



Direct Contracting (Professional and Global)

Frequently Asked Questions

Version 2

Date: August 2020

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General Questions

1. Q: What is the Direct Contracting Model?

The Direct Contracting Model creates a new opportunity for the Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (Innovation Center) to test an array of financial risk-sharing arrangements expected to reduce Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries. The Direct Contracting Model leverages lessons learned from other Medicare Accountable Care Organization (ACO) initiatives, such as the Medicare 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 Innovation Center to use the redesign of primary care as a platform to drive broader health care delivery system reform. The model creates a variety of pathways for participants to take on financial risk supported by enhanced flexibilities. Because the model reduces burden, supports a focus on complex, chronically and seriously ill patients, and aims to encourage organizations to participate that have not typically participated in Medicare fee-for-service (FFS) Innovation Center models, we anticipate that this model will appeal to a broad range of physician organizations and other types of health organizations.

2. Q: What are the model options under Direct Contracting?

The CMS Innovation Center will test up to three voluntary risk-sharing *options*: 1) *Professional, a lower-risk option (50 percent Shared Savings/Shared Losses) and Primary Care Capitation (PCC) equal to seven percent of the total cost of care benchmark for enhanced primary care services; and 2) Global, a full risk option (100 percent Shared Savings/Shared Losses) and either PCC or Total Care Capitation (TCC). CMS has also sought comment on a potential third option, the Geographic Option, which is another full risk option (100 percent Shared Savings/Shared Losses) that will offer an opportunity for participants 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 the current Request for Applications (RFA) is for the Professional and Global Options of Direct Contracting only. CMS anticipates issuing an RFA for the Geographic Option at a later date.***

3. Q: What are the benefits of participating in Direct Contracting?

Direct Contracting is intended to test whether the risk-based payment strategies available under the model align financial incentives and offer model participants (Direct Contracting Entities or DCEs) flexibility in engaging health care providers and patients in care delivery that results in preserving or enhancing quality of care while at the same time reducing the total cost of care. Specifically, Direct Contracting offers:

- Multiple risk-sharing arrangements,
- Flexible beneficiary alignment options, including enhancements to voluntary alignment relative to existing Medicare initiatives,
- Capitation payment options that vary by risk-sharing arrangement,
- Benefit enhancements and payment rule waivers to improve care coordination and service delivery,

- A focus on complex chronic and seriously ill beneficiaries, and
- Options for organizations that have not participated in Medicare FFS previously

4. Q: How many years is Direct Contracting? *(Updated, June 2020)*

The model will be implemented over six years, with an optional initial Implementation Period (IP), followed by five performance years (PY1-5). The IP will occur from October 2020 through March 2021, and PY1, PY2, PY3, PY4 and PY5 will occur in calendar years 2021, 2022, 2023, 2024 and 2025 respectively.

5. Q: What is the purpose of the Implementation Period (IP) and when will it begin? *(Updated, June 2020)*

To help organizations new to Medicare FFS and/or Innovation Center models build an aligned Medicare FFS population, Direct Contracting provides enhanced opportunities for voluntary alignment relative to existing Medicare initiatives. The optional IP provides DCEs with additional time to engage in beneficiary alignment activities and plan their care coordination and management strategies prior to the first performance year (PY2021), which begins April 1, 2021. The optional IP will begin in October 2020.

6. Q: What is a DCE?

A DCE is a legal entity which participates in Direct Contracting pursuant to a Participation Agreement with CMS. Various types of organizations may apply to become a DCE including Accountable Care Organizations (ACOs). 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 Medicare-only and dually eligible beneficiaries, who are aligned to a DCE through voluntary alignment or claims-based alignment. These organizations may have previously participated in section 1115A models involving shared savings models (e.g., Next Generation ACO Model 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 apply to participate as this DCE type. In either case, CMS expects that providers and suppliers participating within these organizations would have substantial experience serving Medicare FFS beneficiaries.
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, to attain the minimum number of aligned beneficiaries. Claims-based alignment will also be utilized.
3. **High Needs Population DCEs** – DCEs that serve FFS Medicare 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, like the one employed by the Programs of All-Inclusive Care for the Elderly (PACE), to coordinate care for their aligned beneficiaries.

7. Q: How can a DCE assess if they meet the requirements to be a Standard DCE, New Entrant DCE or High Needs Population DCE, for example, if they have sufficient level of experience with Medicare FFS to be a Standard DCE? (*New Question, June 2020*)

Key criteria are outlined below. Complete details of each of the three DCE types are available in the RFA.

Standard DCEs

- Organizations with substantial experience serving Medicare FFS beneficiaries. These may be organizations that previously participated in section 1115A shared savings models (e.g., Next Generation ACO Model and Pioneer ACO Model) and/or the Shared Savings Program, or new organizations, composed of existing Medicare FFS providers and suppliers created in order to participate in Direct Contracting.
- 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

- Organizations with less experience serving a Medicare FFS population and / or taking risk for FFS Medicare beneficiaries.
- May not have more than 50% of DC Participant Providers with prior experience in the Shared Savings Program, the Next Generation ACO Model, the Comprehensive ESRD Care Model, the Pioneer ACO Model or CPC+ Model*
- Must meet an increasing minimum number of aligned beneficiaries, with a minimum of at least 1,000 beneficiaries prior to the start of PY1, 2,000 prior to the start of PY2, 3,000 prior to the start of PY3, and 5,000 prior to the start of PY4 and PY5.
- May not have more than 3,000 beneficiaries that are “alignable” through claims-based alignment in any base year (2017, 2018 and 2019) or in Performance Years 1-3. CMS will evaluate this by assessing the volume of services provided by the applicant’s proposed DC Participant Providers to Medicare FFS beneficiaries. Any FFS beneficiaries with a plurality of Primary Care Qualified Evaluation & Management (PQEM) claims billed by a DCE’s proposed DC Participant Providers in a given year will be considered “alignable” in that year*.

*Organizations found ineligible to participate on the basis of this criterion will have the opportunity to participate as a Standard DCE, provided all other model requirements are met.

High Needs DCEs

- Organizations with experience serving high cost, high acuity individuals.
- Where applicable, CMS will also assess an organization’s experience providing a range of Medicaid-covered services and demonstrated ability to coordinate services across Medicare and Medicaid for dually eligible beneficiaries, and prevent unnecessary utilization of higher cost institutional care.
- Required to have demonstrated 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.
- Must meet an increasing minimum number of aligned beneficiaries, with a minimum of at least 250 beneficiaries prior to the start of PY1, 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. In addition to the beneficiary eligibility requirements that apply to all beneficiaries in Direct Contracting,

beneficiaries must meet additional eligibility requirements to be aligned to a High Needs DCE – see page 54 of the RFA for details.

8. Q: Can a DCE move between the Global and Professional options? *(New Question, June 2020)*

Before signing the PY1 Participation Agreement, the DCE may switch from Global to Professional, and vice versa. The DCE cannot move from Global to Professional options once participation has begun. If the DCE wants to increase from Professional to Global, it can change only at the following times:

- Submit its change during the IP, to take effect PY1
- During PY2, to take effect PY3
- During PY3, to take effect PY4
- During PY4, to take effect PY5

Please note that this information was updated after the release of the RFA dated November 25, 2019.

9. Q: Is Direct Contracting an Advanced Alternative Payment Model (APM)?

Direct Contracting will be an Advanced APM starting in performance year (PY) 2021.

10. Q: How does Direct Contracting differ from Medicare Advantage?

Unlike beneficiaries who enroll in an MA plan, beneficiaries aligned to organizations participating in the payment model options under Direct Contracting are not choosing to leave Medicare FFS. If a Medicare FFS beneficiary voluntarily aligns with a DCE, their health care coverage will not change and they retain the freedom to seek care from their Medicare provider or supplier of choice, unlike enrolling in an MA plan with a network. However, DCEs are like MA plans in that they are risk-bearing entities managing the care of a panel of patients.

