3-Day Skilled Nursing Facility Rule Waiver Benefit Enhancement, DCEs would identify the hospices with which they would partner in this benefit enhancement. Likewise, DCEs will be able to identify non-hospice providers and suppliers to participate under this benefit enhancement. These partner hospices and non-hospice providers and suppliers must be either DC Participant Providers or Preferred Providers. Through the application and an implementation plan, DCEs would be asked to describe how the identified DC Participant Providers and Preferred Providers would have the appropriate staff capacity and necessary infrastructure to carry out proposed care coordination activities, and consistent with existing Hospice Conditions of Participation,⁴ would be asked to explain how the DCE would ensure, working with partner hospices and other non-hospice providers and suppliers, that an appropriate plan of care would be developed for all beneficiaries receiving concurrent care and that these beneficiaries would be fully informed of what care or services would be included in their care plan, what would not, what clinician or organization would be providing which services, how care coordination would be achieved, and whether there are any limitations, including any services that would be provided for transitional purposes only. The DCE will also be expected to ensure that the beneficiary or, as applicable, his or her representative is fully aware of the care plan and informed of the beneficiary’s right to revoke the hospice election at any time consistent with current law. This focus on transparency as a means of safeguarding patient rights is intended to build on a concept from the FY 2020 Hospice Wage Index Final

⁴ <https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Hospice.html>

Rule (84 FR 38484) regarding the availability of an addendum to the hospice election statement. In that addendum, which beneficiaries may receive on request, a hospice program must provide a list of services and items that it will not cover because it has determined such services and items to be unrelated to the patient's terminal illness.⁵

Medicare would retain its existing claims-based edits to prevent non-hospice claims from processing while a beneficiary is under hospice election, except with respect to services furnished by those hospice and non-hospice providers and suppliers identified by the DCE as participating in this benefit enhancement. Medicare FFS claims submitted by these organizations will be paid by Medicare if they are otherwise appropriate for payment absent the restrictions on paying claims for a beneficiary that has elected hospice.

For purposes of this benefit enhancement, a DCE would not be able to partner with any hospice that has existing condition level deficiencies that have not been remediated; all the hospice programs with which a DCE partners with must readily offer beneficiaries access to the four levels of hospice consistent with clinical need.

VII. Quality and Performance

The reporting of quality measures and the collection of survey data are key for CMS to verify clinical improvements, assess patient health outcomes and care coordination activities, and ensure continued quality of care for the beneficiaries. To ensure that DCEs meet the specified goals of improved quality of care and health outcomes for Medicare beneficiaries, during PY1 – PY5 Direct Contracting will include the assessment of DCE quality performance based on claims-based quality measures as well as information from administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) for Accountable Care Organizations (ACOs) surveys. CAHPS® is a program of the Agency for Healthcare Research and Quality, U. S. Department of Health and Human Services.

CMS has designed the quality measures and performance standards that will apply to DCEs under Global and Professional to reduce the burden of measure reporting, while focusing on continuous improvement and sustained exceptional performance. The quality strategy is designed to provide achievable performance criteria that incentivize practice transformations necessary to reduce utilization and improve quality of care. Similar to the Shared Savings Program and previous ACO models, there will be a transition from pay-for-reporting in the first performance year to pay-for-performance in subsequent performance years. Newly developed measures will not be pay-for performance until the measures have been tested and found valid and reliable. DCEs will be required to report quality measures beginning in PY1 (2021).

DCEs may opt to implement a Patient Activation Measure (PAM) survey. Implementing PAM will be optional. However, if a DCE opts to implement PAM, the Innovation Center will cover the costs of licensing, data collection, and analysis. The data collected from this effort will allow the Innovation Center to understand the feasibility of implementing PAM in the future models. DCEs will receive quality performance data for use in their ongoing quality improvement efforts, but the PAM scores will not be considered in determining the quality performance score of the DCE that is used for purposes of

⁵ CMS. Final Rule FY 2020 Hospice Payment Rates and Wage Index (84 FR 38484). August 6, 2019. <https://www.federalregister.gov/documents/2015/08/06/2015-19033/medicare-program-fy-2016-hospice-wage-index-and-payment-rate-update-and-hospice-quality-reporting>

determining how much of the quality withhold the DCE is eligible to recoup.

The quality measure set for Global and Professional can be found in the Appendix C of this RFA. Specifications for the quality measure set and scoring principles will be reviewed annually and may be subject to revision each PY.

A. Quality Monitoring

To ensure quality measures are reported accurately and completely, CMS may conduct data validation audits of DCE quality data. These audits may involve ad hoc or scheduled desk reviews, focused audits, or full audits. These efforts will be in addition to the overall program monitoring and oversight strategy described in the Monitoring and Oversight section of this RFA.

B. Quality in Calculating the Performance Year Benchmark

Quality performance scores achieved on the quality measure set will partly determine the magnitude of the financial opportunity for DCEs in that CMS will apply a quality withhold to the Performance Year Benchmark calculation. Beginning in PY2, DCEs that meet or exceed a pre-defined Continuous Improvement/Sustained Exceptional Performance Criteria (CI/SEP) can earn back all or a portion of their quality withhold based on their quality performance scores. Those that do not meet the CI/SEP criteria can earn back up to half of their quality withhold based on their quality performance scores. The CI/SEP criteria will be provided prior to the start of PY2. The highest performing DCEs that meet or exceed the CI/SEP may also earn a bonus payment from the High Performers Pool (HPP) beginning in PY2 (CY2022), as described above in the Financial Benchmarking Methodology. The HPP will be funded from the quality withholds not earned back by DCEs that also meet or exceed the CI/SEP, based on their quality performance on the quality measure set. DCEs that do not meet or exceed the CI/SEP are not eligible for consideration for HPP Bonus payments and any portion of their quality withhold that is not earned back will not be included in the HPP, but will be retained by CMS.

To implement pay-for-reporting in PY1, CMS will assume DCE achievement of CI/SEP criteria. If the DCE meets all quality reporting requirements through complete and accurate reporting, the DCE will receive a 100% quality score and earn back 100% of the quality withhold for purposes of determining the Performance Year Benchmark used in the final Financial Reconciliation for PY1. In the event a DCE fails to meet the quality reporting requirements successfully for PY1, the DCE will receive a quality score of zero, resulting in losing the entire quality withhold and ultimately reducing the Performance Year Benchmark used to reconcile the DCE's financial performance. Because the quality scores for PY1/CY2021 will not be available when the PY2/CY2022 Performance Year Benchmark is initially calculated, for PY2/CY2022 provisional Performance Year Benchmarks for DCEs will be calculated based on a PY1 quality score of 100%. When PY1 quality scores are calculated at mid-year PY2, CMS will update the PY2 Performance Year Benchmark for these DCEs to reflect those scores.

For PY3, because the quality scores for PY2/2022 will not be available when the PY3/2023 Performance Year Benchmark is calculated ahead of the PY3/2023 performance year, for PY3 provisional Performance Year Benchmarks for the DCEs will be calculated based on the PY1 quality score. PY2 quality scores will be reported and calculated in mid-2023. When PY2 quality scores become available, CMS will update the Performance Year Benchmark to reflect the PY2 quality score.

The Performance Year Benchmark, used in final financial reconciliation for the performance year will

always be updated to include an adjusted quality withhold that reflects the actual performance year quality score attained by the DCE for the applicable performance year.

VIII. DCE Monitoring and Oversight

The model will require waivers of various payment rules and fraud and abuse laws. To ensure that these waivers do not result in beneficiary harm or negatively impact the integrity of the model, participants will be required to monitor their compliance with the terms of the model and to comply with rigorous safeguards that will be specified in the participation agreement.

Under the terms of the Participation Agreement, participating DCEs will be required to develop a compliance plan prior to the start of model participation with at least the following attributes:

- Designated compliance officer with a minimum of 2 years compliance experience, who is not legal counsel to the DCE and who reports directly to the DCE's governing body
- Mechanisms for identifying and addressing compliance problems related to the DCE's operations and performance
- Compliance training programs that the DCE and its DC Participant Providers and Preferred Providers must complete periodically, including within their first 90 days in the model
- A method for employees or contractors of the DCE, DC Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to DCE activities to anonymously report suspected problems related to the DCE to the compliance officer
- A requirement for the DCE to report probable violations of law immediately to an appropriate law enforcement agency
- The DCE's compliance plan must be updated, as necessary, to reflect changes in laws and regulations.

IX. CMS Monitoring

As part of testing Direct Contracting, CMS will implement a monitoring plan designed to protect beneficiaries and address potential program integrity risks. CMS will employ a range of methods to monitor and assess compliance by the DCE and its DC Participant Providers and Preferred Providers with the terms of the Participation Agreement, including, but not limited to:

- Audits of charts, medical records, Implementation Plans, and other data from the DCE and its DC Participant Providers and Preferred Providers and claims analyses to identify fraudulent behavior or program integrity risks such as inappropriate reductions in care, manipulation of organizational or corporate structures to participate as one entity type versus another, efforts to manipulate risk scores for aligned populations, overutilization, and cost-shifting to other payers or populations;
- Interviews with any individual or entity participating in DCE activities, including members of the DCE leadership and management, DC Participant Providers, and Preferred Providers;
- Interviews with DC Beneficiaries and their caregivers;
- Site visits to the DCE and its DC Participant Providers and Preferred Providers; and

- Documentation requests sent to the DCE, its DC Participant Providers, and/or Preferred Providers, including surveys and questionnaires.

CMS will conduct comprehensive annual audits related to compliance with the Participation Agreement and identifying potential program integrity risks, with more limited targeted or ad-hoc audits as necessary. These audits will include targeted assessments for each DCE type, such as a review of charts and medical records for beneficiaries aligned to High Needs Population DCEs to ensure that beneficiary eligibility requirements are fully met and documented.

