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Health Care ADVISORY ■

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The Primary Cares Initiative: What to Know and How to Prepare

The Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) Innovation Center (CMMI) announced the CMS Primary Cares Initiative (PCI) as the latest HHS effort to transform the health care system to value-based care. CMS has the ambitious goal of covering 25 percent of the Medicare fee-for-service (FFS) beneficiary population through these new voluntary models, and it is critical for providers, plans, and other stakeholders to understand how the PCI may impact health care delivery. CMS expects these efforts to greatly transform how health care is delivered to Medicare beneficiaries, including through expanded access to primary care services and eventually fostering multipayer alignment.

The PCI is composed of two pathways, each with several models within them. The Primary Care First (PCF) pathway includes two overlapping models, while the Direct Contracting (DC) pathway includes three distinct models. Additional details on these five models will be released over the coming weeks and through requests for applications (RFAs). The PCF RFA is expected in the coming weeks, practices will be selected in the fall or winter, and the models are expected to launch in January 2020.

The letter of intent for two of the DC models, which is nonbinding but required if an organization intends to submit an application, is due on August 2. The DC RFA is expected in the summer or fall, and DC organizations will be selected in the fall or winter. There will be an optional beneficiary alignment year starting January 1, 2020, but the first DC performance year will begin January 1, 2021. The specifics of the third DC model are not yet defined, but CMMI anticipates that the RFA will be released in the fall, and the first performance year will begin January 1, 2021.

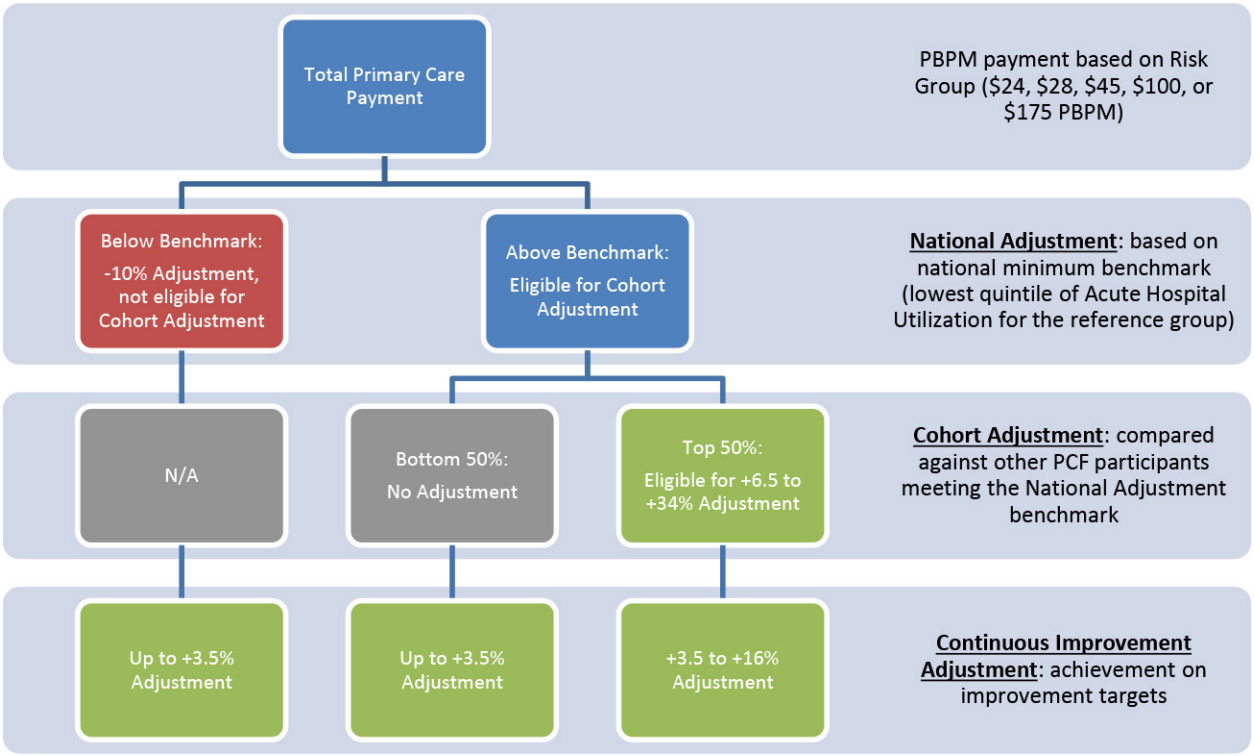
While there is still uncertainty around these models, it is critical for providers, plans, and other stakeholders to understand how these models may impact health care delivery.

Primary Care First Models

The PCF models are designed generally for primary care physician practices with "advanced primary care" capabilities (i.e., provide 24/7 access to a care team practitioner with real-time access to the electronic health record). Under PCF, practices would elect to participate for five years to be eligible for financial rewards for improving health outcomes. The PCF model will be limited to 26 regions, including the 18 Comprehensive Primary Care Plus (CPC+) regions. PCF is based on the CPC+ model design, which is a national primary care medical home model intended to strengthen primary care through public-private partnerships to invest in and improve care while reducing unnecessary health care services.