11. Q: How does Direct Contracting differ from the NGACO Model?

Direct Contracting builds on the experience of the NGACO Model and incorporates innovative approaches from MA and the private sector. Direct Contracting incorporates opportunities for greater financial risk than the NGACO Model supported by enhanced flexibilities and additional benefit enhancements. Direct Contracting builds on the cash flow mechanisms of the NGACO Model by introducing capitation, requiring DCEs to receive upfront, at-risk, capitated payments and to pay their downstream providers and suppliers that participate in such capitated payment arrangements for services, allowing the DCE to better coordinate care delivery. Additionally, the Direct Contracting Model has a new financial methodology that features a benchmark developed based on the MA rate-book and a new risk adjustment strategy that mitigates coding intensity and improves the accuracy of risk adjustment for complex, high-risk patients. In order to support this new methodology, Direct Contracting also offers an enhanced voluntary alignment methodology relative to existing Medicare initiatives, Prospective Plus Alignment, which allows DCEs to incorporate new beneficiaries into their aligned beneficiary population on a quarterly basis. Direct Contracting's benchmarking methodology and risk-sharing and beneficiary alignment options support the participation of organizations new to Medicare FFS and organizations focused on the provision of care to high needs beneficiaries.

12. Q: Can CMS provide more information about the risk adjustment methodology paper and financial methodology paper that will be available in the future? *(New Question, June 2020)*

CMS anticipates publishing a risk adjustment methodology technical methods paper in late 2020. This technical paper will address various aspects of the risk adjustment methodology for Global and Professional under Direct Contracting. CMS also expects that a detailed financial methodology paper will be made available to potential participants prior to the deadline for signing the PY1 Participation Agreement. Additional information regarding the modified risk adjustment methodology will also be provided in the financial methodology paper.

Application Process

13. Q: What is the updated model timeline? *(New Question, June 2020)*

The first performance year of the Direct Contracting Model was scheduled to begin January 1, 2021. However, in recognition of the impact of the COVID-19, CMS is delaying the start of the Performance Period of the Model by three months, such that the first performance year will begin April 1, 2021. The implementation period will begin in October 2020 for organizations that have already applied and are selected to begin participation during the Implementation Period. The application for participation beginning April 1, 2021 opened on June 4, 2020 and will close on July 6, 2020. Additionally, CMS plans to open a second application period in 2021 for organizations to enter the Direct Contracting Model on January 1, 2022.

14. Q: If our organization already submitted an application, do we need to reapply? *(New Question, June 2020)*

- If you applied to begin participation in the IP, were accepted, and sign the IP PA, you do not need to reapply to continue participating in PY1 (starting April 1, 2021).
- If you applied to begin participation in the IP and were not accepted, you may reapply during either of the two subsequent application periods.
- If you apply to begin participation in PY1 and are not accepted, you may reapply in the next application period to start January 2022.
- If you applied to begin participation in the IP or PY1 and are accepted, but wish to delay your start, you do not need to reapply.

15. Q: Will there be additional opportunities to apply for Direct Contracting after Performance Year 1 begins in 2021? *(New Question, June 2020)*

CMS intends to have an additional application period in early 2021 for those interested in beginning participation in the model on January 1, 2022. A previously submitted Letter of Intent (LOI) **is not** required to apply for this application period.

16. Q: How does an organization apply to participate in the model?

The Request for Applications has been posted to the Direct Contracting website. Applicants may access the application portal at: <https://app1.innovation.cms.gov/dcrfa/dcrfaLogin>.

17. Q: Is a letter of intent (LOI) required to apply to Direct Contracting? (Updated, June 2020)

Yes, a LOI must be submitted before you can access the PY1 application portal. The LOI portal is open until July 6, 2020, you can submit a LOI at: <https://app1.innovation.cms.gov/dc>. To apply to begin the model in 2022, a LOI is not required to access the PY2 application portal.

18. Q: If I have technical questions about the application tool, to whom should I send them?

Technical questions regarding the application should be sent to CMMIForceSupport@cms.hhs.gov. We will attempt to address all inquiries within three business days, however some questions may take longer to answer.

19. Q: How will CMS select participants for the model?

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 the RFA. In addition, CMS will consider whether applicants have demonstrated 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.

20. Q: When will CMS announce the model participants and when does the model start? (Updated, June 2020)

Model Timeline – Dates are subject to change

Timeline	Implementation Period (PY0) DCE Applicants	Performance Period (PY1) DCE Applicants
Application Period	November 25, 2019 – February 25, 2020	June 4 – July 6, 2020
LOI Open for PY 1 Applicants who did not submit an LOI before the Implementation Period	n/a	June 10 – July 6, 2020
DCE Selection	July 2020	September 2020
Deadline for applicants to sign and return PA to the Innovation Center	September 2020 <i>(Implementation Period PA)</i> March 2021 <i>(Performance Period PA)</i>	March 2021 <i>(Performance Period PA)</i>
Initial Voluntary Alignment Outreach and start date	October 2020 (IP)	April 2021 (PY)

21. Q: If an applicant is accepted to participate as a DCE during the Implementation Period for the Professional or Global Option, can it also apply for the Geographic Option? (Updated, June 2020)

The Geographic Option is still under development and the application for it will not be available during the Implementation Period for the Professional and Global Options.

22. Q: When are the DCE's arrangements with DC Participant Providers and Preferred Providers due to CMS and how are they submitted? *(New Question, June 2020)*

A sample arrangement between the DCE and the DC Participant Providers and Preferred Providers must be submitted with the application as well as a DC Participant Provider and Preferred Provider notification attestation signed by the DCE.

23. Q: Can a DCE update the list of DC Participant Providers and Preferred Providers after submitting its application for the Implementation Period? *(New Question, June 2020)*

Yes. DCEs that have applied to participate beginning in the Implementation Period will have an opportunity to update the DC Participant Provider List and Preferred Provider List for the IP provided with their application. DC Participant Providers and Preferred Providers do not carry over from year to year. DCEs that begin participation during the IP will be required to submit a new DC Participant Provider List and a new Preferred Provider List for PY1 and each subsequent PY. DC Participant Providers and Preferred Providers can be added mid-Performance Year as part of an ad-hoc process; however, DC Participant Providers that are added mid-Performance Year will not contribute to claims-based alignment for that PY.

24. Q: What are the processes, deadlines and consequences for withdrawing early from Direct Contracting should a DCE choose to do so? *(New Question, June 2020)*

DCEs may participate in the IP and choose not to sign the PY1 Participation Agreement, which would signal a withdrawal from Direct Contracting, without any consequences.

To withdraw from Direct Contracting once a Performance Year begins, DCEs generally must terminate their Participation Agreement prior to February 28th of a Performance Year to avoid liability for shared losses (note: PY1 is the exception – since it starts on April 1, there will be no opportunity to terminate during the PY to avoid liability for shared losses for that PY). DCEs will face financial consequences for withdrawal prior to the final reconciliation for Performance Year 1 depending on the type of retention withhold a DCE chooses when it signs the PY1 Participation Agreement, from two options:

- 1) DCEs may choose 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. CMS will conduct final reconciliation approximately six months after the performance year ends.
- 2) 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.

Eligibility

25. Q: What types of organizations can apply for the Direct Contracting model? *(New Question, June 2020)*

In addition to providing an option for NGACO participants who are seeking to continue their value based work with CMS, a key objective of Direct Contracting is to incent organizations that have not traditionally provided services to a Medicare FFS population or have not previously participated in Innovation Center models to join a risk-based total cost of care model for the Medicare FFS population. Therefore, a wide variety of organizations may be eligible to apply. The following are examples of organization types that may be eligible:

- ACOs or ACO-like organizations
- Network of individual practices (e.g., IPA)
- Hospital system(s)
- Integrated delivery system
- Partnership of hospital system(s) and medical practices
- Medicaid Managed Care Organizations (MCOs)
- Other payers
- Skilled Nursing Facilities (SNFs)
- Other

26. Q: What eligibility criteria do potential DCEs need to meet to be accepted into the model?

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.

