December 20, 2019

Value-Based Direct Contracting Models: CMS Announces RFA

In April 2019, the Centers for Medicare & Medicaid Services ("CMS") announced the Direct Contracting model, offering three voluntary risk-based payment options: (1) the Professional Option, (2) the Global Option, and (3) the Geographic Option. The model is part of the CMS vision to redesign primary care services to drive broader health care reform. (See here for our prior alert with an overview of the Direct Contracting model options, as well as their key features and program logistics.) The Direct Contracting models will start in 2020 and will run for six years. On November 25, 2019, CMS released a Request for Applications ("RFA") for the Professional Option and the Global Option.[1]

Organizations that have submitted a Letter of Intent ("LOI") are eligible to apply to participate. The first round of applications is due on **February 25, 2020**.[2]

This alert summarizes key components of the RFA.

I. REQUEST FOR APPLICATIONS

The current RFA focuses on two of the three Direct Contracting options: (1) the Professional Option, which involves 50% sharing of savings and losses, and (2) the Global Option, which involves 100% shared risk. The program is expected to take place over an "implementation period" during 2020, followed by five program years. Although the RFA sets forth program requirements for the Professional Option and the Global Option, CMS reserves the right to modify the terms of the program, meaning that the participation agreements between CMS and successful applicants may contain terms that differ from those specified in the RFA. The models ultimately may offer fraud and abuse waivers, but they do not yet appear in the RFA.

Application Scoring and Selection. CMS will review applications and score them based on the following elements:

- Organizational structure;
- Leadership and management;
- Financial plan and risk-sharing experience;
- Patient-centeredness and beneficiary engagement; and
- Clinical care.[3]

Applicants must also provide a list of diverse providers and suppliers. Applicants with prior experience in a CMS program, demonstration, or model, will be asked to demonstrate their compliance with the terms of such programs. A panel of experts from CMS and other organizations will select the participants based upon the scoring, program integrity considerations, and market effects. CMS may also interview applicants as part of the evaluation process.

Contracting with Providers. Participants in the Direct Contracting model (referred to as "Direct Contracting Entities" or "DCEs") must contract with Direct Contracting ("DC") Participant Providers and Preferred Providers. Both Participant and Preferred Providers must enter into a written agreement with the DCE to participate in the Direct

[1] The RFA is available at https://innovation.cms.gov/Files/x/dc-rfa.pdf.

[2] Applications can be accessed and submitted through an online portal, *available at* https://app1.innovation.cms.gov/dcrfa/dcrfaLogin. Applications for the second cycle will likely be available in the spring of 2021.

[3] A detailed outline of the selection and scoring criteria for each of these elements is available in Appendix D of the RFA.

Contracting. However, DC Participant Providers must also agree to report quality data through the DCE and to comply with care improvement objectives and model quality performance standards. In addition, DC Participant Providers must participate in the payment mechanism chosen by the DCE, while Preferred Providers may enter into a more flexible, downstream risk arrangement with the DCE (discussed below). Thus, DC Participant Providers should be the DCE's core providers and suppliers, while Preferred Providers are intended to extend care relationships.

As part of the application process, CMS will screen DCEs, DC Participant Providers, and Preferred Providers, and may deny their participation in Direct Contracting based on the results of a program integrity review, as discussed in more detail in the "Screening" section below.

DCE Organization Types. The RFA specifies three organization types for DCEs:

- Standard. The DCE consists of organizations that generally have experience serving Medicare fee-for-service ("FFS") beneficiaries.
- New Entrant. The DCE consists of organizations that have not traditionally provided services to a Medicare FFS population.
- High Needs Population. The DCE serves Medicare FFS beneficiaries with complex needs, such as dually eligible beneficiaries.

Varying elements of the Direct Contracting model will be applied to DCEs, based on the organizations' assignment to one of these three types.