X. Remedial Actions

Noncompliance with the terms of the Participation Agreement will trigger appropriate actions based on the type of issue, degree of severity, and the DCE's compliance record while in the model. If CMS determines that any provision of Participation Agreement may have been violated, CMS may take one or more of the following actions:

- Notify the DCE and, if appropriate, the DC Participant Provider or Preferred Provider of the violation
- Require the DCE to provide additional information to CMS or its designees
- Conduct on-site visits, interview beneficiaries, or take other actions to gather information
- Provide the DCE education on how to operate in compliance with relevant terms of the Participation Agreement
- Place the DCE on a monitoring and/or auditing plan developed by CMS
- Request a Corrective Action Plan (CAP) from the DCE, that will be subject to approval by CMS, detailing what actions the DCE will take (or will require any DC Participant Provider, Preferred Provider, or other individual or entity performing functions or services related to DCE Activities to take) within a specified time period to ensure that all deficiencies will be corrected and that the DCE will be in compliance with the terms of the Participation Agreement
- Suspend or terminate data sharing rights, if data sharing is implicated in the violation
- Suspend or terminate payments due to the DCE
- Prohibit the DCE from making payments to a DC Participant Provider or Preferred Provider
- Suspend or terminate the use of one or more benefit enhancements by the DCE, DC Participant Provider, or Preferred Provider
- Suspend or terminate the DCE's ability to engage in activities related to voluntary alignment
- Suspend or terminate voluntary alignment as an alignment option for the DCE
- Suspend or terminate the DCE from Direct Contracting
- Suspend or terminate the availability of any or all waivers of existing law made pursuant to section 1115A(d)(1) of the Act
- Require the DCE to remove a DC Participant Provider or Preferred Provider from the Participant List

or Preferred Provider List and terminate its agreement, immediately or within a timeframe specified by CMS, with such DC Participant Provider or Preferred Provider with respect to this model

- Require the DCE to terminate its relationship with any other individual or entity performing functions or services related to DCE Activities
- Prohibit the DCE from distributing model-related payments to a DC Participant Provider or Preferred Provider

XI. Data Sharing and Reports

A. Data Sharing

The exchange of timely, appropriate and useful data continues to be a top priority for CMS. Direct Contracting will build upon the data sharing strategies and data reports established in earlier shared savings initiatives and other Innovation Center models.

CMS plans to make several types of Medicare data available to DCEs participating in Direct Contracting. During the IP and the Performance Period, the DCE may request the minimum necessary data for their respective provisionally aligned and aligned beneficiaries to develop and implement care coordination and quality improvement activities. For the IP, the data may be used for planning and development of care management and care coordination strategies, because no care will be provided during this period. For the Performance Period, DCEs will also be permitted to reuse data provided for purposes of clinical treatment, care management and coordination, quality improvement activities, and provider incentive design and implementation. For both the IP and the Performance Period, the data may be used only consistent with the terms of the applicable CMS agreements, including the Participation Agreement, DC Participant Provider/Preferred Provider Certification forms and Data Use Agreements (DUAs).

During the IP and the Performance Period, CMS will provide DCEs with detailed claims data that will include individually identifiable Claim and Claim Line Feed (CCLF) reports for services furnished by Medicare-enrolled providers and suppliers to provisionally aligned and aligned beneficiaries during the IP or PY. At the beginning of a PY, CMS will additionally provide DCEs with historical CCLF files, which will capture a 36-month lookback of claims for newly aligned beneficiaries. Only 12 months of CCLF data will be made available during the IP.

During both the IP and the PYs, CMS will provide DCEs with operational reports on a regular basis. These reports may include, but will not be limited to: Quarterly and Annual Utilization; Monthly Expenditures; Beneficiary Data Sharing Preferences; Monthly Claims Lag; and Beneficiary Alignment reports.

During PY1 – PY5, CMS will provide quarterly baseline benchmark reports (BBRs) to DCEs to enable them to monitor their financial performance throughout the performance year. The BBRs will not contain individually identifiable data. The same design and data source used to generate the BBRs will also be used for the interim and final reconciliation report. These reports will not be provided during the IP.

During PY1 – PY5, the DCEs will receive feedback on their quality performance. Please review the Quality and Performance section for more information on quality data sharing.

B. Data Suppression and Beneficiary Data Sharing Opt Out

DCEs will be required to provide provisionally aligned and aligned beneficiaries who inquire about or wish to modify their preferences regarding claims data sharing for care coordination and quality improvement purposes with information about how to modify their data sharing preferences and opt out of data sharing.

Reports containing individually identifiable data will not include beneficiaries who opt out of data sharing with the DCE. Aggregate reports will incorporate de-identified data from DC beneficiaries who have opted out of data sharing. Moreover, Direct Contracting will honor the data sharing opt-out decisions by beneficiaries who were previously given that choice while an aligned beneficiary in another Medicare shared savings initiative. Data sharing will be offered for all provisionally aligned and aligned beneficiaries who were either: (1) not previously aligned to any ACO; or (2) previously aligned to an ACO and did not opt out of data sharing. A beneficiary who has opted out of data sharing remains aligned to the DCE.

DCEs may inform each newly-aligned beneficiary, in compliance with applicable laws, that he or she may elect to allow the DCE to receive beneficiary-level data regarding the utilization of substance use disorder services, the mechanism by which the beneficiary can make this election, and contact information for answers to any questions about sharing of data on substance use disorder services. CMS will provide DCEs with the Substance Use Disorder Treatment Opt-In Form that beneficiaries will use to make this election.

Services furnished to beneficiaries who have opted out of data sharing will still remain subject to the DCE's selected capitation arrangement, therefore, DC Participant Providers and Preferred Providers will still submit claims for services delivered to beneficiaries who have opted out of data sharing. These claims remain necessary for a number of purposes, including claims-based alignment, risk adjustment, cost sharing, stop-loss, monitoring, and model evaluation.

Under the terms of the Participation Agreement, if a participant is terminated from the DCE and an aligned beneficiary solely had claims with that terminated participant and no other DCE participant in the prior twelve months, CMS will suppress that beneficiary's identifiable data and not include it as part of data sharing. If during the IP or a PY another participant of the DCE submits a claim for that suppressed beneficiary, data sharing of the beneficiary's identifiable data will be resumed.

The DCE agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data received from CMS and to prevent unauthorized use or access to it.

XII. Evaluation

All DCEs will be required to cooperate with efforts to conduct an independent, federally funded evaluation of the model by CMS and/or its designees, which may include: participation in surveys; interviews; site visits; and other activities that CMS determines necessary to conduct a comprehensive formative and summative evaluation.⁶ The evaluation will assess the impact of Direct Contracting on the goals of better health, better health care, and lower per beneficiary expenditures. The evaluation will be used to inform

⁶ In accordance with 42 C.F.R. 403.1110(b), "Any State or other entity participating in the testing of a model under section 1115A of the Act must collect and report such information, including 'protected health information' as that term is defined at 45 C.F.R. 160.103, as the Secretary determines is necessary to monitor and evaluate such model. Such data must be produced to the Secretary at the time and in the form and manner specified by the Secretary."

policy makers about the effect of Direct Contracting concepts. To do so, the evaluation will seek to understand the behaviors of providers, suppliers, and beneficiaries, the impacts of increased financial risk, the effects of various payment arrangements and benefit enhancements, the impact of the model on beneficiary engagement and experience, and other factors associated with patterns of results. Each DCE must require its DC Participant Providers and Preferred Providers to participate and cooperate in any such independent evaluation activities conducted by CMS and/or its designees. If a DCE does not provide the data necessary for CMS and/or its designees to complete the evaluation, upon request, CMS may terminate the DCE's Participation Agreement.

XIII. Information Resources for Beneficiaries and Providers

The primary resource for beneficiaries with questions about Direct Contracting will be 1-800-MEDICARE. CMS has developed scripts for customer service representatives (CSRs) that will answer anticipated questions related to the model. Questions that CSRs cannot answer will be triaged to CMS Regional Offices. DCEs will also be required to establish processes to answer beneficiary queries. Because of potentially substantial enhancements to certain Medicare benefits in Direct Contracting, CMS will develop processes for DCEs and CMS to notify and educate beneficiaries of these changes. Finally, CMS will maintain an email inbox for inquiries related to Direct Contracting at DPC@cms.hhs.gov.

XIV. Application Scoring and Selection

CMS will assess applications in accordance with specific criteria in five key domains: (1) organizational structure; (2) leadership and management; (3) financial plan and risk-sharing experience; (4) patient centeredness and beneficiary engagement; and (5) clinical care. These domains and associated point scores are detailed in Appendix D of this RFA. In addition, applicants should demonstrate that their organizational structure promotes the goals of the model by including a diverse set of providers and suppliers who demonstrate a commitment to high quality care. Lastly, applicants with prior participation in a CMS program, demonstration, or model will be asked to demonstrate routine compliance with the terms of such CMS programs, demonstrations, or models.

As part of the Direct Contracting application process, applicants will be asked questions specific to their proposed implementation of benefit enhancements, patient engagement incentives, and Capitation Payment Mechanisms. Acceptance into Direct Contracting is not contingent upon a DCE implementing any particular benefit enhancement, patient engagement incentive, or risk arrangement. Responses to questions regarding proposed implementation of these approaches will assess interest in model design elements, assist with CMS planning, and model implementation.

A panel of experts that may include individuals from the Department of Health and Human Service (HHS) and other organizations will review complete applications from eligible applicants, with an emphasis on expertise in provider payment policy, care improvement and care coordination. Final selection for participation in the model will be based on, but not limited to, the scoring criteria set forth in Appendix D of this RFA, as well as assessments of program integrity risks and potential market effects. CMS may choose to interview applicants and/or conduct pre-selection reviews of applicants during the application process in order to better understand applicant organizations and their proposed DC Participant Providers and Preferred Providers.

XV. Duration of Direct Contracting

The Direct Contracting Model will consist of an optional IP and five performance years (PY1-PY5). The IP will extend from the start date of the initiative until December 31, 2020. The first performance year will begin January 1, 2021, and extend until December 31, 2021. Subsequent performance years will each last 12 months.

CMS reserves the right to modify or terminate the model at any time if it is determined that it is not achieving the aims of the initiative or as required under section 1115A of the Social Security Act.

XVI. Learning and Diffusion Resources

CMS will support DCEs in accelerating their progress by providing them with opportunities to both learn about achieving performance improvements and share experiences with one another and with participants in other Innovation Center initiatives. This will be accomplished through a “learning system” for the DCEs. The learning system will use various group-learning approaches to help DCEs effectively share experiences, track progress, and rapidly adopt new methods for improving quality, efficiency, and population health. DCEs are required to participate in the learning system by attending periodic conference calls and meetings and actively sharing tools and ideas.

XVII. Public Reporting

Direct Contracting emphasizes transparency and public accountability. At a minimum, DCEs will be required to publicly report information regarding their (1) organizational structure, including identification of the members of the DCE’s governing body and the DCE’s DC Participant Providers and Preferred Providers; (2) Shared Savings and Shared Losses information; and (3) performance on the quality measures. Specific public reporting requirements will be clearly described in the Participation Agreement.