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).

27. Q: How can health insurers participate in Direct Contracting? Can a health insurer apply as a DCE?
(New Question, June 2020)

Health insurers are able to apply and participate as a DCE in either model option (Professional or Global). They may choose to apply as a Standard, New Entrant or High Needs DCE and are required to enter into arrangements with DC Participant Providers like all DCEs.

28. Q: Can an ACO apply to become a DCE if it is presently participating in the NGACO Model, Medicare Shared Savings Program (Shared Savings Program), or another Innovation Center model? *(Updated, June 2020)*

Yes, participants in other shared savings initiatives – such as the Shared Savings Program or NGACO Model – can apply to participate in Direct Contracting. During the Implementation Period, the entities may simultaneously participate in either of these initiatives and the Direct Contracting Model. However, during the model performance years (PY1– PY5), the DCE and its 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, during a Performance Year of the Direct Contracting Model, the DCE and its DC Participant Providers may not participate in the Maryland Total Cost of Care Model (all programs), the Vermont All-Payer ACO Model, or the NGACO Model. In addition, despite the fact that CPC+ and Primary Care First are not shared savings models, overlapping participation in the Direct Contracting Model is prohibited for clinicians (determined based on the TIN/NPI combination) participating in the CPC+ and Primary Care First models due to similar payment structures existing in these models. DCEs and their DC Participant Providers may participate in other Medicare demonstrations or Innovation Center Models.

29. Q: If an organization is participating in another shared savings initiative and elects to participate as a DCE in Direct Contracting during the Performance Period, will CMS provide a pathway for organizations to transition from the existing shared savings initiative to Direct Contracting? Of particular interest is the ease with which CMS will allow organizations to exit existing shared savings agreements to participate in Direct Contracting. *(New Question, June 2020)*

Organizations potentially interested in participating in Direct Contracting will need to timely submit an application to begin participation during the IP, PY1, or PY2. The ease with which an organization can leave one shared savings initiative to join Direct Contracting depends on the initiative in which they are currently participating. While organizations generally cannot participate in two shared savings initiatives simultaneously, organizations currently in NGACO or the Shared Savings Program can apply to participate

in the Direct Contracting Model during the IP and stay in their current model/program for some or all of the IP. Organizations may also choose to apply to begin participation in the Direct Contracting Model starting in PY1, which starts April 1, 2021, or PY2 which starts January 1, 2022.

30. Q: Does Direct Contracting have any regional eligibility requirements? How many DCEs are selected in each region? *(New Question, June 2020)*

No, there are no regional eligibility requirements. Participation in Direct Contracting is open to organizations across the country. CMS will select DCEs based on the quality of their application and the criteria listed in the RFA.

31. Q: What eligibility criteria do providers need to meet to participate as part of a DCE?

Each DCE must contract with one or more DC Participant Providers. At least 25 percent control of the DCE's governing body must be held by DC Participant Providers or their designated representatives. DCEs may also elect to enter into arrangements with Preferred Providers. DC Participant Providers and Preferred 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)

While a DCE will not be required to be a Medicare-enrolled provider or supplier in order to participate in the Direct Contracting Model, each DC Participant Provider and Preferred Provider under the DCE must be a Medicare-enrolled provider (as defined at 42 CFR § 400.202) or supplier (as defined at 42 CFR § 400.202) by no later than June 30, 2020, in order to be eligible to participate in the model during PY1.

For subsequent performance years, DCEs will be able to update their list of DC Participant Providers and Preferred Providers annually to add Medicare-enrolled DC Participant Providers or Preferred Providers that satisfy the requirements of the model and are not Prohibited Participants.

32. Q: Must all downstream providers, including all DC Participant Providers and Preferred Providers, meet CEHRT Requirements? *(New Question, June 2020)*

DCEs are required to 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), currently 75%. If palliative care, hospice or home health providers are DC Participant Providers then they would be subject to this requirement and included in the denominator of the 75% requirement. Preferred Providers are not subject to this requirement.

33. Q: What is the difference between DC Participant Providers and Preferred Providers?

DC Participant Providers are the core providers and suppliers in the Professional and Global Options. 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. DC Participant Providers, unlike Preferred Providers, are subject to the Capitation Payment Mechanism selected by the DCE, which involves Medicare Fee-For-Service claims reductions and the requirement that the DCE and the DC Participant Provider enter into a negotiated payment arrangement.

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. Services furnished by Preferred Providers will not be considered in beneficiary alignment and Preferred Providers are not responsible for reporting quality through the DCE.

In addition to DC Participant Providers and Preferred Providers, beneficiaries aligned to a DCE may also choose to receive services from Medicare FFS providers and suppliers that are not associated with the DCE.

34. Q: Can DCEs, DC Participant Providers and Preferred Providers also participate in the Medicare Shared Savings Program or other Innovation Center models? *(Updated, June 2020)*

During the IP, DCEs and their DC Participant Providers and Preferred Providers can participate in both the Direct Contracting Model and the Shared Savings Program. During each performance year starting with 2021, DCEs and their DC Participant Providers may not simultaneously participate in the Shared Savings Program. The determination of whether such an overlap exists will be made at the TIN level prior to the start of each performance year. This requirement does not apply to Preferred Providers.

During the IP, DCEs and their DC Participant Providers and Preferred Providers may participate in other Innovation Center models if they meet all applicable eligibility criteria under the applicable demonstration or model. During each performance period, DCEs and their DC Participant Providers may only participate in other Innovation Center models that do not involve shared savings. They 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, including CPC+ and Primary Care First. In addition, DC Participant Providers may not simultaneously participate in multiple DCEs in the Direct Contracting Model. These restrictions do not apply to Preferred Providers.

35. Q: If the DCE's TIN is associated with another program, for example a Shared Savings Program ACO, does it need to create a new TIN in order to apply to the Direct Contracting Model as a DCE? *(New Question, June 2020)*

During the IP, DCEs can participate in both Direct Contracting and the Shared Savings Program. During each performance year, however, DCEs and their DC Participant Providers may not simultaneously participate in 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.

Direct Contracting uses a TIN-NPI combination to identify participating providers and suppliers, while the Shared Savings Program identifies ACO participants at the TIN level. The same TIN cannot be associated with a DCE or DC Participant Provider and a Shared Savings Program ACO or ACO Participant simultaneously during a performance year of the Direct Contracting Model.

36. Q: Our organization is currently an ACO in the Next Generation ACO Model (NGACO) or Shared Savings Program for 2020. What is the deadline for deciding between NGACO, Shared Savings Program and the Direct Contracting Model for 2021 participation? Since PY1 for the Direct Contracting Model doesn't start until April 1, 2021, can I participate in NGACO or Shared Savings Program from January-March of 2021 before switching to the Direct Contracting Model for the rest of the year? *(New Question, July 2020)*

For 2020 NGACOs deciding between NGACO and Direct Contracting for 2021 participation, the deadline to decide is 10/23/20 (when final DC provider lists are due for 2021). For 2020 Shared Savings Program ACOs deciding between Shared Savings Program and Direct Contracting for 2021 participation the deadline is 9/22/20 (when final SSP provider lists are due for 2021). While we try to offer participants as much flexibility as possible to make decisions, there are operational limitations that require the decision to be linked to the submission of final provider lists. Claims-based alignment, which functions similarly across these programs, aligns beneficiaries to the entity whose participating providers have provided the plurality of each beneficiary's primary care within a lookback period. By definition, this is a competitive process since the amount of primary care provided to a given beneficiary is compared across entities both in and outside of each program. As a result, alignment within one model can affect alignment within other models. Accordingly, alignment (specifically provider overlaps) needs to be set for when NGACO and Shared Savings Program begin their 2021 performance years (January), despite the Direct Contracting Model not starting Performance Year 1 until April 1, 2021.