Legal Entity and State Licensure. DCEs must be legal entities formed under and in compliance with applicable laws, and must be separate from any DC Participant Provider or Preferred Provider. DCEs' compliance obligations include any applicable state licensure requirements pertaining to risk-bearing entities, such as those applicable to insurers or third-party administrators. A DCE will not be required to be a Medicare-enrolled provider or supplier.

Screening. DCEs and the providers with which they contract must undergo a program integrity review as part of the screening process. The screening may include confirmation of Medicare enrollment status of DCEs (if applicable) and their Participant and Preferred Providers, review of performance in other CMS models, and review of billing history and any activities conducted regarding potential program fraud and abuse. Applicants and their senior leadership will also be required to disclose a five-year history of investigations and sanctions. Pending the results of the screening, CMS may deny the DCE or individual providers with which the DCE contracts.

Governing Body. CMS requires that each DCE must have a governing body separate and unique to the DCE (*e.g.*, not the same governing body of an entity participating in the DCE) that is responsible for overseeing and directing the DCE. Members of this governing body must have a fiduciary duty to the DCE, and membership must include at least one Medicare beneficiary served by the DCE and at least one consumer advocate. The governing body must also have a conflict-of-interest policy in place that requires disclosure of relevant financial interests, specifies a process by which the body can determine the existence and resolution of potential conflicts, and addresses remedial actions for failure to comply with the policy.

Program Overlap. The Direct Contracting model prohibits DCEs and their Participant Providers from participating in other shared savings programs during PY1 – PY5, but DCEs and DC Participant Providers can participate in both Direct Contracting and the Medicare Shared Savings Program during the implementation period. CMS permits program overlap with other Medicare demonstrations or Innovation Center models, such as the Vermont All-Payer ACO Model or the Maryland Total Cost of Care Model, as long as they do not involve shared savings. In contrast, the limitations on program overlap generally do not apply to Preferred Providers – they may participate in Direct Contracting with one or more DCEs, as well as accountable care organizations and other Medicare initiatives that involve shared savings.

Beneficiary Alignment. DCEs are accountable for the cost of care of beneficiaries aligned to their organization. Beneficiary alignment is also used to determine the DCE's baseline expenditure in order to calculate the Performance Year Benchmark (*i.e.*, a target per beneficiary per month ("PBPM") dollar amount representing the total cost of Medicare services provided to the participant's Medicare beneficiaries). Beneficiary alignment requirements vary across the three DCE organization types. For example, DCEs belonging to the New Entrant or High Needs Population types must maintain a lower minimum number of aligned beneficiaries per Program Year compared to the Standard type.

Financial Methodology. As mentioned above, the Professional Option and the Global Option involve 50% and 100% of savings and losses, respectively. CMS will reconcile the difference between the DCE's Medicare expenditures and the Performance Year Benchmark approximately six months after the Performance Year ends. CMS also provides an optional provisional reconciliation at the end of each Performance Year (January 31 target) to provide more timely distribution of shared savings/repayments. To mitigate risk, the Direct Contracting model incorporates risk corridors and stop-loss arrangements.

- Risk corridors: Cap the shared savings/losses based on "risk bands," meaning that greater deviance from the Performance Year Benchmark will move the DCE to the next risk band, resulting in a lower percentage of shared savings/losses for experience within the higher band. For example, a DCE in the Professional Option would experience 50% of savings and losses within 5% of the benchmark, but would be exposed to only 35% of losses more than 5% above the benchmark (up to 10%, where another band with still-lower exposure would begin).
- Stop-loss arrangements: Reduce risk associated with outlier expenditures by limiting DCEs' financial liability for beneficiary expenditures above a prospectively determined "attachment point." Notably, such arrangements limit but do not eliminate risk. DCEs retain responsibility for a percentage of expenditures above the attachment point, as incentive to continue managing costs. DCEs interested in this arrangement must opt in at the beginning of each Performance Year.