XVIII. Termination

CMS reserves the right to terminate a DCE’s Participation Agreement at any point during the model for reasons associated with poor performance, non-compliance with the terms and conditions of the Participation Agreement, or as otherwise specified in the Participation Agreement or required by section 1115A(b)(3)(B) of the Social Security Act.

To determine whether DCEs can succeed in improving quality and reducing costs over a longer period of time, DCEs will be incentivized to participate in the model for a minimum of two performance years (PY1 and PY2), in addition to the optional IP. During PY1 (CY2021), DCEs will be subject to a 2% “retention withhold,” in the amount of an additional 2% discount applied to the DCE’s Performance Year Benchmark. If the DCE’s Participation Agreement remains in effect at the time of PY1 final reconciliation, the 2% retention withhold will be refunded to the DCE, as part of PY1 final reconciliation. If, on the other hand, the DCE terminates its Direct Contracting Participation Agreement before PY1 final reconciliation occurs, the DCE will not receive the 2% withhold as part of PY1 reconciliation.

Alternatively, the DCE may choose to secure a “retention amount,” calculated to be equivalent to the retention withhold (i.e., 2% of the DCE’s Performance Year Benchmark), either with the same financial guarantee the DCE will be required to secure to ensure its ability to repay CMS Shared Losses or Other Monies Owed, or a separate financial guarantee. In the event that the DCE’s Participation Agreement does not remain in effect at the time of PY1 final reconciliation, the DCE will be required to pay CMS the

retention amount. If the DCE does not pay the retention amount to CMS, CMS would collect the retention amount under the terms of the DCE's financial guarantee. A DCE that selects to secure a retention amount would be required to continue its financial guarantee through the end of PY2 or until the retention amount is paid to CMS, whichever is later.

XIX. Amendment

CMS may modify the terms of Direct Contracting in response to stakeholder input, to reflect the agency's experience with the model, or as may be required under section 1115A of the Social Security Act or any other applicable provision of law. The terms of Direct Contracting as set forth in this Request for Applications may differ from the terms of the model as set forth in the Participation Agreement between CMS and the DCE. Unless otherwise specified in the Participation Agreement, the terms of the Participation Agreement, as amended from time to time, shall constitute the terms of Direct Contracting.

Appendices

Appendix A: Glossary of Key Definitions

The following terms have the meaning set forth below. CMS may modify these definitions as it further refines Direct Contracting.

BENEFIT ENHANCEMENTS: For purposes of Direct Contracting, CMS will use the authority under section 1115A(d)(1) of the Social Security Act (section 3021 of the Affordable Care Act) to conditionally waive certain Medicare payment rules in order to further emphasize high-value services and support the ability of DCEs to manage the care of beneficiaries. This suite of payment rule waivers is referred to as benefit enhancements. Acceptance into Direct Contracting is not contingent upon the DCE implementing any particular benefit enhancement.

DIRECT CONTRACTING BENEFICIARY: A Medicare beneficiary who has been aligned to a DCE as described in Section VI.B. for a given Performance Year.

DIRECT CONTRACTING ENTITY (DCE): An organization/entity participating in Direct Contracting pursuant to a Participation Agreement with CMS.

DIRECT CONTRACTING (DC) PARTICIPANT PROVIDER: An individual or entity that: (1) is a Medicare-enrolled provider or supplier (as described in 42 C.F.R. § 400.202); (2) is identified on the DCE's list of DC Participant Providers by name, National Provider Identifier (NPI), TIN, Legacy TIN or CCN (if applicable), and CMS Certification Number (CCN) (if applicable); (3) bills for items and services it furnishes to Medicare FFS beneficiaries under a Medicare billing number assigned to a TIN in accordance with applicable Medicare regulations; (4) is not a Preferred Provider nor a Prohibited Participant; and (5) has agreed, pursuant to a written agreement with the DCE, to participate in the model, to report quality data through the DCE, and to comply with care improvement objectives and model quality performance standards. The Capitation Payment Mechanism chosen by the DCE will apply to all DC Participant Providers that have an agreement with that DCE.

DISCOUNT: The discount is a fixed percentage adjustment to the trended, regionally blended, risk adjusted historical expenditures for DCEs participating in Global to determine the Performance Year Benchmark. This discount is utilized in Global only, serving as the primary mechanism for CMS to obtain savings from DCEs participating in this option. This discount will be set at two percent of the trended, regionally blended, risk adjusted historical expenditures during PY1 and PY2 and increase by one percentage point each subsequent performance year. For example: Baseline, trend, and risk adjustment calculations indicate that a DCE is projected to spend \$10,000 per beneficiary. If the DCE's discount is 2%, the Performance Year Benchmark will be \$9,800 per beneficiary prior to the application of the quality withhold.

HIGH NEEDS POPULATION DIRECT CONTRACTING ENTITY (DCE): DCE that serves beneficiaries with complex, high needs including individuals dually eligible for Medicare and Medicaid and Medicare-only beneficiaries that are at risk of becoming dually eligible.

MARKETING ACTIVITIES: The distribution of Marketing Materials or other activities conducted by or on behalf of the DCE, its DC Participant Providers, or its Preferred Providers, when used to educate, solicit, notify, or contact beneficiaries regarding Direct Contracting.

MARKETING MATERIALS: General audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, webpages, mailings, social media, sent by or on behalf of the DCE, its DC Participant Providers, or its Preferred Providers when used to educate, solicit, notify, or contact beneficiaries regarding Direct Contracting.

NEW ENTRANT DIRECT CONTRACTING ENTITY (DCE): DCEs with limited experience delivering care to Medicare FFS beneficiaries that meet the eligibility criteria for New Entrant DCEs.

NPI: National provider identifier.

OTHER MONIES OWED: Any monetary amount owed to CMS by the DCE or vice versa that is neither Shared Savings nor Shared Losses. It represents a reconciliation of payments made by CMS during a performance year, including payments made through Capitation Payment Mechanisms. For example, a DCE may elect a Capitation Payment Mechanism in which it receives Advanced Payments that are reconciled following the end of the performance year. Any excess payments will be recouped from the DCE as Other Monies Owed, but are not considered Shared Losses. There may also be cases in which the DCE has been underpaid in monthly payments because of an estimate made by CMS. In these cases, CMS may owe the DCE additional money, but that money is not considered Shared Savings. Shared Savings or Shared Losses are determined by comparing spending for Direct Contracting beneficiaries during the performance year to the DCE's Final Performance Year Benchmark.

PARTICIPANT LIST: The list that identifies each DC Participant Provider that is approved by CMS for participation in Direct Contracting and designates the benefit enhancements, if any, in which each DC Participant Provider participates, as updated from time to time in accordance with the Participation Agreement.

PATIENT ENGAGEMENT INCENTIVES: For purposes of testing Direct Contracting, CMS will use the authority under section 1115A(d)(1) of the Social Security Act (section 3021 of the Affordable Care Act) to allow for certain in-kind incentives, chronic disease management rewards, and cost sharing support. DCEs will be able to provide these items or services when they are reasonably related to a beneficiary's medical care and can be either preventive care items or services, or advance one or more specified clinical goals.

PREFERRED PROVIDER: A Medicare provider or supplier that: (1) is a Medicare-enrolled provider (as defined at 42 C.F.R. § 400.202) or supplier (as defined in 42 C.F.R. § 400.202); (2) is identified on the DCE's list of Preferred Providers by name, NPI, TIN, Legacy TIN or CCN (if applicable), and CMS Certification Number (CCN) (if applicable); (3) bills for items and services it furnishes to Medicare FFS beneficiaries under a Medicare billing number assigned to a TIN in accordance with applicable Medicare regulations; (4) is not a DC Participant Provider nor a Prohibited Participant; and (5) has agreed to participate in the model pursuant to a written agreement with the DCE.

PREFERRED PROVIDER LIST: The list that identifies each Preferred Provider that is approved by CMS for participation in Direct Contracting, specifies which Preferred Providers, if any, have agreed to receive payments under a Capitation Payment Mechanism, and designates the benefit enhancements, if any, in which each Preferred Provider participates, as updated from time to time in accordance with the Participation Agreement.

PRIMARY CARE QUALIFIED EVALUATION AND MANAGEMENT (PQEM) SERVICES: PQEM services are a subset of the Qualified Evaluation & Management (QEM) services as identified by the Healthcare Common Procedure Coding System (HCPCS) codes listed in Table 6.12 of this RFA. Specifically, a PQEM service is a claim for a primary care service provided by a primary care specialist or one of the selected

non-primary care specialists.

PROHIBITED PARTICIPANT: An individual or entity that is: (1) a Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier, (2) an ambulance supplier, (3) a drug or device manufacturer, and/or (4) excluded or otherwise prohibited from participation in Medicare or Medicaid.

PROSPECTIVE CLAIMS REDUCTION: A reduction in Medicare FFS payments to the DC Participant Providers and/or Preferred Providers who, pursuant to a written agreement with the DCE, have agreed to receive such reduced FFS payment for covered services furnished to DC beneficiaries. The projected total annual amount taken out of the base Medicare FFS rates will be distributed to the DCE in monthly per-beneficiary per-month payments.

RURAL: A DCE will be considered to be rural if at least 40 percent of the Federal Information Processing Standard (FIPS) codes in its service area are determined to be rural according to the definition of “rural” used by the Health Resources and Services Administration (HRSA) Office of Rural Health Policy. Such definition includes all non-Metropolitan counties, census tracts inside Metropolitan counties with Rural-Urban Commuting Area (RUCA) codes 4-10, and census tracts with RUCA codes 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people per square mile. Any of the DCE types could be considered to be rural if they meet the rural requirements specified.

SHARED LOSSES: Any monetary amount owed to CMS by the DCE according to the applicable risk arrangement due to Medicare expenditures (inclusive of capitated payments (Total Care Capitation or Primary Care Capitation) and Advanced Payments paid by CMS to the DCE as well as FFS claims paid by CMS directly to the Medicare providers and suppliers during the performance year) for Medicare Parts A and B items and services furnished to DC beneficiaries in excess of the DCE’s Final Performance Year Benchmark for the applicable performance year.

SHARED SAVINGS: The monetary amount owed to the DCE by CMS in accordance with the applicable risk arrangement due to Medicare expenditures (inclusive of capitated payments (Total Care Capitation or Primary Care Capitation) and Advanced Payments paid by CMS to the DCE as well as FFS claims paid by CMS directly to the Medicare providers and suppliers during the performance year) for Medicare Parts A and B items and services furnished to DC beneficiaries being lower than the DCE’s Final Performance Year Benchmark for the applicable performance year.