Given the above, entities are not able to participate in NGACO or Shared Savings Program in the first quarter of 2021 before switching to Direct Contracting. Entities that choose to participate in Direct Contracting in 2021 will therefore not be in the performance period of any model from January-March of 2021, but this will not impair the ability to meet Qualifying APM Participant (QP) status, since there are three 'snapshot' dates for meeting QP requirements, two of which will occur after April 1, 2021.

37. Q: Can a DCE choose which of its associated NPIs participate in Direct Contracting and which do not? Can the DCE have some National Provider Identifiers (NPIs) in Shared Savings Program and some NPIs in Direct Contracting? *(New Question, June 2020)*

Direct Contracting is a split TIN model, meaning that all providers and suppliers billing under a TIN do not have to participate in Direct Contracting. Only providers and suppliers that are included on the DC Participant Provider List submitted by the DCE will be included in the DCE. DC Participant Providers and Preferred Providers are identified based on the TIN-NPI combination.

During the IP, DCEs and their DC Participant Providers and Preferred Providers can participate in both Direct Contracting and the Shared Savings Program. During each performance year of the Direct Contracting Model, however, they may not participate in the Shared Savings Program using the same TIN for the DCE or the DC Participant Providers. This restriction is not applicable to Preferred Providers.

38. Q: How many beneficiaries does each DCE need to begin in PY1? *(Updated, June 2020)*

DCEs are required to meet beneficiary alignment thresholds prior to the start of each performance year. The IP provides additional time for DCEs concerned about meeting the minimum beneficiary thresholds to align beneficiaries prior to the start of PY1. In both the Professional and Global Options, DCEs will be expected to meet the minimum number of aligned beneficiaries outlined in the list below prior to the start of PY1.

- **Standard DCE** - a minimum of 5,000 aligned Medicare FFS beneficiaries
- **New Entrant DCE** - a minimum of 1,000 aligned Medicare FFS beneficiaries with an increasing minimum beneficiary threshold each year to 5,000 prior to the start of PY4 and PY5
- **High Needs Population DCE** - a minimum of 250 aligned Medicare FFS beneficiaries with an increasing minimum beneficiary threshold each year to 1,400 prior to the start of PY5

New Entrant DCEs must not exceed 3,000 beneficiaries aligned via claims in any baseline year (2017, 2018, 2019) or any of the first three performance years (2021, 2022, and 2023). 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.

39. Q: Is a DCE still eligible to participate in PY 1 if it does not meet the beneficiary alignment requirements and thresholds during the IP? *(New Question, June 2020)*

In order to participate in the IP, the DCE does not need to meet the minimum beneficiary alignment thresholds. However, the DCE should use the Implementation Period to align beneficiaries prior to the start of PY1 and must meet the applicable minimum beneficiary threshold prior to the start of PY1. 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.

40. Q: Can a Standard DCE split to form a separate High Needs DCE? *(New Question, July 2020)*

Standard DCEs are not allowed to split and form two separate DCEs – one High Needs DCE for their High Needs beneficiaries and one Standard DCE for their remaining beneficiaries.

41. Q: What happens if a High Needs Population DCE has high numbers of beneficiaries that can be used to construct a credible benchmark? *(New Question, July 2020)*

High Needs DCEs that reach 3,000 claim-based aligned beneficiaries will convert to a Standard DCE for purposes of their benchmark, similar to New Entrant DCEs. These High Needs DCEs will still have the flexibility to focus only on High Needs beneficiaries but their benchmark will incorporate a historical baseline component for claims-aligned beneficiaries.

Beneficiary Alignment

42. Q: What eligibility criteria do beneficiaries need to meet to be aligned?

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, Programs of All-Inclusive Care for the Elderly (PACE) organization, or other Medicare health plan;
- Have Medicare as the primary payer;
- Are a resident of the United States; and
- Reside in a county included in the DCE's service area (defined below).

For individuals to be eligible to be aligned to a High Needs Population DCE, they must also meet one or both of the following conditions: (1) have conditions that impair their mobility; and/or (2) meet the high needs special conditions for eligibility described in the RFA. Dually eligible beneficiaries and Medicare-only beneficiaries meeting one or both conditions are eligible for alignment to High Needs Population DCEs.

43. Q: How does CMS align beneficiaries to DCEs?

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 furnished by DC Participant Providers, as evidenced in claims utilization data.
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).

44. Q: What is voluntary alignment?

Voluntary alignment is 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. In most cases, voluntary alignment will override claims-based alignment to another organization, model, or program.

45. Q: How does voluntary alignment work?

CMS will permit DCEs to proactively communicate with beneficiaries regarding voluntary alignment, provided such communications comply with all applicable laws, regulations, guidance, and with the requirements of the Participation Agreement. Beneficiaries may voluntarily align with a DCE by

designating a DC Participant Provider as their primary clinician or main source of care by either selecting a “primary clinician” on [MyMedicare.gov](https://www.medicare.gov) (referred to as electronic voluntary alignment) or completing a paper-based voluntary alignment form. In the event of a conflict, the most recent valid attestation will take precedence. The paper-based voluntary alignment will make use of a standardized template developed by CMS for Direct Contracting.

Beginning in the IP, DCEs may take steps, within certain parameters, to affirmatively ask beneficiaries to confirm their care relationships with the DCE’s DC Participant Providers. This outreach is limited to a DCE’s service area, which consists of a Core Service Area and an Extended Service Area.

46. Q: What is the frequency of voluntary alignment?

DCEs will have two choices for the frequency of beneficiary voluntary alignment (1) Prospective Alignment, or (2) Prospective Plus Alignment. Both policies rely on establishing the DCE’s aligned population prospectively to provide a stable prospectively set benchmark for DCEs. 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 to support more “real time” alignment for those beneficiaries who choose to voluntarily align.

47. Q: Will CMS identify and align the High Needs beneficiaries to DCEs? *(New Question, June 2020)*

Yes, CMS will align Medicare FFS beneficiaries to all DCE Types based on voluntary alignment and claims-based alignment. CMS will align individuals to a High Needs Population DCE if they meet the high needs criteria prior to initial alignment and are otherwise eligible for alignment to a DCE. 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. Medicare FFS beneficiaries, including dually eligible beneficiaries, meeting at least one of these conditions are eligible for alignment to a High Needs Population DCE.

48. Q: How will CMS determine a DCE’s Core Service Area and Extended Service Areas?

CMS will identify a DCE’s service area for purposes of beneficiary alignment based on the list of the DC Participant Providers submitted by the DCE during the application process. A DCE’s Core Service Area includes all counties in which the DCE’s DC Participant Providers have physical office locations. The Extended Service Area includes all counties contiguous to the Core Service Area. The DCE’s service area is distinct from the DCE’s region, which includes all counties where DCE-aligned beneficiaries reside.

49. Q: Can a DCE operate in multiple regions that are geographically separate?

Yes, a DCE will be permitted to operate in multiple, non-contiguous regions.

50. Q: What is the difference between DCE service area and its region?

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.G. in the RFA.

51. Q: Do beneficiaries retain freedom of choice in this model? Can beneficiaries switch primary care providers?

Beneficiaries will retain their choice of health care providers in this model and may switch health care providers at any time.

52. Q: Will the beneficiary alignment processes differ for New Entrant DCEs given they may have no experience with FFS beneficiaries? *(New Question, June 2020)*

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. Fundamentally, the mechanics of alignment will not change: voluntary alignment and claims-based alignment will serve as the sources of beneficiary alignment for these DCEs.