Beneficiary Engagement. The Direct Contracting model prohibits DCEs from providing gifts or remuneration to beneficiaries as inducement to receive items or services from the DCE. However, the model permits DCEs to encourage beneficiary engagement by providing certain in-kind items or services to their beneficiaries.

- Examples: Examples of patient engagement incentives include vouchers for over-the-counter medication recommended by a health care provider, wellness program memberships, and meal programs.
- Cost-Sharing Support for Part B Services: DCEs are permitted to enter into cost-sharing arrangements with their Participant and Preferred Providers. Those arrangements can provide for a DCE to pay all or part of the amount of beneficiary cost-sharing for certain categories of beneficiaries and Part B services that would ordinarily be collected by its Participant and Preferred providers. DCEs planning on providing cost-sharing support must submit an implementation plan to CMS.
- Chronic Disease Management Reward Program: A DCE may provide gift cards to its beneficiaries (from the DCE's funds, in an amount up to $75) to encourage participation in a chronic disease management program.

DCEs interested in cost-sharing arrangements or the chronic disease management reward program must provide to CMS an implementation plan that outlines these arrangements in more detail.

Payment Mechanisms. The Direct Contracting model uses a series of payment mechanisms through which CMS pays DCEs on a PBPM basis. Each DCE is required to select one of the following payment mechanisms:

- Total Care Capitation: CMS provides a capitated payment for all services provided by the DCE, as well as its Participant and Preferred Providers, that reflects the estimated total cost of care for the DCE's beneficiaries. DCEs participating in the Professional Option may not select this payment mechanism.

- Primary Care Capitation: CMS provides a capitated payment for certain primary care services provided by the DCE and its Participant and Preferred Providers; the payment will amount to 7% of the estimated total cost of care for the DCE's beneficiaries.[4] This mechanism is available for DCEs in the Professional Option and the Global Option.

DC Participant Providers are required to participate in the payment mechanism chosen by the DCE. With respect to reimbursement, this means that DC Participant Providers continue to submit claims to CMS for services rendered to DCE beneficiaries, upon which CMS zeroes out the reimbursement for the services provided under the applicable capitation payment mechanism (*i.e.*, total care vs. primary care).

In contrast, *Preferred Providers* may, but are not required to, participate in the DCE's chosen payment mechanism. This added flexibility is intended to allow DCEs to enter into downstream value-based arrangements with their Preferred Providers. Preferred Providers that opt to negotiate a downstream arrangement with their DCE agree to reduced FFS claims payment (between a 1% and 100% reduction) from CMS. In turn, the DCE pays the Preferred Provider in accordance with the terms of the downstream arrangement, which may be value-based or on a fee-for-service basis. To illustrate, if the Preferred Provider agrees to an FFS claims payment reduction of 80%, it would receive 80% of its payments from the DCE and the remaining 20% would be paid by CMS. If a DCE has any Preferred Providers that elect not to participate in the DCE's chosen capitation payment mechanism or agree to a downstream arrangement involving less than a 100% reduction, CMS will withhold part of the monthly capitated payment due to the DCE to offset the expected payments that CMS will make to such providers. The difference between the withholding and CMS's actual payments to such providers would be settled during the reconciliation period.

For DCEs that choose the Primary Care Capitation mechanism, CMS provides the option to receive "Advanced Payments," which are designed to provide DCEs under the Primary Care Capitation mechanism with the flexibility to enter into value-based arrangements with providers for non-primary care services. A DCE under the Primary Care Capitation mechanism may negotiate with its Participant and Preferred Providers to reduce non-primary care FFS claims. Accordingly, CMS would provide a monthly Advanced Payment (based on historical utilization and the non-primary care FFS claims reduction amounts negotiated by the DCE and its Participant and Preferred Providers) to the DCE in the amount of the estimated value of reductions. This monthly payment would then be used by the DCE to pay its Participant and Preferred Providers. Differences between the Advanced Payments and actual FFS claims would be settled during the reconciliation period.