STANDARD DIRECT CONTRACTING ENTITY (DCE): A DCE with substantial experience serving Medicare FFS beneficiaries and most likely prior experience participating in Medicare ACO initiatives.

TIN: Federal taxpayer identification number.

VOLUNTARY ALIGNMENT: A process whereby CMS aligns to a DCE those beneficiaries who have designated a DC Participant Provider as their primary clinician or main source of care. A beneficiary who indicates that a DC Participant Provider is his or her primary clinician or main source of care generally will be aligned to the DCE, even if the beneficiary would not otherwise be aligned to the DCE based on claims-based alignment.

Appendix B: Summary Table of DCE Types by Design Elements

Summary Table of DCE Types by Design Elements

	Standard	New Entrant	High Needs Population
Description	<ul style="list-style-type: none"> DCEs with substantial historical experience serving Medicare FFS beneficiaries and most likely prior experience participating in Medicare ACO initiatives. 	<ul style="list-style-type: none"> DCEs with limited historical experience delivering care to Medicare FFS beneficiaries. Beneficiaries aligned via claims must not exceed 3,000 in PYs1, 2 and 3. If the number of beneficiaries aligned via claims in any of the baseline years exceeds this threshold, the DCE will have the opportunity to participate as a Standard DCE, provided model requirements are met. For PY4 and onwards, DCEs must have 5,000 beneficiaries at a minimum, more than 3,000 of which must be aligned on the basis of claims. 	<ul style="list-style-type: none"> DCEs that serve beneficiaries with complex, high needs including dually eligible individuals.
Beneficiary Alignment Options	<ul style="list-style-type: none"> Voluntary⁷: based on beneficiary’s selection of a DC Participant Provider as their “primary clinician” or their main source of care 	<ul style="list-style-type: none"> Voluntary: based on beneficiary’s selection of a DC Participant Provider as their “primary clinician” or 	<ul style="list-style-type: none"> Voluntary: based on beneficiary’s selection of a DC Participant Provider as their “primary clinician” or

⁷ Beneficiaries who could be aligned via both voluntary and claims-based alignment will be treated as having claims-based alignment for benchmarking purposes.

	Standard	New Entrant	High Needs Population
	<ul style="list-style-type: none"> • Claims-based: based on the beneficiary’s receiving the plurality of primary care services from DC Participant Providers, provided the beneficiary has not voluntarily aligned with another DCE. 	<p>their main source of care</p> <ul style="list-style-type: none"> • Claims-based: based on the beneficiary’s receiving the plurality of primary care services from DC Participant Providers, provided the beneficiary has not voluntarily aligned with another DCE • Qualify for alignment “glide path.” 	<p>their main source of care</p> <ul style="list-style-type: none"> • Claims-based: based on the beneficiary’s receiving the plurality of primary care services from DC Participant Providers, provided the beneficiary has not voluntarily aligned with another DCE • Qualify for alignment “glide path.”
Overview of Benchmarking Methodology: Voluntary Alignment	<ul style="list-style-type: none"> • Prospective benchmark. • For the first three years of a beneficiary’s alignment to the DCE: <ul style="list-style-type: none"> - Regional expenditures (Adj MA Rate Book). - Aligned beneficiary historical expenditures not incorporated. • For all subsequent years of alignment to the DCE: <ul style="list-style-type: none"> - Blend of regional expenditures with aligned beneficiary historical expenditures. - Risk adjusted, with the intent to better address costlier expenditures for high needs populations - Discounted for Global. 	<ul style="list-style-type: none"> • Prospective benchmark. • For the first three years of a beneficiary’s alignment to the DCE: <ul style="list-style-type: none"> - Regional expenditures (Adj MA Rate Book). - Aligned beneficiary historical expenditures not incorporated. • For all subsequent years of alignment to the DCE: <ul style="list-style-type: none"> - Blend of regional expenditures with aligned beneficiary recent historical expenditures. - Risk adjusted, with the intent to better address costlier expenditures for high needs populations. - Discounted for Global. 	<ul style="list-style-type: none"> • Prospective benchmark. • For the first three years of a beneficiary’s alignment to the DCE: <ul style="list-style-type: none"> - Regional expenditures (Adj MA Rate Book). - Aligned beneficiary historical expenditures not incorporated. • For all subsequent years of alignment to the DCE: <ul style="list-style-type: none"> - Blend of regional expenditures with aligned beneficiary recent historical expenditures. - Risk adjusted, with the intent to better address costlier expenditures for high needs populations. - Discounted for Global.

	Standard	New Entrant	High Needs Population
Overview of Benchmarking Methodology: Claims-based Alignment	<ul style="list-style-type: none"> • Prospective benchmark. • Blend of regional expenditures (Adj MA Rate Book) with aligned beneficiary historical expenditures (CY 2017-19). • Risk adjusted, with the intent to better address costlier expenditures for high needs populations. • Discounted for Global. 	<ul style="list-style-type: none"> • Prospective benchmark. • For the first three years of beneficiary alignment to the DCE: <ul style="list-style-type: none"> - Regional expenditures (Adj MA Rate Book). - Aligned beneficiary historical expenditures not incorporated. • For all subsequent years of alignment to the DCE: <ul style="list-style-type: none"> - Blend of regional expenditures with aligned beneficiary recent historical expenditures. 	<ul style="list-style-type: none"> • Prospective benchmark. • For the first three years of beneficiary alignment to the DCE: <ul style="list-style-type: none"> - Regional expenditures (Adj MA Rate Book). - Aligned beneficiary historical expenditures not incorporated. • For all subsequent years of alignment to the DCE: <ul style="list-style-type: none"> - Blend of regional expenditures with aligned beneficiary recent historical expenditures.
Benefit Enhancements and Patient Engagement Incentives	<ul style="list-style-type: none"> • Yes, generally via DC Participant Providers and Preferred Providers. 	<ul style="list-style-type: none"> • Yes, generally via DC Participant Providers and Preferred Providers. 	<ul style="list-style-type: none"> • Yes, generally via DC Participant Providers and Preferred Providers.
Capitation to DCEs	<ul style="list-style-type: none"> • Total care capitation or primary care capitation required. 	<ul style="list-style-type: none"> • Total care capitation or primary care capitation required. 	<ul style="list-style-type: none"> • Total care capitation or primary care capitation required.
DC Participant Providers & Preferred Providers	<ul style="list-style-type: none"> • DC Participant Providers and Preferred Providers defined at the TIN/NPI level. 	<ul style="list-style-type: none"> • DC Participant Providers and Preferred Providers defined at the TIN/NPI level. 	<ul style="list-style-type: none"> • DC Participant Providers and Preferred Providers defined at the TIN/NPI level.
Payment to DC Participant Providers and Preferred Providers	<ul style="list-style-type: none"> • DC Participant Providers and Preferred Providers receive payments for Part A and Part B services from the DCE and/or CMS based on their contractual arrangement with the DCE. The payments from the DCE may include sub- 	<ul style="list-style-type: none"> • DC Participant Providers and Preferred Providers receive payments for Part A and Part B services from the DCE and/or CMS based on their contractual arrangement 	<ul style="list-style-type: none"> • DC Participant Providers and Preferred Providers receive payments for Part A and Part B services from the DCE and/or CMS based on their contractual arrangement

	Standard	New Entrant	High Needs Population
	<p>capitation and other value-based payments. All DC Participant Providers must participate in the Capitation Payment Mechanism selected by the DCE. Preferred Providers have the option to participate in the Capitation Payment Mechanism. Both DC Participant and Preferred Providers also have the option to participate in Advanced Payments, if the DCE elects to do Primary Care Capitation.</p>	<p>with the DCE. The payments from the DCE may include sub-capitation and other value-based payments. All DC Participant Providers must participate in the Capitation Payment Mechanism selected by the DCE. Preferred Providers have the option to participate in the Capitation Payment Mechanism. Both DC Participant and Preferred Providers also have the option to participate in Advanced Payments, if the DCE elects to do Primary Care Capitation.</p>	<p>with the DCE. The payments from the DCE may include sub-capitation and other value-based payments. All DC Participant Providers must participate in the Capitation Payment Mechanism selected by the DCE. Preferred Providers have the option to participate in the Capitation Payment Mechanism. Both DC Participant and Preferred Providers also have the option to participate in Advanced Payments, if the DCE elects to do Primary Care Capitation.</p>
Service Area	<ul style="list-style-type: none"> Defined by the physical practice location of the DCE’s DC Participant Providers. 	<ul style="list-style-type: none"> Defined by the physical practice location of the DCE’s DC Participant Providers. 	<ul style="list-style-type: none"> Defined by the physical practice location of the DCE’s DC Participant Providers.

Appendix C: Proposed Global and Professional Quality Measures for PY1

The following quality measures are the proposed measures for use in establishing quality performance standards in PY1 of the model (CY 2021). Note, there are no quality performance standards for the IP.

Proposed Quality Measures

Domain	ACO Measure	Measure Title	Method of Data Submission	Pay-for-Performance Phase In R—Reporting P—Performance PY1
Patient/ Caregiver Experience	ACO - 1	CAHPS®: Getting Timely Care, Appointments, and Information	Survey	R
Patient/ Caregiver Experience	ACO - 2	CAHPS®: How Well Your Doctors Communicate	Survey	R
Patient/ Caregiver Experience	ACO - 3	CAHPS®: Patients' Rating of Doctor	Survey	R
Patient/ Caregiver Experience	ACO - 5	CAHPS®: Health Promotion and Education	Survey	R
Patient/ Caregiver Experience	ACO - 6	CAHPS®: Shared Decision Making	Survey	R
Patient/ Caregiver Experience	ACO – 7	CAHPS®: Health Status/Functional Status	Survey	R
Patient/ Caregiver Experience	ACO - 34	CAHPS®: Stewardship of Patient Resources	Survey	R
Patient/ Caregiver Experience	ACO - 45	CAHPS®: Courteous and Helpful Office staff	Survey	R
Patient/ Caregiver Experience	ACO - 46	CAHPS®: Care Coordination	Survey	R
Patient Reported Outcome (optional)*	NQF – 2483	Gains in Patient Activation Measure at 12 months	Survey	N/A
Care Coordination/ Patient Safety	ACO – 8	Risk-Standardized, All Condition Readmission	Claims	R
Care Coordination/ Patient Safety	ACO – 38	All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions	Claims	R
Care Coordination/ Patient Safety	NQF – 326	Advanced care plan	Claims	R
Care Coordination/ Patient Safety	TBD	Days at home (proposed – to be developed) DCEs with overall HCC risk score of 2+	Claims	R

*Gains in Patient Activation Measure at 12 months is an optional measure. DCEs that opt to implement and report on this measure will not receive any quality credit.