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 (April 1, 2021). New Entrant DCEs will be required to increase the minimum number of aligned beneficiaries to 2,000, 3,000 and 5,000 prior to the start of PY2, PY3 and PY4 respectively. They will further be required to maintain a minimum of 5,000 aligned beneficiaries prior to the start of PY5. Further, prior to the start of both PY4 and 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.

53. Q: What is the difference between Prospective Alignment and Prospective Plus Alignment? If a beneficiary voluntarily changes their alignment, does the selection of Prospective Alignment or Prospective Plus Alignment affect when the beneficiaries are voluntarily aligned to a DCE? *(Updated, August 2020)*

Both of these alignment options rely on establishing the DCE’s aligned beneficiary population prospectively; however, they differ in the frequency with which CMS aligns beneficiaries through voluntary alignment.

- **Prospective Alignment** will function similarly to the prospective alignment methodology currently used in the NGACO Model. All claims-based alignment and voluntary alignment will be completed prior to the start of each performance year. If a DCE selects Prospective Alignment and a beneficiary who is not otherwise aligned to any model or entity voluntarily aligns to that DCE after the annual alignment process is run for a performance year, the beneficiary will not be aligned to the DCE until the following performance year.
- **Prospective Plus Alignment** will allow DCEs to have beneficiaries who have voluntarily aligned (through either electronic or paper-based) to the DCE since the annual prospective alignment process added to their aligned beneficiary population on a quarterly basis throughout the performance year. Only those beneficiaries who were not already aligned to another DCE or an

organization participating in another initiative for the performance year will be aligned to the DCE mid-performance year under Prospective Plus Alignment.

54. Q: Can beneficiaries opt-out of CMS data sharing with DCEs?

Yes. Beneficiaries can opt out of data sharing at any time by contacting 1-800-MEDICARE and indicating their preference that CMS not share their data with the DCE.

Benefit Enhancements and Beneficiary Engagement Incentives

55. Q: What are some examples of benefit enhancements and beneficiary engagement incentives that will be offered in Direct Contracting? *(Updated, June 2020)*

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 to conditionally waive certain Medicare payment requirements as part of testing Direct Contracting. Beneficiary engagement and coordination of care could be further enhanced by providing additional incentives to beneficiaries that would potentially motivate and encourage beneficiaries to become actively involved in their care. While we expect to include the benefit enhancements and beneficiary engagement incentives currently permitted in the NGACO Model, we are also considering including new ones in Direct Contracting. The benefit enhancements and beneficiary engagement incentives under consideration for Direct Contracting are highlighted in the table below:

Benefit Enhancements

Benefit Enhancements Anticipated for PY1	Proposed Benefit Enhancements and Beneficiary Engagement Incentives for PY1	Potential Future Benefit Enhancements and Beneficiary Engagement Incentives Under Consideration by CMS
<ul style="list-style-type: none"> • Skilled nursing facility (SNF) 3-Day Rule Waiver • Telehealth Expansion • Post-discharge Home Visits • Care Management Home Visits 	<ul style="list-style-type: none"> • Homebound Home Health Waiver • Concurrent Care for Beneficiaries that Elect the Medicare Hospice Benefit • Beneficiary engagement incentives in the form of certain in-kind items and services • Cost-sharing Support for Part B Services • Chronic Disease Management Reward Program 	<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

56. Q: Can CMS provide a comprehensive list of benefit enhancements and beneficiary engagement incentives that are available in the NGACO model currently and expected to be available in Direct Contracting? *(New Question, June 2020)*

The NGACO model currently allows the following benefit enhancements and beneficiary engagement incentives, which CMS expects to include in the Direct Contracting Model beginning in PY1:

- 3-Day SNF rule waiver: Would conditionally waive the requirement for the three-day inpatient stay prior to the admission to a SNF.
- Telehealth expansion: Would conditionally waive the rural geographic requirement for an originating site and allow the beneficiary's place of residence to serve as an originating site when telehealth services are furnished by Preferred Providers, and also include coverage of certain teledermatology and teleophthalmology services furnished by DC Participants and Preferred Providers through asynchronous (i.e., store and forward) technologies.
- Post-discharge home visits: Would allow auxiliary personnel (e.g., licensed clinicians) to perform "incident to" post-discharge home visit services to non-homebound aligned beneficiaries under the general supervision of a DC Participant Provider or Preferred Provider for up to nine visits in a 90-day period.
- Care management home visits: Would allow auxiliary personnel (e.g., licensed clinicians) to perform "incident to" care-management home visit services to non-homebound aligned beneficiaries under the general supervision of a DC Participant Provider or Preferred Provider up to twelve times within a performance year.
- Cost Sharing Support for Medicare Part B Services: This beneficiary engagement incentive would allow DCEs to make payments to a DC Participant Provider or Preferred Provider to cover some or all of the amounts of beneficiary cost sharing not collected.
- Chronic Disease Management Reward Program: This beneficiary engagement incentive would allow DCEs to provide gift cards to eligible beneficiaries for the purpose of incentivizing participation in a qualifying chronic disease management program. Among other requirements, the aggregate value of any and all gift cards provided to a beneficiary in a year cannot exceed \$75, cannot be offered in the form of cash or monetary discounts or rebates, including reduced cost-sharing or reduced premiums, and cannot be redeemable for cash.

57. Q: Are DCEs required to offer these benefit enhancements and beneficiary engagement incentives?

A DCE may choose not to implement some or all benefit enhancements and beneficiary engagement incentives offered under Direct Contracting. Applicants will be asked to provide information regarding their proposed implementation of any benefit enhancements or beneficiary engagement incentives they select, but acceptance into Direct Contracting is not contingent upon the applicant agreeing to implement any particular benefit enhancement or beneficiary engagement incentive.

58. Q: Are benefit enhancements available to DCEs during the IP? *(New Question, June 2020)*

No, there will be no benefit enhancements allowed during the IP.

Financial Model

59. Q: What risk-sharing options are offered in the Direct Contracting Model?

CMS will test up to three voluntary risk-sharing options in the Direct Contracting Model. The current Request for Applications is seeking applicants for two risk-sharing options: 1) Professional, a lower-risk option (50% Shared Savings/Shared Losses (SS/SL)); and 2) Global, a full risk option (100% SS/SL). Additional information will be provided at a later date regarding a third option that CMS is considering offering, Geographic, which is a full risk option for Medicare FFS beneficiaries in a defined target region.

60. Q: What data will CMS provide, including benchmark and historical data, to organizations during the IP and PYs? *(New Question, June 2020)*

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 aligned beneficiaries to develop and implement care coordination and quality improvement activities. 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 those DCEs the opportunity to request detailed claims data. Such claims data will include individually identifiable Claim and Claim Line Feed (CCLF) reports for services furnished by Medicare-enrolled providers and suppliers to aligned beneficiaries during the IP or PY, respectively, as well as historical CCLF files. The historical CCLF files provided at the beginning of a performance year will capture a 36-month lookback of claims for newly aligned beneficiaries. Only 12 months of historical CCLF data will be made available during the IP.

During both the IP and the PYs, CMS will also provide DCEs, upon request, 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 the PYs, CMS will also 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.

61. Q. How will DCEs be paid in the Direct Contracting Model?

DCEs will be required to have a capitated payment arrangement whereby CMS makes a capitation payment to the DCE, which may be used by the DCE to support population health, for example by allowing the DCE to enter into value based payment arrangements with its downstream DC Participant Providers and Preferred Providers, or to invest in health care management tools, such as health care technologies. The type of risk-sharing arrangement the DCE enters will determine the type of capitation payments available to the DCE.

DCEs electing the Professional risk-sharing arrangement are required to receive PCC whereby CMS will pay 7% of the Performance Year Benchmark (based on Part A and B services) to the DCE. This payment is intended to cover the primary care based services furnished to aligned beneficiaries by DC Participant Providers and Preferred Providers participating in PCC with the DCE, along with an additional amount for

enhanced primary care services, such as increased access to primary care, enhanced provision of care, and care coordination. DC Participant Providers and Preferred Providers delivering primary care services and participating in PCC will receive some or all of their payment for such primary care services from the DCE; the remainder, if any, will be paid through the CMS payment systems. All DC Participant Providers and Preferred Providers will continue to submit claims to the Medicare payment systems.