Optional Benefit Enhancements. As part of the Direct Contracting Model, CMS has waived certain Medicare payment restrictions to allow DCEs the option to implement benefit enhancements designed to reduce costs. Examples of such waivers include:

- Post-Discharge Home Visits: The requirement for direct supervision will be conditionally waived for qualified DCEs to provide home visits furnished by auxiliary personnel under general (rather than direct) supervision.
- Certification of Home Health Services by Nurse Practitioners: Under this conditional waiver, DCEs may allow nurse practitioners to certify that a beneficiary is eligible for home health benefits. Without the waiver, a physician would have had to make such a certification. This change fosters greater ability for nurse practitioners to coordinate beneficiary care.

[4] CMS proposes the following primary care services and their associated CPT codes to be included under this mechanism: new patient visit (99201 – 99205); established patient visit (99211 – 99215); prolonged care for outpatient visit (99354 – 99355); transitional care management (99495 – 99496); home care evaluation and management (99324 – 99328, 99334 – 99337, 99339 – 99345, 99347 – 99350); advance care planning (99497 – 99498); Welcome to Medicare and annual wellness visits (G402, G0438, G0439); chronic care management (99490); and virtual check-ins (G20212).

- Concurrent Care for Beneficiaries Who Elect the Medicare Hospice Benefit: Traditionally, election of the Medicare hospice benefit involves foregoing the right to receive curative care. Under this conditional waiver for DCEs in the Global Option, a DCE and its Participant and Preferred Providers may provide curative care to beneficiaries who have elected hospice care. Costs of both hospice and curative care would be accounted for as part of the DCE's total cost of care.

CMS has specified that the benefit enhancements discussed in the RFA will be available for PY1, with additional benefit enhancements being considered for subsequent Performance Years. DCEs wishing to offer one or more of the benefit enhancements must first submit an implementation plan for CMS approval.

Quality Reporting. The Direct Contracting model will require DCEs to report quality measures for each Performance Year. CMS will evaluate whether quality care is being delivered to beneficiaries by assessing DCEs' claims-based quality measures and information from Consumer Assessment of Healthcare Providers and Systems ("CAHPS") for Accountable Care Organization ("ACO") surveys. In Appendix C of the RFA, CMS provides a list of proposed quality measures, which include timeliness of care, care coordination, and readmissions. However, the agency reserves the right to review and revise the measures and scoring principles on an annual basis. The quality performance scores will inform CMS's application of a quality withhold to the DCEs' Performance Year Benchmark calculation (with the exception of the first Performance Year, during which CMS permits pay-for-reporting to facilitate transition to pay-for-performance for the subsequent Performance Years). DCEs that meet or exceed predefined performance criteria can earn back all or a portion of their quality withhold based on their quality performance scores. Those falling short of the criteria can earn back up to half of the quality withhold.

Monitoring. Both the DCE and CMS must monitor compliance with the terms of the Direct Contracting model, as well as any requirements specified in the participation agreement. To participate in the model, DCEs must develop a compliance plan that includes compliance training programs, the designation of an experienced compliance officer, and a means by which individuals may anonymously report suspected problems to the compliance officer, among other elements. CMS will also engage in various monitoring activities, such as audits, interviews of DCE members and beneficiaries, and site visits. CMS will also conduct annual audits of the DCEs to evaluate compliance with the terms of the participation agreement.

Remedial Actions. If any DCE fails to comply with the terms of its participation agreement, remedial actions may ensue. Such actions may include, but are not limited to, education of the DCE, implementation of a corrective action plan subject to approval by CMS, termination of payments due to the DCE, and the suspension or termination of the DCE from the Direct Contracting model.

* * *

Interested organizations that have submitted an LOI have until **February 25, 2020** to submit an application. Others wanting to participate beginning PY1 (*i.e.*, 2021) may submit applications in spring 2020.