Appendix D: Applicant Selection Criteria and Scoring

Organizational Structure

Points: 10

Selection Criteria

- Demonstrate a history of proven successful collaboration between Providers and Suppliers within the health care community and/or a credible plan for how care coordination will work within Direct Contracting.
- Have an organizational structure that promotes patient-centered care and the goals of Direct Contracting. The applicant DCE should provide added value to its stakeholders by providing support to a diverse set of DC Participant Providers that demonstrate a clear commitment to providing high quality, coordinated care to beneficiaries.
- If applicable, identify a past history working with high needs and dually eligible populations.

Leadership and Management

Points: 20

Selection Criteria

- Demonstrate an effective governance structure plan, exclusive to the DCE, including a governing body and/or organizational mechanisms to make decisions and distribute payments, with a commitment to provide high quality care to beneficiaries consistent with the three-part aim of better health, better care, and lower costs.
- Have a multi-stakeholder board comprised of well-qualified individuals, who collectively adequately represent the interests of patients and health care providers.
- Governing body must be separate and unique to the DCE and must not be the same as the governing body of any other entity participating in the DCE.
- At least 25% or 3 individuals (whichever is greater) of the governing body shall be DC Participant Providers or their designated representatives.
- The DCE governing body must include at least one Medicare beneficiary served by the DCE and for the High Needs Population, at least one dually eligible beneficiary served by the DCE must be included. The DCE governing body must also include at least one consumer advocate, who may be the same person as the Medicare beneficiary.
- The DCE's operations must be managed by an executive, officer, manager, general partner, or similar party whose appointment and removal are under the control of the DCE's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve the efficiency of processes and outcomes.
- Identify, or demonstrate plans to identify, executives and lead staff throughout the organization with responsibility for clinical, financial, management, health information technology (HIT), and quality of care improvement functions.
- Demonstrate routine compliance with the terms of CMS programs, demonstrations, and/or models.

Financial Plan and Risk-Sharing Experience

Points: 20

Selection Criteria

- Demonstrate experience in the past 3 years with outcomes-based arrangements. Outcomes-based contracts must include: (1) financial accountability; (2) evaluation of patient experiences of care; and (3) substantial quality performance incentives. Indicate the level of experience with regard to the number of lives served relative to the number of lives the DCE is planning to serve under this model.
- If applicable, demonstrate good performance in past CMS programs, demonstrations, and/or models. In particular, note any experience working with high needs populations.
- Document significant degrees of financial risk and revenue derived from outcomes-based contracts.
- Document reductions in medical expenditures achieved through previous outcomes-based contracts.
- Demonstrate a credible plan for using the preponderance of revenue from the capitated payment to the DCE to fund outcomes-based contracts with DC Participant Providers and Preferred Providers.
- Have a DCE funding approach (including any savings/losses distribution, if applicable) that demonstrates: (1) a strong commitment to the three-part aim of better health, better care, and lower costs; and (2) if losses occur, a credible plan for ensuring repayment to CMS of its share of losses relative to the Performance Year Benchmark.

Patient Centeredness & Beneficiary Engagement

Points: 25

Selection Criteria

- Demonstrate the ability to engage beneficiaries and their caregivers in shared decision making, taking into account patient preferences and choices.
- Have a feasible plan to establish mechanisms to conduct patient outreach and education on the benefits of care coordination.
- Demonstrate the ability to effectively involve beneficiaries in care transitions to improve the continuity and quality of care across settings.
- Demonstrate existing or potential partnerships with local aging/disability partners, like Area Agencies on Aging (AAAs) and Centers for Independent Living (CILs).
- If applicable, describe how the identified DC Participant Providers and Preferred Providers have the appropriate staff capacity and necessary infrastructure to carry out coordination activities necessary to implement the 3-day SNF waiver, home health homebound requirement, and concurrent care for beneficiaries that elect hospice.
- Demonstrate the ability to engage and activate beneficiaries at home to improve self-management. Have mechanisms to evaluate patient satisfaction with access and quality of care, including choice of providers and choice in care settings.

Clinical Care

Points: 25

Selection Criteria

Clinical Process Improvement (10 points)

- Demonstrate past experience and future plans for designing, implementing, and assessing the effectiveness of specific care improvement interventions.
- Provide credible plan for incorporating medication management into the care coordination approach.

Care Coordination (10 points)

- Demonstrate existing capacity, or plans to expand capacity, to coordinate care through an interdisciplinary team structure that includes a diverse set of practitioners with the necessary areas of expertise and appropriate staffing to meet the needs of a complex set of patients.
- Demonstrate a history of collaboration among major stakeholders in the community being served, including incorporation of relevant social services in care plans and management.
- Demonstrate a compelling plan to succeed in the areas of quality improvement and care coordination.
- For High Needs Population DCEs, demonstrate training and experience serving high cost, high acuity individuals and demonstrate capabilities in coordination of services that emphasize person-centered care such as an interdisciplinary care team that includes primary care, behavioral health, and LTSS providers.

Data Capacity (5 points)

- Provide a clear and detailed plan for how the DCE shall ensure that the percentage of DC Participant Providers that are eligible clinicians that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the CEHRT use criterion for Advanced APMs at 42 C.F.R. 414.1415(a)(1)(i).
- Have population health management tools and functions or concrete plans to develop and invest in such tools and functions.
- Have the ability, or credible plans to develop the ability, to electronically exchange patient records across DC Participant Providers, Preferred Providers, and other providers and suppliers in the community to ensure continuity of care.
- Have the ability to, or credible plans to gain the ability to, share performance feedback on a timely basis with participating DC Participant Providers and Preferred Providers.

Appendix E: Application Template

CMS will safeguard the information provided in accordance with the Privacy Act of 1974, as amended (5 U.S.C. § 552a). For more information, please see the CMS Privacy Policy at https://www.cms.gov/AboutWebsite/02_Privacy-Policy.asp.

The application can be found and completed at: <https://innovation.cms.gov/initiatives/direct-contracting-model-options/>

Questions about the application for the Direct Contracting Model (Professional or Global) should be directed to DPC@cms.hhs.gov.

Background Information

A. DCE Organization Information

- a. Organization Name
- b. Organization TIN/EIN
- c. Street Address
- d. City
- e. State
- f. Zip Code
- g. Website, if applicable

B. DCE Organization Profile

1. Type of Applicant organization. Check only one:
 - i. Medical group practice
 - ii. Network of individual practices (e.g., IPA)
 - iii. Hospital system(s)
 - iv. Integrated delivery system
 - v. Partnership of hospital system(s) and medical practices
 - vi. Other, please describe

2. Does the Applicant DCE include any of the following providers or suppliers as DC Participant Providers or Preferred Providers? Check all that apply:
 - i. Cancer or specialty hospitals
 - ii. Psychiatric hospital or other mental or behavioral health facility
 - iii. Hospital(s) receiving disproportionate share (DSH) payments or uncompensated care payments from Medicare or Medicaid
 - iv. Critical Access Hospital (CAH)
 - v. Other rural hospital
 - vi. Federally Qualified Health Center (FQHC)
 - vii. Other Community Health Centers
 - viii. Skilled Nursing Facility (SNF)
 - ix. Inpatient Rehabilitation Facility (IRF)
 - x. Home Health Agency (HHA)
 - xi. Other

3. Please indicate whether the applicant organization, or any of the proposed DC Participant Providers, is currently participating in, has formerly participated in, or has applied to any of the following initiatives listed below? Check all that apply:

- i. None
- ii. ACO Investment Model (AIM)
- iii. Care Management for High-Cost Beneficiaries Demonstration
- iv. Comprehensive ESRD Care Initiative (CEC)
- v. Comprehensive Primary Care Initiative (CPC)
- vi. Comprehensive Primary Care Plus Initiative (CPC+)
- vii. Primary Care First (PCF)
- viii. Independence at Home Medical Practice Demonstration (IAH)
- ix. Medicare Health Care Quality Demonstration Programs (including Indiana Health Information Exchange and North Carolina Community Care Network)
- x. Multi-payer Advanced Primary Care Practice Demonstration with a Shared Savings arrangement (MAPCP)
- xi. Medicare Shared Savings Program
- xii. Next Generation ACO Model
- xiii. Other (please specify):

4. Is the DCE or any of the proposed DC Participant Providers or Preferred Providers currently participating in the Bundled Payment for Care Improvements (BPCI) Advanced Model? (Yes/No) For more information: <https://innovation.cms.gov/initiatives/bpci-advanced>.

5. Beginning in PY1 (CY2021), Professional and Global DCEs may not simultaneously participate in the Shared Savings Program, a model tested or expanded under section 1115A of the Social Security Act that involves shared savings, or any other Medicare initiative that involves shared savings. Please confirm that the DCE will not be simultaneously participating in another Medicare shared savings initiative while participating in Direct Contracting, beginning in PY1.

6. Please provide an executive summary describing the Applicant DCE. This description should include the Applicant DCE's: composition, including the DCE type, number of hospitals, number of skilled nursing facilities, types of providers and suppliers (primary care and types of specialists); geographic service area including where most of the Applicant DCE's Medicare fee-for-service beneficiaries reside, if the service area encompasses urban, suburban, and/or rural locations, and if the area is a health professional shortage area. Please include any other applicable narrative describing the DCE.

7. All DC Participant Providers and Preferred Providers under the DCE must be Medicare-enrolled providers or suppliers by the beginning of the IP. Please confirm this will be the case.

8. Please attach a copy of a certificate of incorporation or other documentation that the Applicant DCE is recognized as a legal entity by the state in which it is located. Organizations who have not yet formed a legal entity will need to provide this information prior to executing a participation agreement to CMS.

9. Using the provided template, please upload an Excel spreadsheet identifying all the Proposed DC Participant Providers that will constitute the Applicant DCE.
 - a. The Participant List template will be made available.
 - b. Using the form provided, please upload a signed provider notification attestation form.
 - c. Submit a description of how your DCE will conduct its voluntary alignment activities during the IP or CY2020, including your proposed criteria for determining which beneficiaries will receive targeted outreach. If you would like to participate in Paper Voluntary Enrollment, please upload an edited version of the form available here.