CMS is offering a "General" PCF model and a "High Need Populations" PCF model. Under the General model, participants will receive a risk-adjusted, per-beneficiary per-month payment in addition to a flat fee for each primary care visit. CMMI will utilize a three-step performance adjustment to calculate whether participants will receive a positive adjustment (up to 50 percent) or a negative adjustment (up to 10 percent). Participants can opt in to the High Need Populations model, which will provide additional payments for practices that choose to serve the seriously ill population (SIP) who do not have consistent primary care providers.

PCF Performance-Based Adjustment Flowchart



Direct Contracting Models

Similar to PCF, DC is a set of voluntary payment models. In an effort to support multipayer alignment, the DC models are intended to offer a broader range of organizations, including accountable care organizations (ACOs), MA plans, and Medicaid managed care organizations (MCOs), an opportunity to participate in CMMI-led risk-sharing arrangements. CMS rolled out two models (Global and Professional) and solicited feedback on a third model (Geographic). The Global and Professional models will be available nationwide, while CMMI has indicated the Geographic model may be limited to four to-be-defined geographic regions. Overall, CMS expects approximately 75 organizations to participate in the DC models as direct contracting entities (DCEs), each of which would have at least 5,000 aligned FFS Medicare beneficiaries.

Organizations like ACOs, MA plans, and Medicaid MCOs would participate in the Global and Professional DC models as DCEs. DCEs would be the lead model participants, but would contract with other "DC participants" (i.e., providers and suppliers used to align beneficiaries to the DCE) and with "preferred providers" (i.e., providers that participate in downstream arrangements). DCEs could choose from two different payment and risk-sharing arrangements, taking on as much as 100 percent of the shared savings and losses.

Beneficiaries will be assigned to DCEs prospectively, before each performance year, through potentially four different attribution methods. The DC models would follow a more traditional CMMI demonstration framework where there would be a calculated benchmark, risk mitigation (e.g., established risk corridors and stop-loss), a reconciliation to determine payment, and quality adjustment. CMMI also is considering benefit enhancements and payment rule waivers to provide flexibility on home health certification (and potentially others, including the skilled nursing facility three-day stay waiver).

CMMI continues to work on the Geographic model, but our understanding is it would provide DCEs an opportunity to assume responsibility for all assigned beneficiaries in a to-be-defined geographic region with 100 percent shared savings and losses. Through a request for information (RFI), CMMI solicited feedback from stakeholders and interested parties on the Geographic model. Overall, CMMI sought feedback on:

- The general model design and how this model could address social determinants of health, including barriers to and ways to encourage participants to address social determinants of health.
- The criteria to be considered for selecting target regions (e.g., penetration of advanced alternative payment models, high health care costs).
- The eligibility criteria for DCE participants, including whether states should be allowed to participate.
- The beneficiary alignment methodology (CMMI is considering either randomly aligning beneficiaries or allowing beneficiaries to voluntarily align themselves).
- The payment methodology, including a discount to the benchmark and how it should be calculated and whether Part D costs should be included.
- Considerations related to program integrity and beneficiary protections.

Comparison of PCI Models

PCF Models	Participants	Payment (calculated monthly; paid quarterly)	Performance-Based Adjustment	Quality Metrics	Beneficiary Count	Benefit Attribution	Areas
General Model	Physician practices that: • Have some experience in value-based payment arrangements • Use the 2015 edition of CEHRT • Have advanced primary care delivery capabilities *Note*: CPC+ participants are not eligible to participate in the first year	Population-based payment: • Risk-adjusted payment for services in or outside the office • 5 practice risk groups ranging from $24–175 per patient based on overall average HCC score for beneficiaries attributed to the practice $50 flat primary care visit fee	50% upside • National adjustment (based on acute hospital utilization (AHU)) • Cohort adjustment (up to 34%) • Continuous improvement adjustment (up to 16%) 10% downside risk	Years 1–5: AHU Years 2–5: CAHPS-like survey, diabetes HbA1c poor control (>9%), controlling high blood pressure, advance care plan, colorectal cancer screening	At least 125 attributed Medicare beneficiaries Have primary care services account for the "predominant share" of collective billing based on revenue (70–80%)	More details forthcoming, potentially based on historical claims over a baseline period	Arkansas, Colorado, Hawaii, Greater Kansas City Region (KS + MO), Louisiana, Michigan, Montana, Nebraska, New Jersey, Greater Buffalo Region (NY), North Hudson-Capital Region (NY), North Dakota, Ohio and Northern Kentucky Region, Oklahoma, Oregon, Greater Philadelphia Region (PA), Rhode Island, Tennessee; Alaska, California, Delaware, Florida, Maine, Massachusetts, New Hampshire, Virginia
High-Need Populations	Physician practices that meet the General model requirements and serve seriously ill population (SIP) and complex patients (can include hospice and palliative care)	$325 one-time payment for first visit with SIP patient $275 PBPM SIP payment for up to 12 months $50 flat visit fee	Up to $50 quality payment	To be developed during the model, but could include 24/7 patient access and patient days at home	Opt-in to be assigned SIP patients	Options: Participants can choose to only have SIP patients attributed	