DCEs in the Global risk-sharing arrangement may either choose to receive the PCC described above or may select TCC, which encompasses all Medicare Part A and B services furnished to aligned beneficiaries by DC Participant Providers and Preferred Providers, who have agreed to participate. Under TCC, CMS will pay the DCE 100% of the Performance Year Benchmark (based on Part A and B services) minus a percentage for services expected to be billed by providers and suppliers not participating in TCC for the care of the aligned beneficiaries based on historic experience. Monthly capitated payments will be paid to DCEs. DC Participant Providers would receive 100% of their payments from the DCE. Preferred Providers who have elected to participate in TCC would receive between 1-100% of their payments through the DCE; the remainder would be paid through the CMS payment systems. All DC Participant Providers and Preferred Providers will continue to submit claims to the Medicare payment systems.

Money paid to the DCE, either through the PCC or TCC, will be factored into shared savings/shared losses calculations.

Advanced Payment is an optional payment mechanism only available to DCEs that select PCC and functions like the population-based payments available in the NGACO Model. Advanced Payments are a cash flow mechanism under which CMS prospectively pays DCEs the estimated value of the reduction in Medicare payments for non-primary care claims submitted by DC Participant Providers and Preferred Providers who have agreed to an FFS claims reduction. DCEs can negotiate with their DC Participant Providers and Preferred Providers to enter into an arrangement under which they agree to an FFS Medicare claims reduction (between 1 – 100% of FFS claims). In exchange, CMS reduces FFS claims payments made to these providers and suppliers through the Medicare payment systems and pays the DCE a prospective per beneficiary per month (PBPM) payment representing the estimated value of the difference between the reduced FFS claims and the full FFS claims payment amount. Unlike the Capitated Payment Mechanisms, the value of Advanced Payments made to DCEs will be reconciled against the actual value of the Medicare FFS claims for services furnished to aligned beneficiaries after the end of the Performance Year.

62. Q: Are DCEs required to participate in PCC, TCC, or Advanced Payments?

DCEs are required to participate in PCC or TCC, depending on which risk-sharing option they select. DCEs selecting the Professional Option are required to be paid through PCC. DCEs selecting the Global Option can choose either PCC or TCC. DCEs in either risk option (Professional or Global) that select PCC may also select Advanced Payments.

63. Q: Why is CMS requiring the Capitation Payment Mechanisms of PCC and TCC as part of this model?

CMS is requiring Capitation Payment Mechanisms in Direct Contracting to provide DCEs with an opportunity to administer the flow of funds while they manage total cost of care. By giving DCEs the funds to pay for services, DCEs will have greater leverage and increased flexibilities to enter into downstream

payment arrangements that can incent providers and suppliers to work together and coordinate care for a defined set of aligned beneficiaries, with the potential to generate better outcomes and lower costs.

64. Q: What does CMS mean when indicating that the DCE will be responsible for paying downstream providers? Will all providers and suppliers still bill Medicare and receive payment under current models? *(New Question, June 2020)*

CMS will be making the capitated monthly payments directly to the DCE depending on the DCE's PCC or TCC election. The DCE would then have its own payment arrangements with DC Participant Providers and Preferred Providers participating in capitation. DCEs must have payment arrangements with its DC Participant Providers and Preferred Providers for any payments subject to capitation or advanced payment. All other claims submitted that are not subject to reductions for capitation or advanced payment will continue to be paid in full by CMS.

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-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.

65. Q: Are DCEs required to pay their DC Participant Providers and/or Preferred Providers through their own FFS mechanisms?

No, DCEs may enter into their own downstream payment arrangement with their DC Participant Providers and Preferred Providers and are not required to pay them FFS. However, any such arrangements must comply with the applicable terms of the Participation Agreement.

66. Q: Will CMS process claims for the capitated population-based payments? *(New Question, June 2020)*

DCEs are required to receive capitation payments from CMS for services provided by their DC Participant Providers and Preferred Providers participating in the capitation payment to aligned beneficiaries. While these providers and suppliers will still be expected to submit claims to CMS, the DCE, rather than CMS, will pay these providers and suppliers. Depending on the type of capitation the DCE chooses, claims will be zeroed out, either for primary care services for Primary Care Capitation, or all services for Total Care Capitation. Submitted claims that are subject to reduction will still be processed and adjudicated according to regular processes. Upon request, the claims data, including allowed charges and paid amount, will be made available to DCEs. DCEs must work with their DC Participant Providers and Preferred Providers to determine and administer the appropriate payment that the providers and suppliers should receive based on their agreements with the DCE.

67. Q: What are the differences between the Global and Professional Options? *(Updated, June 2020)*

A DCE can choose either option when entering Direct Contracting. The table below highlights the differences between the options.

Comparison of the Professional and Global Options

	Policy	Professional	Global
1	Risk Arrangement	50% of savings/losses.	100% of savings/losses.
2	Capitation Option	PCC Only (set at 7% of the Performance Year Benchmark).	Both options available: PCC or TCC
3	Discount and Quality Withhold	5% Quality Withhold.	Discount of 2% in PY1/PY2 (increasing to 3% in PY3, 4% in PY4, and 5% in PY5); 5% Quality Withhold.

68. Q: Why is the PCC set at 7% of the total cost of care? Is there any flexibility around the 7%?
(Updated, June 2020)

Primary care expenditures are approximately 2-3% of the total cost of care in Medicare FFS. CMS has set the PCC at a higher value (7%) of the Performance Year Benchmark for total cost of care to promote the delivery of enhanced and more comprehensive primary care services. The PCC includes two components, a base PCC amount and an enhanced PCC amount for providing enhanced primary care services. The base PCC amount is calculated based on the actual claim expenditures for primary care services provided to aligned beneficiaries during the baseline period by DC Participant Providers and Preferred Providers. The enhanced PCC amount is calculated as the difference between 7% and the base primary capitation amount. DCEs that select the PCC option will still be subject to risk sharing against the Performance Year Benchmark, in which all performance year expenditures are collectively compared to the benchmark value to determine shared savings/shared losses. CMS will treat the base PCC amount as an expenditure against that benchmark. CMS will recoup the enhanced PCC amount prior to the calculation of shared savings/shared losses.

While we expect PCC to function as described in the RFA and in the paragraph above in general, we acknowledge that there may be specific DCEs that would prefer flexibility in how they receive PCC payments. As such, we are allowing the following flexibilities:

- DCEs whose Participant Providers have historically provided primary care services that exceed 7% of total expenditures for their historically aligned population will be allowed to have their Base PCC amount match that historical amount (e.g., if Base PCC is calculated to be 8%, we will keep it at 8% rather than constrain it down to 7%). Note: we expect this to be rare.
- DCEs for whom Base PCC exceeds 5% will still be entitled to up to 2% Enhanced PCC. This means that total PCC payments can exceed 7% (again we expect this to be rare). For example, if Base PCC is calculated to be 6% or 8%, in both cases the DCE would be allowed to receive up to 2% Enhanced PCC. The Enhanced PCC would be fully recouped separate to final reconciliation, just as described in the RFA.
- DCEs will be allowed to elect to receive lower Enhanced PCC payments than they are entitled to. For example, for a DCE whose Base PCC = 3%, Enhanced PCC would be 7% - 3% = 4%. The DCE in

this example could receive up to 4% Enhanced PCC but is able to elect a lower amount if they choose (e.g., 0%, 1%, 2% or 3%).