10. As described in the Federal Trade Commission and the Department of Justice Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program ("Antitrust Policy Statement"), does the Applicant organization's share of any common service, where two or more of its participants are providing that service to patients from the same Primary Service Area, exceed 50%? (To calculate the Primary Service Area, please access: <http://www.cms.gov/apps/files/aco/application-zipcodes.zip>). Organizations that are fully integrated entities and/or were formed before March 23, 2010, may answer N/A.
 - i. Yes
 - ii. No
 - iii. N/A, formed before March 23, 2010
 - iv. N/A, fully integrated entity

If you answer yes, you understand and agree that CMS will share a copy of your application (including all information and documents submitted with the application) with the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DOJ).

Contact Information (primary and secondary contacts are pre-filled from Letter of Intent)

- A. Application Contact(s)
 - a. First Name
 - b. Last Name
 - c. Title/Position
 - d. Business Phone Number
 - e. Business Phone Number Ext.
 - f. Alternate Phone Number
 - g. E-mail Address
 - h. Street Address
 - i. City
 - j. State

- k. Zip Code
- B. Secondary Contact
 - a. First Name
 - b. Last Name
 - c. Title/Position
 - d. Business Phone Number
 - e. Business Phone Number Ext.
 - f. Alternate Phone Number
 - g. E-mail Address
 - h. Street Address
 - i. City
 - j. State
 - k. Zip Code
- C. Executive Contact
 - a. First Name
 - b. Last Name
 - c. Title/Position
 - d. Business Phone Number
 - e. Business Phone Number Ext.
 - f. Alternate Phone Number
 - g. E-mail Address
 - h. Street Address
 - i. City
 - j. State
 - k. Zip Code
- D. IT/Technical Contact
 - a. First Name
 - b. Last Name
 - c. Title/Position
 - d. Business Phone Number
 - e. Business Phone Number Ext.
 - f. Alternate Phone Number
 - g. E-mail Address
 - h. Street Address
 - i. City
 - j. State
 - k. Zip Code

Leadership and Management

- A. Leadership Team
 - 1. Please provide a proposed organizational chart for the Applicant DCE. The proposed organizational chart should depict the legal structure, the proposed composition of the DCE (e.g., all of the TINs and organizations included in the DCE), and any relevant committees.

2. Please describe the contractual and/or employment relationships between and among the Applicant DCE and proposed DC Participant Providers and Preferred Providers, as well as any contractual and/or employment relationships with other partners or entities that will provide health-related services to the DCE.
3. Please upload:
 - i. A sample contract or an amendment or addendum to a current contract between the DCE and proposed DC Participant Providers and Preferred Providers; and
 - ii. A sample contract or an amendment or addendum to a current contract between the DCE and any other partners or entities that will provide health-related services to the DCE (if applicable).
4. For proposed DC Participant Providers and Preferred Providers participating in your DCE, please report the following. The term “primary employer” below refers to the employer for whom the clinician delivers health services (not just to Medicare patients) and that the clinician considers to be their primary place of employment (e.g. accounts for the majority of the clinician’s income).
 - i. The total number of clinicians participating in your DCE:
 - ii. The total number of clinicians participating in your DCE for whom the DCE is their primary employer. (Clinicians whose primary employer is a hospital or group practice directly owned by the DCE or one of its subsidiaries should be treated as clinicians whose primary employer is the DCE):
 - iii. The total number of clinicians participating in your DCE for whom a non-DCE hospital (e.g. hospital that is not directly owned by the DCE or one of its subsidiaries) is their primary employer:
 - iv. The total number of clinicians participating in your DCE whose primary employer is a non-DCE group practice (e.g. group practice that is not directly owned by the DCE or one of its subsidiaries) with **10 or more** clinicians:
 - v. The total number of clinicians participating in your DCE whose primary employer is a non-DCE group practice (e.g. group practice that is not directly owned by the DCE or one of its subsidiaries) with **less than 10** clinicians:
5. Please describe the history of the Applicant DCE organization and its major member organizations in terms of prior business relationships (if any) and collaboration between members on care improvement or cost containment efforts (if any) as well as any anticipated upcoming business relationships.
6. Does the applicant organization have a leadership team exclusive to the DCE?
 - i. Yes
 - ii. No
7. Please complete the table below with information specific to the Applicant DCE's proposed leadership team. The leadership team may include, but is not limited to: key executives; finance officers; clinical improvement officers; compliance officers; information systems leadership; and the individual responsible for maintenance and stewardship of clinical data. If specific individuals have not yet been identified, please note that in the Leadership Team Member column and provide the anticipated date by which the individual will be identified.

Applicant DCE’s Proposed Leadership Team

Leadership Team Member	Position/Role

B. Legal Entity and Governing Body

1. For DCEs that are formed by one DC Participant Provider, the DCE’s legal entity may be the same as the legal entity of its DC Participant Provider. For DCEs that are formed by two or more DC Participant Providers, the DCE shall be a legal entity separate from the legal entity of any of its DC Participant Providers or Preferred Providers. Please select one:
 - i. Applicant DCE shall be a legal entity that is the same as its single DC Participant Provider.
 - ii. Applicant DCE shall be a legal entity separate from the legal entity of any of its DC Participant Providers or Preferred Providers.
 - iii. Applicant DCE was a Next Generation ACO or was a Medicare Shared Savings Program ACO and Applicant DCE will be the same as that of the existing legal entity.

2. Please complete the table below for the Applicant DCE’s proposed governing body:

Applicant DCE’s Proposed Governing Body

Name	Title	Expertise	Beneficiary (Y/N)	Consumer Advocate (Y/N)	Percent of Board Control

3. Please describe how responsibilities and accountability will be shared across the leadership team and governing body structures in the Applicant DCE.
4. Please describe how the governing body will ensure that the interests of beneficiaries and providers and suppliers will be represented adequately. Specifically, explain the following:
 - i. The role of the independent Medicare beneficiary and the independent consumer advocate who will participate in the governing body;
 - ii. The rationale for the proposed or existing composition of the governing body and voting power distribution.
5. Please provide a narrative explanation of why the Applicant DCE wishes to participate in Direct Contracting and how participation in the model will help CMS and the Applicant DCE’s proposed DC Participant Providers achieve the goals of better health and better care for Medicare beneficiaries while at the same time lowering the cost of care.
6. Please upload the compliance plan intended for use by the Applicant DCE and specify whether the compliance officer reports directly to the governing body.
7. Innovation Center model applications require all applicants to disclose the following with respect to the applicant, its owners, key executives, DC Participant Providers, and Preferred Providers: (i) any sanctions or corrective action plans imposed under Medicare, Medicaid, or state licensure authorities within the last three years; (ii) any fraud investigations initiated, conducted, or resolved within the last three years; and (iii) any

outstanding debts owed to the Medicare program, including any debts owed under an Innovation Center model. For purposes of this disclosure, key executives are individuals who manage or have oversight responsibility for the DCE, its finances, personnel, and quality improvement, including without limitation, a CEO, CFO, COO, CIO, medical director, compliance officer, or an individual responsible for maintenance and stewardship of clinical data. Please provide this information using the table below.

Provider and Supplier Information

Provider/Supplier	Federal or State Agency or Accrediting Body (e.g., licensure authorities, DOJ, OIG, the Joint Commission State Survey Agencies)	Description of Infraction (including date)	Resolution Status (including date)

- i. N/A, Applicant DCE and/or DCE’s proposed DC Participant Providers and Preferred Providers have no investigations, sanctions, penalties, or corrective action plans in the past three years.

C. Financial Experience and Information

1. What percentage of the Applicant DCE's total clinical revenues in the last fiscal year was derived from the following sources? Applicants may approximate this through summation of the revenue received by all proposed DC Participant Providers and Preferred Providers for clinical services (e.g., fee-for-service, per-member per-year, per-member per-month, per- episode).
 - i. Medicare fee-for-service
 - ii. Medicare Advantage
 - iii. Other Medicare health plans (e.g., PACE, Medicare cost plans)
 - iv. Commercial health plans
 - v. Medicaid
 - vi. Self-pay patients
 - vii. Other sources of funding (e.g., local uncompensated care funds)
2. Describe financial assurance plans and experience such as having funds placed in escrow, using a line of credit, a surety bond, or propose an alternative financial guarantee mechanism for approval by CMS that complies with all applicable state laws and regulations regarding provider-based risk-bearing entities. Any proposed alternative approach should address the following: state requirements, including attesting that they apply to the DCE, and how the proposed financial guarantee mechanism will offer sufficient protection to CMS for any Shared Losses or other monies owed under the model.
 - i. Escrow

- ii. Line of Credit
- iii. Surety Bond
- iv. Other

D. Risk-Sharing Experience

1. Please describe the Applicant DCE's performance under prior or current outcomes-based contracts, if any. Outcomes-based contracts must include: (1) financial accountability; (2) evaluation of patient experiences of care; and (3) substantial quality performance incentives. If applicable, please include performance under CMS programs, demonstrations, and models that meet the definition of outcomes-based contracts. Check N/A if no prior or current risk-sharing arrangements. Please also indicate the number of covered lives in outcomes-based contracts with any of the applicant DCE's proposed DC Participant Providers.
2. Please indicate the percentage of the Applicant DCE's clinical revenues (or an approximation based on the summation of clinical revenue from the DCE's proposed DC Participant Providers) in the last fiscal year derived from outcomes-based contracts.

Note: DCE total revenues include: (1) basic payments received by all proposed DC Participant Providers for clinical services (e.g., fee-for-service, per member per year, per member per month, or per episode); (2) supplemental payments all proposed DC Participant Providers received or returned due to risk as part of a financial or cost reconciliation for shared savings; (3) supplemental payments received as quality or cost bonuses (pay-for-performance) for all proposed DC Participant Providers. Total revenue excludes revenues not related to clinical services (e.g., rent, investments) and any revenues specified above that are received by the DCE.

3. Please describe how the Applicant DCE calculated the percentage of revenue cited above (e.g., which proposed DC Participant Providers were included, which services were included).
4. What is the business model for your organization as you transition from the financial incentives of FFS payment to those of risk-based and outcomes-based contracts? How has this been informed by your experience to date with risk-based and outcomes-based contracts? This response may include, but does not need to be limited to, prior ACO experience.
5. Please describe the Applicant DCE's relationship (e.g., geographic, age, relative dominance in major areas of service delivery) to other health care entities in its market. Include information on what other organizations are its main competitors and the Applicant DCE's market share in its primary service area for professional and hospital services.
6. Please describe the history of collaboration among major stakeholders in the community being served and commitment from relevant community stakeholders to achieve seamless care. Include specific examples, if any.