DC Models (2021)	Participants	Payment	Risk-Sharing Arrangement	Payment Methodology	Beneficiary Count	Benefit Attribution	Areas
Global	*DC Entities (DCEs)* ACOs, MA plans, Medicaid MCOs *DC Participants* "Core" providers and suppliers used to align beneficiaries to DCEs and responsible for reporting and improving quality *Preferred Providers* *Not* used to align beneficiaries but participate in downstream arrangements (e.g., specialists, those who contribute to DCE performance)	Total Care Capitation, (risk-adjusted monthly payment for all services provided by DC participants and preferred providers the DCE has an agreement with)	100% shared savings/losses calculated through a final reconciliation after the performance year (PY) (compares actual expenditures and total cost of care benchmark)	*Benchmark* Blend of historical spending and adjusted MA regional expenditures; will be adjusted to reflect risk and geographic price factors *Risk Mitigation* Risk corridors and stop-loss determined on the aggregate expenditure of shared savings/losses DCEs are eligible to receive. Risk corridor limits upside and downside while stop-loss would be calculated at the beneficiary level *Reconciliation* Conducted following the PY, DCEs can request a "provisional reconciliation" that reflects the first 6 months of the PY *Quality* Quality performance will impact the discounted benchmark amounts and final shared savings/losses. More details forthcoming	5,000 (although CMS is considering exceptions for certain organizations new to Medicare FFS, such as Medicaid MCOs and MA organizations	Attribution established prospectively before each PY through: (1) claims-based alignment; (2) enhanced voluntary alignment; or (3) Medicaid MCO enrollment-based alignment Additional option: prospective alignment plus (allows beneficiaries to align to a DCE quarterly)	National
Professional		Primary Care Capitation (7% total cost of care of enhanced primary care services)	50% shared savings/losses with CMS calculated through a final reconciliation after the PY (compares actual expenditures and total cost of care benchmark)				
Geographic	DCEs, DC Participants, Preferred Providers DCEs could include health plans, health care technology companies, providers, supplier organizations	Potential participants would assume responsibility for the total cost of care for all Medicare FFS beneficiaries in a defined target region	100% shared savings/losses calculated through a final reconciliation after the PY	Participants would have a choice of full financial risk with FFS claims reconciliation and total care capitation *Benchmark* One year of historical per capita FFS spend in the target region trended forward (would include certain negotiated discount)	5,000?	Random assignment?	Defined target region, subject to RFI comments (potentially limited to 4 regions)

Key Considerations and How to Prepare

While the two pathways are distinct, there is significant potential for overlap. For example, it appears a PCF participant also could partner with a DCE. There also could be implications for PCF and DC model overlap with other ACOs and CMMI demonstrations. In addition, the parameters of these models will inevitably force out certain practices. Smaller practices may be pressured to participate through a DCE while "tweener" practices (i.e., those who may be too small for DC) will have to carefully consider their PCI pathway. One of the primary benefits of participating is that both PCF and DC are likely to qualify as advanced alternative payment models, meaning participants will be eligible for the 5 percent incentive payment and will not have to participate in the Medicare Quality Payment Program's Merit-based Incentive Payment System.

To best prepare, practices should conduct a comprehensive self-evaluation and determine the best pathway, taking into account the practice's likely beneficiaries and historical performance. For larger entities that may be interested in participating as a DCE, the key consideration will be selecting the appropriate payment arrangement based on the appetite for risk. Under the DC pathway, the ability to develop a strong network of partners will be critical for success.

In addition, participants should assess the legal and regulatory restrictions, such as those related to the fraud and abuse laws (e.g., False Claims Act, Anti-Kickback Statute, Stark Law) as well as CMS payment rules, to ensure compliance with federal requirements. CMS, in conjunction with the Office of Inspector General, typically releases *guidance* documents on fraud and abuse waivers for the models, but it is essential that participants understand how to appropriately operationalize these waivers to avoid civil monetary penalties (CMPs). Typical payment rule waivers include a waiver of the beneficiary inducements CMP and physician self-referral, Anti-Kickback Statute, and gainsharing CMP.

Further, CMS has indicated that it will waive some of the Medicare program rules (e.g., waiver of the three-day stay requirement for skilled nursing facility care, waiver of certain home health service requirements). Using these waivers have been shown to reduce overall costs and improve quality, but are closely monitored by CMS during model implementation. Participants must understand the limitations and parameters of these waivers to ensure compliance with the model requirements and any Medicare program rules that the waivers may not cover.

The most important activities in the near term are close monitoring of additional details and developments, a comprehensive review of the RFAs, and drafting a highly specific and tailored application. More details are expected in the coming weeks.

Alston & Bird is prepared to assist with evaluating model participation, reviewing the RFA and submitting responses, and conducting outreach to CMMI to address any questions or concerns.

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