69. Q: What is included in the total cost of care calculation? *(New Question, June 2020)*

All expenditures incurred by Medicare, including capitation payments, non-claims-based payments, and FFS claims paid, on behalf of aligned beneficiaries would be included as part of total cost of care of the DCE for the relevant performance year. This includes all out-patient services such as primary care and specialist services, SNF services, ER and hospital visits and in-patient services. For beneficiaries who have elected hospice, all care, whether for hospice or non-hospice services, will be included. The Advanced APM 5% incentive payment (discussed at <https://qpp.cms.gov/apms/advanced-apms>) will not be included in the Benchmark or counted as part of the Total Cost of Care for a DCE aligned population.

70. Q: How are the PCC, TCC and Advanced Payments considered in final shared savings/losses calculations?

The TCC and the base PCC portion of PCC will be treated as an expenditure in shared savings/shared losses calculations. That is, when CMS calculates the total cost of care at the end of the performance year, we will incorporate these payments, as well as additional Medicare expenditures made on behalf of aligned beneficiaries for claims and services not covered by the capitation payments, and determine whether together these expenditures exceed the Performance Year Benchmark. If yes, the DCE must repay CMS shared losses in an amount calculated according to its risk sharing arrangement. If no, CMS will pay the DCE shared savings in an amount calculated according to its risk sharing arrangement. CMS will not reconcile payments made through the PCC and TCC against actual services rendered to make DCEs whole—the DCE is at risk for expenditures that exceed what CMS pays through the PCC and TCC.

Advanced Payments, however, are treated differently than the PCC and TCC. The full amount of Advanced Payments will be reconciled against the actual claims submitted by providers and suppliers participating in this alternative funding flow. For example, if CMS underpaid the DCE based on the claims submitted, CMS would increase funds to equal the amount that would have been paid through the CMS payment systems. CMS will monitor claims submission and Advanced Payments to adjust payments as needed to protect against too much or too few funds being provided. A final reconciliation for Advanced Payments will be conducted as part of the calculations of Medicare expenditures for a performance year and shared savings/shared losses determination.

71. Q: What is the patient financial responsibility for cost sharing in Direct Contracting? Does this vary based on which providers are participating and/or who is in Advanced Payment? *(New Question, June 2020)*

In general, the Direct Contracting Model does not require any change in the cost sharing responsibilities for beneficiaries regardless of the DCE type or how providers are paid.

However, CMS is considering including an optional beneficiary engagement incentive under which a DCE may (but is not required to) 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. For example, a High Needs DCE may decide to limit cost sharing responsibilities for certain high needs beneficiaries who need to visit providers on a monthly basis in order to decrease hospital utilization. This would be an optional arrangement that a DCE can pursue.

72. Q: How is the Performance Year Benchmark calculated?

The benchmark will be developed by: (1) calculating the DCE’s historical baseline spending for its aligned beneficiary population; (2) trending the historical baseline expenditures forward based on the U.S. Per Capita Cost growth trend; (3) blending the historical baseline expenditures with regional expenditures using an adjusted Medicare Advantage Rate Book; (4) making adjustments to the blended expenditures to account for the risk of the aligned beneficiaries; and (5) applying a discount for DCEs that selected the Global Option and withholding a portion of the benchmark “at risk” subject to the DCE’s performance on quality measures. More details on the benchmarking methodology can be found in the RFA. Additional detail will also be provided in a Payment Methodology webinar later this year.

73. Q: Will the benchmark include Medicare Part D prescription drug spending?

The Direct Contracting benchmarks will not include Medicare Part D prescription drug spending. However, CMS remains interested in exploring ways in which DCEs can support beneficiaries in their management of and adherence to prescription drugs.

74. Q: How will risk adjustment be incorporated in Direct Contracting?

CMS will use risk adjustment to account for the underlying health status of the population of beneficiaries aligned to a DCE for the baseline period (i.e. a weighted average of 2017, 2018, and 2019) relative to the population of beneficiaries aligned to the DCE for each performance year. CMS will design the Direct Contracting Model’s risk adjustment methodology to achieve two primary goals:

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

Additional information regarding the model’s risk adjustment methodology will be provided in subsequent financial methodology papers. CMS anticipates publishing a risk adjustment methodology paper at a later date. This paper will address various aspects of the risk adjustment methodology for Global and Professional under the Direct Contracting Model.

75. Q: Why is a discount applied to the benchmark for DCEs that select the Global Option? How is it calculated?

The discount is an adjustment that is incorporated into the benchmark for DCEs in the Global Option. As DCEs in the Global Option are eligible to retain up to 100% of savings, this discount will provide the primary mechanism for CMS to obtain savings from the DCEs participating in this option. CMS will apply the discount to the trended, regionally blended, risk adjusted benchmark. This discount will be set at two percent of the benchmark for PY1 and PY2 and increased by one percentage point for each subsequent

year, requiring continuous improvement from DCEs in the Global Option. A discount is not applied for the Professional Option.

76. Q: Do all services count toward Shared Savings/Shared Losses? *(Updated, June 2020)*

Yes, all Parts A and B services for aligned beneficiaries will count toward shared savings/shared losses. Under the Direct Contracting Model, Professional DCEs will bear risk for 50% of shared savings/shared losses on the total cost of care (i.e. all Parts A and B services) for their aligned beneficiaries. Global DCEs will bear risk for 100% of shared savings/shared losses on the total cost of care for aligned beneficiaries.

For both TCC and PCC, shared savings/losses are based off of total cost of care and are calculated by comparing the DCE's benchmark with all Medicare expenditures for services delivered to aligned beneficiaries. Medicare expenditures are defined as capitation payments, Advanced Payments, and FFS claims billed for aligned beneficiaries. Under TCC, capitation includes payments made for claim reductions for all Participant Providers and Preferred Providers that opt into capitation; there is no Advanced Payment for TCC. Under PCC, capitation is the 'Base PCC amount,' defined as the percent of historical spending represented by primary care billing by all Participant Providers and Preferred Providers that opt into capitation; 'Enhanced PCC amount,' which is the difference between the Base PCC amount and 7% of the benchmark. The Enhanced PCC amount is recouped fully by CMS separately from the reconciliation process, and so is not included in our definition of 'Medicare expenditures' in this context.

77. Q: Will non-claims-based payments be included as expenditures? *(New Question, June 2020)*

Non-claims based payments from CMS will be included in the Performance Year Benchmark (and performance year expenditures) when they take the place of claims that would have otherwise been paid through FFS. This will include Capitation Payments or Advanced Payments in the Direct Contracting model. Non-claims based payments that are independent of claims, such as the infrastructure payments offered in the NGACO model, will not be included in the benchmark or expenditures.

78. Q: What risk mitigation strategies will be available in Direct Contracting?

Direct Contracting employs several risk mitigation strategies. Risk corridors are applied to all DCE types and vary based on risk option (Professional or Global). Risk corridors mitigate extreme shared savings or shared losses for DCEs if their actual performance year expenditures are far lower or higher than the benchmark. DCEs also have the option of electing a stop-loss arrangement prior to the start of each performance year. Stop loss is intended to reduce financial uncertainty associated with infrequent, but high-cost, expenditures for aligned DCE beneficiaries. It is calculated at the beneficiary level and the benchmark is adjusted to account for a DCE opting to have stop loss.

79. Q: How will CMS calculate the maximum upward and downward adjustment that occurs to the financial benchmark each year when combining baseline and regional expenditures? *(New Question, June 2020)*

CMS will calculate a maximum upward and downward adjustment in the benchmarking methodology that includes a historical baseline component in PY1. When combining the baseline with the regional

expenditures, we 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, and the overall downward adjustment to a flat dollar amount equal to two percent of the FFS USPCC.

80. Q: When is final reconciliation conducted? *(Updated, June 2020)*

Starting in PY2, CMS will conduct final reconciliation approximately six months after the performance year ends. To provide more timely distribution of shared savings/shared losses, CMS will also provide the option for DCEs to select a provisional reconciliation option (selected at the start of the Performance Year). Under provisional reconciliation, CMS will distribute interim shared savings and collect interim shared losses shortly after the end of the performance year reflecting cost experience through the first six months of the performance year, with a final reconciliation taking place once complete data are available for the full performance year (approximately six months after the performance year ends).