E. Alignment Frequency

1. Please indicate the intended alignment frequency:
 - i. Prospective Alignment (all-claims-based and voluntary alignment will be completed prior to the start of each performance year)
 - ii. Prospective Plus Alignment (beneficiaries added to DCE's aligned population prior

to the start of each of the first three quarters of each performance year through voluntary alignment)

2. Is the Applicant DCE interested in electing a stop-loss arrangement to protect the DCE from financial liability for individual beneficiary expenditures above the stop-loss attachment points?

F. Financial Plan if Selected for the Direct Contracting Model

1. Please attest that that the Applicant DCE has been licensed by the state(s) in which it is located as a risk-bearing entity or that it is exempt from such licensure and/or other such requirements.
 - i. Applicant DCE has been licensed as a risk-bearing entity in state(s) in which it will operate. Upload certification/documentation.
 - ii. Applicant is required to obtain licensure as a risk-bearing entity in state(s) in which it will operate, but the DCE is not yet currently licensed as a risk-bearing entity in one or more of these states.
 - iii. N/A (e.g., state does not have licensure requirement for DCEs or DCE not required to be licensed as risk-bearing entity).

G. Funding Ongoing DCE Activity

1. Please describe how Applicant DCE intends to fund ongoing DCE activity. Indicate how the funding plan supports the aim of better health, better health care, and lower per-capita costs and how it ties individual providers and suppliers into the overall outcomes-based revenue strategy. To the extent applicable, please describe how Shared Savings or Shared Losses will be distributed among DC Participant Providers and, if applicable, Preferred Providers.
2. Please describe how the Applicant DCE plans to ensure payment to Medicare of its Shared Losses relative to the Performance Year Benchmark.
3. Please explain any plans the Applicant DCE has to better manage Part D utilization and expenditures. Please include any plans the DCE has to partner with Part D Plans, which must preserve beneficiary choice. Please include information on the types of activities that would fall under such a Part D partnership, such as data sharing or medication reconciliation.
4. Please indicate intended Capitation Payment Mechanism. The DCE's selected Capitation Payment Mechanism is separate from the DCE's risk arrangement selection. The alternative payment mechanism dictates the method of payment for DC Participant Provider claims and affords the DCE the option of receiving monthly payments. Please select all that apply.
 - i. Total Care Capitation
 - ii. Primary Care Capitation
 - iii. Claims Reduction

Patient Centeredness and Beneficiary Engagement

1. Is the Applicant DCE interested in serving individuals dually eligible for Medicare and Medicaid?

- i. Describe the Applicant DCE's experience in providing Medicare-covered services and plans to coordinate with state Medicaid agencies to ensure appropriate coordination of services and prevent unnecessary utilization of higher cost institutional care in both Medicare and Medicaid. Describe any potential support that may be received from state Medicaid agencies for these purposes.
2. For provider-led entities interested in replicating the successful clinical approaches of the Programs of All-Inclusive Care for the Elderly (PACE) at greater scale and for new populations, (1) Describe the Applicant DCE's experience and expertise serving high cost, high acuity individuals; and (2) Demonstrate existing capabilities in coordinating services that emphasize person-centered care such as experience delivering care through an interdisciplinary care team that includes primary care, behavioral health, and Long-Term Services and Supports (LTSS) providers.

Goals and Objectives

1. Please describe the Applicant DCE's ability to accomplish the items below. The narrative should address the ability to achieve the following goals and objectives of the Direct Contracting Model related to patient centeredness:
 - i. Promotion of evidence-based medicine, such as through the establishment and implementation of evidence-based guidelines at the organizational or institutional level. A genuine evidence-based approach would also provide for regular assessments of and updates to such guidelines.
 - ii. Process to ensure patient/caregiver engagement and shared decision-making processes employed by DC Participant Providers take into account the beneficiaries' unique needs, preferences, values, and priorities. Measures for promoting patient engagement include, but are not limited to, the use of decision support tools and shared decision-making methods with which the patient can assess the merits of various treatment options in the context of his or her values and convictions. Patient engagement also includes methods for fostering what might be termed "health literacy" in patients and their families.
 - iii. Coordination of care and care transitions (e.g., sharing of electronic summary records across providers, telehealth, remote patient monitoring, other enabling technologies).
 - iv. Providing beneficiaries access to their own medical records and to clinical knowledge so that they may make informed choices about their care.
 - v. Ensuring individualized care, such as through personalized care plans.
 - vi. Routine assessment of beneficiary and caregiver and/or family experience of care and seek to improve where possible.
 - vii. Providing care that is integrated with community resources beneficiaries require.

Beneficiary Engagement

1. Please describe the existing, or planned, approach that the Applicant DCE will use to conduct beneficiary outreach.

2. Describe how the Applicant DCE will recruit beneficiaries through voluntary alignment to ensure the organization meets the minimum number of aligned beneficiaries required in each performance year.
3. Please describe the Applicant DCE's existing, or planned approach, for evaluating beneficiary satisfaction in addition to CMS required beneficiary experience surveys and how the DCE intends to use such information to improve its care management and coordination processes.

Clinical Care Model

A. Care Coordination and Health IT Capability

1. Please describe the Applicant DCE's historical and future plans to achieve better health, better care, and lower costs through integrated and coordinated care interventions. Please address the following in your narrative:
 - i. The Applicant DCE's historical use of interdisciplinary care teams to coordinate care for patients;
 - ii. The Applicant DCE's methods and processes to coordinate care throughout an episode of care and during care transitions, such as discharge from a hospital or transfer of care between providers (both inside and outside the DCE);
 - iii. The Applicant DCE's historical and future planned use of health information technology;
 - iv. The Applicant DCE's strategies for improving beneficiary access to care;
 - v. The Applicant DCE's development and use of population health management tools;
 - vi. The Applicant DCE's plan to incorporate medication management into its care coordination approach; and,
 - vii. Additional specific care interventions and tools.
2. Please provide the anticipated percentage of eligible clinicians in the Applicant DCE that will have attested to the Promoting Interoperability performance category measures under the Quality Payment Program by April 1, 2019. Please provide any additional information regarding the ability of Applicant DCE's eligible clinicians to meet the CEHRT requirements (42 C.F.R. 414.1305).

Please answer the following questions which describe the proposed Direct Contracting Participant Providers' ability to conduct the following activities electronically using either the currently implemented EHR or another platform that the DCE plans to implement.

3. Is the DCE a physician-based organization (e.g., a physician group or another legal entity formed by physicians)?
 - i. Yes
 - ii. No
 - iii. Please select one of the following categories that best reflects the EHR/HIT system functionality of the majority of ambulatory care practices in the applicant DCE:
 - a. Paper chart based.
 - b. Desktop access to clinical information, unstructured data, multiple data sources, intra-office/informal messaging.

- c. Beginning of a clinical data repository (CDR) with orders and results, computers may be at point-of-care, access to results from outside facilities.
 - d. Electronic messaging, computers have replaced the paper chart, clinical documentation and clinical decision support.
 - e. Computerized physician order entry (CPOE), use of structured data for accessibility in electronic medical record (EMR) and internal and external sharing of data.
 - f. Health Information Exchange (HIE) capable, sharing of data between the EMR and community based EHR, business and clinical intelligence.
4. Is the DCE hospital-based (e.g., a physician hospital organization (PHO) or management service organization (MSO) that includes hospitals)?
 - i. Yes
 - ii. No
 5. Please select one of the following categories that best reflects the functionality of the majority of providers' EMR/HIT systems in the applicant DCE:
 - i. Some clinical automation exists; however, systems allowing laboratory, pharmacy, and/or radiology services to be automated are not installed.
 - ii. Systems allowing laboratory, pharmacy, and radiology to be automated are installed.
 - iii. Computerized practitioner/physician order entry (CPOE) installed and available. If one patient service area has implemented CPOE and completed previous stages, this stage has been achieved.
 - iv. The closed loop medication administration environment implemented in at least one patient care service area. Electronic medication administration record (eMAR) system is implemented and integrated with CPOE and pharmacy.
 - v. Full physician documentation/charting (structured templates) implemented for at least one patient care service area. Full radiology picture archive and communication system (PACS) implemented (i.e. all images available to physicians via intranet or other secure network).
 - vi. Hospital has paperless EMR environment. Clinical information can be readily shared via Continuity of Care (CCD) electronic transactions with all entities within health information exchange networks (i.e., other hospitals, ambulatory clinics, sub-acute environments, employers, payers and patients).
 6. Please describe the Applicant DCE's and proposed DC Participant Providers' ability to use EHR data and electronic tools to understand patient risk, risk stratify, and use this information for decision-making.
 7. Does the Applicant DCE have interest and the capabilities to utilize tools to retrieve bulk Medicare claims data related to the DCE's attributed population for purposes of care coordination and quality improvement activities?
 8. Please describe the Applicant DCE's and proposed DC Participant Providers' ability to transfer patient data and care plans between health care settings both inside and outside the DCE for purposes of care management and care coordination.
 9. Please describe the experience of the proposed DC Participant Providers with reporting on established clinical and patient satisfaction quality measures. Please be specific

about the measure set and purpose for collection. If applicable, include a description of any formal, third-party assessments within the past two years (2016-2018) of the Applicant DCE's performance on quality of care metrics relative to peers.

10. Please provide a narrative description and quantitative documentation of at least one illustrative instance in which the Applicant DCE has designed, implemented, and assessed the effectiveness of specific care improvement interventions. Include information on how the problem(s) was identified, why and how the intervention(s) was selected and designed, how progress (or lack thereof) was measured, and any corrective action or adjustments made.

Appendix F: Illustrative Mobility Impairment Codes for High Needs Population DCEs

The following diagnoses for mobility-related conditions are drawn from the list of Other Chronic or Potentially Disabling Conditions in the CMS Chronic Condition Data Warehouse. For a list of the ICD-10 codes associated with these diagnoses, please see the Condition Algorithms at:

<https://www.ccwdata.org/web/guest/condition-categories>.