Since PY1 lasts only 9 months, it will function differently. Provisional reconciliation will occur approximately six months after the performance year ends, while final reconciliation will occur 12 months after provisional reconciliation (at the same time as final reconciliation for PY2). While provisional reconciliation starting in PY2 is optional, it will be required in PY1. This change is a result of the shortened duration of PY1 and more details will be made available in the financial specification papers [and the PY1 Participation Agreement?].

81. Q: Are the capitation payments to DCEs subject to sequestration?

Yes. In accordance with the Balanced Budget and Emergency Deficit Control Act of 1985 (BBEDCA), as amended, CMS will reduce the payments made to DCEs by 2% to account for sequestration. The benchmark and performance year expenditures will be calculated on a pre-sequestration basis. TCC, PCC, and, if selected, Advanced Payments paid to DCEs will be calculated on a post-sequestration basis; where sequestration will result in a 2% reduction in any capitated payments and Advanced Payments paid by CMS to the DCE. At provisional and final financial reconciliation, any shared savings will be calculated on a post sequestration basis, where any shared savings earned by the DCE will also be reduced by 2%. Reductions for sequestration will not apply to the calculation of shared losses.

82. Q: Will ACOs know the stop loss attachment points specific to their ACO prior to their decision to purchase or not purchase stop loss from CMS for any given performance year? *(New Question, June 2020)*

Yes, full details about stop loss attachments points will be made available prior to signing the PY1 Participation Agreement.

83. Q: Are DCEs required to secure a financial guarantee?

Each DCE must secure a financial guarantee for each Performance Year to ensure it can repay all Shared Losses and any other amounts owed under Direct Contracting. If CMS does not receive payment for Shared Losses and other amounts owed by the date the payment is due, CMS will 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.

Quality and Reporting

84. Q: What quality measures will be included in the proposed core set? *(Updated, June 2020)*

To ensure that DCEs meet the model goals of improved quality of care and health outcomes for Medicare beneficiaries, the Direct Contracting Model will include the assessment of quality performance during each of the performance years. The quality strategy is designed to provide achievable performance criteria that incent the care delivery transformations necessary to reduce unnecessary utilization while maintaining quality of care. The proposed quality measures for the PY 1 are as follows:

Core Set

1. Consumer Assessment of Healthcare Providers and Systems (CAHPS®) for Accountable Care Organizations (ACOs) surveys.¹ CAHPS is a program of the Agency for Healthcare Research and Quality, U. S. Department of Health and Human Services. Adaptation to include a measure of 24/7 access will be added later in the model.
2. All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions (Claims Based)
3. Risk-Standardized All Condition Readmission (Claims Based)
4. Advanced Care Plan (NQF 0326) has been removed from the proposed measure set.

Test Measures/Measures in Development

1. Days spent at home (Claims Based). This measure will be developed during the initial years of the model. The measure will be utilized by High Needs DCEs.
2. Care Coordination (Claims Based) is replacing Advanced Care Plan in the measure set. This measure will be developed during the initial years of the model. The measure will be utilized by Global and Professional DCEs.

85. Q: What is the Continuous Improvement and Sustained Exceptional Performance (CI/SEP) criteria and how will it be applied? *(New Question, June 2020)*

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 PY 1 and 2, a pre-defined performance benchmark will serve as the CI/SEP criteria. Specifically, 1% of quality withhold will be tied to a pre-defined performance benchmark criterion. In PY 3-5, half (2.5%) of the quality withhold will be tied demonstrable continuous improvement and 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.

86. Q: What is the High Performers Pool (HPP)?

Direct Contracting will test the use of an HPP to further incentivize high performance and continuous

¹ CAHPS® is a program of the Agency for Healthcare Research and Quality, U. S. Department of Health and Human Services.

improvement on the model's quality measures. A DCE will qualify for a bonus from the HPP if in addition to meeting the model's continuous improvement/sustained exceptional criteria, the DCE also demonstrates a high level of performance or meets 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 continuous improvement/sustained exceptional criteria. There will be no HPP in the first performance year. Additional information on the HPP criteria will be shared prior to PY 2.

87. Q: How does quality reporting fit into the benchmark? (Updated, June 2020)

Similar to NGACO, CMS will use a quality "withhold," in which a portion of a DCE's Performance Year Benchmark is held "at-risk," contingent upon the DCE's quality score. Five percent of the benchmark will be withheld during each performance year for DCEs as the quality withhold amount. The DCEs' performance on quality measures will determine how much of the quality withhold they will earn back.

In PY 1 and 2, DCEs are required to meet a pre-defined performance benchmark on one of two utilization measures (Risk-Standardized, All Condition Readmission or All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions) to earn back 1% of their quality withhold. All other measures are Pay-for-Reporting to earn back the remaining quality withhold. For PY 3-5, payment for quality will be tied to CI/SEP criteria and overall quality performance. DCEs that improve their performance each year and/or are among the highest performing DCEs will earn back higher levels of the withhold, and potentially even more via HPP. More details on this methodology will be included in a future financial methodology paper.

88. Are DCE's DC Participant Providers and Preferred Providers eligible for Qualifying APM Participant (QP) status under the Quality Payment Program (QPP)? (New Question, June 2020)

DC Participant Providers may attain Qualifying APM Participant (QP) status for a year that may be entitled to an APM Incentive Payment and be exempt from MIPS reporting requirements and payment adjustments. However, **Preferred Providers are not eligible for QP status under the Direct Contracting Model**. For additional questions related to MIPS and the APM Incentive Payment, you can see the qpp.cms.gov website for more details or contact the Quality Payment Program help desk at qpp@cms.hhs.gov.

89. Q: Is the APM Incentive Payment considered an expenditure when calculating shared savings? (New Question, June 2020)

The APM Incentive Payment will not be included in the Benchmark or counted as part of the Total Cost of Care for a DCE aligned population.

Appendix

Appendix A:

The select non-primary care specialists that may bill Primary Care Qualified Evaluation and Management (PQEM) codes has been updated to include additional specialists as noted below.

Code¹	Specialty
6	Cardiology
10	Gastroenterology
12	Osteopathic manipulative medicine
13	Neurology
16	Obstetrics/gynecology
17	Hospice and palliative care
23	Sports medicine
25	Physical medicine and rehabilitation
26	Psychiatry
27	Geriatric psychiatry
29	Pulmonology
39	Nephrology
44	Infectious disease
46	Endocrinology
66	Rheumatology
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

Appendix B:

The list of PQEM codes has been updated to include additional codes, as noted below.

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	
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	
99339	Brief
99340	Comprehensive
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
Prolonged care for outpatient visit	
99354	Prolonged visit, first hour
99355	Prolonged visit, add'l 30 mins
Telephone Visits – Audio Only	
99421	Online digital, Established Patient, 5–10 mins
99422	Online digital, Established Patient, 10–20 mins
99423	Online digital, Established Patient, 21+ mins
99441	Phone, Established Patient, 5–10 mins
99442	Phone, Established Patient, 10–20 mins
99443	Phone, Established Patient, 21+ mins

Chronic Care Management Services	
99490	Comprehensive care plan establishment/implementations/revision/monitoring
Transitional Care Management Services	
99495	Communication (14 days of discharge)
99496	Communication (7 days of discharge)
Advance Care Planning	
99497	ACP first 30 mins
99498	ACP add'l 30 mins
Wellness Visits	
G0402	Welcome to Medicare visit
G0438	Annual wellness visit
G0439	Annual wellness visit
Virtual check-ins	
G2010	Remote evaluation, Established Patient
G2012	Brief communication technology-based service, 5-10 mins of medical discussion