Cerebral Palsy

Code	Condition
33371	Athetoid cerebral palsy
343	Infantile cerebral palsy
3430	Congenital diplegia
3431	Congenital hemiplegia
3432	Congenital quadriplegia
3433	Congenital monoplegia
3434	Infantile hemiplegia
3438	Other specified infantile cerebral palsy
3439	Infantile cerebral palsy unspecified

Cystic Fibrosis and Other Metabolic Developmental Disorders

Code	Condition
243	Congenital hypothyroidism
2552	Congenital adrenal hyperplasia
2692	Unspecified vitamin deficiency
2701	Phenylketonuria (pku)
2702	Disturbance of aromatic amino-acid metabolism
2703	Disturbances of branched chain amino acid metabolism
2704	Disturbance of sulfur-bearing amino-acid metabolism
2706	Disorders of urea cycle metabolism
2707	Other disturbances of straight-chain amino-acid metabolism
2711	Galactosemia
2770	Cystic fibrosis
27700	Cystic fibrosis without mention of meconium ileus
27701	Cystic fibrosis with meconium ileus
27702	Cystic fibrosis with pulmonary manifestations
27703	Cystic fibrosis with gastrointestinal manifestations
27709	Cystic fibrosis with other manifestations
27781	Primary carnitine deficiency
27785	Disorders of fatty acid oxidation
2776	Other deficiencies of circulating enzymes (Biotinidase deficiency)

Mobility Impairments

Code	Condition
3341	Hereditary spastic paraplegia
34200	Flaccid hemiplegia and hemiparesis affecting unspecified side
34201	Flaccid hemiplegia and hemiparesis affecting dominant side
34202	Flaccid hemiplegia and hemiparesis affecting non-dominant side

Code	Condition
34210	Spastic hemiplegia and hemiparesis affecting unspecified side
34211	Spastic hemiplegia and hemiparesis affecting dominant side
34212	Spastic hemiplegia and hemiparesis affecting non-dominant side
34280	Other specified hemiplegia and hemiparesis affecting unspecified side
34281	Other specified hemiplegia and hemiparesis affecting dominant side
34282	Other specified hemiplegia and hemiparesis affecting non-dominant side
34290	Hemiplegia, unspecified, affecting unspecified side
34291	Hemiplegia, unspecified, affecting dominant side
34292	Hemiplegia, unspecified, affecting non-dominant side
344	Other paralytic syndromes
3440	Quadriplegia and quadripareisis
34400	Quadriplegia, unspecified
34401	Quadriplegia, C1-C4, complete
34402	Quadriplegia, C1-C4, incomplete
34403	Quadriplegia, C5-C7, complete
34404	Quadriplegia, C5-C7, incomplete
34409	Other quadriplegia
3441	Paraplegia
3442	Diplegia of upper limbs
3443	Monoplegia of lower limb
34430	Monoplegia of lower limb affecting unspecified side
34431	Monoplegia of lower limb affecting dominant side
34432	Monoplegia of lower limb affecting non-dominant side
3444	Monoplegia of upper limb
34440	Monoplegia of upper limb affecting unspecified side
34441	Monoplegia of upper limb affecting dominant side
34442	Monoplegia of upper limb affecting non-dominant side
3445	Unspecified monoplegia
3446	Cauda equina syndrome
34460	Cauda equina syndrome without mention of neurogenic bladder
34461	Cauda equina syndrome with neurogenic bladder
3448	Cauda equina syndrome with neurogenic bladder
34481	Locked-in state
34489	Other specified paralytic syndrome
3449	Paralysis, unspecified
43820	Late effects of cerebrovascular disease, hemiplegia affecting unspecified side
43821	Late effects of cerebrovascular disease, hemiplegia affecting dominant side
43822	Late effects of cerebrovascular disease, hemiplegia affecting non-dominant side
43830	Late effects of cerebrovascular disease, monoplegia of upper limb affecting unspecified side
43831	Late effects of cerebrovascular disease, monoplegia of upper limb affecting dominant side
43832	Late effects of cerebrovascular disease, monoplegia of upper limb affecting non-dominant side
43840	Late effects of cerebrovascular disease, monoplegia of lower limb affecting unspecified side
43841	Late effects of cerebrovascular disease, monoplegia of lower limb affecting dominant side
43842	Late effects of cerebrovascular disease, monoplegia of lower limb affecting non-dominant side
43850	Late effects of cerebrovascular disease, other paralytic syndrome affecting unspecified side

Code	Condition
43851	Late effects of cerebrovascular disease, other paralytic syndrome affecting dominant side
43852	Late effects of cerebrovascular disease, other paralytic syndrome affecting non-dominant side
43853	Late effects of cerebrovascular disease, other paralytic syndrome, bilateral

Multiple Sclerosis and Transverse Myelitis

Code	Condition
340	Multiple sclerosis
341	Other demyelinating diseases of the central nervous system
3410	Neuromyelitis optica
3412	Acute (transverse) myelitis
34120	Acute (transverse) myelitis nos
34121	Acute (transverse) myelitis in conditions classified elsewhere
34122	Idiopathic transverse myelitis
3418	Other demyelinating diseases of the central nervous system
3419	Demyelinating diseases of central nervous system

Muscular Dystrophy

Code	Condition
359	Muscular dystrophies and other myopathies
3590	Congenital hereditary muscular dystrophy
3591	Hereditary progressive muscular dystrophy

Spina Bifida and other Congenital Anomalies of the Nervous System

Code	Condition
7400	Anencephalus
7401	Craniorachischisis
7402	Iniencephaly
741	Spina bifida
7410	Spina bifida with hydrocephalus
74100	Spina bifida unspecified region with hydrocephalus
74101	Spina bifida cervical region with hydrocephalus
74102	Spina bifida dorsal (thoracic) region with hydrocephalus
74103	Spina bifida lumbar region with hydrocephalus
7419	Spina bifida without mention of hydrocephalus
74190	Spina bifida unspecified region without hydrocephalus
74191	Spina bifida cervical region without hydrocephalus
74192	Spina bifida dorsal (thoracic) region without hydrocephalus
74193	Spina bifida lumbar region without hydrocephalus
7420	Encephalocele
7421	Microcephalus
7422	Congenital reduction deformities of brain
7423	Congenital hydrocephalus
7424	Other congenital anomalies of nervous system
7425	Other specified congenital anomalies of spinal cord
74251	Diastematomyelia

Code	Condition
74253	Hydromyelia
74259	Other specified congenital anomalies of spinal cord
7428	Other specified congenital anomalies of nervous system
7429	Unspecified congenital anomaly of brain, spinal cord, and nervous system

Spinal Cord Injury

Code	Condition
9072	Late effect of spinal cord injury
95200	C1-C4 level with unspecified spinal cord injury
95201	C1-C4 level with complete lesion of spinal cord
95202	C1-C4 level with anterior cord syndrome
95203	C1-C4 level with central cord syndrome
95204	C1-C4 level with other specified spinal cord injury
95205	C5-C7 level with unspecified spinal cord injury
95206	C5-C7 level with complete lesion of spinal cord
95207	C5-C7 level with anterior cord syndrome
95208	C5-C7 level with central cord syndrome
95209	C5-C7 level with other specified spinal cord injury
95210	T1-T6 level with unspecified spinal cord injury
95211	T1-T6 level with complete lesion of spinal cord
95212	T1-T6 level with anterior cord syndrome
95213	T1-T6 level with central cord syndrome
95214	T1-T6 level with other specified spinal cord injury
95215	T7-T12 level with unspecified spinal cord injury
95216	T7-T12 level with complete lesion of spinal cord
95217	T7-T12 level with anterior cord syndrome
95218	T7-T12 level with central cord syndrome
95219	T7-T12 level with other specified spinal cord injury
9522	Lumbar spinal cord injury without evidence of spinal bone injury
9523	Sacral spinal cord injury without evidence of spinal bone injury
9524	Cauda equina spinal cord injury without evidence of spinal bone injury
9528	Multiple sites of spinal cord injury without evidence of spinal bone injury
9529	Unspecified site of spinal cord injury without evidence of spinal bone injury

Appendix G: PQEM Codes

Office or Other Outpatient Services

Code	Office or Other Outpatient Services
99201	New Patient, brief
99202	New Patient, limited
99203	New Patient, moderate
99204	New Patient, comprehensive
99205	New Patient, extensive
99211	Established Patient, brief
99212	Established Patient, limited
99213	Established Patient, moderate
99214	Established Patient, comprehensive
99215	Established Patient, extensive

Domiciliary, Rest Home, or Custodial Care Services

Code	Domiciliary, Rest Home, or Custodial Care Services
99324	New Patient, brief
99325	New Patient, limited
99326	New Patient, moderate
99327	New Patient, comprehensive
99328	New Patient, extensive
99334	Established Patient, brief
99335	Established Patient, moderate
99336	Established Patient, comprehensive
99337	Established Patient, extensive

Domiciliary, Rest Home, or Home Care Plan Oversight Services

Code	Domiciliary, Rest Home, or Home Care Plan Oversight Services
99339	Brief
99340	Comprehensive

Home Services

Code	Home Services
99341	New Patient, brief
99342	New Patient, limited
99343	New Patient, moderate
99344	New Patient, comprehensive
99345	New Patient, extensive
99347	Established Patient, brief
99348	Established Patient, moderate
99349	Established Patient, comprehensive
99350	Established Patient, extensive

Transitional Care Management Services

Code	Transitional Care Management Services
99495	Communication (14 days of discharge)
99496	Communication (7 days of discharge)

Chronic Care Management Services

Code	Chronic Care Management Services
99490	Comprehensive care plan establishment/implementations/revision/monitoring

Wellness Visits

Code	Wellness Visits
G0402	Welcome to Medicare visit
G0438	Annual wellness visit
G0439	Annual wellness visit

Primary Care Specialist Table

Code ¹	Specialty
1	General Practice
8	Family Medicine
11	Internal Medicine
37	Pediatric Medicine
38	Geriatric Medicine
50	Nurse Practitioner
89	Clinical nurse specialist
97	Physician Assistant

¹The Medicare Specialty Code. A cross-walk between Medicare Specialty Codes and the Healthcare Provider Taxonomy is published on the CMS website at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/TaxonomyCrosswalk.pdf>

Other Selected Specialist Table

Code ¹	Specialty
6	Cardiology
12	Osteopathic manipulative medicine
13	Neurology
16	Obstetrics/gynecology
23	Sports medicine
25	Physical medicine and rehabilitation
26	Psychiatry
27	Geriatric psychiatry
29	Pulmonology
39	Nephrology
46	Endocrinology
70	Multispecialty clinic or group practice
79	Addiction medicine
82	Hematology
83	Hematology/oncology
84	Preventative medicine
90	Medical oncology
98	Gynecological/oncology
86	Neuropsychiatry

¹The Medicare Specialty Code. A cross-walk between Medicare Specialty Codes and the Healthcare Provider Taxonomy is published on the CMS website at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/TaxonomyCrosswalk.pdf>